BRIAN SANDOVAL
Governor

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
1100 E. William Street, Suite 101
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MICHAEL J. WILLDEN
Director

LAURIE SQUARTSOFF
Administrator

Nevada Medicaid
Drug Use Review (DUR) Board
Agenda

The Division of Health Care Financing and Policy (DHCFP) Drug Use Review (DUR) Board will conduct a public meeting on January 23, 2014 beginning at 5:30 pm at the following location:

BEST WESTERN AIRPORT PLAZA HOTEL
1981 TERMINAL WAY
RENO, NV 89502-3215

Reasonable efforts will be made to assist and accommodate physically challenged persons desiring to attend the meeting. Please call Rita Mackie at: 775-684-3681 or email: rmackie@dhcfp.nv.gov in advance, but no later than two working days prior to the meeting, so that arrangements may be conveniently made.

Meeting material may be found at: http://www.medicaid.nv.gov/providers/rx/rxmeetings.aspx

Items may be taken out of order.
Items may be combined for consideration by the public body.
Items may be pulled or removed from the agenda at any time.

Public comment is limited to 5 minutes per individual, organization, or agency, but may be extended at the discretion of the Chairperson.

1) Call to Order and Roll Call

2) Public Comment

No action may be taken on a matter raised under this item of the agenda until the matter itself has been specifically included on the agenda as an item upon which action can be taken.

3) Administrative

a) For Possible Action: Review and approve July 25, 2013 Meeting Minutes

b) Status Update by DHCFP
   i) Public Comment

ii) Program Updates
    1. Health Care Reform

4) Clinical Presentations

a) Presentation of antihyperlipidemic agents for treating homozygous familial hypercholesterolemia (HoFH) use and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria

b) Presentation of ibuprofen-famotidine combo utilization and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria

c) Presentation of immunomodulators use and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Update of Clinical Prior Authorization Criteria.

d) Presentation of long and short-acting opioid use and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Update of Clinical Prior Authorization Criteria and/or Quantity Limits

e) Presentation of platelet inhibitor use and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Update of Clinical Prior Authorization Criteria.

f) Presentation of botulinum toxin use and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Update of Clinical Prior Authorization Criteria

g) Review of buprenorphine and buprenorphine/naloxone use and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Update of Clinical Prior Authorization Criteria

h) Presentation of injectable epinephrine products use and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria

i) Presentation of Promethazine with Codeine use and clinical information
   i) Public Comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action**: Adoption of Clinical Prior Authorization Criteria and/or quantity limits

j) Review of psychotropic drug use in children
   i) Public Comment
   ii) Discussion by the Board on Review of Utilization Data
   iii) **For Possible Action**: Update of Clinical Prior Authorization Criteria

5) DUR Board Requested Reports

a) Report on Top 10 Black Box warning medications:
   i) Public comment
   ii) Discussion by Board on Review of Utilization Data
   iii) **For Possible Action by the Board**

6) Standard DUR Reports

a) Review of Prescribing/Program Trends
   i) Program Trends
   ii) Top 10 Therapeutic Classes for Q2 2013, Q3 2013, and Q4 2013 (by Payment and by Claims)
   iii) Top 50 Drugs of Q2 2013, Q3 2013, and Q4 2013 (by Payment and by Claims)

b) Concurrent Drug Utilization Review (ProDUR)
   i) Review of Q2 2013, Q3 2013, and Q4 2013
   ii) Review of Top Encounters by Problem Type

c) Retrospective Drug Utilization Review (RetroDUR)
   i) Public Comment
   ii) Review of Responses
   iii) Status of Previous Quarter
   iv) Status of Current Quarter
   v) **For Possible Action**: Board Discussion and Approval of Future Criteria Selection

7) Closing Discussion

a) Public Comment

b) Date and Location of next meeting
   i) Discussion of new time of next meeting.

c) Adjournment

This notice and agenda has been posted on or before 9:00 am on the third working day before the meeting at the following locations:

Notice of this meeting will be available on or after the posting date of this Agenda at the DHCFP Web site (www.medicaid.nv.gov).

Posting of the Agenda will be at the Nevada Medicaid Central offices in Carson City and Las Vegas; Nevada State Library; Carson City Library; Churchill Country Library; Las Vegas Library; Douglas County Library; Elko County Library, Lincoln County Library; Lyon County Library; Mineral County Library; Tonopah Public Library; Pershing County Library; Goldfield Public Library; Eureka Branch Library; Humboldt County Library; Lander County Library Storey County Library; Washoe County Library; and White Pine County Library and may be reviewed during normal business hours.

If requested in writing, a copy of the action items will be mailed to you or they may be reviewed Monday through Friday from 9:00 until 5:00 pm or at the meeting. Please call at least one day ahead for an appointment for document review. You may request meeting materials or provide written comments by writing to Rita Mackie, DHCFP, 1100 E. William Street, Suite 102, Carson City, NV 89701.

All persons that have requested in writing to receive the Open Meeting Agenda have been duly notified by mail or e-mail.

Anyone presenting documents for consideration during the public comment portion of the meeting must provide sufficient copies for each member of the committee and the official record. Copies are to be distributed at the time of the meeting and should be provided at meeting locations; DHCFP or its contractor will not distribute public comment information or materials prior to the public meeting.

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Draft Meeting Minutes
July 25, 2013

BEST WESTERN AIRPORT PLAZA HOTEL
1981 TERMINAL WAY
RENO, NV 89502-3215

Committee Members Present:

Paul Oesterman, Pharm.D., Chairman; James Marx, M.D.; Dave England, Pharm.D.; Larry Nussbaum, M.D, Joram Seggev, MD

Others Present:

DHCFP:

Coleen Lawrence, Chief, Program Services; Darrell Faircloth, Senior Deputy Attorney General; Laurie Squartsoff, Administrator; Marta Stagliano

HPES:

Beth Slamowitz, Pharm.D.

Catamaran:

Carl Jeffery, Pharm.D. Account Manager; Daniel Medina

Others:

Charrissa Anne, J&J; Jeff Forny, Shire; Eric Bizjak, Shire; Marykay Queener, J&J; Phillip Kenner, Acorda; Juan Trippe, Reckitt; Sarica Cohen, Acorda; Brooks Hubbard, BIPI; Debbie Lin, BIPI; Jenny Blackham, Lilly; Didic Dilli, Pfizer; Sandy Sierkowsky, Pfizer; Scott Larson, BMS; Charlie Collins, Gilead; Jeanette Belz, NV Psychiatric Association; Karen Campbell, Allergan; Joanne Stoche, VinoPharms; Nancy Wilson, Aegerion; Patrick Jensen, Aegerion; Julie Bertuleit, GSK; Nidal Naser, GSK; Helen Liau, Lilly; Davey Desai, St. Mary's

1) Call to Order and Roll Call

Paul Oesterman, Pharm.D. Chairman: Good afternoon everyone thank you for coming today on this nice weather day in Reno. This is the meeting of the Nevada Medicaid Drug Use Review Board and we will start with the call of the meeting to order and take a roll call with the members present starting on my left.

Coleen Lawrence: Good evening Colleen Lawrence, DHCFP

Larry Nussbaum, MD: Larry Nussbaum, University of Nevada school of Medicine

Dave England, Pharm.D: David England, pharmacist, Las Vegas

Paul Oesterman, Pharm.D. Chairman: Paul Oesterman, Pharmacist, Reno

Darrell Faircloth: Darrell Faircloth, Senior Deputy Attorney General for the committee

James Marx, MD: Dr. Jim Marx, MD, Las Vegas

Carl Jeffery, Pharm.D.: Carl Jeffery with Catamaran

Beth Slamowitz: Beth Slamowitz with HP

Paul Oesterman, Pharm.D. Chairman: We do have a quorum present so we will go ahead and proceed as everyone is aware we have a very full agenda, so a couple of ground rules. If you are going to speak please limit your presentation to no more than 5 minutes, if you go beyond that we will ask you to stop. Do not read us the package insert, we can all read. We want to try to give everyone a time to address the Board this afternoon. As a reminder, if you have cell phones please make sure they are on vibrate. We have the minutes from the meeting on October 25th to review and I would ask the committee members to review and if they have any questions or changes or if not if someone would make a motion to approve them as submitted.

2) Public Comment

Paul Oesterman, Pharm.D. Chairman: Okay we're going to divert for a moment does anyone have any public comment prior to us going into the agenda?
None.

3) Administrative

a) For Possible Action: Review and approve October 22, 2012 Meeting Minutes.

Paul Oesterman, Pharm.D. Chairman: The one question I had on the minutes is on the agenda it says to approve the October 22nd minutes but the minutes themselves state October 25th. Personally I don't remember which day it was.

Carl Jeffery, Pharm.D.: I would have to check, whatever that Thursday was.

Paul Oesterman, Pharm.D. Chairman: And then if you could also make sure to include my name on the minutes.

James Marx, MD: I move we accept the minutes.

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D. Chairman: A second, any questions, hearing none I will call for a vote. In favor of passing approving minutes as submitted with the amendments please indicate by saying "Aye."

Board: "Aye."

Paul Oesterman, Pharm.D. Chairman: All opposed say, "Nay". Ok, the minutes pass. Our next item on the agenda is our status update from a Division of Health Care Financing and Policy, Coleen?

b) Status Update by DHCFP

Coleen Lawrence: Good evening for the record this is Coleen Lawrence with Nevada Medicaid first of all thank you very much for showing up at or new time. We thought it was a good time considering a lot of the public comment we have received, to try an evening meeting. Please let me know what you think about doing it at this time and moving the DUR Board to Reno. First of all I would like to welcome our Administrator, we have not had a DUR Board meeting since the appointment of our new Administrator, Laurie Squartsoff. I have a couple announcements that we talked about at the P&T, if you have not had a chance to attend the P&T the last couple of times. The Division is getting ready for the implementation of ICD-10 programming and just to let you know there will not be any transition time where we will be running double codes between ICD-9 and ICD-10, we will be running ICD-10 when this starts with CMS. This is a large impact for our pharmacy system as you know, if you're reading Chapter 1200, we have ICD 9 codes throughout the Chapter. We also do a lot of programming based on the feedback from the Drug Use Review Board and a lot of our policies are based on diagnosis codes. So our pharmacy specialist, Mary Griffith who is not here today, has painstakingly gone through the process of converting the ICD-9 to ICD-10 and that process will continue over the next year. How can we partner over the next year? We are going to ask for your partnership when you're out there and working with the physicians to educate them on the ICD-10 when you are looking at our policies and to get them prepared. We have done several studies with ICD-10 and it is a whole new world if you have not looked at it. ICD-10s are nothing like the old ICD-9. They are numerically different, they are alphabetically different, everything about them is different. Even the concept of how they are used is different. The Division will not be posting any training. We will be depending on the private sector and trainings so we will be definitely partnering with training for other entities for training the prescribers. That is our biggest project we have coming down the pike for the pharmacy world. Do you have any questions regarding ICD-10? Each quarter we will update you on where we are with ICD-10.

Dave England, Pharm.D.: The question I have is the PAs that have been sent out before with the ICD-9 codes, have they all been automatically updated with ICD-10?

Coleen Lawrence: We are going to be doing updates of the policy number one, and then we are looking at a database with Point Of Sale and we have a table that we've already crosswalked to ICD-10. Our team members have already done a lot of hard work on the ICD-10 project.

James Marx, MD: I don't understand how you can cross walk over from 9 to 10. The 10s are far more specific and there really is no crosswalk from 9 to 10.

Coleen Lawrence: There is no actual crosswalk, the team actually had to go in and look up every ICD-10 and look up what the meaning of it and create new tables. No, they were not very happy, it was not a good day for months in my office. But the best thing is education out to the prescriber community for ICD-10.

Paul Oesterman, Pharm.D. Chairman: Is there a formal switchover date?

Coleen Lawrence: There is, it keeps getting pushed back and moving around right now but we'll keep giving you updates on the actual dates itself. Oh I'm sorry, I have one more, the other issue is the

ACA implemented ordering, prescribing and referring physicians, we call it the OPR process, because we need another acronym. CMS has actually put a halt on the process. It was something that was easier to the pharmacy system because we already pulled those fields but what it requires is every Medicaid provider be enrolled in our system. So for pharmacy what we care about is if you wrote a prescription you must be enrolled in the program. That is not a requirement at this time. So as you can imagine that is a large education outreach for us also. That date has been on hold right now for CMS. We have done preliminary rounds based upon the pharmacy prescriptions and the good news was it was largely residents that were not enrolled into our system. However we did we receive word from CMS that that was okay and they were going to be exempt from this and some out of state providers that were related to facilities and those types of things, so for us with education and facilities and teaching hospitals and those types of things. Our plan overall was to implement the pharmacy edits first with some soft edits, notify them that way and then turn on the rest of the system. It affects other types of providers as well such as home health agencies, DME providers and those sorts. Again, that is on hold right now and it is exciting for you guys because we will get better reporting out of it. That is all I have, I promise.

c) For Possible Action: Approval of 2011 Annual DUR report.

Paul Oesterman, Pharm.D. Chairman: Thank you. So we have in front of us the 2011Annual DUR Report. This report has already been submitted and it's just for us to after- the-fact review.

Carl Jeffery, Pharm.D.: The 2011 is in here for more of a formality because reading through the past meeting minutes we neglected to actually vote and approve the report. I think you reviewed them, but never actually voted to approve, we just need the formal vote to approve.

Paul Oesterman, Pharm.D. Chairman: Out of curiosity what would happen if we didn't?

Carl Jeffery, Pharm.D.: I don't know.

Paul Oesterman, Pharm.D. Chairman: So I will go ahead and ask the Board for a motion to approve the 2011 annual DUR report that we have read and approved previously. We have a motion and a second. Any questions or discussion? Seeing none I will go ahead and call for vote. All in favor of approving the 2011 DUR Annual report indicated by saying Aye.

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those opposed, nay. Motion carries.

d) For Possible Action: Review and approval of the 2012 Annual DUR report

Paul Oesterman, Pharm.D. Chairman: We also have in front of us the 2012 Annual DUR Report to review and approve. So I will open it up for any discussion regarding this report. It is a report that is pretty much fill in the blanks.

Carl Jeffery, Pharm.D.: They are asking for standard reporting so all the states have to do the same reporting to CMS. This one has also been submitted so hopefully you guys will approve it because it's too late at this point. I think it has pretty standard information, the actual screen prints are difficult to read because they're all sorts of tables to scroll over to fill out, those don't contain the best information, but the tables will have the best information.

Coleen Lawrence: We were caught in another timing issue with this because we didn't have our DUR Board last time. We had a time issue. Whereas the last Board report, we hit the timing perfectly right before it was submitted. This one we just ran out of time because of the last meeting.

Paul Oesterman, Pharm.D. Chairman: The one thing that I did notice in comparison between the 2011 and 2012 was very good trend towards generic utilization 71 percent to 77 percent and I think the practitioners should be commended for that.

Coleen Lawrence: As you'll notice the trend with all the review criteria the Board adopts through the whole Federal Fiscal Year, is listed throughout the attachment.

Dave England, Pharm.D.: I'm just kind of curious because this is a standard report that all states submit and the criteria is the same, where does Nevada fit into the mix with all the other states as far as with the specific criteria, are we at the top or the bottom?

Carl Jeffery, Pharm.D.: That is a good question. I've never actually seen CMS produce a report. We submitted it and it goes into a big black hole and we never see again. We never see a report saying OK Nevada here's where you fall.

Coleen Lawrence: The idea is to reformat the report and put them on the website so we can compare. The last couple of years they have been tweaking the reports. So this is the second report and the second revision of this Annual Report. The whole idea is that they are supposed to take this report and they are supposed to start trending the States. This is the second year they have taken this report. This report this year came out, I want to say around two weeks before it was due and hit the cycle and it was very quick because we had to reformat the report. So I know that is the goal from CMS because all the states reports are available on their website once they are submitted, but it is a matter of how they're submitted and they have to go through all the states reports for the trending reports.

Dave England, Pharm.D.: Thank you. You think they would have a best practice posting from the CMS.

Paul Oesterman, Pharm.D. Chairman: Any further discussion on this 2012 report.

James Marx, MD: I move to approve.

Dave England, Pharm.D.: Second

Paul Oesterman, Pharm.D. Chairman: We have a motion to approve and a second. Any further discussion? Seeing none, call for a vote, all in favor of approving the 2012 reports indicate by saying "Aye."

Board votes unanimous: "Aye."

Paul Oesterman, Pharm.D. Chairman: All opposed say "Nay", motion carries.

4) Clinical Presentations

a) Presentation of Hereditary Angioedema Agents (HAE) use and clinical information.

Paul Oesterman, Pharm.D. Chairman: Moving forward on our agenda. We have a series of therapeutic categories that we are going to be reviewing for clinical presentation and Prior Authorization criteria. If

someone wants to address the Board please step forward identify yourself and which company you represent and you will be limited to no more than 5 minutes. Our first one is the presentation of hereditary angioedema (HAE) agents and clinical information. We will start off by asking for any public comment.

Eric Bizjak: I will be less than 2 minutes Eric Bizjac, Pharm.D., Medical Science Liaison for Shire, here to talk about Firazyr or icatibant for HAE. This is an ultra-orphan disorder with five to seven thousand patients in the United States with this disease. It is a disease of deficiency of a C1 protein or a defect in that protein that ultimately results in the creation of bradykinin and that's what leads to the localized swelling. This disease is not only disabling, but it is also can be life-threatening with untreated angioedema having a mortality rate of about 30 percent. These attacks can occur any time and without warning. Several drugs are now available which is very rare in the ultra-orphan disease. Recent guidelines and consensus papers suggest and outline the indications and they do recommend all patients have on demand therapy for home administration. Firazyr is a synthetic dipta-peptide that blocks the bradykinin receptor. It was approved in 2011 for the treatment of HAE attacks in adults 18 and older. Clinical trials have shown Firazyr to be safe and effective when compared with placebo with over 90 percent of the patients being treated with one syringe, but our label in our trial allowed patients to receive a second dose after 6 hours and up to three in 24 hours. The major side effect is redness at this injection site and over half the patients having some burning. Firazyr is a sub-q injection supplied in a prefilled syringe and can be kept at room temperature. This portability is one aspect that makes us different from the other agents out there. Kind of like an Epipen for people with peanut allergies or albuterol for asthma. These people can carry this drug around with them, keep it at room temperature and inject themselves whenever an attack occurs and this is the one thing that is important because a laryngeal attack can occur at any time any place. And that's it, thank you.

Paul Oesterman, Pharm.D. Chairman: Do we have a second person indicating they want to speak? Okay. Just as a reminder, please try to keep it to new information about the medication. Carl if you want to go ahead and address.

Carl Jeffery, Pharm.D.: I think he gave a very good thorough review of the disease state product available. There's one drug that is indicated for prophylaxis treatment and given every 2 to 3 days depending on what kind of reaction the patient has. I think the most common one is one where there is a known procedure that initiates this response so they can give it before a dental procedure or something. All the other ones are indicated for treatment. So with these, they are incredibly expensive. So I think what we want to do is, what our intent with this is to make sure use is appropriate. We don't want this drug thrown at every person who comes in with an ACE or ARB related angioedema. It really only works for the C1 protein deficiency. We have the criteria here, it identifies which patients should meet the criteria.

Paul Oesterman, Pharm.D. Chairman: So the criteria that is proposed, the recipient must have a diagnosis of hereditary angioedema and the product must be prescribed by or in consultation with an allergist or immunologist, and the medication is being used for prophylaxis for the treatment.

Carl Jeffery, Pharm.D.: And to point out that the prophylaxis is just for that one drug.

Paul Oesterman, Pharm.D. Chairman: And obviously this is not the first line therapy, they would have failed other treatments. I am very naïve, so I will ask those who know, who've had a patient experiencing more than one severe attack per month. How do we define severe?

Carl Jeffery, Pharm.D.: Oh, that's a good question. Is it a visit to the ER department? Or is it the need for a rescue agent?

Paul Oesterman, Pharm.D. Chairman: It is in there as part of the proposed criteria and I want to try to have it a little bit more quantified, if it requires a visit to the emergency department or intervention with the primary care provider.

Carl Jeffery, Pharm.D.: Or used as a rescue treatment.

Coleen Lawrence: Are you going to do it on the Prior Authorization form? So the doctor is attesting to it being severe?

Carl Jeffery, Pharm.D.: Right.

Coleen Lawrence: So then you don't have to define what severe is, the doctor then would identify what severe is.

Dave England, Pharm.D.: Is there a medical definition of being mild, moderate or severe? Is there specific parameters? If I was the patient going through this, then anything would be severe.

Carl Jeffery, Pharm.D.: I don't know enough about the disease to tell you that.

Paul Oesterman, Pharm.D. Chairman: I would propose that may be eliminating the severe wording and just have wording that the recipient routinely experiences 1 or more angioedema attacks per month. That way you don't have the gradation.

James Marx, MD: They have to experience one per month and then they don't meet the criteria, and they have recurrent episodes?

Carl Jeffery, Pharm.D.: Oh, so this is just for prophylactic therapy, they would not be using it for treatment they would carry the other products for emergency treatment.

Paul Oesterman, Pharm.D. Chairman: So we have the proposed criteria for the inclusion of the hereditary angioedema agents for both prophylaxis and treatment. Do we have a motion to approve the Prior Authorization criteria?

Larry Nussbaum, MD: Motion to approve as amended.

Paul Oesterman, Pharm.D. Chairman: So moved. Do we have a second?

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D. Chairman: So we have a second. Any further discussion on this? Seeing none then we will call for a vote. All those in favor of approval of the presented criteria please indicate by saying "Aye.".

Board votes unanimous: Aye

Paul Oesterman, Pharm.D. Chairman: Those opposed say "Nay". It passes unanimously.

b) Presentation of Colony Stimulating Factors use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next class is going to be Colony Stimulating Factors. We will ask for any public comment. This is your chance going once.

So we have the Colony Stimulating Factors that are a covered benefit if the recipient meets the criteria. We have their requests for several products including Leukine, Neulasta and Neupogen. Carl do you want to go ahead and differentiate them out for us?

Carl Jeffery, Pharm.D.: There is the Neupogen and the Neulasta, they really are similar agents. They're Colony-Stimulating Factors and are mostly used for patients receiving chemotherapy or other medications that cause decreased white blood cells. Probably 70 percent of these are given in a physician's office, so it creates some sensitivity because we have to understand how physician's bill. It's often given then billed after the fact. So if we decide to move forward with Prior authorizing these for physician administered drugs, we need to make sure we communicate to the physicians. Then there is Leukine which hasn't really shown as effective as some of the other ones, but it is a little bit different. It is called a granulocyte macrophage CFS. It really has the same result.

Paul Oesterman, Pharm.D. Chairman: Up to this point how many patients have we had? It has to be a relatively small number.

Carl Jeffery, Pharm.D.: Yeah they're in your binder there's a graph, this shows how many patients you have. As of June 2013, this is the number of claims so under 50 claims per month for the Neulasta for the last several months, for the Neupogen, 30 per month.

Paul Oesterman, Pharm.D. Chairman: I don't for see this as being something that everyone would run out and prescribe.

Carl Jeffery, Pharm.D.: Its certainly up to the Board to decide that they don't want to put any criteria on it as well. We bring these before the Board as just ideas for the agents that are expensive and have potential for misuse. Looking at the numbers here, I don't see a lot of misuse.

Paul Oesterman, Pharm.D. Chairman: Our concern is more the misuse, P&T can deal with the costs. Do you potentially foresee any concern for the Neulasta or Neupogen with the "and" or the "or" in the criteria? It looks pretty straightforward to me but I would like you to throw it out for discussion.

Carl Jeffery, Pharm.D.: Please let the record show that Doctor Seggev has joined the meeting.

Joram Seggev, MD: I understand it's already past ready hereditary angioedema, but I like to go back if possible.

Paul Oesterman, Pharm.D. Chairman: Perhaps we can finish this one and we'll go back to and angioedema. So Carl to "and/or" statements with the Neulasta, it looks pretty straightforward to me, I just want to make sure we are all in agreement.

Carl Jeffery, Pharm.D.: It looks fine to me, I've stared at these long enough, it makes sense to me.

Paul Oesterman, Pharm.D. Chairman: So I will go ahead and ask for a motion to approve the for the Prior Authorization criteria for these three products.

Carl Jeffery, Pharm.D.: I don't know if you want to make a distinction if this is going to be for physicians drug claims or just outpatient Point Of Sale claims?

Paul Oesterman, Pharm.D. Chairman: I think it should be just for the Point Of Sale. So we will request a motion to approve this criteria for point of sale recipients, not for physician administered.

Dave England, Pharm.D.: Moved as amended.

Paul Oesterman, Pharm.D. Chairman: So moved as indicated.

James Marx, MD: Second

Paul Oesterman, Pharm.D. Chairman: So we have a motion and a second to approve the Colony Stimulating Factor Prior Authorization, slightly modified. Any further discussion? All those in favor please indicate by saying "Aye."

Board: Unanimously, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those oppose, say "Nay". Motion carries.

Dr. Seggev has a request to speak on the hereditary angioedema. Just to give you the background, we did approve the criteria.

Joram Seggev, MD: I understand, but there a couple things, the most important reference just came out less than a month ago and this is the focus and I have the article here. The most important thing is the medication is for any patient with a severe attack regardless of what's causing it. Either medication should be started right away and the most important thing is the need to add to the criteria is, A: outside the hospital and B: in case of failure in the area. And the most important thing to add to the criteria because it is not FDA approved, but there are good data for ACE inhibitor induced severe angioedema. Both medications have been shown in clinical studies to be effective for patients who have life-threatening angioedema. That is more in the larynx and the mouth than hereditary angioedema, and so it should be available for patients who face a life-threatening reaction.

Paul Oesterman, Pharm.D. Chairman: OK, Coleen, let me ask a question, can we approve anything that is not FDA approved like an off label indication?

Coleen Lawrence: No unfortunately, it must be an FDA approved indication, so what occurs if a drug is prior authorized is that that will require that the drug have an FDA indication for the utilization of the drug. So this class of drugs we're looking at, the indication must be for an approved indication. Does that answer your question?

Dave England, Pharm.D.: So if a physician called in and said he wanted one that wasn't successful but he had some literature or do they call that to the PA center to get that override?

Carl Jeffery, Pharm.D.: Our call center will take that into consideration, if there is peer reviewed literature available or if it is an accepted indication available in the community, they will approve it.

Joram Seggev, MD: The whole issue is that the study, it has not been peer reviewed. All that is available right now is case reports. The problem is, those patients that have absolutely no other medications available, Firazyr is not indicated for the end-point only, so physiologically, it is unlikely to have an effect for the patients because the problem they have is not with the C1 protein, it is a problem caused by the bradykinin. I personally treated a patient that required a tracheostomy. I realize we're talking about something from a medical aspect is very significant, so I want to separate the two issues. One is the patients who have severe HAE, classically speaking, and need to have an emergency injection and need to have these products available to them at home. The other is a patient with HAE induced, life-threatening angioedema that requires the patient to have a tracheostomy otherwise, the drug should be available for those cases.

Carl Jeffery, Pharm.D.: Help me understand, does the article state the treatment of choice is to stop the medication causing angioedema, do the effects last after that?

Joram Seggev, MD: The treatment of choice is to stop the medication. If a patient comes in with a drug induced case of life-threatening angioedema, the patient is going to die if we can't open the airway. We can't wait 3 days for the medication to wear off and the angioedema to resolve on its own. There are no other classes of medications that will be effective.

Carl Jeffery, Pharm.D.: If we make a distinction here, it sounds like if someone is having acute attack from an ACE inhibitor, they show up at the emergency department or urgent care, they administer one of these agents in the office, this isn't something we would give to the patient to have be filled at the pharmacy so the patient can have this at home with them. With that distinction the physician administered drug claims, they are exempt from this criteria.

Joram Seggev, MD: The practical problem is that most hospitals and urgent cares will not carry these medications because of the cost. We are having a problem in principal and practical.

Paul Oesterman, Pharm.D. Chairman: In the interest of time, in order for us to proceed forward on this we would have to receive a motion from somebody, other than yourself, to recall the prior approval of the criteria and then we can re-open it and discuss it. Do we have a motion to reopen it and discuss it and it's not to say we can't reopen it again at a future Board meeting but do we have a motion to recall the approval of the Prior Authorization criteria that has been approved?

James Marx, MD: I move to reconsider, I think the information is sufficiently novel for us to talk about.

Paul Oesterman, Pharm.D. Chairman: So we have a motion to recall do have a second?

Larry Nussbaum, MD: I second.

Paul Oesterman, Pharm.D. Chairman: So we have a motion and a second. For the committee, all those in favor of recalling the previous motion please indicate by saying "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those opposed, say "Nay". So we will recall our prior approval so we want to add to the Prior Authorization criteria that for somebody in the event of…

Coleen Lawrence: Mr. Chairman let me give you some for information that may be helpful. So doctor, let me try to assist a little bit here. So, we have two separate issues so you might want to take the first issue first. The second issue is I heard you say is definitely on a compassionate needs basis. And so when you are looking at the overall development of the policy for Prior Authorization, first of all you were not able to hear the first part of the conversation, so this Prior Authorization criteria that you're voting on is only for claims that are going to be processed through the retail pharmacy. So they're not going to be processed through the outpatient hospital that is probably where it may be an incident or through the physician's office. So I want to make sure that you knew which environment we're talking about, because we talk about the physician claims and throw terms around. Secondly, if this is something more of an exception to the environment we're looking at I would encourage the Board to look at it like it might be an exception to the rule verses the rule itself of what occurs. So if its compassionate need then we might want to look at how it applies to the policy too because if we say it's a child who is under 21 then we have what's called EPSDT. That means we can look at children a different way and take a medical necessity, outside of the actual policy, and look at children and we will look at peer reviewed literature, we will look at everything else. It's almost like when clinical trials come in. We turn around and look at all peer reviewed literature in addition to what is written in the criteria. So I would consider if this is a compassionate need or more of an exception to the rule, if you're trying to write the policy around.

Joram Seggev, MD: For compassionate use, what I'm talking about so we're talking about ACE inhibitors. Most patients, when a patients comes in with life-threatening angioedema and can't breathe, there's no time to wait. On the other hand, this is definitely something that will be given in an urgent care or a hospital.

Coleen Lawrence: So we would never see them for this policy then. Because this policy is only going to be at Walgreens or Walmart or the other outpatient pharmacy at the retail corner pharmacy because you guys already exempted the physician's office and it will not apply at the emergency room.

James Marx, MD: I think we're trying to create a policy for a problem that doesn't exist. Has it been an issue where retail pharmacies have been dispensing this?

Coleen Lawrence: That is what I'm trying to hear from the Board and that is what I'm trying to make it clear for the doctor because he didn't hear the first part of the conversation where this policy takes place. I wanted to reiterate that conversation because he was saying when and how quick it happened, I want to get the setting straight.

Joram Seggev, MD: The other problem we have relates to is the patient with documented HAE, who has severe HAE and is required to have this at his disposal.

Paul Oesterman, Pharm.D. Chairman: That's covered.

Coleen Lawrence: I think we already have this covered with your intent.

Paul Oesterman, Pharm.D. Chairman: So my understanding is, right now the recall of what we passed, do we want to rescind our recall and go back? I think we have your concern addressed. Can we reverse our reverse?

Darrell Faircloth, DAG: Sure, your previous action is still in place, so if you want to call for a motion to leave in place.

Paul Oesterman, Pharm.D. Chairman: So I want to call for a motion to leave our motion that we passed and approved in place.

Dave England, Pharm.D.: Moved

Paul Oesterman, Pharm.D. Chairman: Second?

Larry Nussbaum, MD: Second

Paul Oesterman, Pharm.D. Chairman: All those in favor of approving what we already approved, say "Aye.".

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay". Ok great, thank you.

c) Presentation of Ampyra use and clinical information

Paul Oesterman, Pharm.D. Chairman: Ok, moving to our next topic is the use and clinical information regarding Ampyra. Do we have anyone in the audience who wishes to address the Board, please come forward.

Phillip Kenner: My name is Philip Kenner, I'm a medical science liaison with Accorda Therapeutics. I just wanted to share some new safety information that we found post marketing. And I just want to report that the safety information that you have seen in the package insert is very consistent with what we saw post-marketing so there's nothing new to report there. As a result of the consistency, the FDA has allowed us to cancel our REMS program that we were approved with. Any questions?

Paul Oesterman, Pharm.D. Chairman: Thank you, so okay Carl equally quick review?

Carl Jeffery, Pharm.D.: In your packets, I printed off the current Chapter 1200 about Ampyra and it has been three years since this has been reviewed. So this is why we brought this before the Board because there has been some new information about the walk test and we were requested to review this. There hasn't been a whole lot of changes when we went back to review it. We bought this forward based on what the manufacturer provided. Comparing the old and the new criteria, section D, that is the one that has been removed, the patient has undergone the 25 foot walk test, steps based on walking speed and walking speed is documented to be between 8 and 25 seconds. So that's the biggest thing to change that has been stricken.

Dave England, Pharm.D.: I also see ICD-9 codes, you will changing to ICD-10?

Carl Jeffery, Pharm.D.: Right.

Paul Oesterman, Pharm.D. Chairman: The Prior Authorization criteria, A. had the prescriber being a neurologist, that has been removed.

Carl Jeffery, Pharm.D.: Well the second one in the new criteria is in consultation with a neurologist so we switched it.

Paul Oesterman, Pharm.D. Chairman: Okay

Carl Jeffery, Pharm.D.: So the new criteria is just clearer and follows the new step guidelines.

Larry Nussbaum, MD: I move to accept the great new criteria.

Dave England, Pharm.D.: Second

Paul Oesterman, Pharm.D. Chairman: We have a motion and a second. Do we have any further discussion? Seeing none, I will call for a vote. All those in favor say "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those opposed say, "Nay". Okay the motion passes.

d) Presentation of Cymbalta use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next topic is presentation of Cymbalta. Do we have anyone in the audience who wishes to come forward and speak. Was it something I said? Okay, so duloxetine, Carl do you want to go ahead?

Carl Jeffery, Pharm.D.: A couple pages back in the packet is Chapter 1200 and the current Cymbalta criteria. But we have done is expand the coverage because the past criteria was really only limited to two diagnoses and more has been approved. You can see in Chapter 1200, the only listed diagnoses are Diabetic Peripheral Neuropathy and Fibromyalgia. It has indications for muscular pain, Generalized Anxiety and Major Depressive Disorder. So we would add those in the new criteria. Also in the handouts is a comparison of the other agents in this class. Cymbalta by far has the majority of the claims.

Paul Oesterman, Pharm.D. Chairman: I had one question for you in regards to number one, the product for musculoskeletal pain, it looks like there is a section A., part one and part two, part two reads, "the recipient has an allergy or contraindication to all NSAIDS". How do you define that, do they have to try every single NSAID?

Carl Jeffery, Pharm.D.: I guess we can modify that to say 2 NSAIDS, or if it is a severe enough reaction, you wouldn't want to retry a second.

Dave England, Pharm.D.: Would that be two different NSAIDS or two different classes?

Carl Jeffery, Pharm.D.: Personally I would just leave it as NSAID.

Dave England, Pharm.D.: I don't know that would make a difference, if you want to get that selective, but having two NSAIDs would be fine.

Joram Seggev, MD: Well, there is an option of Aspirin, with desensitizing the patient to be able to take aspirin.

Larry Nussbaum, MD: Carl, when I looked over the previous Prior Authorization, we use Cymbalta for psychiatric purposes, was there not a Prior Authorization needed for Cymbalta?

Carl Jeffery, Pharm.D.: There was, and that is why we are bringing it up today. We were getting a lot of requests for depression and generalized anxiety and our call center really had nothing consistent to hold the criteria to. Basically, everything was kind of a gray area for every request they received.

Larry Nussbaum, MD: So was it being approved for major depressive disorder?

Carl Jeffery, Pharm.D.: Yes it was.

Paul Oesterman, Pharm.D. Chairman: Anybody wish to make a motion to approve the proposed Prior Authorization criteria as amended?

Joram Seggev, MD: Moved.

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D. Chairman: Any further discussion from the Board on the proposed criteria for Cymbalta? Seeing none, all those in favor please indicate by saying, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, say "Nay" motion carries.

e) Presentation of Celebrex use and clinical information

Paul Oesterman, Pharm.D. Chairman: Okay the next presentation is Celebrex use and clinical information. Anybody in the audience?

Sandy Sierawski: Hi, I'm Sandy Sierawski I'm a pharmacist, I work for Pfizer in the Medical Division. Celebrex has had CoxII Prior Authorization criteria and it has been in place for a number of years. Last year it was discussed at the July meeting with this Board of potentially removing the bone pain indication because that's not an FDA approved indication. That discussion occurred, but it never got to the public hearing approval process. So I'm hoping this is just a housekeeping formality and request that you remove the bone pain indication because it's not an FDA approved indication. Otherwise, we're good.

Carl Jeffery, Pharm.D.: Sandy's exactly right this is a housekeeping issue to remove the bone pain from the criteria.

Paul Oesterman, Pharm.D. Chairman: Do we have a motion from the Board to approve this minor change this bone pain indication.

Dave England, Pharm.D.: I make a motion.

James Marx, MD: Second.

Paul Oesterman, Pharm.D. Chairman: We have a motion and a second, any discussion? All those in favor indicate by saying, "Aye.".

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: All those opposed say, "Nay". The motion carries.

f) Presentation of Botulinum Toxin use and clinical information

Paul Oesterman, Pharm.D. Chairman: On to next Botulinum Toxin. Anybody?

Karen Campbell: Good evening my name is Karen Campbell. I am a Pharm.D and the Senior Scientific Manager with Allergan. I want to thank the Board for allowing me to make comments related to the Botulinum Toxin class. There are currently four toxins available in the US. Each has a unique list of FDA approved indications. Botox has 8 indications the others have one or two. Cervical dystonia is the only indication shared by all toxins. We support the proposed clinical Prior Authorization criteria and commend the Committee for differentiating coverage based on the evidence and labeled indications. However, we also want to encourage the DUR Committee to recommend that an update be made to the 2013 Medicaid Services Manual Chapter 600 attachment A, 6-11, Botulinum Policy. We request that the committee update this policy to reflect what is currently proposed in the Prior Authorization criteria. The policy does not include all the indications that are in the proposed Prior Authorization criteria nor does the Prior Authorization criteria include all the ICD-9 codes that are currently listed in the provider billing guidelines. The policy has not been updated since 2007.

Coleen Lawrence: On Botox?

Karen Campbell: On Botox.

Carl Jeffery, Pharm.D.: I'm not familiar enough with Chapter 600 to speak on it.

Coleen Lawrence: The DUR Board will have to have that document before we do.

Karen Campbell: So we're just asking the Committee to make that consistent with the proposed criteria presentation and that the billing guidelines, and the ICD 9 codes also be included in the Prior Authorization criteria. I have the ICD 9 codes that have been, for the conditions that have been added to the proposed criteria. Does the committee have any questions for me? We're just asking for the three documents to be consistent.

Paul Oesterman, Pharm.D. Chairman: That's beyond our realm, but we will ask Colleen, and to provide us with the ICD-10 codes.

Karen Campbell: Yes, we will be happy to help you, Medicaid with the conversion to ICD-10.

Coleen Lawrence: So Mr. Chairman, there is a Botox policy in Chapter 600 and what we will do at the next DUR Board, we can pull that and we can look at that based on the new recommendations for Point of Sale. Depending on how you apply it here, we will work on having Chapter 600 next time so we can make it consistent.

Paul Oesterman, Pharm.D. Chairman: So probably what we'll do is make a motion to ask you to do that.

Coleen Lawrence: Absolutely, and we can bring it back, because it is in the physician's offices.

Dave England, Pharm.D.: This is another question, a lot of stuff we are dealing with have an impact on that manual as well. Are these automatically being updated in that manual as well? Or is it completely separate?

Coleen Lawrence: We have our Medicaid Service Manual Chapter 1200, so when you make a change in the pharmacy system, then we have another string of updates in the Chapter 1200 for the pharmacy section, we just happen to have a policy for a procedure in the Physician's Chapter, and that is what the last speaker was asking to make similar. You can review this now or table it and we could bring Chapter 600 to the next meeting and do it together, or you could update this now. You do have the authority to look at Chapter 600,

just because it happens to be the physicians chapter is irrelevant. That is a regulatory process on how we placed it in a chapter.

Dave England, Pharm.D.: I think we would want to be consistent.

Larry Nussbaum, MD: I would like to make motion that we table this and bring them both back at the same time.

Dave England, Pharm.D.: Second

Paul Oesterman, Pharm.D. Chairman: Any further discussion? Ok, we'll call for a vote. All those in favor, say, "Aye."

Board: Unanimous, "Aye.".

Paul Oesterman, Pharm.D. Chairman: Those opposed, say, "Nay".

g) Presentation of buprenorphine and buprenorphine/naloxone use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next topic for discussion is the buprenorphine and the buprenorphine/naloxone. Anybody in the audience?

Juan Tripp: My name is Juan Tripp, clinical pharmacist with Beckett Pharmaceuticals, we are the manufacturers of Suboxone and Suboxone Film, here to speak on continued access to office based opioid treatment. And a key component is appropriate use and is outlined in the guidelines. A clear diagnosis of opioid dependence, which is consistent with the current criteria, DABA 2000 waiver prescribers, limiting those restrictions because of the chronic nature of this disease. Ensuring there is therapeutic dosing and the flexibility with 2, 4, 8 and 12mg doses currently available. The company also supports clinical monitoring of the patient with urine drug screens, where appropriate, to ensure taking the medication buprenorphine and also not taking other illicit substances. And of course psycho-social support, documented counseling that is critical for recovery for this patient population. Suboxone Film was designed to decrease the misuse, abuse and diversion in accordance with the recent research in the abuse and addiction related surveillance data showing significantly less pediatric exposure when compared to the tablet. I would request continued access with flexible dosing of Suboxone film with the appropriate use of guidelines for the class as currently in the criteria. Any questions?

Paul Oesterman, Pharm.D. Chairman: Thank you. Not sure I am up on this, but we are seeing an increase in the use of illicit products by younger and younger patients. We have the criteria here of 16 years of age, is that part of the packaging?

Juan Tripp: Yes, that is the package insert, the clinical studies were done only in a patient population above 16.

Paul Oesterman, Pharm.D. Chairman: Are there any on-going studies looking at the younger patients?

Juan Tripp: There are not.

James Marx, MD: I have a comment on the criteria. There was a recent study, done last December, that showed there was absolutely no difference whatsoever in patients who receive counseling and those not

receiving counseling in terms of success in treatment whether it be on treatment or off treatment. So I'm not sure making the criteria…I mean politically it is correct to say that these people should be counseled, but in fact a fairly large study shows that there was no difference. I'm sure you are aware of that study. So I'm not sure that should be part of our criteria. What will happen is, some patients may get denied because they did not receive counseling, in fact the upshot of the study, was that if the patient received it, they were more successful than not receiving it. While counseling, while we should encourage it, I don't think it should be mandatory.

Carl Jeffery, Pharm.D.: What if we rephrased that to say, "Counseling is offered."? Or available,

Coleen Lawrence: Encouraged? I think we have used that in other areas in the policy.

James Marx, MD: I don't think it should be a barrier to getting approval.

Coleen Lawrence: I think we have used is somewhere else, I think you decided on, "encouraged."

Carl Jeffery, Pharm.D.: I can give a quick overview of our intent with updating the criteria. We wanted to call out, if you look at the current Chapter 1200, it has both Suboxone and Subutex combined in the same criteria, we wanted to call them out because the Subutex should be limited either for the first couple days while being transitioned from methadone or if they are pregnant or breastfeeding. There is really no evidence to say that a narcotic addicted baby gets any naloxone through the breast milk, but we put it in there to be safe. That is why we have this here.

Paul Oesterman, Pharm.D. Chairman: So the fourth bullet point regarding counseling is going to be rewritten to read some to the effect that formal substance abuse counseling and treatment is encouraged and leave it at that.

Joram Seggev, MD: The other point, is perhaps we should try to specify the Subutex should be limited to a short time.

Carl Jeffery, Pharm.D.: You're right, we do not have any criteria that states that. I think it really is up to the practitioner. The guidelines state that the patient should be moved to the Suboxone as soon as possible, because the more Subutex you have on the street, the more potential it has for illicit use. So often times, the guidelines state to give two days at a time of the Subutex until they feel they can transition.

Paul Oesterman, Pharm.D. Chairman: Could we consider a quantity max on the Subutex?

Carl Jeffery, Pharm.D.: Given the nature of the disease, I would be hesitant to put a solid max on there.

James Marx, MD: I think it should be up to the prescriber.

Carl Jeffery, Pharm.D.: Maybe we could put that in the criteria, like we are encouraging counseling, we could say we encourage the prescriber to switch to Suboxone as soon as possible.

Paul Oesterman, Pharm.D. Chairman: That might be something on the next update for the newsletter.

Coleen Lawrence: One thing if you would like us to do, is look at the dispensing patterns of Subutex.

Carl Jeffery, Pharm.D.: They are in here.

Coleen Lawrence: The days supply? Until they move to the Suboxone?

Carl Jeffery, Pharm.D.: In the graph here, they are listed, but they are all together.

Coleen Lawrence: That's why I was thinking if we could get creative to see how long they are on the Subutex before they transition to Suboxone to see if it is an issue.

Joram Seggev, MD: Something that suggests a time, like 5 days or two days limit, this way having to get this re-authorized.

Carl Jeffery, Pharm.D.: Would it add an undue burden to give a week-long PA and have the prescriber renew the PA if they want more than a week?

Coleen Lawrence: Or instead of doing a PA up front, do a quantity limit and after 7 days, then flip it to a PA. Pick a reasonable time frame of quantity limit, and then after the quantity limit, then flip it over to a PA as necessary. And you could have that many however during a 90 day period. You might want to look at it that way.

Joram Seggev, MD: Seems like more and more of this drug hits the street, by limiting the initial number, or quantity limit, I think limiting the number of days is a better idea because that limits the number of pills, the pharmacy may not have the correct strength, so they could double up on a lower strength if necessary.

Larry Nussbaum, MD: It might be helpful for a provider who specializes in this type of treatment come talk to the Board about the treatment and what their suggestion is for the appropriate treatment.

Coleen Lawrence: I could do that, I will reach out to our sister agency and ask them if they can come give a presentation.

Larry Nussbaum, MD: That would make more sense rather than doing a PA from the front end or back end. I don't think we have a real clear sense on the treatment parameters.

Coleen Lawrence: OK.

James Marx, MD: I think the main thing that we have encountered with other pharmacy benefit managers, is a limitation on the period. I'm glad to see there is no limitation on the length of treatment. The other part of that study was that virtually all the patients reverted to their previous drug seeking behavior once treatment was stopped. So I think you want to make sure there are criteria to limit the length of time.

Coleen Lawrence: I will take that away for the next Board meeting to get a presentation.

Paul Oesterman, Pharm.D. Chairman: In the meantime, we can always revamp or readdress the criteria. Do we want to move forward with the proposal that is in front of us now? Without putting any other limitations on this, so there is something you can work with.

Carl Jeffery, Pharm.D.: As a caveat, and something we can discuss at the next meeting, is there is supposed to be another buprenorphine product available in the next couple months. So maybe October would be a good time to discuss.

Paul Oesterman, Pharm.D. Chairman: Do we want to table this or pass what we have? Any strong feelings? Where does it stand right now?

Carl Jeffery, Pharm.D.: Right now, there is no distinction between the Suboxone and the Subutex, and I think that is what our concern is, that potentially we have a provider requesting just the Subutex and it ends up on the street for illicit use. The new criteria adds the different criteria to the Subutex, the breastfeeding or stepping down from another drug.

Paul Oesterman, Pharm.D. Chairman: We have the old criteria, and the proposed new one.

Coleen Lawrence: And it doesn't put a time limit on the use of the drug. So the differentiation is that the Subutex allows for if the recipient is pregnant or breastfeeding an infant.

Carl Jeffery, Pharm.D.: Right, it does add more restrictions on the Subutex from the old one. I would like to see the updated criteria pass, because I think it means there may be less Subutex on the street.

Paul Oesterman, Pharm.D. Chairman: Can we get a motion to approve these criteria, with the addition that we will re-review them at the next meeting with a presentation.

Coleen Lawrence: The one thing I want to point out, is that it doesn't address counseling is in place, not encouraged.

Paul Oesterman, Pharm.D. Chairman: So we want to change that part. "Formal substance abuse counseling treatment is encouraged." And leave it at that. Looking for a motion to approve.

James Marx, MD: I'll move to accept.

Larry Nussbaum, MD: Second

Paul Oesterman, Pharm.D. Chairman: Any discussion from the Board? All those in favor as amended, indicate by saying, "Aye."

Board: unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say "Nay". Motion carries.

h) Presentation of Fentanyl Immediate-Release products use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next topic, Fentanyl Immediate Release products. Anybody in the audience wish to speak? We have in front of us the proposed Prior Authorization criteria for immediate release Fentanyl products.

Carl Jeffery, Pharm.D.: Our intent with this was to expand to the new products that have been introduced. Right now, Chapter 1200 only identifies Fentora and Actiq, so we are missing a whole bunch of other ones. I have a lot of faith in our prescriber community, but things do slip through, there is always something. This would apply the same criteria that are on the others currently.

Paul Oesterman, Pharm.D. Chairman: I have two questions for you. Under the last bullet point of number 1, you have listed some immediate release products, what about the inclusion of Methadone in this list?

Carl Jeffery, Pharm.D.: I think we may have some differences of opinion, but I don't know that I would consider methadone as a medication for breakthrough pain. I think that was the intent with these others, were they are for breakthrough pain or acute pain.

Paul Oesterman, Pharm.D. Chairman: And my second comment, the first part is the authorization, and then the second part goes into, "Immediate release Fentanyl products will NOT be covered…" I would not necessary include things that are not covered in a Prior Authorization criteria. I would just say this is what it is covered for, it is a redundancy to me, to be consistent with the other policies.

James Marx, MD: I think the reason that is in there, is there was a retro-DUR a few years ago, we had about 42 patients receiving Actiq or Fentora and only 3 had a malignant diagnosis. I think that is probably what Carl is trying to get at and I think it really is critical because those 42 claims resulted in about $4 million in expense.

Paul Oesterman, Pharm.D. Chairman: The second part of A . says the patient has pain resulting from malignancy, so it is in there as a positive.

Coleen Lawrence: I have to ask on this one because when we are doing Prior Authorizations, if we can move it to the therapeutic class or to the higher level, your intent is to cover the entire class, we can write it, verses doing drug A., drug B., drug C. I would like to get that in policy rather than naming the drugs, if that is the intent of this policy.

James Marx, MD: Why don't we say it covers the transmucosal oral fentanyl?

Coleen Lawrence: I'm all for that, because we may be back here next meeting with a new product. So that is where we would like to take the policy.

Carl Jeffery, Pharm.D.: I think that works really well here in particular. Not every drug here has a different indication.

Paul Oesterman, Pharm.D. Chairman: So we will revamp this to Immediate Release Oral Fentanyl products.

Carl Jeffery, Pharm.D.: Do you want to say, "Oral"? Because there is a nasal spray too.

Paul Oesterman, Pharm.D. Chairman: Ok, Oral and Nasal.

Joram Seggev, MD: Or immediate release.

Carl Jeffery, Pharm.D.: And did you want to strike the bottom part of this?

Paul Oesterman, Pharm.D. Chairman: I would like to. One other thing we might want to address is the quantity restrictions. You have lozenges and tablets, what about nose spray.

Carl Jeffery, Pharm.D.: Oh yeah, missed that.

Paul Oesterman, Pharm.D. Chairman: I have never seen the nose spray.

Carl Jeffery, Pharm.D.: Do we want to limit that to 120 doses per rolling 30 days?

Paul Oesterman, Pharm.D. Chairman: I would say that is the same base supply, so yes. With the lozenges, they are the only ones available with a generic form right now, correct?

Carl Jeffery, Pharm.D.: Yes

Paul Oesterman, Pharm.D. Chairman: Can we get a report for next time giving us the breakdown of how many of these products are being used of all the IR Fentanyl products?

Carl Jeffery, Pharm.D.: Actually, you do have a report. The products that are not listed have no usage. There is really, we have 8 in January 2013 of the Fentora, so we're spending a lot of time on a few claims.

Darrell Faircloth, DAG: Sorry, Carl, what were you referring to when you said to strike the bottom part of this? I just want to make it clear for the record.

Carl Jeffery, Pharm.D.: Sure, Chairman Oesterman had suggested that we strike the bottom part that includes the exclusion criteria on the form that starts, "Immediate release fentanyl products will not be covered for the following…" and the it lists out A, B, C, D and E.

Darrell Faircloth, DAG: Thank you.

Paul Oesterman, Pharm.D. Chairman: Just to recap, we have a proposal for immediate release Fentanyl products, oral and nasal, having the inclusion criteria and the change of the quantity limitations to include 120 nasal sprays per rolling 30 days. We need a motion to approve.

Joram Seggev, MD: Move.

Dave England, Pharm.D.: Second.

Paul Oesterman, Pharm.D. Chairman: Any further discussion? All those in favor of the revised criteria, say, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed, say, "Nay". Motion carries.

i) Presentation of Oral Anticoagulants use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next topic is the Oral Anticoagulants. Anybody in the audience?

Diana Dills: I am Diana Dills, I am an endorcrinolgist and an internist and I am a research medical specialist and I work with Pfizer Cardiovascular. Today I wanted to address apixiban, or Eliquis. I believe today we are trying to establish reasonable Prior Authorization criteria for apixiban. One of the criteria being considered is warfarin failure. First of all, apixiban is an anticoagulant, and like warfarin, a common side effect is bleeding. Also, as an anticoagulant, if you stop therapy you will increase your risk of having a stroke. But what does it mean to fail warfarin? Even the best Coumadin clinics obtain an INR in a goal range about 72% of the time. While the national average in the US is about 51% in the community. We know that with an INR outside the goal range the patient is more prone to bleeding if too high or stroke if too low. As it turns out, most patients who present with a bleed on warfarin are within the goal range. From the ARISTLE trial, apixiban will decrease the risk of stroke of 21% over warfarin and decrease the risk of major bleeding by 31% and will lower overall mortality by 11%. Two of the most dreaded complications of anticoagulants are intracranial hemorrhage and fatal bleeding. In spite of the fact that warfarin has an antidote and apixiban doesn't, intracranial hemorrhage was decreased by over 51% with apixiban when compared to warfarin. As far as fatal

bleeding, there were 36 fatal bleeds in the ARISTLE study on warfarin and only 10 on apixaban. This was a relative risk reduction of 73%, which was statistically significant. In AVEROSE, it is a study of stroke prevention and a-fib in patients who were deemed suitable for warfarin by the investigator. There, the fatal and intracranial bleeding rates for apixiban were identical to aspirin. The relative risk reduction for stroke however for apixiban was 55% over aspirin. In other words, by requiring that patient fail warfarin, we are subjecting patients to a substantial increase risk of stroke, intracranial hemorrhage, major bleeds and death. By requiring a prior auth on this class we may interrupt therapy, and if you interrupt therapy, you may increase the risk of stroke. The long term safety record of warfarin is well established. It is not a safe drug, it is an effective drug, but not safe, otherwise we wouldn't have put up with it for the last 50-60 years. So ARISTLE is the largest single study of a-fib, it demonstrated that apixiban is clearly the safer and more effective drug. AVEROSE established that apixiban was safe and effective for patients that were deemed unsuitable for warfarin for a variety of reasons. Costs are always a concern, but we really have to consider safety above cost. Any questions.

Joram Seggev, MD: In the data that we were provided, we have the cost provided of generic Coumadin. Can you give us an estimate of how much Coumadin therapy costs with labs compared to these others?

Carl Jeffery, Pharm.D.: I can't site any actual numbers, I have seen some at one point, but I think you still come out slightly ahead with warfarin.

Diana Dills: We do have some data on cost and therapy if you would like.

Sandy Sierawski: Sandy Sierawski with Pfizer. Pfizer works with IMS who has a lot of claims data, and we put together a data base. One of our tools we utilize is this claims database. They put together an a-fib cohort of patients. So we look back at two years worth of data, patients who had at least two diagnosis codes of a-fib, it could be outpatient or inpatient, identified them in the cohort. Once they were in the cohort, we were able to do some analysis of these patients, we have all their medical claims and pharmacy claims etc. So the new oral anticoagulants have only been out for a short period of time, the data we have in here is from the two year timeframe July 1, 2010 to June 30, 2012 and within that cohort there were only two products in there, so Eliquis is not in this data, it is only data on Pradaxa and Xarelto. But it was still striking. I can share this report and pass it around, but the basic demographics, looking at patients who were newly prescribed on warfarin or one of the newer agents and separated them out into two groups. And then looked at those patients, CHADS risk score, age, demographics very similar in the two groups, so we ended up with 2700 patients in the warfarin group and 2200 patients in the new oral anticoagulants. And we were able to look, and yes, when you look at the cost of the medications, compared the two classes, it was higher with the new agents, but when you looked at the total overall health care costs when you looked at outpatient facilities, ER visits, hospitalizations, other medication, etc. The total health care cost, mean cost per utilizing member was $35,000 in the warfarin patient and $28,500 in the new oral anticoagulants. And so I have other data to show how it pans out. But we do have data to show the utilization of data resources in this patient population is less than utilizing warfarin.

Paul Oesterman, Pharm.D. Chairman: I think what we are doing here today is to include apixiban with the others. What I would encourage Pfizer to do is to fund a study, head-to-head study of the three new products.

Sandy Sierawski: Now you're always asking for head-to-head data. We have head-to-head data with warfarin, which has been the traditional product out there.

Dave England, Pharm.D.: I have seen some presentations in some other places as well, along with the new anticoagulants with the old standby, warfarin. The question some of the physicians have been presenting is the problem they are having with the new anticoagulants is with warfarin, you kind of have an idea of when you are getting close to having problems. With the new agents, you don't know you have a problem until you have a problem, and then you have to fix it now, rather than with warfarin, its high or low, you have an idea of where you are going with it. The new medication, you have an NDR, you have an NDR going right now, there is no inkling it is going to happen, and then you have to treat it, emergently.

Paul Oesterman, Pharm.D. Chairman: How do you treat it?

Dave England, Pharm.D.: Is there any data from the studies that show for patient that do have bleeds on warfarin verses patients who have bleeds with the new anticoagulants, what the mortality rate is?

Diana Dills: The bleeds on warfarin, at least in ARISTLE were more severe and were left with more neurological impairment if they were on warfarin, than on apixiban. So they are more severe and more hemorrhagic bleeds. It seems to be a characteristic of warfarin, and all the studies show less intracranial hemorrhage. It is all less with all the products.

Dave England, Pharm.D.: How much sway is in the numbers, because there are so many more people on warfarin than the new anticoags? Even though, we have more issues with the warfarin, was it because we have more people on it? Is the mortality up? Is the bleed greater or worse with the new agents?

Diana Dills: That is what I was saying, in the fatal bleeding group, a lot of the fatal bleeds, there were 36 that happened with warfarin and 10 with apixiban, and this is with equal numbers in each group, 73% less fatal bleeding with apixiban than warfarin, and that is a huge trial, 1000's and 1000's of patients.

Dave England, Pharm.D.: That is good, I haven't seen any of that data.

Sandy Sierawski: That is what is exciting about looking at this data, because this is real world data, it isn't clinical trial data. This is just a sample of patients in a claims data base that we looked at and did some comparisons and identified that it is playing out in the real world.

Dave England, Pharm.D.: Thank you.

Mary Kay Queener: My name is Mary Kay Queener, I am a clinical liaison with the health outcomes group for Johnson and Johnson. I am here to talk about Xarelto or rivaroxiban. I was going to focus on the newest indication. This is a Xa inhibitor, it does have the widest breadth of indications. The first indication was prophylaxis of DVT following hip and knee replacement surgery. The second was reduction of stroke risk in non-valvular a-fib and the most recent indications we got at the end of 2012 was the treatment of DVT and PE and the secondary prevention of DVT and PE in recurrents. So that is really what I was going to speak to just for a few minutes. Because of the acute nature of DVT and PE, Xarelto really does provide an advantage over the standard of care of LMWH bridging over to Coumadin. In that they can be started on Xarelto either in the emergency room or wherever they are seen and then continued as an outpatient. It provides a good continuity of care and obviously that is extremely important in these patients. So there isn't a need for bridging, there isn't a need for INR monitoring, and following the first three weeks of twice a day dosing, it is a once-daily administration of the product, so very easy for the patient to maintain compliance. Also, Xarelto is on all the hospital formularies, so that continuity of care would be easy to maintain. So what I am asking is that you would extend the coverage without a prior auth for this indication. In addition, I think the proposed criteria

has a 30 tablet quantity limit, but with this indication, it is BID for 3 weeks, so the 30 tablet quantity limit would be problematic, so I would ask for the 15 mg dose have a quantity limit be adjusted for this indication. And finally, I just had a question, because the 10mg dose for the DVT prevention following hip and knee surgery is not addressed in the PA criteria, is that because it is new proposed language, is it because it doesn't require a PA? I only saw the stroke prevention and the DVT and PE treatment. I just want to make sure it will still be available.

Carl Jeffery, Pharm.D.: If it is an approved indication, it will be approved.

Mary Kay Queener: Thank you.

Debbie Lin: My name is Debbie Lin, Associate Director of Health Economics and Outcomes Research for BI. I am going to be providing testimony on Pradaxa, an oral anticoagulant. It was approved about three years ago in the fall of 2010 with over 4.3 years of safety trial data. It has been prescribed in over 750,000 patients in the US and over 5 million prescriptions to date. It is a direct thrombin inhibitor indicated to reduce the risk of stroke and system embolism in non-valvular a-fib patients. It is my understanding that in Nevada, there are restrictions for this class, one being the failure of warfarin. I would like to review some recent changes of the label, key defining features and answer any questions. Pradaxa 150mg twice daily is the first and the only approved oral anticoagulant shown to be superior in reducing the rate of ischemic and hemorrhagic strokes relative to warfarin. It is based on the pivotal RELY trial in 18,000 patients. Efficacy data demonstrates that this is the only oral anticoagulant that shows statistically significant reduction in both risk of stroke and systemic embolism and a statistically significant reduction in ischemic strokes and hemorrhagic strokes. We know that 9 out of 10 strokes is ischemic in nature. Further from the label in the RELY trial, the rate of all-c ause mortality was lower on Pradaxa 150mg than warfarin. That is 3.6% vs. 4.1% and to address the questions we just had about the fatal bleeds, it is 28 on Pradaxa vs. 39 on warfarin in the trial. Per the drug safety, November 2, 2012, the FDA conducted the mini sentinel assessment to evaluate risk of GI and major bleeding in the new users of Pradaxa vs. warfarin. Over one year time span what they found was that bleeding rates for both GI and intracranial hemorrhage associated with the new use of Pradaxa do not appear higher vs. new users of warfarin. And those results are consistent with observations from the pivotal RELY trial. As a result of this assessment, the FDA said that it hasn't changed any of its recommendations regarding Pradaxa and Pradaxa provides an important health benefit when used as indicted. It has been recommended as the anticoagulant over warfarin in the CHEST guidelines this year in February 2013, as an alternative to warfarin in the ACCHA and the AHRS guidelines published per its indications. In summary, Pradaxa is the first and only anticoagulant to show superiority in both reducing ischemic and hemorrhagic strokes relative to warfarin in patients with non-valvular a-fib. There are similar rates of major bleeding. Based on this information, we want to suggest that Pradaxa be retained on the PDL and there are no restrictions or PA requirements.

Carl Jeffery, Pharm.D.: The reason we are here is because Eliquis is the new agent to add criteria.

Paul Oesterman, Pharm.D. Chairman: Correct me if I'm wrong, but what I'm hearing is they are trying to compare these three relatively new products, that are good products, with the standard of many years that is also an effective product. We want to level the playing field, but we also want to make sure these products are not being used inappropriately. I think the PA criteria process has been made it such a manner that it is relatively easy for a practitioner to go through this process and I don't know that it is necessarily a bad thing to have in here that the patient had an adverse event with warfarin. I think what we are trying to do today is include a level playing field for the three new products.

Carl Jeffery, Pharm.D.: From my standpoint, what I would like the Board to do is have a discussion about this step through therapy through warfarin. The guidelines are evolving, and warfarin will not always be first line therapy.

Joram Seggev, MD: I think the one thing to take away from the presentation and my experience, is having patients on well-controlled warfarin. The patients we are talking about here are not always the most compliant, and the overall cost of the readjustments, are probably really costing more than any of these newer agents. More importantly, we are talking about patients who are in the hospital for an average of 4-5 days and are on a heparin drip plus warfarin for an average of 5 days, where patients on one of these agents can be out in 2. Observationally, the patient can go home early, we are saving three days of hospitalization. Another issue, is that the only medication that has all the indications is rivaroxiban, so any other medication is limited. Spending the money that can be used for other indications would be a plus.

Carl Jeffery, Pharm.D.: And to follow up on what Dr. Seggev was saying, if you look at the utilization in your binder, right now, the Eliquis has no clinical Prior Authorization criteria. The criteria for the Xarelto was added in May. Looking at the utilization of warfarin in May, there was a small dip and then went back up. Before then, the Xarelto is pretty consistent. I don't know that adding the PA criteria stopped any over-use. It has been flat the whole time.

Dave England, Pharm.D.: So with this, we are just adding Eliquis to the same scrutiny as the others.

Carl Jeffery, Pharm.D.: Right, that is why we are discussing it.

Coleen Lawrence: So let me ask the Board, what if a patient was discharged from the emergency room and they weren't by chance on warfarin, what if we did a continuity of care clause for one of these other drugs. Would that assist? Because that would mean the treatment was established if they were started in a clinic.

Dave England, Pharm.D.: I thought that was in there already, we wouldn't want a patient already established on this already somewhere else, and then we wouldn't make them switch to warfarin.

Carl Jeffery, Pharm.D.: Not specifically for this class. What probably happens, is a patient takes a prescription for Xarelto to the pharmacy, it stops for PA, the pharmacy can fill a 72 hours emergency supply while the PA is processed, but if they don't meet the criteria, that PA may get denied and then the patient may end back up in the hospital.

Coleen Lawrence: I think we could do something like what we do with the antidepressants, I don't know if that meets what you're looking at.

Dave England, Pharm.D.: I think that makes sense, I wouldn't want to take someone off this medication that is already working to make them try something else. If they are already established on this, I think we should continue on this.

Carl Jeffery, Pharm.D.: But how many people are started in the outpatient setting on one of these agents? They are probably all started in the hospital?

Joram Seggev, MD: Cardiac patients with a-fib would be started by an internist, but these really need to meet the criteria. In the hospital, quite a few will start in the hospital, but they are saving 3-5 hospital days. I guess the majority would be started by physicians in the offices.

Dave England, Pharm.D.: How would we want to word it if a patient is already established on this medication, to allow to continue? It would be added to a list of provided medications, it could be the first line check box.

Paul Oesterman, Pharm.D. Chairman: Continuation of therapy. I think we want to word this very carefully, I am thinking we might want a stop-gap measure to approve the addition of apixiban, and then put on the agenda for the next meeting some in-depth processing to assure patients that are started on this don't have an interruption in therapy.

Dave England, Pharm.D.: Right now, if someone had been established on any of these three, and a request comes in, the doctor explains the patient has been on this before, we would still have to go and make our modification to the PA next time.

Carl Jeffery, Pharm.D.: If you approve the criteria as stated now, a patient shows up to a Walgreens, the pharmacy could fill a 72 hours supply while the PA is processed, but the doctor would still have to complete the PA and justify why the patient either can't take warfarin or why they failed. So they would still have to have the step-through program or justify why they can't take warfarin.

Dave England, Pharm.D.: They may still have to go to warfarin after they get their three days?

Coleen Lawrence: They could show why warfarin was unsuccessful and get that.

Carl Jeffery, Pharm.D.: But if they don't have the documentation in the chart, or if the doctor isn't willing to complete the paperwork, there is a good chance the patient is going to go without therapy or they are going to be on a trial of warfarin.

Paul Oesterman, Pharm.D. Chairman: The other alternative would be to add another "or" is currently on the medication.

Carl Jeffery, Pharm.D.: I was trying to see if we could use the same wording as the antidepressants.

Coleen Lawrence: The antidepressants is continuation of therapy. It is in our PDL exception criteria. We can come back with it. All the other policy you have done is for existing Medicaid recipients. They have had the claim that has hit the system before, so if they have had the drug before, then it bypasses the requirement.

Carl Jeffery, Pharm.D.: The problem is with these patients being in a hospital, we may not see that claim for days or months.

Dave England, Pharm.D.: So at the retail level, the retail pharmacy could produce the medical reconciliation to show they were on it in the hospital.

Coleen Lawrence: On the antidepressants, one of our continuity of care is "was discharged on a hospital on this medication" and it is on the PA form that way as a check-box.

Paul Oesterman, Pharm.D. Chairman: Do we want to add that.

Carl Jeffery, Pharm.D.: I'm just thinking of the logistics of how it would work in a pharmacy. Right now we only accept PAs from the prescriber, not the pharmacy. So if we were going to go down that avenue, I would like some criteria either the pharmacist can call the call center, because if they have to call the doctor, it is going to delay the PA. Either that, or we have the ability in our system where a pharmacist can put in an override themselves.

Paul Oesterman, Pharm.D. Chairman: For today, what do we wish, to move forward? What is going to work best for you?

Carl Jeffery, Pharm.D.: I think to make it level for all the products, whatever we decide on, it needs to be equal for all agents. As it stands now, if we table, it is unfair to some of the manufacturers. How I would like to see, from what I have seen clinically, and what we have discussed at P&T is to remove the step through for warfarin. We could also put an edit in place where the pharmacy can transmit a diagnosis and get that approved immediately.

Coleen Lawrence: What you could do on the drug classes is, make it at the drug class level so if new products come out…

Carl Jeffery, Pharm.D.: Because they have different indications, that may not really work. I don't think there are any more in the pipeline.

James Marx, MD: I have an issue to that I think it is sort of punitive to require the patient to either not achieve an INR of 2-3 or have an adverse event before they meet the criteria. I think those two bullet points should be removed, I think it is totally inappropriate given the current knowledge, I have a problem with that.

Carl Jeffery, Pharm.D.: That is where I would like to see it go too.

Paul Oesterman, Pharm.D. Chairman: Has P&T addressed this yet?

Carl Jeffery, Pharm.D.: P&T just looked at the preferred agents, and they are all preferred right now.

Paul Oesterman, Pharm.D. Chairman: We could be very assertive and remove the warfarin criteria that is in there, and include the continuation of therapy.

Carl Jeffery, Pharm.D.: We don't have a system to look at continuation of therapy.

Coleen Lawrence: You wouldn't need to if you are going to remove the warfarin criteria.

Paul Oesterman, Pharm.D. Chairman: That's true.

Carl Jeffery, Pharm.D.: I think what the option is, if you remove the warfarin criteria, just make the edit so if the ICD-9 is transmitted on the pharmacy claim, the claims would pay. That way, at least we would check the diagnosis is matching up.

Dave England, Pharm.D.: I move to make that amendment.

Coleen Lawrence: So for warfarin, they're going to have a diagnosis?

Carl Jeffery, Pharm.D.: No, for the Eliquis, Pradaxa and Xarelto.

Dave England, Pharm.D.: We would have to have the ICD-9 diagnosis.

Carl Jeffery, Pharm.D.: Would be for a-fib for Eliquis and Pradaxa, and then Xarelto would have a-fib and the DVT and PE treatment and prophylaxis.

Dave England, Pharm.D.: I make that motion.

Joram Seggev, MD: I second.

Paul Oesterman, Pharm.D. Chairman: We have a motion and a second to approve the revised criteria for the newer anticoagulants that will have the pre-requirement for warfarin failure or adverse event and specific indications for the respective products.

Carl Jeffery, Pharm.D.: I would also strike, if we want this to go through at the pharmacy level, I would also strike the contraindication bullet point, that is not something the pharmacy can evaluate.

Paul Oesterman, Pharm.D. Chairman: Ok, then we would remove that.

Coleen Lawrence: But if they do not have the diagnosis, then they are subject to the Prior Authorization criteria.

Carl Jeffery, Pharm.D.: Right, the claim would deny, needing PA, but then it would it would go to the doctor and the criteria as stated would just be to check the diagnosis.

Paul Oesterman, Pharm.D. Chairman: Any further discussion? All those in favor of the amended criteria, indicate by saying, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed, say, "Nay." The motion carries.

a) Presentation of Antiviral influenza products use and clinical information

Paul Oesterman, Pharm.D. Chairman: Good discussion. Our next topic is the antiviral, influenza products. Anybody to speak? So we have the criteria.

Carl Jeffery, Pharm.D.: The only reason we wanted to bring this up, and this was a suggestion from our clinical call center from what they have seen in other states is people who get a new Tamiflu every flu season. Based on their recommendation, we want to add some quantity limits for Tamiflu and Relenza.

Paul Oesterman, Pharm.D. Chairman: Based on this, how many courses of therapy per year are you seeing?

Carl Jeffery, Pharm.D.: So it would be two courses every 90 days.

Dave England, Pharm.D.: In the criteria, does it state they need the diagnosis of influenza. If it has been five days of therapy…

Carl Jeffery, Pharm.D.: We don't have any clinical criteria, we're only doing quantity limits right now. But we can certainly add some criteria.

Dave England, Pharm.D.: Especially with the shortage of Tamiflu we have seen in the past few years. Because of the prophylaxing rather than treatment.

Coleen Lawrence: And you guys have the utilization in the binder.

Paul Oesterman, Pharm.D. Chairman: At least the use is in flu season.

Joram Seggev, MD: The problem with pre-authorization for this medication is because you have 48 hours to start therapy. I think adding criteria would be detrimental. These are the clinical criteria, one of the things could be a post-treatment option for education. But for practical reasons, I think limiting quantity is the best practical option.

Carl Jeffery, Pharm.D.: We could also put criteria after the first course, so the first course is free, the next one you have to justify why you need additional doses. As it states now, it is just quantities.

Paul Oesterman, Pharm.D. Chairman: These quantities are consistent with what other states are doing?

Carl Jeffery, Pharm.D.: Yes.

Paul Oesterman, Pharm.D. Chairman: Requesting a motion?

Joram Seggev, MD: I'll move.

James Marx, MD: Second.

Paul Oesterman, Pharm.D. Chairman: Any discussion? All those in favor say, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay." Motion carries.

b) Presentation of Antihyperlipidemic Agents for treating Homozygous Familial Hypercholesterolemia (HoFH) use and clinical information

Paul Oesterman, Pharm.D. Chairman: Our next criteria is for the Antihyperlipidemic Agents for treating Homozygous Familial Hypercholesterolemia use and clinical information.

Anyone wish to speak?

Patrick Jensen: Good evening, my name is Patrick Jensen, I am an MSL with Agerion. I am a Pharm.D. by training and prior to coming to Agerion, I managed a lipid clinic. Today we will be reviewing the limitations of therapy and then discussing some of the safety and efficacy of Juxtapid by reviewing some of the pivotal phase three studies. As many of you are aware, HoFH is a rare condition with a historically estimated prevalence of approximately of 1 in one million. HoFH is a serious life-threatening disease, characterized by elevated LDL-c levels despite lipid lowering therapies, resulting in premature arterial sclerosis. Diagnostic criteria for HoFH is variable and not universally defined. Generic testing is rarely used in the diagnosis as there are over 1600 mutations, with others yet to be identified. Which leads to a high false negative rate of about 20%. Due to the inaccuracies of genetic testing, a medical diagnosis is much more prevalent. The clinical diagnosis in the literature typically includes significantly elevated LDL levels in treatment naive patients. In patients on LDL lowering therapy, the LDL range can be wide due to the variability of the disease. In our phase three study, we had confirmed HoFH patients on LDL lowering therapy including apheresis ranging from 152 to 565. Other studying HoFH have documented LDL's in the 190's. Physical features may also be present and include corneolarkus, cutaneous or tendenous anthalmus. Parenteral history of significant hypercholesterolemia and or premature cardiovascular disease may also be present. So now a little on Juxtapid, which is an oral microsomal tryglyceride transfer protein inhibitor. Which prevents the assembly of Apo B containing lipoproteins. Which leads to the reduction in LDL-c, total cholesterol, ApoB

and non-HDL cholesterol. Juxtapid is contraindicated during pregnancy, with the concomitant use of strong or moderate 3A4 inhibitors and those who have moderate or severe hepatic impairment or active liver disease. Limitations include the safety and efficacy have not been established in patients who do not have HoFH. The effect on cardiovascular morbidity and mortality has not been determined. In addition, the safety and efficacy in the pediatric population has not been established. In addition, Juxtapid has a boxed warning regarding the risk of hepatotoxicity because of the potential for liver enzyme abnormalities as well as an increase in hepatic fat. Because of the potential for hepatotoxicity, Juxtapid is only available through a REMS program, which includes the mandatory certification of prescribers and an attestation form that is signed by the prescriber affirming the diagnosis of HoFH. I would also like to quickly review our pivotal phase three study, which was a multi-national, single arm, open label 78 week trial involving 29 HoFH patients. The primary endpoint of this study is the reduction of LDL-c at week 26. The study began with a 6 week run in period to stabilize other lipid lowering therapies including apheresis, and initiate a low-fat diet with less than 20% of calories from fat, which is important to assist in the GI tolerability. After the 6 week run in period, the patients entered the efficacy period from week zero to week 26 during which time they were started on 5mg for two weeks and then based on tolerability, the dose was increased every 4 weeks to the individualized dose which may have included a max of 60mg daily. After 26 weeks, the patients entered a one year safety phase, during which time, the max tolerable dose was continued and background lipid therapy could be altered. For example if a patient was on apheresis at week 26 through 78, the investigator could adjust the LDL apheresis regimen based on their thoughts. So almost 80% completed the primary endpoint at week 26 and the same approximately 80% completed the entire trial. At week 26, the mean percent reduction in LDL-c in the intent to treat population was a statistically significant 40%, and again that is on top of their existing therapy. The 23 patients that completed the 26 weeks, a statistically significant 50% reduction of LDL-c was observed. The most important and common side effects were GI in nature, reported by 93% of patients. And in closing, when used within the guidelines of the prescribing information as well as REMS program, the potential for the 40-50% LDL-c reduction on top of existing therapy provides the effective treatment option with patients with HoFH. Any questions?

Carl Jeffery, Pharm.D.: Do you have some cost data for apheresis?

Patrick Jensen: Heparin based or dextran sulfate columns?

Carl Jeffery, Pharm.D.: Either one, I just know that treatment is often an alternative to Juxtapid. Or can be adjunctive as well.

Patrick Jensen: Yeah, it can be adjunctive, in our study, we included LDL apheresis patients, and of the 13 patients who were on LDL apheresis at week 26 when lipid therapy can be changed, half of those patients were able to have their LDL apheresis adjusted. So of those 13, 6 had their LDL apheresis changed, three stopped LDL apheresis all together, the other three had theirs reduced. The costs is really treatment center dependent, it's going to be roughly anywhere between $50,000 to $100,000 per year, so it's not cheap.

Carl Jeffery, Pharm.D.: We're here for two new agents for a very rare disease, extremely expensive agents here. That is why we wanted to make sure they are being used appropriately. They are in limited distribution and in a REMS program. My fear is that a family practice doc may look in the book and see Juxtapid for high LDL's. I highly doubt that will ever happen, but one time it happens, is all it takes. So that is the reason for the criteria here.

Dave England, Pharm.D.: Basically we have nothing else other than the lipid lowering agents that we have right now.

Carl Jeffery, Pharm.D.: And the mechanical apheresis. Which is kind of a dialysis for your LDL's.

Paul Oesterman, Pharm.D. Chairman: Anybody have any insight? Have we had any patients with a diagnosis of HoFH?

Carl Jeffery, Pharm.D.: We have no use of either of these agents so far. There are two of them, there is an injectable one and an oral agent. The other one is Kynamro.

Joram Seggev, MD: So we are looking at an extremely small number of patients, and we should probably get some input here from an endocrinologist.

Carl Jeffery, Pharm.D.: Growth hormones are next, any endocrinologists around?

Scott Steppi: My name is Scott Steppi and I work for Novo-Nordisk, thank you for allowing me to speak. There are seven growth hormones…

Paul Oesterman, Pharm.D. Chairman: No, we don't want a growth hormone talk yet, this doesn't count toward your five minutes, we were looking for someone, endocrinology wise to speak on HoFH.

Scott Steppi: So I just embarrassed myself by coming up here. Should I go back and we can start over?

Paul Oesterman, Pharm.D. Chairman: You can just stay there.

Carl Jeffery, Pharm.D.: I think what the manufacturer didn't like about the criteria was using the genes for diagnosis. I think that was their heartburn when I spoke to them previously. It is really hard to diagnose based on this.

Dave England, Pharm.D.: Do we want to table this until next time? We might not see it between now and next time, so do we want to come back with an endocrinologist?

Paul Oesterman, Pharm.D. Chairman: Or do we want to include criteria that it must be prescribed by or in consultation by an endocrinologist?

??: These are lipid specialists, they are not always endocrinologists, it could be a cardiologist. There are a couple identified in Nevada, a couple lipidology specialists, but so far no patients as you mentioned.

Patrick Jensen: The majority of patients that see these HoFH patients are cardiologists and lipidologists. There are a couple endocrinologists, but the vast majority are cardiologists and lipidologists.

James Marx, MD: Does that REMS program limit the prescriber, so isn't there already a process in place to limit the prescribing of this already, so only REMS certified pharmacies too. So there is already a two level means of preventing inappropriate use already.

Patrick Jensen: We did self-impose a more stringent REMS program, actually we went to the FDA prior to them telling us what they would like our REMS program to be and asked them to include an attestation form that the prescriber has to sign affirming the diagnosis of HoFH. So to Carl's point, if you're worried about a family practice doc who maybe a lipidologist or a specialist in the field, whoever prescribes this is going to

have to sign that attestation form affirming the diagnosis. So that will definitely put the brakes on anybody whimsically prescribing Juxtapid.

Coleen Lawrence: But that is one drug right? So is that for Kynamro too?

Inaudible: They also have a REMS program.

Coleen Lawrence: So maybe the policy is to say participation in the REMS program.

Paul Oesterman, Pharm.D. Chairman: But they have no choice on that. Do we want to add, even though it is redundant, participation in the REMS program?

Coleen Lawrence: I don't know, that is something we can look at and discuss a little bit more.

Carl Jeffery, Pharm.D.: And if that is our criteria, why add that extra burden to the prescriber.

Dave England, Pharm.D.: They would have to be on the REMS program anyway.

Coleen Lawrence: But we could check out the other drug.

Dave England, Pharm.D.: I move we table this discussion.

James Marx, MD: Second

Paul Oesterman, Pharm.D. Chairman: So we have a motion and a second to table this until we have additional discussion information. All those in favor say, "Aye.'

Board: Unanimous, "Aye.".

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay".

c) Presentation of Growth Hormone agents use and clinical information

Paul Oesterman, Pharm.D. Chairman: Now, Growth Hormone.

Scott Steppi: Hi, my name is Scott Steppi and I work for NovoNordisk. There are seven growth hormone products on the market, there are no head-to-head trials. Norditropin Flex Pro is one of the products that is available for Nevada Medicaid. What I wanted to do is just show the Board how we are different because they are all somotropin products, but the pen devices are very different. Our pen, when the doctor prescribes it, the patient gets it just like this, so it is already prefilled, premixed, preloaded, refrigerated when it comes, the patient just puts the needle on the pen, and after the first dose, they are able to keep this next to their bedside at room temperature for three weeks. It is the only delivery device that does not have to be refrigerated after the first dose. So that makes it very convenient for patients when they are traveling to their grandparents or camp and they keep it in their backpack. Because it is small, they can administer it themselves after they get started on it. So I wanted to show you the device, it is available.

Carl Jeffery, Pharm.D.: This hasn't been reviewed since 2008. Had a lot of feedback from the endocrinologists about the criteria and how it doesn't meet the current guidelines. So we have updated it. One of the biggest changes we have made, and I think it may cause some problems, is we have taken out the idiopathic short stature indication as an approval. Take it for what you want, if it is cosmetic or how you

interpret that, but it is no longer an approved indication in our criteria. I'm warning the Board that you may get some pushback from the community.

Dave England, Pharm.D.: Does that reference this letter from this doctor in Vegas?

Carl Jeffery, Pharm.D.: Right, I'll highlight that letter from Dr. Saad here. She is a pediatric endocrinologist and we see a lot of requests from her and her office. Some of the bigger changes is for the recertification, right now we have a hard time recertifying these kids. The way it reads now is the kids have to have a bone age of less than 2 standard deviations below the mean. So the way we have it established now, we give them growth hormone until they catch up with their peers, and then we stop it and they fall back until they need it again and catch up. So the recertification criteria has been made a little easier. So once the kids qualify, it is easier to re-qualify, it is not a constant up and back.

Dave England, Pharm.D.: So basically, her comment here in paragraph four in here, once they reach the percentile, they are not cut off, so they can still continue therapy. But they are going to be out of luck if it is for idiopathic short stature.

Carl Jeffery, Pharm.D.: Right.

Dave England, Pharm.D.: She comments in here, in order to get around that idiopathic short stature, all they have to do is recode it as a growth hormone deficiency.

Carl Jeffery, Pharm.D.: Not all idiopathic short stature have a low growth hormone levels. This is one of our most challenging things is that we see that they have normal growth hormone, they are just small kids, so it is a tough decision.

Coleen Lawrence: That is one of the main reasons we go to hearing on growth hormone.

Carl Jeffery, Pharm.D.: Since I have been here, we have gone twice to hearing for growth hormone and it has been for idiopathic short stature. Right now they don't meet the recertification criteria because their bone age is caught up. But making the criteria more solid here, because I'm sure it will come up again.

Coleen Lawrence: So if this is removed completely, there would not be any coverage criteria, but it isn't a non-coverage.

Carl Jeffery, Pharm.D.: That's a good point, we may be setting ourselves up for a problem, because it is an approved indication and there is peer reviewed literature, and so potentially, they could get around it that way.

Coleen Lawrence: Because if you don't have it addressed in the policy as a non-covered indication, and you have peer reviewed literature and it is an actual approved indication for that drug, then the call center still has to address it. You are just in limbo of what is defined as short stature. And that has been the limbo, is the child just small or is it another diagnosis. I don't know by eliminating that written policy if it addresses the situation. I do know for the Board that this is an issue and I think we have seen some issues around inappropriate use for children trying to excel in athletics, unfortunately it is a sad thing, but you do see it. It is the next wave of trying to do things.

Dave England, Pharm.D.: By putting this idiopathic short stature as a cutoff, does it decrease that?

Coleen Lawrence: I don't know because one of her things says, no means can be identified for short stature. That means it is not diagnosable. Well then you would hope that you would throw a diagnosis on there. That goes back to another subject that every other drug we cover comes with a diagnosis. If you exclude it and you silence it, then you pretty much ok'd it. Does that make sense?

Paul Oesterman, Pharm.D. Chairman: So do we want to approve the criteria as it has been presented? A motion to approve?

Dave England, Pharm.D.: I move to approve.

Larry Nussbaum, MD: Second

Paul Oesterman, Pharm.D. Chairman: I have a motion to approve and a second. Just for documentation purposes for the record, Dr. Seggev had to leave, but we do still have a quorum.

Any further discussion? I will call for a vote, all those in favor please indicate by saying, "Aye.".

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay". The motion carries.

d) Presentation of PA criteria for psychoactive medications for children – child psychiatrist updated rules

Paul Oesterman, Pharm.D. Chairman: Ok, we have the presentation of Prior Authorization criteria for psychoactive medications for children, child psychiatrist updated rules.

Anybody in the audience wish to speak regarding psych meds in children? Carl.

Carl Jeffery, Pharm.D.: There isn't any clinical information in your binder, just some utilization report, but what brought this up is a few pediatric psychiatrists in Las Vegas that would like a little bit easier access for their clientele to get these medications without having the burden of a PA. I think what they would love is to not have any criteria at all, but that isn't going to happen. So the options are that we have, we have some exceptions for the ADHD medications, if the prescriber is a child psychiatrist and the pharmacy transmits a diagnosis of ADHD. And for the anti-seizure medications, there is a bypass if the prescriber is a neurologist and the pharmacy transmits a diagnosis of a kind of seizure related code, the claim passes any kind of clinical edit. Outside of that, all claims need to meet the criteria that is outlined in the Chapter 1200. I think where they want to go is expand that to these other classes and the antipsychotics is the biggest class.

Coleen Lawrence: For the Board members, there are two reports that were handed out which is a prescribing pattern handout and a second from 2008 to 2012 and it breaks down all the psychotropic meds by class. And then we asked Catamaran to break down the prescribing pattern on the top 25 prescribers. We redacted the information because we are in an open meeting. How you read that report, because it is important to look at because everyone has their own information that when you're looking at these psychotropic medications that it might be your general practitioners who are your top prescribers, and this has always been the trend honestly in our area. So when you look at this report, if it says psychiatrist and 500 claims, that is one psychiatrist, psychiatrist A, we just wrote the specialty, just redacted the names. So we went to the next one is a pediatrician and then the next one. So you can see all the different groups of medications by class and then the

subspecialty underneath, by claim count and then the number of recipients next to that. I think that is your best information.

Larry Nussbaum, MD: This is a year?

Carl Jeffery, Pharm.D.: This is October 2012 through June 2013, 9 months.

Dave England, Pharm.D.: A lot of meds for kids.

Coleen Lawrence: And you have to remember that is with the Prior Authorization criteria for kids. The anticonvulsants, we are doing the bypass now, so if you're a neurologist if it is for seizure diagnosis.

Dave England, Pharm.D.: So the antipsychotics, the majority are written almost two to one by a pediatrician?

Coleen Lawrence: That is just one pediatrician, but the next one is a psychiatrist and the third one down is a child psychiatrist.

Larry Nussbaum, MD: There are multiple issues here. There are very few FDA approved rationales for giving antipsychotics to kids under 18. There are several, but certainly not to the extent of the adult doses. That in itself is a concern, just the number of medications, not necessarily the prescribers.

Coleen Lawrence: You can see that in the larger report that talks about the pattern and trend of number of prescriptions. Look at the zero to four, we have 2 point something prescriptions per month for 4 year olds on antipsychotics. And they took a blip back up. Remember, we're on Prior Authorization criteria right now, the way the criteria reads is that we are just asking for them to disclose a diagnosis or indication for each prescription that they are getting authorized. It really isn't that we have education or consultation with a psychiatrist, when possible, be prescribed or in consultation with a child psychiatrist, and should be part of a comprehensive treatment plan.

James Marx, MD: I'm trying to figure out 2011 to 2012, zero to four year olds.

Coleen Lawrence: I know, we have seen that before too, and then it spikes back up again. I know that there was a request to bring it back to the Board and asked what our proposal was and I have no proposal. I want to stay neutral and stay as-is. Dr. Nussbaum, he goes through the process on a Prior Authorization, and we made this in 2009, the criteria was made with five psychiatrists when developed initially. We extended it to over 18 policy in 2010 because we weren't seeing the change in the over 18 policy, and that is where it changes. And you can see where we implemented it in 2009 because there was a delay in our system, it made a difference in the zero to four and then it creeped back up again. So I don't…

Dave England, Pharm.D.: So even with that criteria we had five psychiatrists help us develop it and we're still getting this.

Coleen Lawrence: I think that…well the zero to four did take a drop and then has come back up and is leveling, I think that I would be cautious if I removed anything because even if you removed a child psychiatrist or psychiatrist in that arena, you could see some of your top prescribers are still, are bypassing that arena. And I always say that it is not the good ones that I am worried about, but there are some in that arena. And all we're asking for is that disclosure for indication or diagnosis. And if it is that we need to start looking at what we're collecting and do something different with and see how we can collect information on the system and start doing something with it.

James Marx, MD: Are there any cross steps that we have concern with, I mean for the zero to four groups where there are 250 kids with an anxiety diagnosis, to me that seems pretty incredible. I would like to see who is making that diagnosis, and the same is true for anticonvulsants, I don't have a problem with, but antidepressants and antianxiety agents, I think there can be severe consequences in using these drugs in patients in such an immature group. Plus the additional potential and the cost later on, this is just an incredible number, I'm shocked.

Coleen Lawrence: Honestly, every time we start looking at these numbers, that is usually the reaction we get. I don't mean that sarcastically by any means, every time we want to present something for relaxing our Prior Authorization criteria, we start showing these numbers and that is exactly it. Whatever data you would like us to try to get off the Prior Authorization, it is a manual process, but we will go through it.

Carl Jeffery, Pharm.D.: Especially diagnosis codes, those are more difficult to match up.

Coleen Lawrence: But they are collected on the Prior Authorization criteria though, that is why we have done this exercise before.

Carl Jeffery, Pharm.D.: But still they only have to put one in there, if a patient has multiple diagnosis, then it will just list the first one.

James Marx, MD: If you look at the atypical for the zero to four year old, you can make the diagnosis of anxiety or depression of any kind.

Larry Nussbaum, MD: I guess the question is, I'm not so sure the Drug Use Review Board is the arena to deal with this. I wonder from my point of view it seems like it is such an issue and these numbers are so compelling, that I guess I wonder if we want to put some kind of group together of both public and private sector people to address this issue. I don't think you're going to have strength coming from just a Prior Authorization standpoint. These numbers are crazy, and part of that is, I don't prescribe a lot of medication, but these numbers are ridiculous. These are only Medicaid sector, and this is probably nothing compared to the private sector. I guess I wonder if we can use this for a spring board for making some kind of cohesive group to address this important issue right now.

Coleen Lawrence: Absolutely, and there is a larger format with our counties and our partnership with DCFS, and I will tell you that they rely on our Drug Use Review criteria to manage those children right now, and so, we can definitely do that, and we can look at some data to pull together for that. I think with that, off line. My first question to you, is do you want to do anything with this Prior Authorization criteria then?

Paul Oesterman, Pharm.D. Chairman: I would propose at this time that we ask you to go ahead and leave that until we get more guidance and direction from what Dr. Nussbaum has proposed or another group.

Dave England, Pharm.D.: Do we want to initiate these now or come back to these too?

Larry Nussbaum, MD: I think there needs to be some pressure on the system to change. I think if you attempt to change things by changing the Prior Authorization criteria, you're always going to have that pressure.

Coleen Lawrence: And I will work with you on another group.

Paul Oesterman, Pharm.D. Chairman: So we're going to table any action on this.

Dave England, Pharm.D.: So moved

James Marx, MD: Second.

Paul Oesterman, Pharm.D. Chairman: All in favor, say, "Aye."

Board: Unanimous, "Aye."

Paul Oesterman, Pharm.D. Chairman: Those opposed say, "Nay".

5) DUR Board Requested Reports

a) Report on Promethazine with Codeine syrup use

Paul Oesterman, Pharm.D. Chairman: Now on to our requested reports. Promethazine with codeine use. I know we requested a report on this and the background on this is promethazine with codeine is one of the more widely misused products, abused products. We have this report showing the usage from October 2012 to June of 2013.

James Marx, MD: Are these individual patients?

Carl Jeffery, Pharm.D.: Yes, this one number…

James Marx, MD: This is incredible, this is what we expected.

Paul Oesterman, Pharm.D. Chairman: I'm just mind boggled, first of all that someone would have 18 different submission in less than a year for a quantity of almost 8 liters, there is a problem with our system. I don't want to sit here and put a Prior Authorization on this, but a quantity limit or something.

Coleen Lawrence: Well, it is one pharmacy and two prescribers.

Paul Oesterman, Pharm.D. Chairman: The next question I have, you mention two prescribers, these patients that have an excess of 10 claims, is it the same prescriber.

Carl Jeffery, Pharm.D.: We have the number of unique prescribers over here, so there are two different prescribers.

Paul Oesterman, Pharm.D. Chairman: No, I understand that, but is patient A. and patient C. seeing the same prescriber. We need to do something.

Coleen Lawrence: I can work with Dr. Marx off line, to come up with a number one, a web announcement for…

James Marx, MD: This is just incredible, in the good old days, about 20 years I got a pint bottle of promethazine with codeine and it lasted me 15 years, I know it is outdated, but it still worked.

Coleen Lawrence: We will work with you for a web announcement, because that is our first level of education on this. Obviously our pharmacies are, not that many.

Carl Jeffery, Pharm.D.: Well if you look at the third one down, they have 5 pharmacies, that person is shopping around, but most are ones and twos, so they are…

Coleen Lawrence: We'll see if we can find a pattern.

Paul Oesterman, Pharm.D. Chairman: Thank you for providing this report, it did provide some eye-opening information and if you can dig a little deeper, there might be something to address with action items next time. Any other discussion?

b) Report on Top 10 Black Box warning medications:

Paul Oesterman, Pharm.D. Chairman: Ok, the report on the top 10 black box warning drugs.

Carl Jeffery, Pharm.D.: I don't have that one, I didn't have time.

Paul Oesterman, Pharm.D. Chairman: Ok, so we will defer that to the next meeting. Ok, the DUR reports.

6) Standard DUR Reports

Paul Oesterman, Pharm.D. Chairman: Ok, so we will defer that to the next meeting. Ok, the DUR reports.

Carl Jeffery, Pharm.D.: We have the top 10 therapeutic classes by amount paid separated by quarter, pretty much what you would expect, hemophilia products, we had a guy that gets a lot of factor product that was hospitalized, so that is why it took a little dip. That's why it went down and then back up.

Coleen Lawrence: I want to point something out with hemophilia, our patients, we know them so well, Carl actually looks at the processing of those factor drugs to make sure they are billed correctly down to the decimal point, calls the pharmacy to make sure they go through the system correctly because obviously they are a very high dollar in our system. But I just wanted to point that out.

Carl Jeffery, Pharm.D.: I don't do anything clinically, but check for keying errors, but when they are putting in 100's of 1000's of units, it is pretty easy to miss a decimal point. Then the next page the top 10 classes by number of claims, just what we expect, the hydrocodone products.

Paul Oesterman, Pharm.D. Chairman: It looks like the number of claims is consistent. A little off topic, the number of recipients in Nevada Medicaid, is that increased, decreased?

Coleen Lawrence: Laurie would have the best numbers, our eligibility count?

Laurie Squartsoff: It is about 321,000 covered under the whole program and about 60% are managed care, so those numbers won't show up in this report.

Coleen Lawrence: But we have been pretty consistent on the increase lately, we haven't had a spike, last year we had a spike.

Laurie Squartsoff: No, it's been pretty steady.

Carl Jeffery, Pharm.D.: It usually bumps right around 124-125,000 in the fee for service.

Coleen Lawrence: Last year we had a spike, but we haven't had any spikes that I know of lately. We'll have a large spike January 1, 2014, but honestly most are going to managed care.

Carl Jeffery, Pharm.D.: So then the top 50 drugs by claim count is a little skewed due to a rebill in our system, that isn't a real number.

Paul Oesterman, Pharm.D. Chairman: We had implemented the acetaminophen dose limit of 3 grams per day, how is that going?

Carl Jeffery, Pharm.D.: Yes, that occurred in May, and I haven't heard any pushback or complaints.

Coleen Lawrence: I haven't received any calls on that actually.

Carl Jeffery, Pharm.D.: The numbers are all consistent.

Paul Oesterman, Pharm.D. Chairman: I know in the past, we have had some issues with these reports, so accommodations to consistency with these reports, I appreciate it.

Carl Jeffery, Pharm.D.: And then by payment, Abilify is still our favorite drug, the Synagis pops in there when looking by payment during the season.

Paul Oesterman, Pharm.D. Chairman: Do we have anything coming off patent soon?

Carl Jeffery, Pharm.D.: I should have printed up something for you guys. Nothing really for this year. Starting in 2014 there are a few big ones coming off. And we have the proDUR edits, I believe this is the report you requested. You have the proDUR and clinical response from the pharmacy and if it was filled or not.

Paul Oesterman, Pharm.D. Chairman: Again, useful reports. Does the Board have anything in particular they would like to see for next time?

Carl Jeffery, Pharm.D.: One thing that didn't make it due to the full agenda is last time we tabled the discussion of the long-acting and short-acting narcotics. So we will bring that to the next agenda. And if there are any other topics that you can think of that you are seeing in your practice that you think we should review.

Coleen Lawrence: And as a reminder, any time any of the members of the Board can email us or send us ideas or thoughts for any information you may want in between because it is a quarter in between, so you may send us your ideas at any time.

7) Closing Discussion

Paul Oesterman, Pharm.D. Chairman: Alright, any comments from the audience before closing. Thank you for sticking around and enjoying this TV show. With that, our next meeting is scheduled for…

Carl Jeffery, Pharm.D.: October 24, 2013.

Paul Oesterman, Pharm.D. Chairman: The timing, any input on timing?

Carl Jeffery, Pharm.D.: And location, I would like some input. I know Dr. Marx had to take a few days off his practice to come up here and I will have to reach out to Dr. Seggev separately. Give us some feedback on time and location.

Coleen Lawrence: We can move it off a Thursday too if necessary. We were thinking about moving next to the Board of Pharmacy meeting because I know some of you were working along with that Board, so that was one idea, but they have a two day, but when they're in the North, the same day, the second half of their half a day, but we're better at catching the quorum if we do it in the evening with this Board. You email me with your thoughts of what works best. You want to move it a little earlier to like four?

James Marx, MD: Have you precluded the video conferencing? That seemed to work really well.

Coleen Lawrence: We can do video conferencing, we are just in more than one location.

Larry Nussbaum, MD: It is hard to find a place in the evening where we can video conference here.

Coleen Lawrence: In the evening, the video conferencing was getting difficult. So that does not rule us out, but just with the timing.

Carl Jeffery, Pharm.D.: With our experience with P&T, having all the members in one location, it really opens it up and there is much more dialog. When you have the video, they have to push the button to talk and there is always a delay.

Paul Oesterman, Pharm.D. Chairman: This night is getting late, so we will formally adjourn at 8:41PM. Thank you everyone, we got a lot done.

Meeting adjourned – 8:41PM

Therapeutic Class Overview
Homozygous Familial Hypercholesterolemia Agents

Therapeutic Class

- **Overview/Summary:** Familial hypercholesterolemia is a genetically modulated clinical syndrome in which the phenotype is characterized by a high low density lipoprotein-cholesterol (LDL-C) level from birth and early onset coronary heart disease (even in the absence of other risk factors). Established causes include: LDLR mutations (most common), gain-of-function PCSK9 mutations (<5% of cases in most clinics) and familial defective apolipoprotein B (<5% of cases). The disorder is inherited with a gene dosing effect, in which homozygotes are more adversely affected than heterozygotes. homozygous familial hypercholesterolemia is rare (1 in 250,000 births) unless there is co-sanguineous union in a family with heterozygous familial hypercholesterolemia.[1]

  Lomitapide (Juxtapid®) is microsomal triglyceride transfer protein inhibitor Food and Drug Administration (FDA)-approved as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce LDL, total cholesterol, apolipoprotein B, and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia.[11] This agent directly binds and inhibits microsomal triglyceride transfer protein, which resides in the lumen of the endoplasmic reticulum, thereby preventing the assembly of apolipoprotein B-containing lipoproteins in enterocytes and hepatocytes. This inhibits the synthesis of chylomicrons and very low density lipoprotein (VLDL) leading to reduced levels of plasma LDL-C.[11]

  Mipomersen (Kynamro®) is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis FDA-approved as an adjunct to lipid-lowering medications and diet to reduce LDL-C, apolipoprotein B, total cholesterol, and non-HDL in patients with homozygous familial hypercholesterolemia.[12] This agent is an antisense oligonucleotide targeted to human messenger ribonucleic acid for apolipoprotein B-100. Hybridization to the cognate messenger ribonucleic acid results in inhibition of translation of the apolipoprotein B-100 protein and ultimately decreased formation of low density lipoprotein and VLDL.[12]

Table 1. Current Medications Available in Therapeutic Class[11-12]

Generic (Trade Name)	Food and Drug Administration-Approved Indications	Dosage Form/Strength	Generic Availability
Lomitapide (Juxtapid®)	An adjunct to a low-fat diet and other lipid-lowering treatments, including low density lipoprotein apheresis where available, to reduce low-density lipoprotein cholesterol, total cholesterol, apolipoprotein B, and non-high-density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia*		-
Mipomersen (Kynamro®)	An adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol, apolipoprotein B, total cholesterol, and non-high density lipoprotein-cholesterol in patients with homozygous familial hypercholesterolemia†		-

*The safety and effectiveness have not been established in patients with hypercholesterolemia who do not have homozygous familial hypercholesterolemia. The effect on cardiovascular morbidity and mortality has not been determined.
†The safety and effectiveness have not been established in patients with hypercholesterolemia who do not have homozygous familial hypercholesterolemia. The effect on cardiovascular morbidity and mortality has not been determined. The use as an adjunct to lipoprotein-cholesterol apheresis is not recommended.

Evidence-based Medicine

- In clinical trials, lomitapide evaluated as an adjunctive treatment, was associated with a significant decrease in low density lipoprotein-cholesterol and other secondary measures of cholesterol from

baseline.[13] However, the agent is associated with significant tolerability issues including liver toxicity, increased hepatic fat, teratogenicity, drug-drug interactions and common gastrointestinal side effects.[11]
- In clinical trials, mipomersen evaluated as an adjunctive treatment, was associated with a significant decrease in low density lipoprotein-cholesterol and other secondary measures of cholesterol from baseline.[14] However, the agent is associated with significant tolerability issues including liver toxicity and increased hepatic fat.[12]

Key Points within the Medication Class
- According to Current Clinical Guidelines:
  - Available treatment guidelines support the use of high-dose statins, low density lipoprotein apheresis and other cholesterol lowering agents (e.g., ezetimibe), often as part of combination regimens to reach cholesterol goals.[2-10]
  - In refractory cases, liver transplant may be therapeutic options.
- Other Key Facts:
  - The safety and effectiveness of lomitapide and mipomersen has not been established in patients with hypercholesterolemia who do not have homozygous familial hypercholesterolemia. In addition, the effect of this agent on cardiovascular morbidity and mortality has not been determined.[11-12]

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DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID
DRUG USE REVIEW (DUR) BOARD
PROPOSED PRIOR AUTHORIZATION CRITERIA

Juxtapid® (lomitapide) and Kynamro® (mipomersen) are a covered benefit of Nevada Medicaid for recipients who meet the criteria for coverage.

1. Coverage and Limitations:
Authorization will be given if the following criteria are met and documented:

Requests for Juxtapid® (lomitapide) and Kynamro® (mipomersen)

1. Must have **ALL** of the following:
    a. The recipient has a diagnosis of homozygous familial hypercholesterolemia, confirmed based on mutations in the low-density lipoprotein receptor (LDLR), apolipoprotein B (ApoB) or proprotein convertase subtilisin/kexin type 9 (PCSK9) gene.
    AND
    b. The requested medication will be used as an adjunct to a low-fat diet and other lipid-lowering treatments.
    AND
    c. The recipient has experienced an adverse event, allergy or inadequate response to at least two high-potency statins (atorvastatin, rosuvastatin or simvastatin), or the recipient has a contraindication to treatment with statins (documentation of contraindication is required).
    AND
    d. The recipient has experienced an adverse event, allergy or inadequate response to at least two other antihyperlipidemic agents, or the recipient has a contraindication to treatment with all other antihyperlipidemic agents (documentation of contraindication is required).
    AND
    e. The recipient has experienced an adverse event, allergy or inadequate response to low-density lipoprotein apheresis, or low-density lipoprotein apheresis is unavailable.

2. PA Guidelines:
Initial prior authorization approval will be 6 months.
Recertification approval will be for 1 year.

3. Quantity Limitations:
Juxtapid® (lomitapide): 30 capsules per 30 days
Kynamro® (mipomersen) 30 vials or pre-filled syringes per 30 days

New Drug Overview
Duexis® (ibuprofen/famotidine)

- **Overview/Summary:** The nonsteroidal anti-inflammatory drugs (NSAIDs) are one of the most commonly utilized classes of medications and are prescribed for analgesia in a variety of clinical scenarios, as well as in inflammatory conditions such as arthritis and other musculoskeletal disorders.[4] The use of these agents is limited by their association with mucosal injury to the upper gastrointestinal tract, which can lead to hospitalization in some patients.

  In order to minimize the potential risks associated with NSAID therapy, it is recommended that patients at high risk for NSAID-related gastrointestinal complications be identified and that appropriate management strategies to prevent peptic ulcers and the associated complications be implented.[4]

  Duexis® (ibuprofen/famotidine) was Food and Drug Administration (FDA) approved in April 2011 for the treatment of the signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of gastrointestinal ulcers in patients taking ibuprofen for those indications.[3] Duexis® (ibuprofen/famotidine) is a fixed-dose preparation containing ibuprofen, an NSAID, and famotidine, a competitive inhibitor of histamine 2 receptors. Famotidine exerts its pharmacologic effect through the inhibition of both the concentration and volume of gastric secretion.[3,5]

  Current consensus guidelines support the use of high-dose histamine 2 receptor antagonists to reduce the risk of NSAID-induced endoscopic peptic ulcers, although guidelines do acknowledge that the histamine 2 receptor antagonists are much less effective compared to proton pump inhibitors. It is recommended that patients at moderate to high risk of NSAID-related gastric or duodenal ulceration who require NSAID therapy receive misoprostol or a high-dose proton pump inhibitor.[4]

  The FDA approval of Duexis® (ibuprofen/famotidine) was based on two clinical trials evaluating safety and efficacy in patients 40 to 80 years of age requiring daily NSAIDs for at least six months. In both trials, treatment with ibuprofen/famotidine resulted in fewer gastric ulcers, upper gastrointestinal ulcers and duodenal ulcers compared to treatment with ibuprofen alone.[6]

Table 1. Dosing and Administration[3,5]

Generic Name	Adult Dose	Pediatric Dose	Availability
Ibuprofen/ famotidine	Treatment of the signs and symptoms of rheumatoid arthritis and osteoarthritis in patients at high risk of developing NSAID-induced upper gastrointestinal ulcers: Tablet: 26.6/800 mg three times daily	Safety and efficacy in children have not been established.	Tablet: 26.6/800 mg

NSAID=nonsteroidal anti-inflammatory drug

Evidence-based Medicine

- The Food and Drug Administration (FDA) approval of Duexis® (ibuprofen/famotidine) was supported by two phase III clinical trials, REDUCE-1 and REDUCE-2, that enrolled more than 1,500 patients with mild to moderate pain or arthritis.[6]
- The primary endpoints for REDUCE-1 and REDUCE-2 were the reduction in gastric ulcers during the 24-week treatment period and the reduction in incidence of upper gastrointestinal ulcers during the 24-week period, respectively.[6]
- In REDUCE-1, treatment with ibuprofen/famotidine resulted in a significant reduction in the incidence of gastric ulcers compared to treatment with ibuprofen alone (12.7 vs 22.9%, respectively; *P*=0.0044).[6]
- In REDUCE-2, treatment with ibuprofen/famotidine resulted in significantly fewer upper gastrointestinal ulcers compared to ibuprofen alone (13.0 vs 20.5%; *P*=0.0587).[6]

- Treatment with ibuprofen/famotidine resulted in fewer upper gastrointestinal ulcers and fewer duodenal ulcers compared to ibuprofen in REDUCE-1, as well as fewer gastric ulcers and fewer duodenal ulcers in REDUCE-2.[6]
- Pooled results from both trials indicated that treatment with ibuprofen/famotidine resulted in an absolute risk reduction of 9.6% compared to ibuprofen for the risk of upper gastrointestinal ulcers (95% confidence interval [CI], 5.4 to 13.8%).[6]
- Pooled data also indicated that treatment with ibuprofen/famotidine was associated with an absolute reduction in risk of gastric ulcers and duodenal ulcers (absolute risk reduction [ARR], 7.8%; 95% CI, 3.8 to 11.8 and ARR, 4.0%; 95% CI, 1.9 to 6.1, respectively).[6]
- The most common adverse reactions that occurred ≥1% more frequently in the ibuprofen/famotidine group included nausea, diarrhea, constipation, upper abdominal pain and headache. The discontinuation rate due to adverse events was similar between treatment groups.[6]

Key Points within the Medication Class

- According to Current Clinical Guidelines:
    - According to the American College of Gastroenterology, patients at high risk for nonsteroidal anti-inflammatory drugs (NSAIDs)-related gastrointestinal complications include patients who are >60 years of age; receiving high-dose NSAID therapy or concurrent anticoagulants, corticosteroids or other NSAID agents (including aspirin); had a previous gastrointestinal event; and have a chronic debilitating disorder, especially cardiovascular disease.[2,4]
    - The two commonly utilized methods to prevent the development of peptic ulceration and gastric mucosal injury in high risk patients receiving NSAIDs include co-therapy with a gastroprotective (or cytoprotective) agent such as a proton pump inhibitor, a high-dose histamine 2 receptor antagonist, or an exogenous prostaglandin; and the use of a cyclooxygenase (COX)-2 inhibitor instead of a traditional NSAID.[4]
    - Co-therapy with a gastroprotective agent protects the gastric mucosal tissue through different mechanisms depending on the agent utilized, and a selective COX-2 inhibitor will be less likely to inhibit COX-1, thereby limiting the potential for gastric mucosal injury.[2]
    - Current consensus guidelines support the use of high-dose histamine 2 receptor antagonists to reduce the risk of NSAID-induced endoscopic peptic ulcers, although guidelines do acknowledge that the histamine 2 receptor antagonists are much less effective compared to proton pump inhibitors.[4]
    - Adjunctive therapy with a standard-dose histamine 2 receptor antagonist may prevent duodenal ulcers, but it has not been shown to prevent NSAID-related gastric ulceration. It is recommended that patients at moderate to high risk of NSAID-related gastric or duodenal ulceration who require NSAID therapy receive misoprostol or a high-dose proton pump inhibitor.[4]

- Other Key Facts:
    - The individual components of Duexis® (ibuprofen/famotidine) are available generically over-the-counter.[5]
    - Famotidine is currently available over-the-counter as a 10 and 20 mg tablet and chewable tablet, while ibuprofen is available as a 100 and 200 mg tablet, chewable tablet, liquid capsule or as an oral suspension.[5]
    - There are several proton pump inhibitors that are available generically, including omeprazole, lansoprazole and pantroprazole.[5]

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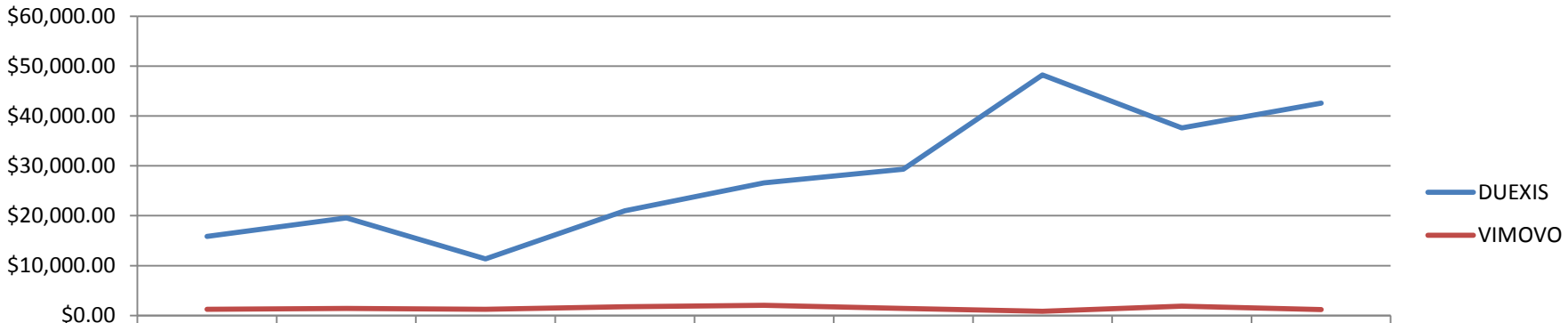
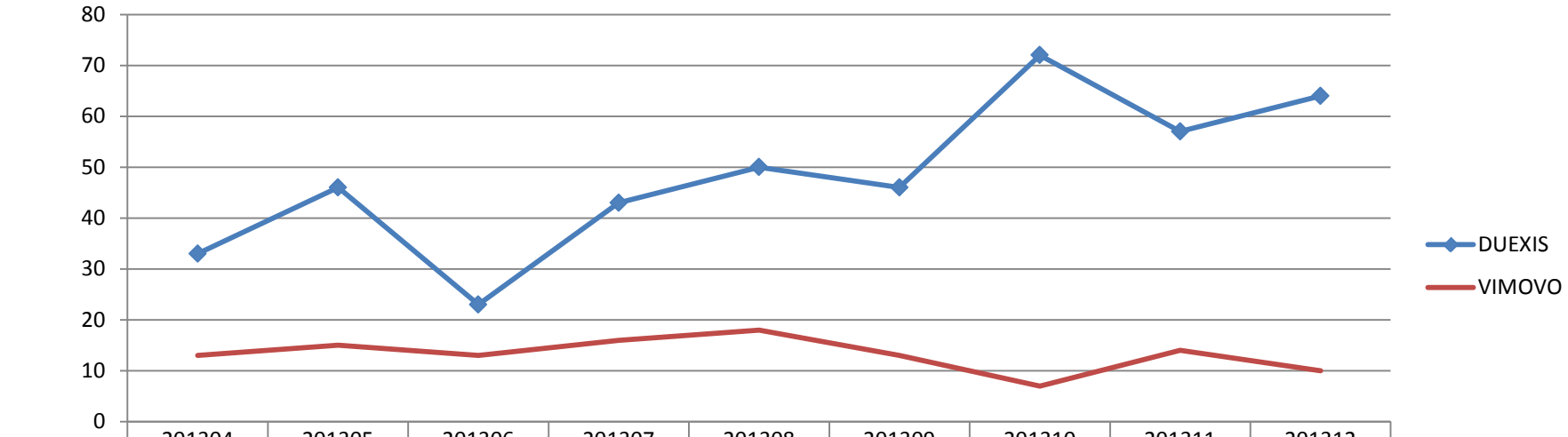
Sum of Pharmacy Paid Amt



	201304	201305	201306	201307	201308	201309	201310	201311	201312
DUEXIS	$15,842.57	$19,561.84	$11,367.38	$21,009.31	$26,574.96	$29,302.55	$48,194.36	$37,595.85	$42,586.14
VIMOVO	$1,224.41	$1,417.28	$1,232.21	$1,773.11	$2,013.69	$1,407.74	$852.53	$1,870.70	$1,159.39

Claim Count



	201304	201305	201306	201307	201308	201309	201310	201311	201312
DUEXIS	33	46	23	43	50	46	72	57	64
VIMOVO	13	15	13	16	18	13	7	14	10

Utilization Data				
Product Name	Sum of Claim Count	Sum of Days Supply	Pharmacy Paid Amt	Cost per claim
ARTHROTEC 75	1	30	$ 3.30	$ 3.30
DICLOFENAC SODIUM/MISOPRO	237	7147	$ 34,985.25	$ 147.62
DUEXIS	434	12440	$ 252,034.96	$ 580.73
VIMOVO	119	3628	$ 12,951.06	$ 108.83
Grand Total	791	23245	$ 299,974.57	$ 379.23

DIVISION OF HEALTH CARE FINANCING AND POLICY
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DRUG USE REVIEW (DUR) BOARD
PROPOSED PRIOR AUTHORIZATION CRITERIA

Duexis® (famotidine/ibuprofen) is a covered benefit of Nevada Medicaid for recipients who meet the criteria for coverage.

1. Coverage and Limitations:
Authorization will be given if the following criteria are met and documented:

Requests for Duexis (famotidine/ibuprofen) will be approved if the following conditions are met:

1. The recipient has an allergy to generic separate famotidine and/or ibuprofen dosage forms OR
2. The recipient has tried and failed separate ingredient famotidine and/or ibuprofen.

2. PA Guidelines:
Initial prior authorization approval will be 6 months.
Recertification approval will be for 1 year.

Therapeutic Class Overview
Immunomodulators

Therapeutic Class

- **Overview/Summary:** This review encompasses immunomodulator agents used in immune-mediated inflammatory diseases. These agents include interleukin (IL) receptor antagonists (anakinra, tocilizumab), tumor necrosis factor (TNF)-blocking agents (adalimumab, certolizumab, etanercept, golimumab, and infliximab) and T-cell activation inhibitors (abatacept). These agents interfere with inflammatory pathways through slightly different mechanisms and are indicated in rheumatoid arthritis, psoriatic arthritis, psoriasis, ankylosing spondylitis, ulcerative colitis, Crohn's disease and neonatal-onset multisystem inflammatory disease.[1-12]

  Generally, current consensus guidelines support the use of the TNF-blockers with respect to their Food and Drug Administration (FDA)-approved indications and no one agent is preferred over another.[13-29] As more recent guidelines are published, the recommendations for use TNF-blockers earlier in therapy is becoming a more common occurance.[20,21,25] Because the immunomodulators are biologic agents made from living organisms and are extremely difficult to duplicate, congress has struggled to create regulations to approve generic versions of these agents. Currently, none of the agents in this class are available generically; however, the recently upheld Patient Protection and Affordable Care provides a legal framework for regulatory approval of biosimilar drugs.[30]

Table 1. Current Medications Available in the Therapeutic Class[3-12]

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
Abatacept (Orencia®)	Monotherapy or concomitantly with disease modifying antirheumatic drugs other than tumor necrosis factor antagonists in moderately to severely active rheumatoid arthritis in adults; monotherapy or concomitantly with methotrexate for moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients six years of age and older	Prefilled syringe: 125 mg/mL Single use vial: 250 mg	-
Adalimumab (Humira®)	Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis; reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (in pediatric patients four years of age and older; reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis; reducing signs and symptoms in adult patients with active ankylosing spondylitis; reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab; inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to	Prefilled pen: 40 mg/0.8 mL Prefilled syringe: 20 mg/0.4 mL 40 mg/0.8 mL Single use vial: 40 mg/0.8 mL	-

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
	immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine; treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate		
Anakinra (Kineret®)	Reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs; treatment of neonatal-onset multisystem inflammatory disease	Prefilled syringe: 100 mg/0.67 mL	-
Certolizumab (Cimzia®)	Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy; treatment of adults with moderately to severely active rheumatoid arthritis; treatment of adults with active psoriatic arthritis; treatment of adults with active ankylosing spondylitis	Prefilled syringe: 200 mg/mL Vial (powder for injection): 200 mg	-
Etanercept (Enbrel®)	Monotherapy or in combination with methotrexate in reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis; reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages two and older; reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and as monotherapy in improving physical function in patients with psoriatic arthritis or in combination with methotrexate in patients who do not respond adequately to methotrexate alone; reducing signs and symptoms in patients with active ankylosing spondylitis; treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	Prefilled "SureClick" autoinjector: 50 mg/mL Prefilled syringes: 25 mg/0.5 mL 50 mg/mL Vial (powder for injection): 25 mg	-
Golimumab (Simponi®, Simponi Aria®)	Treatment of adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate (Simponi® and Simponi Aria®); treatment of adult patients with active psoriatic arthritis alone or in combination with methotrexate (Simponi® only); treatment of adult patients with active ankylosing spondylitis (Simponi® only); treatment of moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine (Simponi® only)	Prefilled "SmartJect" autoinjector: 50 mg/0.5 mL, 100 mg/mL Prefilled syringe: 50 mg/0.5 mL 100 mg/mL Single use vial*: 50 mg/4 mL	-

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
Infliximab (Remicade®)	Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy; reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely ulcerative colitis who have had an inadequate response to conventional therapy; in combination with methotrexate to reduce signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis; reducing signs and symptoms in patients with active ankylosing spondylitis; reducing signs and symptoms of active psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function; treatment of adult patients with chronic severe plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate	Single use vial: 100 mg	-
Tocilizumab (Actemra®)	Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease modifying anti-rheumatic drugs; patients two years of age and older with active polyarticular juvenile idiopathic arthritis; patients two years of age and older with active systemic juvenile idiopathic arthritis	Prefilled syringe*: 162 mg/0.9 mL Single use vial: 80 mg/4 mL 200 mg/10 mL 400 mg/20 mL	-
Ustekinumab (Stelara®)	Treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy Treatment of adult patients (18 years or older) with active psoriatic arthritis alone or in combination with methotrexate.	Prefilled syringe: 45 mg/0.5 mL 90 mg/mL Single use vials: 45 mg/0.5 mL 90 mg/mL	-

*Only indicated for use in patients with rheumatoid arthritis.

Evidence-based Medicine

- The immunomodulators have been shown to be effective for their respective Food and Drug Administration (FDA)-approved indications, particularly in conditions where patients were unresponsive or refractory to traditional disease modifying antirheumatic drugs (DMARDs). Most

research with these agents and FDA-approved indications (with the exception of ustekinumab) are for rheumatoid arthritis. In these trials, the immunomodulator were compared directly to placebo or traditional DMARD medications, either as monotherapy or in combination with a traditional DMARD. Consistently, immunomodulators have shown greater improvement in symptoms over the comparator.[34-115]

- Recently anakinra was FDA-approved for neonatal-onset multisystem inflammatory disease (NOMID), the only agent FDA-approved for this indication. The approval was based on the results of a single trial demonstrating sustained improvements in affected patients over 60 months.[115]
- To date, the majority of trials conducted have been placebo-controlled, with very few trials directly comparing two immunomodulators head-to-head for any of the FDA-approved indications. Those that have been conducted, most have shown comparable results.[34-115] In one trial in RA patients who were either intolerant or were not candidates for methotrexate treatment, significantly greater improvements were observed in patients treated with tocilizumab compared to adalimumab.[106] In another trial in RA patients with inadequate response to methotrexate, similar responses were observed in patients treated with abatacept and adalimumab.[107,108] The few direct head-to-head trials available prevent clearly determining superiority of one agent over another.
- Generally, current consensus guidelines support the use of the TNF-blockers with respect to their FDA-approved indications and no one agent is preferred over another.[13-29] As more recent guidelines are published, the recommendations for use TNF-blockers earlier in therapy is becoming a more common occurance.[20,21,25] The adverse event profiles are similar across the class; however, routes of administration and dosing frequency may vary. Currently, adalimumab and infliximab have the most FDA-approved indications among the agents in the class; however, several other agents have recently gained additional indications.

Key Points within the Medication Class

- According to Current Clinical Guidelines:[13-29]
    - Support the use of the immunomodulators with respect to their Food and Drug Administration (FDA)-approved indications.
    - No one agent is preferred over another.
- Other Key Facts:
    - There are no generic biologic agents.
    - Dosing frequency and route of administration vary between products.
        - Currently none of the agents available may be administered via oral route.
        - Infliximab is administered intravenously and is the only agent in the class that is not available for subcutaneous administration. A loading- dose of abatacept is recommended to be administered IV, but can be given subcutaneously if the patient is not able to received IV infusion.
        - Anakinra is administered subcutaneously (SC), but requires more frequent daily administration.
    - Intravenous formulation of golimumab and subcutaneous formulation of tocilizumab are only indicated in the treatment of rheumatoid arthritis.
    - Anakinra is the only FDA-approved agent for neonatal-onset multisystem inflammatory disease.

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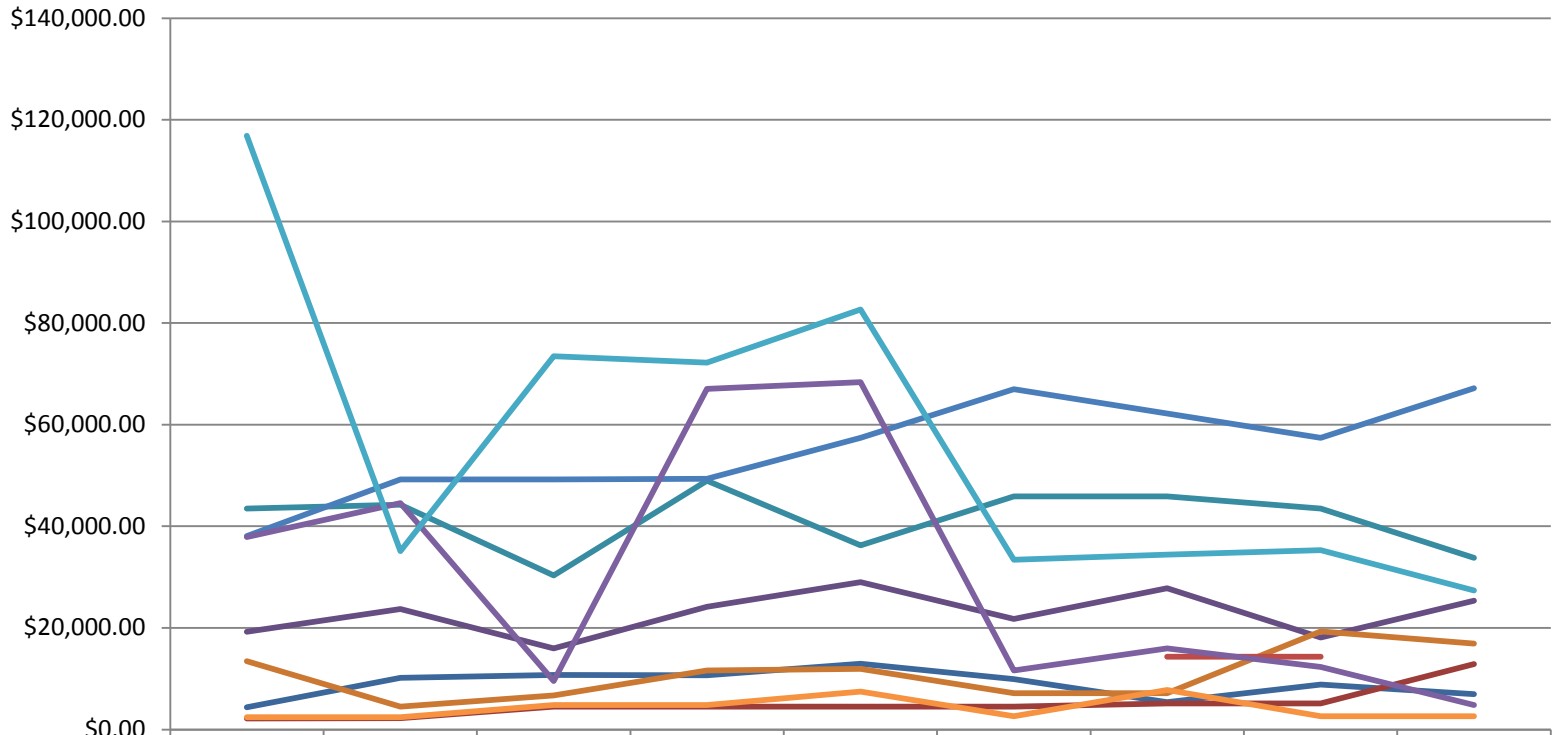
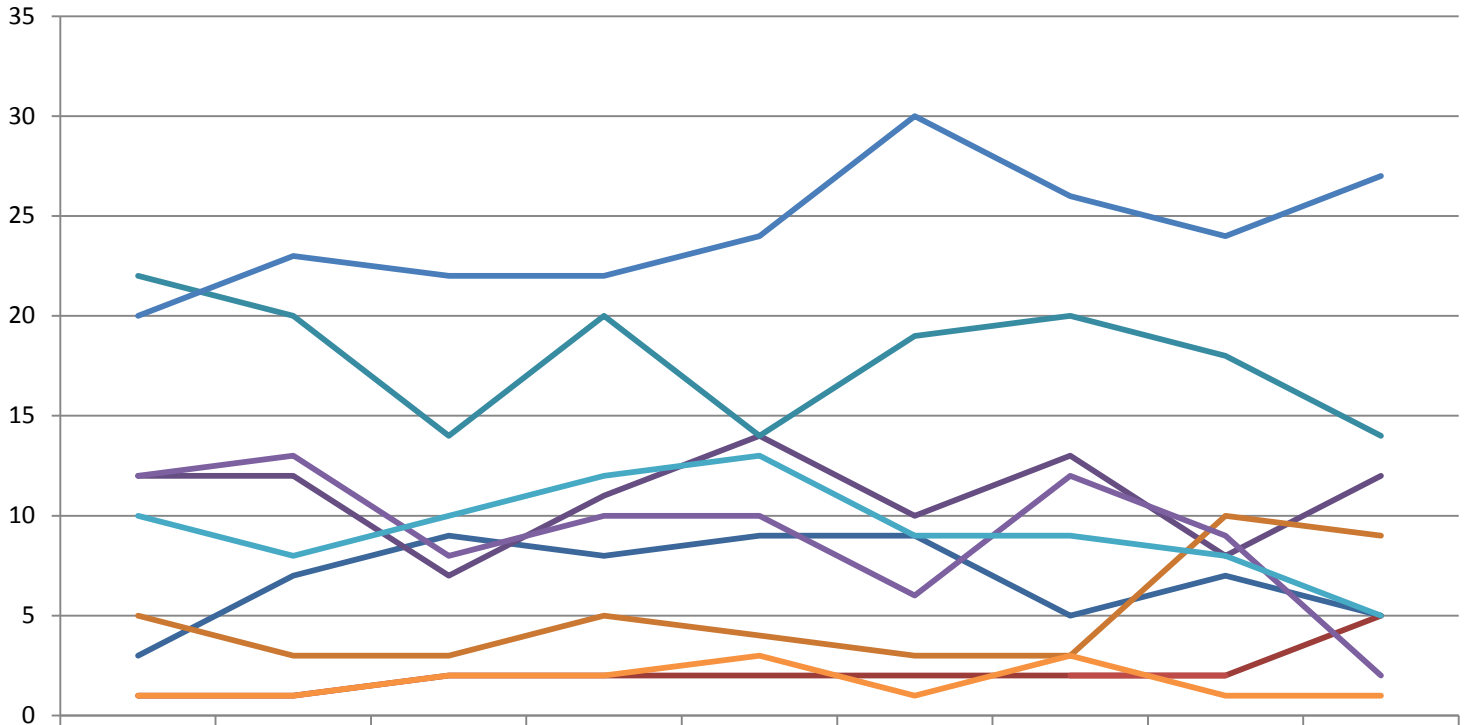


	201304	201305	201306	201307	201308	201309	201310	201311	201312
ACTEMRA	$4,395.25	$10,153.36	$10,744.13	$10,675.19	$12,972.36	$9,903.13	$5,420.80	$8,877.56	$6,972.95
CIMZIA	$2,151.12	$2,269.16	$4,538.32	$4,538.32	$4,538.32	$4,538.32	$5,149.70	$5,149.70	$12,874.25
CIMZIA STARTER KIT		$6,797.96					$7,715.04		$2,574.85
ENBREL	$19,219.45	$23,734.41	$15,974.63	$24,159.45	$28,995.14	$21,743.98	$27,785.03	$18,118.40	$25,369.56
ENBREL SURECLICK	$43,512.67	$44,260.48	$30,353.35	$48,968.59	$36,227.29	$45,893.93	$45,896.17	$43,478.46	$33,816.58
HUMIRA	$13,426.42	$4,480.56	$6,715.59	$11,653.78	$11,958.54	$7,177.98	$7,177.98	$19,310.87	$16,922.96
HUMIRA PEN	$38,065.51	$49,251.16	$49,247.66	$49,324.58	$57,423.84	$67,001.48	$62,206.64	$57,422.58	$67,154.48
HUMIRA PEN-CROHNS DISEASE				$7,168.45			$14,336.90	$14,336.90	
HUMIRA PEN-PSORIASIS STAR			$4,472.30						
ORENCIA	$37,917.16	$44,537.17	$9,521.92	$67,052.23	$68,358.63	$11,635.44	$15,955.33	$12,321.44	$4,831.78
REMICADE	$116,859.41	$35,086.26	$73,483.26	$72,184.52	$82,668.44	$33,392.99	$34,425.01	$35,329.81	$27,342.17
SIMPONI	$2,424.14	$2,424.14	$4,848.28	$4,848.28	$7,439.35	$2,591.07	$7,773.21	$2,591.07	$2,591.07
STELARA			$6,586.24				$14,075.94		$14,075.94

Count of Claims



	201304	201305	201306	201307	201308	201309	201310	201311	201312
ACTEMRA	3	7	9	8	9	9	5	7	5
CIMZIA	1	1	2	2	2	2	2	2	5
CIMZIA STARTER KIT		1					1		1
ENBREL	12	12	7	11	14	10	13	8	12
ENBREL SURECLICK	22	20	14	20	14	19	20	18	14
HUMIRA	5	3	3	5	4	3	3	10	9
HUMIRA PEN	20	23	22	22	24	30	26	24	27
HUMIRA PEN-CROHNS DISEASE				1			2	2	
HUMIRA PEN-PSORIASIS STAR			1						
ORENCIA	12	13	8	10	10	6	12	9	2
REMICADE	10	8	10	12	13	9	9	8	5
SIMPONI	1	1	2	2	3	1	3	1	1
STELARA			1				1		1

DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID
DRUG USE REVIEW (DUR) BOARD
PROPOSED PRIOR AUTHORIZATION CRITERIA

Injectable Immunomodulators are a covered benefit of Nevada Medicaid for recipients who meet the criteria for coverage.

1. Coverage and Limitations:
Authorization will be given if the following criteria are met and documented:

a. Rheumatoid Arthritis (Orencia®, Humira®, Kineret®, Cimzia®, Enbrel®, Remicade®, Simponi®, Simponi® ARIA™, Actemra®)
   1. Diagnosis of moderately to severely active rheumatoid arthritis
      AND
   2. Rheumatology consult with date
      AND
   3. Negative tuberculin test (Orencia®, Humira®, Cimzia®, Enbrel®, Remicade®, Simponi®, Simponi® ARIA™, Actemra®)
      AND
   4. Patient does not have an active infection or a history of recurring infections
      AND
   5. Patient has had RA for ≤ six months (early RA) and has high disease activity and had an inadequate response or adverse reaction of a disease modifying antirheumatic drug (DMARDs) (methotrexate, hydroxychloroquine, leflunomide, minocycline and sulfasalazine)
      OR
   6. Patient has had RA for ≥ six months (intermediate or long-term disease duration) and has moderate disease activity and an inadequate response or adverse reaction of a disease modifying antirheumatic drug (DMARDs) (methotrexate, hydroxychloroquine, leflunomide, minocycline and sulfasalazine)
      OR
   7. Patient has had RA for ≥ six months (intermediate or long-term disease duration) and has high disease activity.

b. Psoriatic Arthritis (Enbrel®, Humira®, Remicade®, Simponi®)
   1. Diagnosis of moderate or severe psoriatic arthritis
      AND
   2. Rheumatology consult with date or dermatology consult with date
      AND
   3. Inadequate response to any one nonsteroidal anti-inflammatory drug (NSAID) or contraindication to treatment with a NSAID OR to any one of the following disease modifying anti-rheumatic drugs (DMARDs) (methotrexate, leflunomide, cyclosporine or sulfasalazine)
      AND
   4. Negative tuberculin test (Enbrel®, Humira®, Remicade®, Simponi®)
      AND
   5. Patient does not have an active infection or a history of recurring infections.

c. Ankylosing Spondylitis (Enbrel®, Humira®, Remicade®, Simponi®)

1. Diagnosis of ankylosing spondylitis
   AND
2. Inadequate response to nonsteroidal anti-inflammatory Drugs (NSAIDs)
   AND
3. Inadequate response to any one of the Disease-Modifying Anti-Rheumatic Drugs (DMARDs) (sulfasalazine, methotrexate, hydroxychloroquine, leflunomide, minocycline)
   AND
4. Negative tuberculin test (Enbrel®, Humira®, Remicade®, Simponi®)
   AND
5. Patient does not have an active infection or a history of recurring infections.

d. Juvenile Rheumatoid Arthritis/ Juvenile Idiopathic Arthritis (Enbrel®, Humira®, Orencia®)
   1. Diagnosis of moderately or severely active juvenile rheumatoid arthritis
      AND
   2. Patient is at least 2 years of age
      AND
   3. At least five swollen joints
      AND
   4. Three or more joints with limitation of motion and pain, tenderness, or both
      AND
   5. Inadequate response to one Disease-Modifying Anti-Rheumatic Drug (DMARD)
      AND
   6. Negative tuberculin test (Enbrel®, Humira®, Orencia®)
      AND
   7. Patient does not have an active infection or a history of recurring infections.

e. Plaque Psoriasis (Enbrel®, Humira®, Remicade®, Stelara®)
   1. Diagnosis of chronic, moderate to severe plaques psoriasis
      AND
   2. Prescribed by a dermatologist
      AND
   3. Failed to adequately respond to a topical agent
      AND
   4. Failed to adequately respond to at least one oral treatment
      AND
   5. Negative tuberculin test (Enbrel®, Humira®, Remicade®, Stelara®)
      AND
   6. Patient does not have an active infection or a history of recurring infections.

f. Crohn's Disease (Cimzia®, Humira®, Remicade®):
   1. Diagnosis of Crohn's Disease
      AND
   2. Failed to adequately respond to conventional therapy (e.g., sulfasalazine, leflunomide, azathioprine, mesalamine, antibiotics, corticosteroids, azathioprine, 6-mercaptopurine)
      OR
   3. Patient has fistulizing Crohn's disease
      AND
   4. Negative tuberculin test (Cimzia®, Humira®, Remicade®)
      AND
   5. Patient does not have an active infection or a history of recurring infections.

g. Ulcerative Colitis (Humira®, Remicade®, Simponi®):
   1. Diagnosis of moderate to severe ulcerative colitis
      AND
   2. Failed to adequately respond to one or more of the following standard therapies:
      a. Corticosteroids
      b. 5-aminosalicylic acid agents
      c. Immunosuppressants
      d. Thiopurines
      AND
   3. Negative tuberculin test (Humira®, Remicade®, Simponi®)
      AND
   4. Patient does not have an active infection or a history of recurring infections.

2. Coverage is not provided for use of more than one biologic at a time (combination therapy).

3. PA Guidelines:
Prior Authorization approval will be 1 year.

Therapeutic Class Overview
Long-acting Opioids

Therapeutic Class

- **Overview/Summary:** Pain is one of the most common and debilitating patient complaints, with persistent pain having the potential to lead to functional impairment, disability, psychological distress and sleep deprivation. Pain can be categorized as being either nociceptive or neuropathic, and the treatments for each are specific. Nociceptive pain is caused by damage to tissues and can further be divided into somatic (pain arising from injury to body tissues) and visceral pain (pain arising from the internal organs). Visceral pain is often described as poorly localized, deep, dull, and cramping. In contrast, neuropathic pain arises from abnormal neural activity secondary to disease, injury, or dysfunction of the nervous system.[1] Pharmacologic therapy should not be the sole focus of pain treatment; however, it is the most widely utilized option to manage chronic pain. Major pharmacologic categories used in the management of pain include nonopioid analgesics, tramadol, opioid analgesics, α-2 adrenergic agonists, antidepressants, anticonvulsants, muscle relaxants, N-methyl-d-aspartate receptor antagonists, and topical analgesics. Combining pharmacologic therapies may result in improved analgesia, and because lower doses of each agent can be used, patients may experience fewer treatment-emergent adverse events. Response to pharmacologic therapies will vary between individual patients, and currently no one approach has been demonstrated to be appropriate for all patients. Treatment decisions are largely based on the type of pain (e.g., neuropathic, nociceptive), comorbidities, concurrent medications, pharmacokinetic/pharmacodynamic properties of the agent and anticipated adverse events.[2]

  As a class, opioid analgesics encompass a group of naturally occurring, semisynthetic, and synthetic drugs that stimulate opiate receptors and effectively relieve pain without producing loss of consciousness.[3-19] These agents primarily produce intense analgesia via their agonist actions at mu receptors, which are found in large numbers within the central nervous system. The binding of these agents to mu receptors produces a variety of other effects including bradycardia, sedation, euphoria, physical dependence, and respiratory depression. Key safety concerns associated with the opioid analgesics include respiratory depression, and to a lesser degree, circulatory depression.[2,20] The long-acting opioids are primarily utilized in the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time.[3] Long-acting opioids are available in a variety of different dosage forms, and currently several agents are available generically.[3]

  OxyContin® (oxycodone extended-release) has received increased attention regarding overuse, abuse, and diversion, but oxycodone itself does not appear to have a greater dependence or abuse liability compared to the other available opioids.[21] The Food and Drug Administration (FDA) approved a new OxyContin® formulation in April of 2010 that was designed to discourage misuse and abuse. The reformulated OxyContin® is intended to prevent the medication from being cut, broken, chewed, crushed, or dissolved to release more medication. The FDA states that the new formulation may result in less risk of overdose due to tampering, and will likely result in less abuse by snorting or injection, but the agent can still be abused or misused by ingesting larger than recommended doses. The manufacturer is required to conduct a postmarketing study evaluating the extent to which the new formulation reduces abuse and misuse.[22] Similarly, a new, crush-resistant formulation of Opana ER® (oxymorphone extended-release) was approved in December 2011; however, the manufacturer notes that it has not been established that the new formulation is less subject to misuse, abuse, diversion, overdose or addiction.[23]

Table 1. Current Medications Available in the Therapeutic Class[4-19]

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
Single-Entity Agents			
Buprenorphine (Butrans®)	The management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time	Transdermal system: 5 µg/hour 10 µg/hour 20 µg/hour	-
Fentanyl (Duragesic®*)	The management of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids	Transdermal system: ‡ 12 µg/hour 25 µg/hour 50 µg/hour 75 µg/hour 100 µg/hour	✔
Hydromorphone (Exalgo®)	The management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time	Extended release tablets: ‡ 8 mg 12 mg 16 mg	-
Methadone (Dolophine®*, Methadose®*)	Treatment of moderate to severe pain not responsive to non-narcotic analgesics, for detoxification treatment of opioid addiction (heroin or other morphine-like drugs) and for maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services	Concentrate (sugar-free available): 10 mg/mL Dispersible tablet: 40 mg Solution: 5 mg/5 mL 10 mg/5 mL Tablet: 5 mg 10 mg	✔
Morphine sulfate (Avinza®, Kadian®*, MS Contin®*, Oramorph SR®)	For the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time (Avinza®), for the relief of moderate to severe pain requiring continuous, around the clock opioid therapy for an extended period of time (Kadian® and MS Contin®) and for the relief of pain in patients who require opioid analgesics for more than a few days (Oramorph SR®)	Extended release capsules: 10 mg§ 20 mg§ 30 mg 45 mg‖ 50 mg§ 60 mg‡,¶ 75 mg‖ 80 mg§ 90 mg‡,‖ 100 mg‡,§ 120 mg‡,‖ 200 mg‡,§ Extended release tablets: 15 mg	✔

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
		30 mg 60 mg 100 mg§ 200 mg§ Tablet (Oramorph SR®) 15 mg 30 mg 60 mg 100 mg	
Oxycodone (OxyContin®*)	For the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time	Extended release tablet: 10 mg 15 mg# 20 mg 30 mg# 40 mg 60 mg‡,# 80 mg‡	✔ †
Oxymorphone (Opana® ER)	For the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time	Extended release tablet: 5 mg 7.5 mg 10 mg 15 mg 20 mg 30 mg 40 mg	-
Tapentadol (Nucynta ER®)	For the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time and treatment of neuropathic pain associated with diabetic peripheral neuropathy in adults	Extended release tablet: 50 mg 100 mg 150 mg 200 mg 250 mg	-
Combination Products			
Morphine sulfate/ naltrexone	For the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time	Extended release capsule: 20 mg/0.8 mg 30 mg/1.2 mg 50 mg/2 mg 60 mg/2.4 mg 80 mg/3.2 mg 100 mg/4 mg‡	-

*Generic is available in at least one dosage form or strength.
†Generic availability is sporadic and does not include all strengths.
‡For use in opioid-tolerant patients only.
§Kadian® only.
‖Avinza® only.
¶ Avinza® 60 mg extended-release capsules are for use in opioid-tolerant patients only.
#OxyContin® only.

Evidence-based Medicine

- In one trial, treatment with the buprenorphine transdermal system significantly improved the average pain score over 24 hours at week 12 compared to treatment with buprenorphine 5 µg/hour (*P*<0.001 for both). In a second trial, treatment with either 10 or 20 µg/hour of buprenorphine transdermal system resulted in a treatment difference favoring buprenorphine (95% confidence interval [CI], -1.02 to -0.14; *P*=0.01) compared to placebo. Two other trials failed to show efficacy for buprenorphine transdermal system in patients with low back pain and osteoarthritis, respectively against oxycodone/acetaminophen and oxycodone immediate-release. In another trial, treatment with either buprenorphine transdermal system 20 µg/hour or oxycodone immediate-release was compared to treatment with buprenorphine transdermal system 5 µg/hour in patients with osteoarthritis. The decrease in the average pain score over the last 24 hours was greater in the buprenorphine transdermal system 20 µg/hour and oxycodone immediate-release treatment groups compared to the buprenorphine transdermal system 5 µg/hour group, however the difference was not significant (*P* values not reported).[4,24]
- The effectiveness of fentanyl in relieving pain appears to be similar to that of morphine sulfate sustained-release for the treatment of cancer and noncancer pain, and chronic lower back pain. Compared to morphine sulfate sustained-release, fentanyl transdermal systems appear to be associated with less constipation.[25-27]
- In one trial, hydromorphone extended-release demonstrated greater efficacy in the treatment of lower back pain with regard to reducing pain intensity (*P*<0.001) and pain scores (*P*<0.01) compared to placebo.[28] In a noninferiority analysis of a hydromorphone extended-release compared to oxycodone extended-release, two agents provided similar pain relief in the management of osteoarthritic pain.[29]
- Methadone has demonstrated a greater efficacy over placebo for the treatment of nonmalignant neuropathic pain and similar efficacy compared to slow-release morphine sulfate for the treatment of cancer pain.[30,31]
- A trial comparing different long-acting formulations of morphine sulfate for the treatment of osteoarthritis pain demonstrated that both Avinza® (morphine sulfate extended-release) and MS Contin® (morphine sulfate controlled-release) significantly reduced pain from baseline (*P*≤0.05 for both). Both treatments also reduced overall arthritis pain intensity, and achieved comparable improvements in physical functioning and stiffness. Each treatment significantly improved certain sleep parameters compared to placebo.[32] In a crossover trial, morphine sulfate (MS Contin®) was compared to fentanyl transdermal systems, and more patients preferred fentanyl transdermal systems (*P*<0.001), and reported on average, lower pain intensity scores than morphine sulfate phase (*P*<0.001).[33]
- Morphine/naltrexone has demonstrated significantly better pain control compared to placebo in patients with osteoarthritis pain.[34]
- Oxycodone controlled-release has demonstrated significantly greater efficacy compared to placebo for the treatment of neuropathic pain and chronic refractory neck pain.[35-37] For the treatment of cancer pain, no significant differences were observed between oxycodone controlled-release and morphine sulfate controlled-release in reducing pain intensity. The average number of rescue doses used within a 24 hour period was significantly less with morphine sulfate controlled-release (*P*=0.01), and the incidence of nausea and sedation were similar between treatments.[38]
- Oxymorphone extended-release has produced similar mean daily pain intensity scores compared to both morphine sulfate and oxycodone controlled-release for the treatment of chronic cancer pain.[39,40] The average scheduled daily dose of study drug and average total daily dose decreased after patients crossed over to oxymorphone extended-release from morphine sulfate or oxycodone controlled-release. No significant changes were observed in visual analog pain scores, quality of life domains, or quality of sleep in any of the treatment groups.[40] In another trial, oxymorphone extended-release demonstrated greater efficacy for the relief of osteoarthritis pain compared to placebo.[41]
- In a 12-week active comparator and placebo-controlled trial, significant pain relief was achieved with tapentadol extended-release compared to placebo (least squares mean difference, - 0.7; 95% CI, -1.04 to -0.33) at week 12. The average pain intensity rating at endpoint with oxycodone controlled-release was reduced significantly compared to placebo for the overall maintenance period (least squares mean difference vs placebo, -0.3), but was not significantly lower at week 12 (least squares

mean, -0.3; *P* values not reported).[42] In a, placebo-controlled and active comparator trial in adults with moderate to severe low back pain, improvements in average pain intensity scores occurred with tapentadol extended-release and oxycodone controlled-release relative to placebo (*P*<0.001).[43] Schwartz et al evaluated tapentadol extended-release among adults with painful diabetic peripheral neuropathy. The least squares mean change in average pain intensity at week 12 was 1.4 in the placebo group, indicating a worsening in pain intensity, and 0.0 in the tapentadol extended-release group, indicating no change in pain intensity, (least squares mean difference, -1.3; 95% CI, -1.70 to -0.92; *P*<0.001).[44]

- Methadone is the only long-acting narcotic that is Food and Drug Administration-approved for the management of opioid addiction; however, in one study slow-release morphine sulfate demonstrated noninferiority to methadone in terms of completion rate for the treatment of opioid addiction (51 vs 49%).[45]

Key Points within the Medication Class

- According to Current Clinical Guidelines:
  - Patients with pain should be started on acetaminophen or a nonsteroidal anti-inflammatory drug (NSAID). If sufficient pain relief is not achieved, patients should be escalated to a "weak opioid" and then to a "strong opioid", such as morphine.[46,47]
  - Opioid selection, initial dosing, and titration should be individualized according to the patient's health status, previous exposure to opioids, attainment of therapeutic goals, and predicted or observed harms. There is insufficient evidence to recommend short-acting vs long-acting opioids, or as needed vs around-the-clock dosing of opioids.[47]
  - Patients with chronic persistent pain controlled by stable doses of short-acting opioids should be provided with round-the-clock extended-release or long-acting formulation opioids with provision of a 'rescue dose' to manage break-through or transient exacerbations of pain.[46]
  - Opioids with rapid onset and short duration are preferred as rescue doses. The repeated need for rescue doses per day may indicate the necessity to adjust the baseline treatment.[46,47]
  - In a patient who has not been exposed to opioids in the past, morphine is generally considered the standard starting drug of choice.[46]
  - Pure agonists (such as codeine, fentanyl, oxycodone, and oxymorphone) are the most commonly used medications in the management of cancer pain. Opioid agonists with a short half-life are preferred and include fentanyl, hydromorphone, morphine, and oxycodone.[46]
  - Meperidine, mixed agonist-antagonists, and placebos are not recommended for cancer patients. Meperidine is contraindicated for chronic pain especially in patients with impaired renal function or dehydration.[46]
  - In patients who require relatively high doses of chronic opioid therapy, clinicians should evaluate for unique opioid-related adverse events, changes in health status, and adherence to the chronic opioid therapy treatment plan on an ongoing basis, and consider more frequent follow-up visits.[46,47]
- Other Key Facts:
  - All of the long-acting opioids are classified as Schedule II controlled substances by the Food and Drug Administration (FDA), with the exception of buprenorphine transdermal systems which are a Schedule III controlled substance.[4-19] Buprenorphine is a partial opiate agonist, and the transdermal system is the first and only seven-day transdermal opioid approved by the FDA.[5]
  - On July 9, 2012, the FDA approved a Risk Evaluation and Mitigation Strategy (REMS) for all long-acting opioids. The program will require companies who manufacture long-acting opioids to make training regarding proper prescribing practices available for health care professionals who prescribe these agents, as well as distribute educational materials to both prescribers and patients on the safe use of these agents.[48]
  - The new REMS program is part of the national prescription drug abuse plan announced by the Obama Administration in 2011 to combat prescription drug misuse and abuse.[48]

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Therapeutic Class Overview
Short-acting Opioids

Therapeutic Class

- **Overview/Summary:** Pain is one of the most common and debilitating patient complaints, with persistent pain having the potential to lead to functional impairment, disability, psychological distress and sleep deprivation. Pain can be categorized as being either nociceptive or neuropathic, and the treatments for each are specific. Nociceptive pain is caused by damage to tissues and can further be divided into somatic (pain arising from injury to body tissues) and visceral pain (pain arising from the internal organs). Visceral pain is often described as poorly localized, deep, dull, and cramping. In contrast, neuropathic pain arises from abnormal neural activity secondary to disease, injury, or dysfunction of the nervous system.[1] Pharmacologic therapy should not be the sole focus of pain treatment; however, it is the most widely utilized option to manage chronic pain. Combining pharmacologic therapies may result in improved analgesia, and because lower doses of each agent can be used, patients may experience fewer treatment-emergent adverse events. Response to pharmacologic therapies will vary between individual patients, and currently no one approach has been demonstrated to be appropriate for all patients. Treatment decisions are largely based on the type of pain (e.g., neuropathic, nociceptive), comorbidities, concurrent medications, pharmacokinetic/pharmacodynamic properties of the agent and anticipated adverse events.[2]

  As a class, opioid analgesics encompass a group of naturally occurring, semisynthetic, and synthetic drugs that stimulate opiate receptors and effectively relieve pain without producing loss of consciousness. These agents primarily produce intense analgesia via their agonist actions at mu receptors, which are found in large numbers within the central nervous system. The binding of these agents to mu receptors produces a variety of other effects including bradycardia, sedation, euphoria, physical dependence and respiratory depression.[3]

  Short acting opioid analgesics are available as single entity and in combination with acetaminophen, aspirin, butalbital, caffeine, carisoprodol and ibuprofen. Acetaminophen, aspirin and ibuprofen are non-opiate analgesics. Butalbital is a barbiturate, which has anxiolytic and muscle relaxant properties. Caffeine is an analgesic adjuvant, as well as a central nervous system stimulant. Carisoprodol is a centrally-acting muscle relaxant.[4,5] In January 2011, the Food and Drug Administration asked manufacturers to limit the amount of acetaminophen in prescription drug products (which are predominantly combinations of acetaminophen and opioids) to 325 mg per dosage form to make these products safer for patient to use.[6]

Table 1. Current Medications Available in Therapeutic Class[7-25]

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
Single-Entity Agents			
Butorphanol	Management of moderate to severe pain in patients where an opioid analgesic is appropriate	Injection: 1 mg/mL 2 mg/mL Nasal spray: 10 mg/mL	✔
Codeine	Relief of mild to moderate pain	Solution: 30 mg/5 mL Tablet: 15 mg 30 mg 60 mg	✔

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
Hydromorphone (Dilaudid®*)	Management of moderate to severe pain in patients where an opioid analgesic is appropriate	Injection: 1 mg/mL 2 mg/mL 4 mg/mL 10 mg/mL 250 mg Liquid: 1 mg/mL Rectal suppository: 3 mg Tablet: 2 mg 4 mg 8 mg	✔
Meperidine (Demerol®*, Meperitab®*)	Relief of moderate to severe pain	Injection: 10 mg/mL 25 mg/0.5 mL 25 mg/mL 50 mg/mL 75 mg/mL 75 mg/1.5 mL 100 mg/mL 100 mg/2 mL Solution: 50 mg/5 mL Tablet: 50 mg 100 mg	✔
Morphine (MSIR®*, Roxanol®*)	Management of moderate to severe pain in patients where an opioid analgesic is appropriate	Epidural: 10 mg/mL Injection: 0.5 mg/mL 1 mg/mL 2 mg/mL 4 mg/mL 5 mg/mL 8 mg/mL 10 mg/mL 15 mg/mL 15 mg/1.5 mL 25 mg/mL 30 mg/30 mL 50 mg/mL 100 mg/4 mL 100 mg/0.1 L 150 mg/30 mL	✔

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
		250 mg/10 mL 250 mg/250 mL Rectal suppository: 5 mg 10 mg 20 mg 30 mg Solution 10 mg/5 mL 20 mg/mL 20 mg/5 mL Tablet: 15 mg 30 mg10 mg 20 mg 30 mg Tablet: 15 mg 30 mg	
Oxycodone (Oxecta®*, Roxicodone®*)	Management of moderate to severe pain in patients where an opioid analgesic is appropriate	Capsule: 5 mg Oral concentrate: 20 mg/mL Solution: 5 mg/5 mL Tablet: 5 mg 7.5 mg 10 mg 15 mg 20 mg 30 mg	✔
Oxymorphone (Opana®*)	Relief of moderate to severe pain	Injection: 1 mg/mL Tablet: 5 mg 10 mg	✔
Tapentadol (Nucynta®)	Management of moderate to severe acute pain in adults	Tablet: 50 mg 75 mg 100 mg	-
Combination Products			
Acetaminophen/ codeine (Capital	Relief of discomfort associated with acute,	Elixir: 12/120 mg/5 mL	✔

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
w/codeine®*, Tylenol-Codeine®*)	painful musculoskeletal conditions in adults	Suspension: 12/120 mg/5 mL Tablet: 15/300 mg 30/300 mg 60/300 mg 30/650 mg 60/650 mg	
Codeine/butalbital/ acetaminophen/ caffeine (Fioricet with Codeine®*)	Relief of tension or muscle contraction headache	Capsule: 30/50/325 mg	✔
Codeine/butalbital/ aspirin/caffeine (Fiorinal with Codeine®*)	Relief of tension or muscle contraction headache	Capsule: 30/50/325 mg	✔
Codeine/ carisoprodol/ aspirin	Relief of discomfort associated with acute, painful musculoskeletal conditions in adults	Tablet: 16/200/325 mg	✔
Dihydrocodeine/ acetaminophen/ caffeine	Relief of moderate to moderately severe pain	Capsule: 16/356/30 mg Tablet: 32/713/60 mg	✔
Dihydrocodeine/ aspirin/ caffeine (Synalgos-DC®*)	Relief of mild to moderate pain	Capsule: 16/356/30 mg	-
Hydrocodone/ acetaminophen (Hycet®*, Lorcet®*, Lorcet-Plus®*, Lortab®*, Maxidone®*, Norco®*, Vicodin®*, Vicodin ES®*, Vicodin HP®*, Xodol®*, Zamicet®*, Zolvit®*, Zydone®*)	Relief of moderate to moderately severe pain	Capsule: 5/500 mg Solution: 2.5/167 mg/5 mL 5/334 mg/10 mL 7.5/325 mg/15 mL 7.5/500 mg/15 mL 10/300 mg/15 mL 10/325 mg/15 mL Tablet: 2.5/500 mg 5/300 mg 5/325 mg 5/400 mg 5/500 mg 7.5/300 mg 7.5/325 mg 7.5/400 mg 7.5/500 mg	✔

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
		7.5/650 mg 7.5/750 mg 10/300 mg 10/325 mg 10/400 mg 10/500 mg 10/650 mg 10/660 mg 10/750 mg	
Hydrocodone/ ibuprofen (Ibudone®*, Reprexain®*, Vicoprofen®*)	Short-term (<10 days) management of acute pain	Tablet: 2.5/200 mg 5/200 mg 7.5/200 mg 10/200 mg	✔
Oxycodone/ acetaminophen (Magnacet®*, Percocet®*, Primlev®*, Tylox®*)	Relief of moderate to moderately severe pain	Capsule: 5/500 mg Solution: 5/325 mg/5 mL Tablet: 2.5/325 mg 5/300 mg 5/325 mg 5/400 mg 5/500 mg 7.5/300 mg 7.5/325 mg 7.5/400 mg 7.5/500 mg 10/300 mg 10/325 mg 10/400 mg 10/500 mg 10/650 mg	✔
Oxycodone/aspirin (Percodan®*)	Relief of moderate to moderately severe pain	Tablet: 4.8355/325 mg	✔
Oxycodone/ ibuprofen	Short term (<7 days) management of acute, moderate to severe pain	Tablet: 5/400 mg	✔

*Generic is available in at least one dosage form or strength.

Evidence-based Medicine

- Overall, clinical trials have demonstrated opioids to be more efficacious than placebo for both pain and function outcomes in patients with nociceptive or neuropathic pain.[26-71] Head-to-head trials involving codeine, levorphanol, butalbital-containing products, dihydrocodeine-containing products or oxycodone/aspirin are not available.
- Systematic reviews and meta-analyses have similar safety and level of analgesia between hydromorphone, morphine, oxycodone and oxymorphone in the management of cancer, non-cancer and acute pain.[59-61,63,64,70,71]

- For postoperative pain, morphine has proven to provide greater pain relief than meperidine, tramadol and codeine.[36,37] In one double-blind, randomized controlled trial involving patients who underwent total hip or knee replacement surgery, patients were significantly more likely to achieve a pain relief of at least 50% following administration of oxymorphone 10 or 20 mg compared to placebo, but not with oxymorphone 30 mg or oxycodone 10 mg. A direct comparison between oxymorphone and oxycodone was not performed.[48]
- When compared to ibuprofen and acetaminophen in children with acute musculoskeletal injury, codeine achieved a level of analgesia that was comparable to acetaminophen but less than that of ibuprofen.[51]
- Several placebo- and active-controlled, randomized studies have demonstrated immediate-release tapentadol to be non-inferior to oxycodone and morphine in the management of pain from various etiologies. Results from these studies also demonstrate that tapentadol may have a more favorable adverse effect profile, specifically in terms of the incidence of gastrointestinal adverse events.[39,40,62]
- The results of randomized controlled trials have generally demonstrated a comparable level of analgesia between codeine/acetaminophen, hydrocodone/acetaminophen, hydrocodone/ibuprofen and oxycodone/acetaminophen in the management of pain.[42,49,50,52-54]

Key Points within the Medication Class

- According to Current Clinical Guidelines:
    - The World Health Organization suggests that patients with pain be started on acetaminophen or a nonsteroidal anti-inflammatory drug (NSAID). If sufficient pain relief is not achieved, patients should be escalated to a “weak opioid” and then to a “strong opioid”, such as morphine.[72,73]
    - Opioid naïve patients (those not chronically receiving opioid therapy on a daily basis) experiencing severe pain should receive rapid titration of short-acting opioids.[72,73]
    - Opioid-naïve patients whose pain intensity is moderate at presentation, the pathways are quite similar to those for severe pain, with slower titration of short-acting opioids.[72,73]
    - Opioid-naïve patients experiencing mild pain intensity should receive nonopioid analgesics, such as NSAIDs or acetaminophen or treatment with consideration of slower titration of short-acting opioids.[72,73]
    - Patients with chronic persistent pain controlled by stable doses of short-acting opioids should be provided with “around-the-clock” extended release or long acting formulation opioids with provision of a ‘rescue dose’ to manage break-through or transient exacerbations of pain.[72,73]
    - Opioids with rapid onset and short duration are preferred as rescue doses. The repeated need for rescue doses per day may indicate the necessity to adjust the baseline treatment.[72,73]
    - Rescue doses of short-acting opioids should be provided for pain that is not relieved by regularly scheduled, “around the clock” doses. Opioids administered on an “as needed” basis are for patients who have intermittent pain with pain-free intervals.[72,73]
    - Clinicians may consider using a written chronic opioid therapy management plan to document patent and clinician responsibilities and expectations and assist in patient education.[72,73]
- Other Key Facts:
    - Generic products are available for all products with the exception of tapentadol (Nucynta®).[4]

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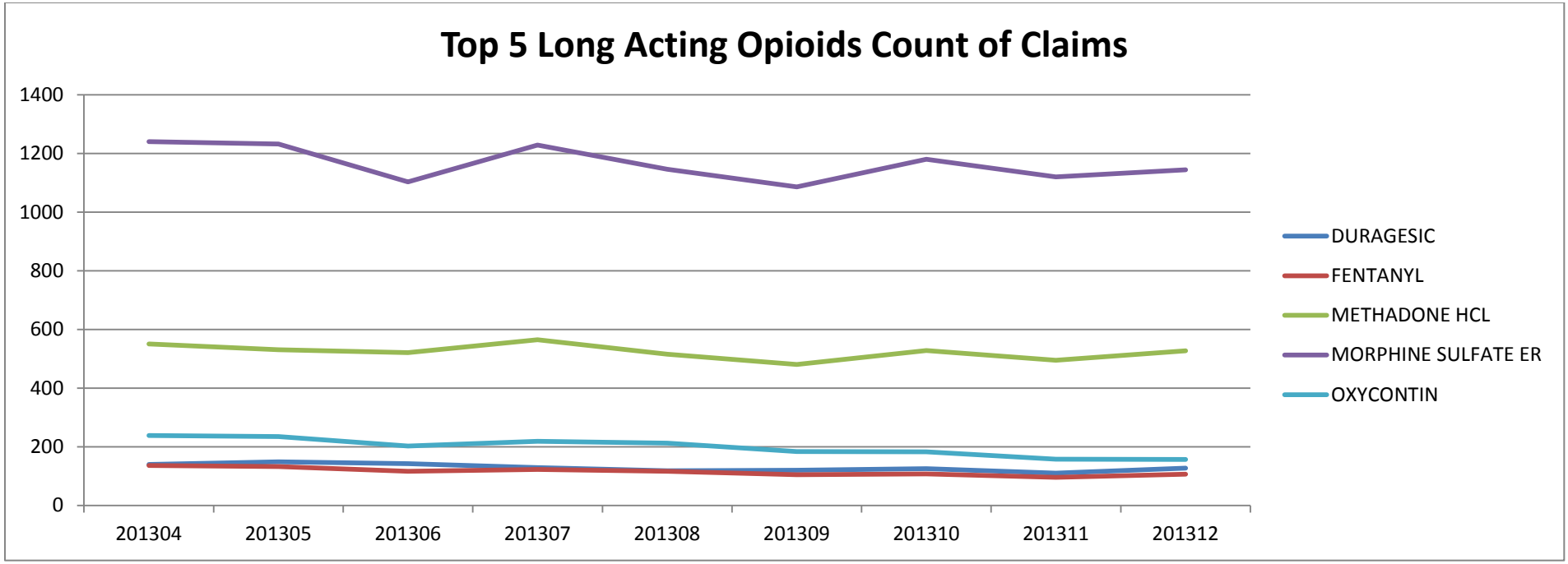
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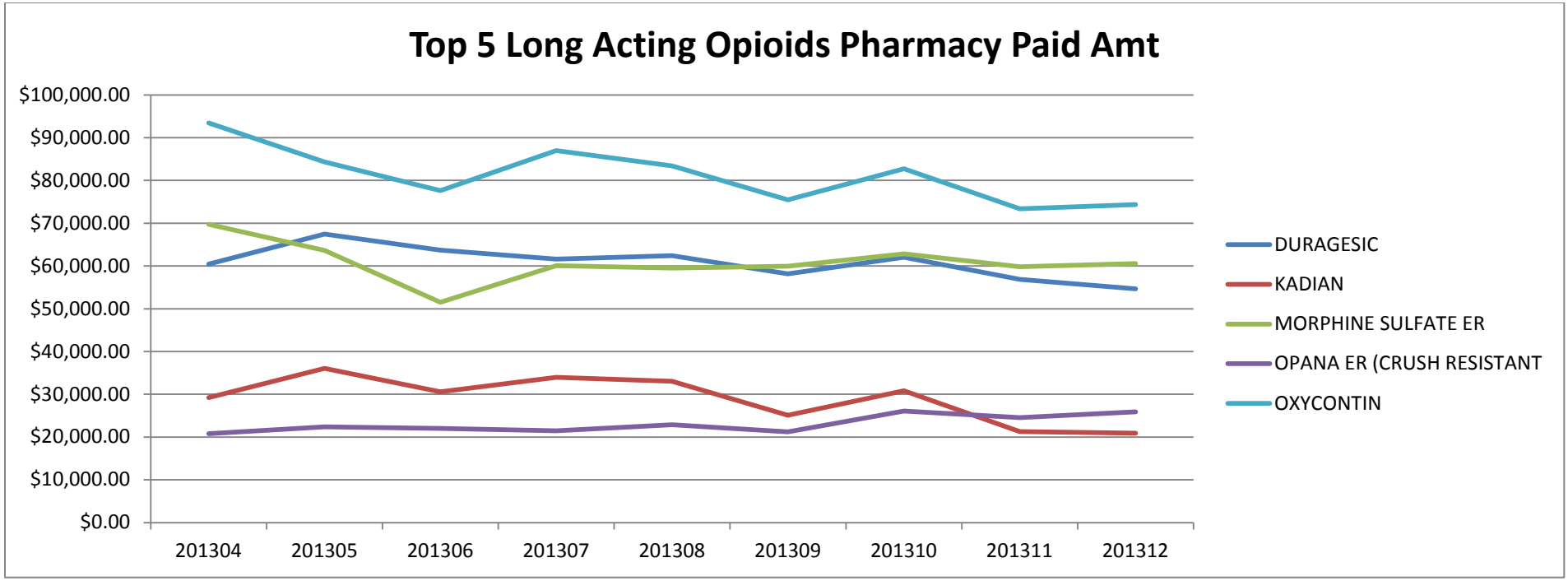
Top 5 Long Acting Opioids Pharmacy Paid Amt
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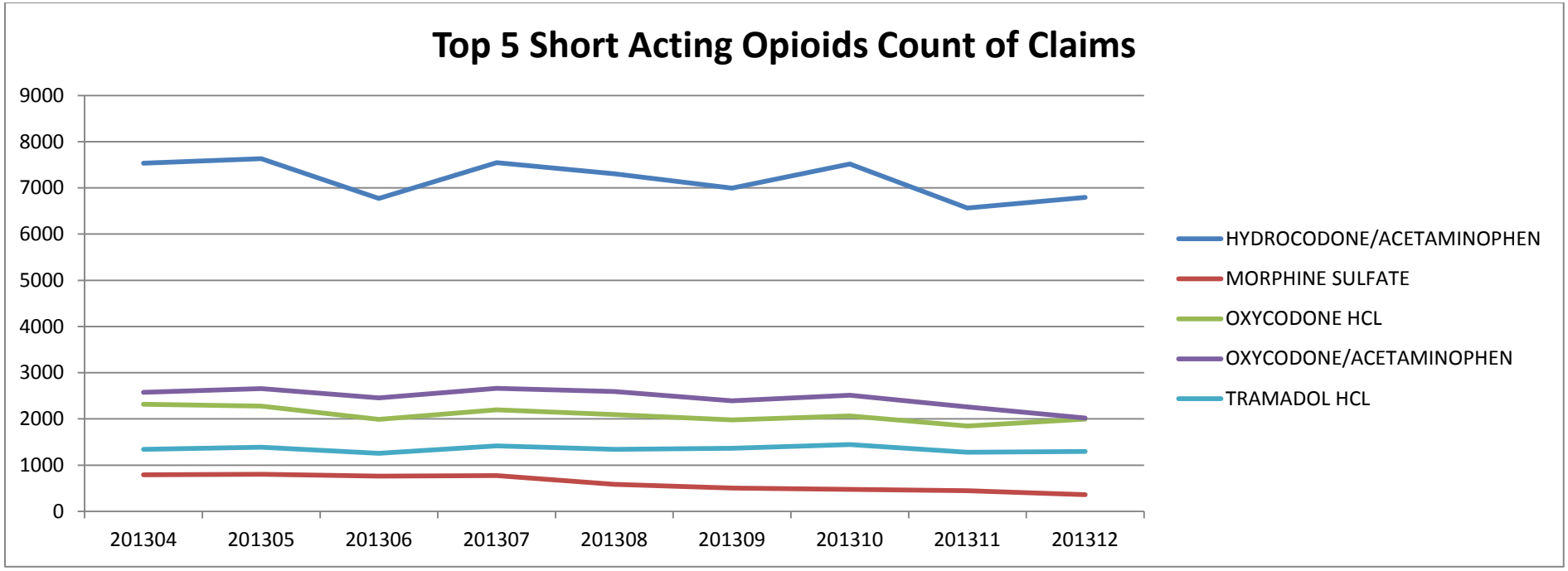
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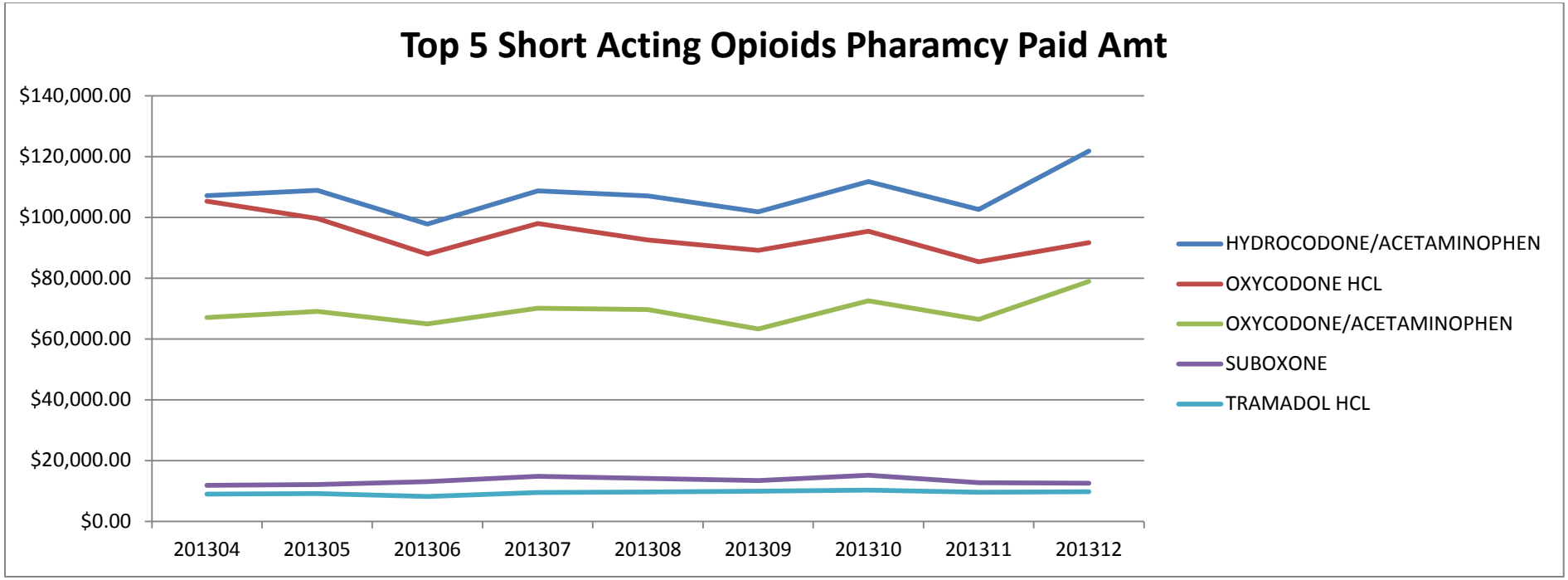
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Therapeutic Class Overview
Platelet Inhibitors

Therapeutic Class

- **Overview/Summary:** Platelet inhibitors play a major role in the management of cardiovascular, cerebrovascular, and peripheral vascular diseases. The agents in the class are Food and Drug Administration (FDA)-approved for a variety of indications including treatment and/or prevention of acute coronary syndromes (myocardial infarction, unstable angina), stroke/transient ischemic attack, and thrombocythemia. The platelet inhibitors are also indicated to prevent thrombosis in patients undergoing cardiovascular procedures and/or surgery. The platelet inhibitors exert their pharmacologic effects through several different mechanisms of action.[1-7] The newest platelet inhibitor to be FDA-approved is ticagrelor (Brilinta®), specifically to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndromes.[5] Ticagrelor is a cyclopentyltriazolopyrimidine and works in a similar manner to the other thienopyridine platelet inhibitors (clopidogrel, prasugrel, and ticlopidine). However, unlike the other agents, ticagrelor is a reversible inhibitor of the $P2Y_{12}$ receptor located on the surface of platelets. In addition, ticagrelor is not a prodrug; therefore, does not require enzymatic conversion to become pharmacologically active, and is not subject to potential drug interactions associated with the other agents.[5,8] Ticagrelor is available for twice-daily dosing, while clopidogrel and prasugrel are administered once-daily.[2,4,5]

Table 1. Current Medications Available in Therapeutic Class[1-7]

Generic Name (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/ Strength	Generic Availability
Single-Entity Agents			
Anagrelide (Agrylin®*)	Treatment of thrombocytopenia associated with myeloproliferative disorders†	Capsule: 0.5 mg 1 mg	✔
Clopidogrel (Plavix®*)	Recent myocardial infarction, recent stroke, or established peripheral arterial disease, reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome‡	Tablet: 75 mg 300 mg	✔
Dipyridamole (Persantine®*)	Prevention of postoperative thromboembolic complications of cardiac valve replacement§	Tablet: 25 mg 50 mg 75 mg	✔
Prasugrel (Effient®)	Reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome who are being managed with percutaneous coronary intervention‖	Tablet: 5 mg 10 mg	-
Ticagrelor (Brilinta®)	Reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome¶	Tablet: 90 mg	-
Ticlopidine (Ticlid®*)	Reduce the incidence of subacute stent thrombosis in patients undergoing successful coronary stent implantation#, reduce the risk of thrombotic stroke (fatal or nonfatal) in patients who have experienced stroke precursors, and in patients who have had a completed thrombotic stroke	Tablet: 250 mg	✔

Generic Name (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/ Strength	Generic Availability
Combination-Products			
Aspirin/ extended-release dipyridamole (Aggrenox®)	Reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis	Capsule: 25/200 mg	-

*Generic available in at least one dosage form or strength.
†To reduce the elevated platelet count and the risk of thrombosis and to ameliorate associated symptoms including thrombohemorrhagic events.
‡For patients with non-ST-segment elevation acute coronary syndrome, including patients who are to be managed medically and those who are to be managed with coronary revascularization, and for patients with ST-elevation myocardial infarction.
§As adjunct to coumarin anticoagulants.
‖Patients who are to be managed with percutaneous coronary intervention as follows: patients with unstable angina or non-ST-elevation myocardial infarction and patients with ST-elevation myocardial infarction when managed with primary or delayed percutaneous intervention.
¶Patients with unstable angina, non-ST-elevation myocardial infarction, or ST-elevation myocardial infarction.
#As adjunct to aspirin.

Evidence-based Medicine

- Clopidogrel, Food and Drug Administration (FDA)-approved in 1997, has been the principle platelet inhibitor for several years as the clinical data supporting its use is well established.[9-14]
- Approval of prasugrel for use in acute coronary syndromes (ACS) was based on the clinical evidence for safety and efficacy derived from the TRITON-TIMI 38 study (N=13,608). Within the study, prasugrel was significantly more effective compared to clopidogrel in reducing ischemic events in patients with ACS who underwent percutaneous coronary intervention. Prasugrel did not demonstrate a mortality benefit and a significantly higher rate of major, minor, life-threatening, and fatal bleeding events was observed with prasugrel.
    - Of note, a benefit with prasugrel was not observed in certain patient subgroups within TRITON-TIMI 38, specifically those who were ≥75 years of age, those weighing <60 kg, and those with a past history of stroke or transient ischemic attack.[15]
- In addition, several subgroup analyses were also conducted based on TRITON-TIMI 38 and one patient subgroup in particular, those with diabetes, were found to have a significantly greater reduction in ischemic events with prasugrel when compared to nondiabetic patients being treated with either prasugrel or clopidogrel.[16-22]
- The approval of ticagrelor for use in ACS was based on the clinical evidence for safety and efficacy derived from the PLATO study. Within the trial, hospitalized patients with documented ACS, with or without ST-elevation, were randomized to either ticagrelor or clopidogrel (N=18,624). After 12 months of treatment, ticagrelor was significantly more effective compared to clopidogrel in reducing the primary composite endpoint of cardiovascular death, myocardial infarction, or stroke; without increasing the risk of major bleeding. Ticagrelor demonstrated a mortality benefit compared to clopidogrel.[23]
- Several subanalyses of the PLATO trial have been conducted.[24-33] In patients with ACS undergoing noninvasive or invasive procedures, ticagrelor remained more efficacious compared to clopidogrel.[24,25] However, in patients with ST-elevation or left bundle branch block, chronic kidney disease or diabetes and in those who underwent coronary artery bypass graft surgery, there was no difference between ticagrelor and clopidogrel with regards to the primary composite endpoint.[26-29] A genetic substudy was also conducted and demonstrated ticagrelor to be more efficacious than clopidogrel, irrespective of cytochrome P450 2C19 and ABCB1 polymorphisms.[30] In the original PLATO trial, a significantly higher rate of dyspnea was observed with ticagrelor; however, data from a substudy revealed ticagrelor had no effect on pulmonary function.[23,32]
- Mahaffey et al compared the effects of ticagrelor and clopidogrel among patients enrolled in the PLATO trial who were from the United States (N=1,413). The “superior” benefits of ticagrelor in reducing thrombotic cardiovascular events were not observed among this specific patient population. Specifically, there was no difference between ticagrelor and clopidogrel in the rate of the primary composite endpoint. The authors discussed that among these patients who were treated with

ticagrelor, the lowest event rates were observed in patients also receiving low-dose aspirin maintenance therapy. In contrast, event rates in those treated with clopidogrel were similar regardless of concurrent high- or low-dose aspirin. Until a prospective clinical trial comparing the effects of low- vs high-dose aspirin maintenance therapy and its effect on the efficacy of ticagrelor is conducted, it remains unclear as to why the diminished effects of ticagrelor in the United States population were observed.[31] Of note, the FDA-approved dosing of ticagrelor recommends that after the initial loading dose of aspirin (325 mg), a daily maintenance dose of aspirin of 75 to 100 mg should be used.[5]

Key Points within the Medication Class

- According to Current Clinical Guidelines:
    - Use of the platelet inhibitors, as monotherapy or combination therapy, is based on the specific clinical indication and the patient's risk for thromboembolic events.[34-51]
    - Antiplatelet therapy (aspirin, aspirin plus extended-release dipyridamole, or clopidogrel) is recommended for long-term secondary prevention in patients with an acute ischemic stroke who are not receiving thrombolysis. Combination aspirin plus dipyridamole extended-release is recommended over aspirin, and clopidogrel is suggested over aspirin. Dual antiplatelet therapy should be used with caution and is favored in patients who have had a recent acute myocardial infarction, other acute coronary syndromes (ACS), or recently placed coronary stent.[35]
    - According to 2013 American College of Cardiology Foundation/American Heart Association guidelines for the management of ST elevation myocardial infarction, aspirin 162 to 325 mg should be given before primary percutaneous coronary intervention (PCI) and after PCI, aspirin should be continued indefinitely. A loading dose of $P2Y_{12}$ receptor inhibitor is recommended to be given as early as possible or at time of primary PCI followed by maintenance therapy as follows: clopidogrel 75 mg/day, prasugrel 10 mg/day or ticagrelor 90 mg twice daily, for one year for patients treated with a stent (bare metal stent [BMS] or drug eluting stent [DES]). For patients with DES, continuation of $P2Y_{12}$ receptor inhibitor beyond one year may be considered. Prasugrel should not be administered to patients with a prior history of stroke or transient ischemic attack.[38]
    - According to 2012 American College of Cardiology Foundation/American Heart Association focused update for the guidelines for the management of patients with unstable angina/non-ST elevation myocardial infarction, a loading dose of $P2Y_{12}$ receptor inhibitor is recommended for whom PCI is planned followed by maintenance therapy as follows: clopidogrel 75 mg/day, prasugrel 10 mg/day or ticagrelor 90 mg twice daily for at least 12 months. For patients treated with a stent (BMS or DES), aspirin should be continued indefinitely. The duration and maintenance dose of $P2Y_{12}$ receptor inhibitor therapy should be as follows:
        - Clopidogrel 75 mg/day, prasugrel 10 mg/day or ticagrelor 90 mg twice daily for at least 12 months in patients receiving DES and up to 12 months for patients receiving BMS.
        - Continuation of $P2Y_{12}$ receptor inhibitor beyond 12 months may be considered in patients following DES placement.[36]
    - According to the 2012 guideline on Antithrombotic Therapy and Prevention of Thrombosis by the American College of Chest Physicians, dual therapy with clopidogrel, prasugrel or ticagrelor in addition to low-dose aspirin is recommended in the first year following ACS in patients regardless of PCI status. Furthermore, the guideline recommends ticagrelor plus low-dose aspirin over clopidogrel plus low-dose aspirin in patients post-ACS independent of whether PCI has been conducted.[34]
    - The 2011 European Society of Cardiology guideline for the management of ACS in patients presenting without persisting ST-elevation recommends ticagrelor first-line in patients at moderate to high risk of ischemic events, regardless of treatment strategy and including those pretreated with clopidogrel.
        - If coronary anatomy is known and PCI is planned, prasugrel is recommended.
        - Clopidogrel is recommended in patients who cannot receive prasugrel or ticagrelor.[37]

  - The 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions guideline for percutaneous intervention recommends clopidogrel, prasugrel, and ticagrelor as treatment options.
    - Prasugrel should not be administered to patients with a prior history of stroke or transient ischemic attack.
    - Treatment with all agents should be continued for at least 12 months.[39]
- Other Key Facts:
  - Anagrelide, clopidogrel, dipyridamole, and ticlopidine are available generically.

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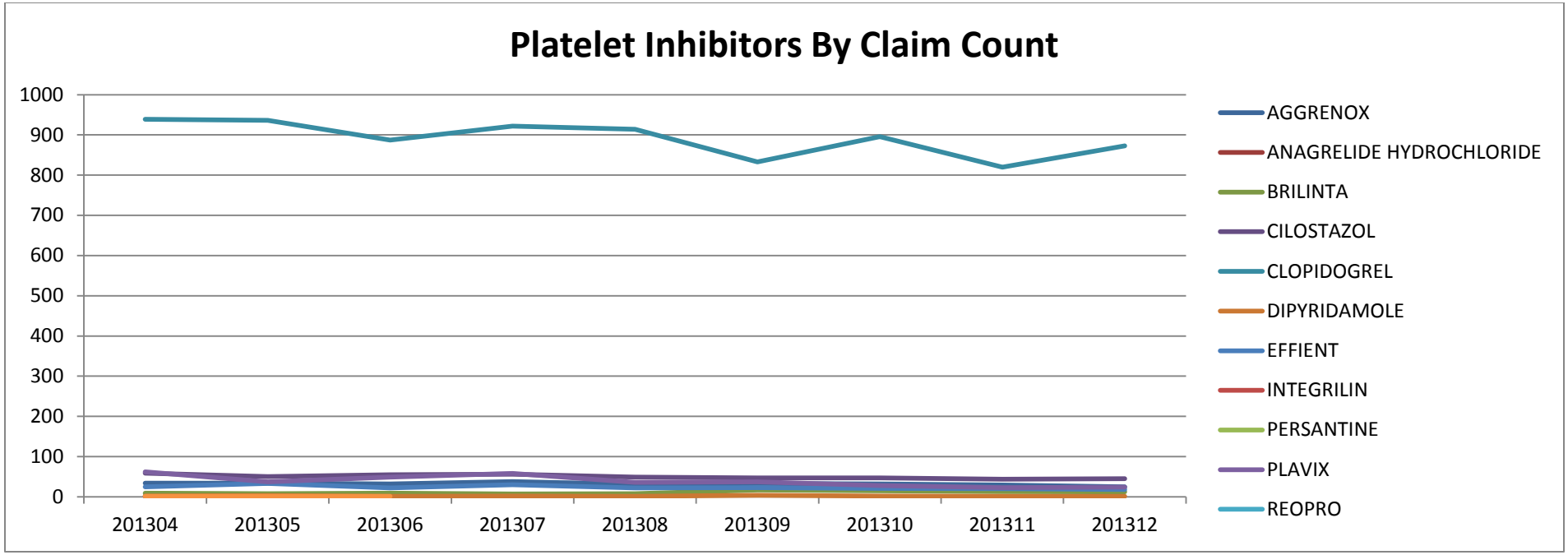
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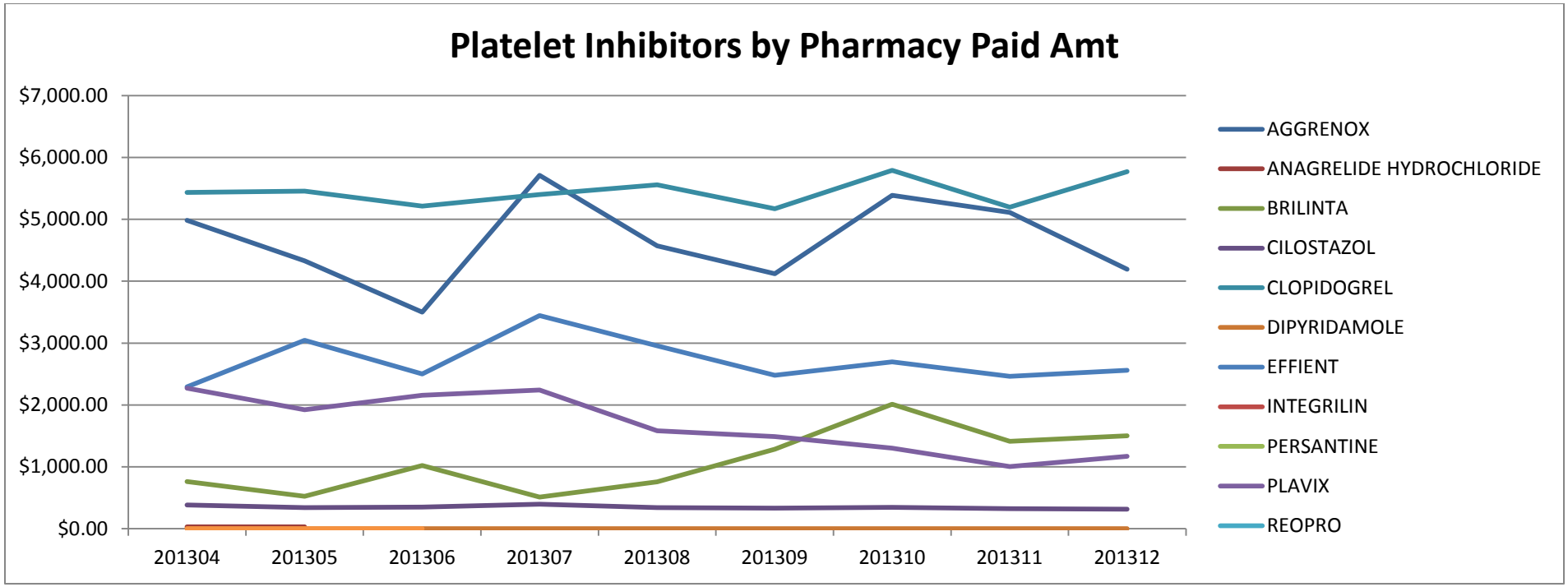
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PERSANTINE
PLAVIX
REOPRO

DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID
DRUG USE REVIEW (DUR) BOARD
PROPOSED PRIOR AUTHORIZATION CRITERIA

Platelet Inhibitors are a covered benefit of Nevada Medicaid for recipients who meet the criteria for coverage.

1. Coverage and Limitations:
Authorization will be given if the following criteria are met and documented:

Requests for Brilinta® (ticagrelor)

a. The recipient has a diagnosis of Acute Coronary Syndrome (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction).
AND
b. The recipient does not have an active pathological bleed or history of intracranial hemorrhage.
AND
c. The recipient will be receiving concomitant treatment with aspirin in a dose of <100 mg/daily.
AND
d. The recipient has been started and stabilized on the requested medication.
OR
e. The recipient has experienced an adverse event with or has an allergy or contraindication with clopidogrel.
OR
f. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

Requests for Effient® (prasugrel)

a. The recipient has a diagnosis of Acute Coronary Syndrome (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction).
AND
b. The recipient does not have an active pathological bleed or history of transient ischemic attack or stroke.
AND
c. The recipient will be receiving concomitant treatment with aspirin in a dose of <100 mg/daily.
AND
d. The recipient has a history of percutaneous coronary intervention.
AND
e. The recipient has been started and stabilized on the requested medication.
OR
f. The recipient has experienced an adverse event with or has an allergy or contraindication with clopidogrel.

OR

f. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

2. PA Guidelines:
Prior Authorization approval will be for 1 year.

3. Quantity Limitations:
Brilinta® (ticagrelor): 60 tablets/30 days
Effient® (prasugrel): 30 tablets/30 days

Therapeutic Class Overview
Botulinum Toxins

Therapeutic Class

- **Overview/Summary:** Botulinum toxin is a neuromodulator derived from neurotoxins produced by the bacteria *Clostridium botulinum*, a gram positive bacillus.[1,2] Botulinum toxin inhibits the release of acetylcholine at presynaptic cholinergic nerve terminals of the peripheral nervous system and at ganglionic nerve terminals of the autonomic nervous system, thereby preventing neurotransmission and inducing flaccid paralysis.[1-6] Botulinum toxins are used for a variety of conditions including, blepharospasm, cervical dystonia, strabismus and upper limb spasticity, in which the goal of therapy is to reduce contraction of striated or smooth muscle.[1-6] Three botulinum toxin A products are approved by the Food and Drug Administration (FDA) including abobotulinumtoxinA (Dysport®), incobotulinumtoxinA (Xeomin®) and onabotulinumtoxinA (Botox®). RimabotulinumtoxinB (Myobloc®) is the only botulinum toxin B product approved by the FDA.[3-6] None of the botulinum toxin products are available generically.[7] Botulinum toxin types A and B primarily differ in the specific mechanism by which they prevent acetylcholine from being released into the neuromuscular junction and in their risk for antibody development.[8] The development of antibodies against botulinum toxin may confer resistance or a diminished therapeutic response with subsequent treatments. RimabotulinumtoxinB appears to carry a higher risk of antibody development compared to the botulinum toxin A products.[3-6] IncobotulinumtoxinA is the only botulinum toxin product that is free of complexing proteins (hemagglutinins and nonhemagglutinins); however, whether this results in a lower rate of antibody development or greater therapeutic benefit compared to the other botulinum toxin products has not been established.[9] The botulinum toxin products are not interchangeable with one another. The potency (in units) of one botulinum toxin product is specific to the preparation and assay method utilized by the manufacturer and units of biological activity of one product cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.[3-6] Following injection, the onset of action occurs within two to six days and the therapeutic effect generally last at least 12 weeks. All botulinum toxin products include a black box warning in their labeling regarding the risk of botulinum toxin spreading beyond the site of injection, resulting in adverse events and death in some cases.[3-6]

Table 1. Current Medications Available in Therapeutic Class[3-6]

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
AbobotulinumtoxinA (Dysport®)	Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and procerus muscle activity in adults younger than 65 years, treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia†	Powder for solution for injection: 300 Units 500 Units	-
IncobotulinumtoxinA (Xeomin®)	Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and procerus muscle activity in adults younger than 65 years, treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia† and treatment of adults with blepharospasm	Powder for solution for injection: 50 Units 100 Units	-

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
	who were previously treated with onabotulinumtoxinA		
OnabotulinumtoxinA (Botox®)	Prophylaxis of headaches in adult patients with chronic migraine*, temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and procerus muscle activity in adults younger than 65 years, treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia†, treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency‡, treatment of severe primary axillary hyperhidrosis§, treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders‖, treatment of upper limb spasticity in adults¶ and treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)‡	Powder for solution for injection: 100 Units 200 Units	-
RimabotulinumtoxinB (Myobloc®)	Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia	Solution for injection: 2,500 Units (0.5 mL) 5,000 Units (1 mL) 10,000 Units (2 mL)	-

*At least 15 days per month with headache lasting four hours a day or longer.
†In toxin-naive and previously treated patients.
‡ In adults who have an inadequate response to or are intolerant of an antimuscarinic medication.
§ Following an inadequate response to topical agents.
‖ In patients 12 years of age and older.
¶To decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), and finger flexors (flexor digitorum profundus and flexor digitorum sublimis).

Evidence-based Medicine

- In adults with cervical dystonia, results of head-to-head studies have not demonstrated a statistically significant difference between botulinum toxin products with regard to improvements in Toronto Western Spasmodic Torticollis Rating Scale total or subscale scores for symptomatic improvement.[10-12]
- In studies comparing incobotulinumtoxinA and onabotulinumtoxinA in patients with blepharospasm, similar improvements in Jankovic Rating Scale scores and other clinical outcomes have been reported, with no statistically significant differences between treatments.[13-16]
- OnabotulinumtoxinA may have a longer duration of action compared to abobotulinumtoxinA, with a similar duration of action as incobotulinumtoxinA and rimabotulinumtoxinB.[14,15,17,18]
- OnabotulinumtoxinA has consistently demonstrated statistically significant improvements in symptoms and quality of life in patients with severe primary axillary hyperhidrosis compared to

placebo.[19-21] Compared to aluminum chloride 20%, significantly more patients treated with onabotulinumtoxinA were achieved a treatment response at 12 weeks (92 vs 33%; *P*<0.001).[22]
- In patients experiencing symptoms of overactive bladder with urge urinary incontinence (UUI), urgency and frequency, onabotulinumtoxinA treatment significantly reduced the number of daily urgency episodes, voids and UUI episodes compared to placebo.[23-25]

Key Points within the Medication Class
- According to Current Clinical Guidelines:
    - The American Academy of Neurology and European Federation of Neurological Societies consider botulinum toxin A (or type B if there is resistance to type A) to be initial treatment for primary cranial or cervical dystonias due to their increased efficacy relative to standard therapies. In addition, botulinum toxin should also be considered for the treatment of blepharospasm, despite suboptimal evidence supporting use its use.[26,27]
    - In adults with spasticity of the upper and lower limb, botulinum toxin reduces muscle tone, improves passive function and may improve active function.[28]
    - In the management of nonneurogenic urinary incontinence, intravesical injections of botulinum toxin A are recommended as a third-line treatment in patients with UUI that is refractory to behavioral modification and antimuscarinic therapy, or when antimuscarinics are poorly tolerated. [29,30]
    - Botulinum toxin injections in the detrusor are considered the most effective minimally invasive treatment to reduce urinary incontinence in patients with neurogenic detrusor overactivity.[31,32]
    - In patients with esotropia or exotropia, injections of botulinum toxin may be an alternative to conventional extraocular muscle surgery in selected patients; however, the value in managing infantile esotropia has not been established.[33]
    - Based on inconsistent results from clinical trials, there is insufficient evidence to support or refute a benefit of botulinum toxin for the treatment of chronic daily headache.[34]
- Other Key Facts:
    - None of the botulinum toxin products are available generically.[7]
    - It is unknown if patients who developed neutralizing antibodies to onabotulinumtoxinA are at increased risk of developing tolerance to rimabotulinumtoxinB.[8]
    - All botulinum toxin A products are available as powders and must be reconstituted prior to use.[3-5]

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Dx Code	Dx Description	# Claims	# Members
346.70	CH MGR WO AR WO NT WO ST	88	35
780.39	CONVULSIONS NEC	66	37
343.9	CEREBRAL PALSY NOS	60	27
728.85	SPASM OF MUSCLE	33	16
333.83	SPASMODIC TORTICOLLIS	25	14
784.0	HEADACHE	21	16
780.93	MEMORY LOSS	18	11
332.0	PARALYSIS AGITANS	13	7
436	CVA	12	9
343.0	CONGENITAL DIPLEGIA	9	3
782.0	SKIN SENSATION DISTURB	8	8
345.11	GEN CNV EPIL W INTR EPIL	7	6
333.1	TREMOR NEC	7	6
596.54	NEUROGENIC BLADDER NOS	7	2
729.5	PAIN IN LIMB	7	4
780.4	DIZZINESS AND GIDDINESS	7	6
333.6	GENETIC TORSION DYSTONIA	6	4
333.81	BLEPHAROSPASM	5	4
342.90	UNSP HEMIPLGA UNSPF SIDE	5	1

Plan Code	# Claims	# Members
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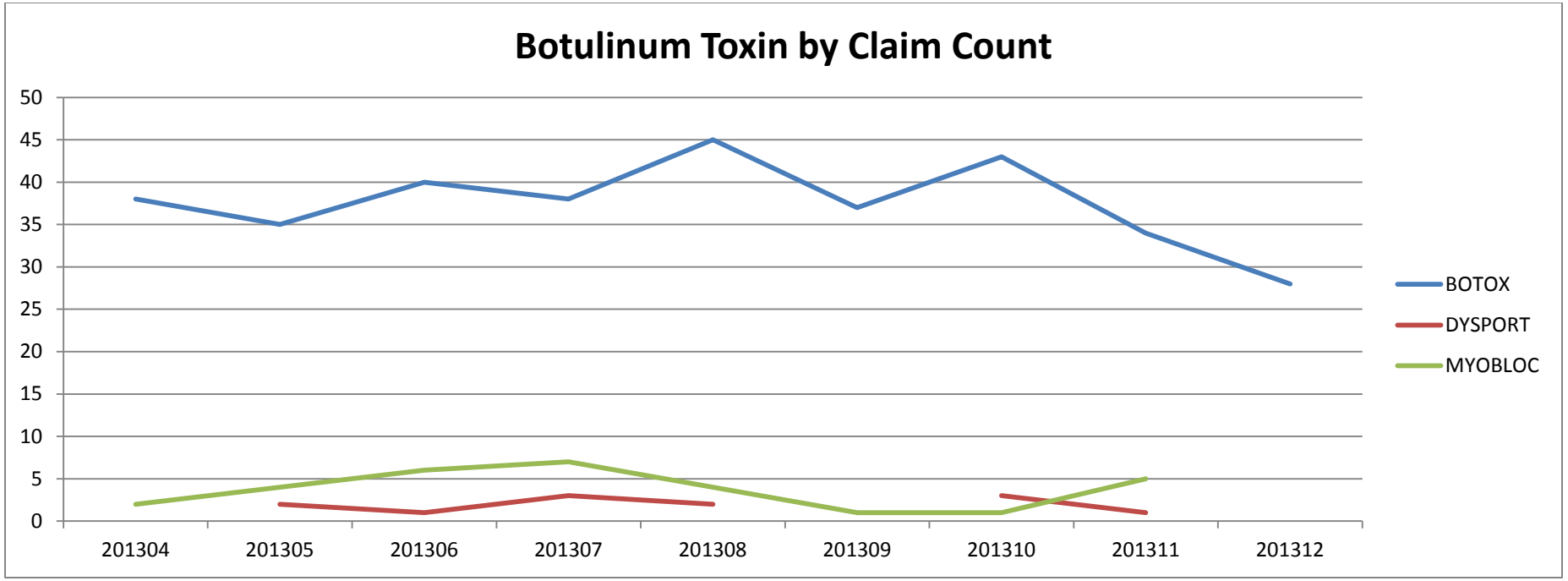
Botulinum Toxin by Claim Count
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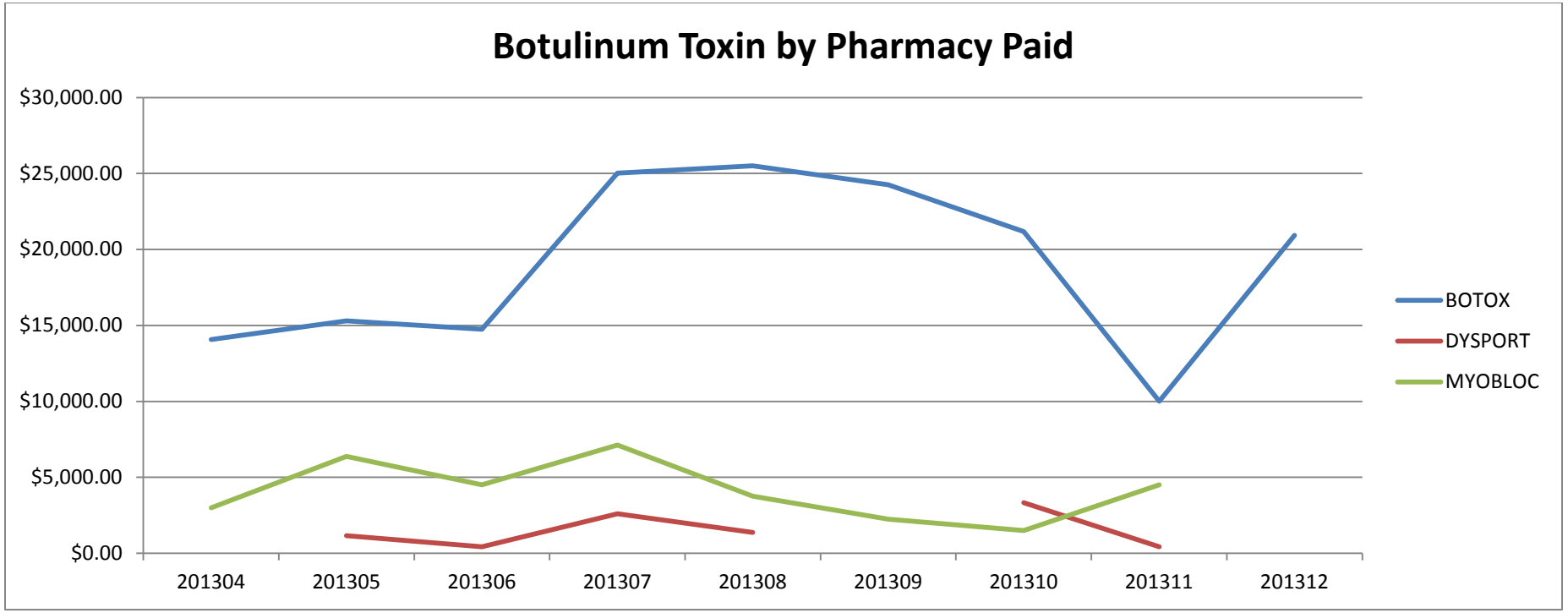
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DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID
DRUG USE REVIEW (DUR) BOARD
PROPOSED PRIOR AUTHORIZATION CRITERIA

Botulinum toxins are a covered benefit of Nevada Medicaid for recipients who meet the criteria for coverage.

1. Coverage and Limitations:
Authorization will be given if the following criteria are met and documented:

Requests for Dysport® (abobotulinumtoxinA)
1. Must have the following:
    a. The recipient has a diagnosis cervical dystonia.

Requests for Xeomin® (incobotulinumtoxinA)
1. Must have ONE of the following:
    a. The recipient has a diagnosis cervical dystonia.

    b. The recipient has a diagnosis of blepharospasm and was previously treated with Botox®.

Requests for Botox® (onabotulinumtoxinA)
1. Must have ONE of the following:
    a. The requested medication will be used for the prophylaxis of chronic migraines.
    AND
    The recipient has ≥15 days per month with headaches that last four hours a day or longer.
    AND
    The recipient has experienced an inadequate response or adverse event with at least one beta blocker, or has a contraindication to treatment with these agents.
    AND
    The recipient has experienced an inadequate response or adverse event with at least one of the following: amitriptyline, topiramate, valproic acid, venlafaxine, or has a contraindication to treatment with these agents.

    c. The recipient has a diagnosis of cervical dystonia.

    d. The recipient has a diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency.
    AND
    The recipient has experienced an inadequate response or adverse event with at least two anticholinergic medications, or has a contraindication to treatment with these agents.

    e. The recipient has a diagnosis of severe primary axillary hyperhidrosis.
    AND

The recipient has experienced an inadequate response or adverse event with aluminum chloride topical solution, or has a contraindication to treatment with this agent.

f. The recipient has a diagnosis of strabismus or blepharospasm associated with dystonia (including benign essential blepharospasm or VII nerve disorders).

g. The recipient has a diagnosis of upper limb spasticity.

h. The recipient has a diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis).
AND
The recipient has experienced an inadequate response or adverse event with at least two anticholinergic medications, or has a contraindication to treatment with these agents.

Requests for Myobloc® (rimabotulinumtoxinB)

1. Must have the following:
   a. The recipient has a diagnosis cervical dystonia.

2. PA Guidelines:
Prior Authorization approval will be 3 months for initial requests.
Prior Authorization approval will be 1 year for requests for continuing treatment.

3. Quantity Limitations:
N/A

Therapeutic Class Overview
Buprenorphine and Buprenorphine/Naloxone

Therapeutic Class

- **Overview/Summary:** Buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®) are Food and Drug Administration (FDA)-approved for the treatment of opioid dependence.[1-3] These products are classified as Schedule III controlled substances. Buprenorphine is a partial opioid agonist at the μ-opioid receptor (associated with analgesia and dependence) and an antagonist at the κ-opioid receptor (related to dysphoria).[1-3] Compared to full opioid agonists, partial agonists bind to the μ-opioid receptor at a higher degree while activating the receptor to a lesser degree. Partial opioid agonists reach a ceiling effect at higher doses and will displace full opioid agonists from the μ-opioid receptor. Although buprenorphine is associated with significant respiratory depression when used intravenously, or by patients with concomitant benzodiazepine or alcohol abuse, it is associated with a lower abuse potential, a lower level of physical dependence and is safer in overdose when compared to full opioid agonists.[4] During buprenorphine administration, opioid-dependent patients experience positive subjective opioid effects which are limited by ceiling effect.[1-3] Naloxone, an antagonist at the μ-opioid receptor, has measurable blood levels following sublingual buprenorphine/naloxone administration. However, due to naloxone's low oral bioavailability, there are no significant physiological or subjective differences when compared to the administration of buprenorphine alone. Following intramuscular or intravenous administration, buprenorphine/naloxone is associated with symptoms of opioid withdrawal and dysphoria which is caused by a stronger affinity of naloxone for the opioid receptor compared to buprenorphine.[2,3] Therefore, the addition of naloxone to buprenorphine results in a decreased risk of diversion compared to buprenorphine monotherapy. Buprenorphine and buprenorphine/naloxone sublingual tablets are currently available generically.[5] Reckitt Benckiser Pharmaceuticals discontinued distribution of buprenorphine/naloxone sublingual tablets in March 2013, as a result of concerns over accidental/unsupervised pediatric exposure compared to the film formulation; however, generic formulations will remain available.[5,6]

Table 1. Current Medications Available in Therapeutic Class[1-3]

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
Single Entity Agent			
Buprenorphine (Subutex®*)	Treatment of opioid dependence	Sublingual tablet: 2 mg 8 mg	✔
Combination Product			
Buprenorphine/naloxone (Suboxone®*)	Treatment of opioid dependence	Sublingual film: 2.0/0.5 mg 4/1 mg 8/2 mg 12/3 mg Sublingual tablet: 2.0/0.5 mg 8/2 mg	✔ †

*Available generically in one dosage form or strength.
† Buprenorphine/naloxone 2.0/0.5 mg and 8/2 mg sublingual tablets only.

Evidence-based Medicine

- Results from one double-blind, placebo- and active-controlled study (N=326) demonstrated that in adult patients with opioid dependence, the percentage of opioid negative urine tests was significantly higher for both buprenorphine 16 mg daily and buprenorphine/naloxone 16/4 mg daily compared to placebo, while no significant difference was seen between the two active treatment groups.[7] A

smaller, randomized controlled trial (N=32) also showed no significant difference in withdrawal symptoms between buprenorphine and buprenorphine/naloxone.[8]

- Several studies have compared the effectiveness of short-term detoxification to medium- or long-term maintenance treatment with buprenorphine monotherapy or buprenorphine/naloxone. Three studies have shown higher treatment retention rate or lower self-reported drug use with longer treatment duration compared to detoxification; however, one of the studies (Woody et al) showed no significant difference in the percentage of positive urine tests between the two treatment groups at 12 weeks.[9-11]
- In a meta-analysis of 21 randomized controlled trials, treatment with buprenorphine at doses ≥16 mg/day was associated with a greater likelihood of remaining in treatment compared to doses <16 mg/day; however, no significant difference was seen in the percentage of opioid positive urine tests between the high and low dose groups.[12]
- Studies that compared different dosing regimens of buprenorphine showed no differences in rate of treatment retention, percentage of urine tests positive for opioids or withdrawal symptoms.[13-15]
- When compared to other agents, one Cochrane review showed that buprenorphine was less effective than methadone in retaining patients in opioid dependence treatment.[16] Another Cochrane review showed that buprenorphine-based therapy was as effective as methadone and more effective than clonidine in the management of opioid withdrawal symptoms.[17]

Key Points within the Medication Class

- According to Current Clinical Guidelines:
    - The United States Substance Abuse and Mental Service Clinical Guideline for the Use of Buprenorphine in the Treatment of Opioid Addiction recommends the use of buprenorphine/naloxone for the induction, stabilization and maintenance phases of opioid addiction treatment for most patients.[4]
    - Buprenorphine alone should be used for pregnant patients and for the induction therapy of patients who are transitioning from methadone treatment.[4]
    - Transitioning patients to buprenorphine/naloxone as early as possible to minimize potential diversion associated with buprenorphine monotherapy is also reccomended.[4,18]
- Other Key Facts:
    - Buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®) sublingual tablets are available generically.[5]

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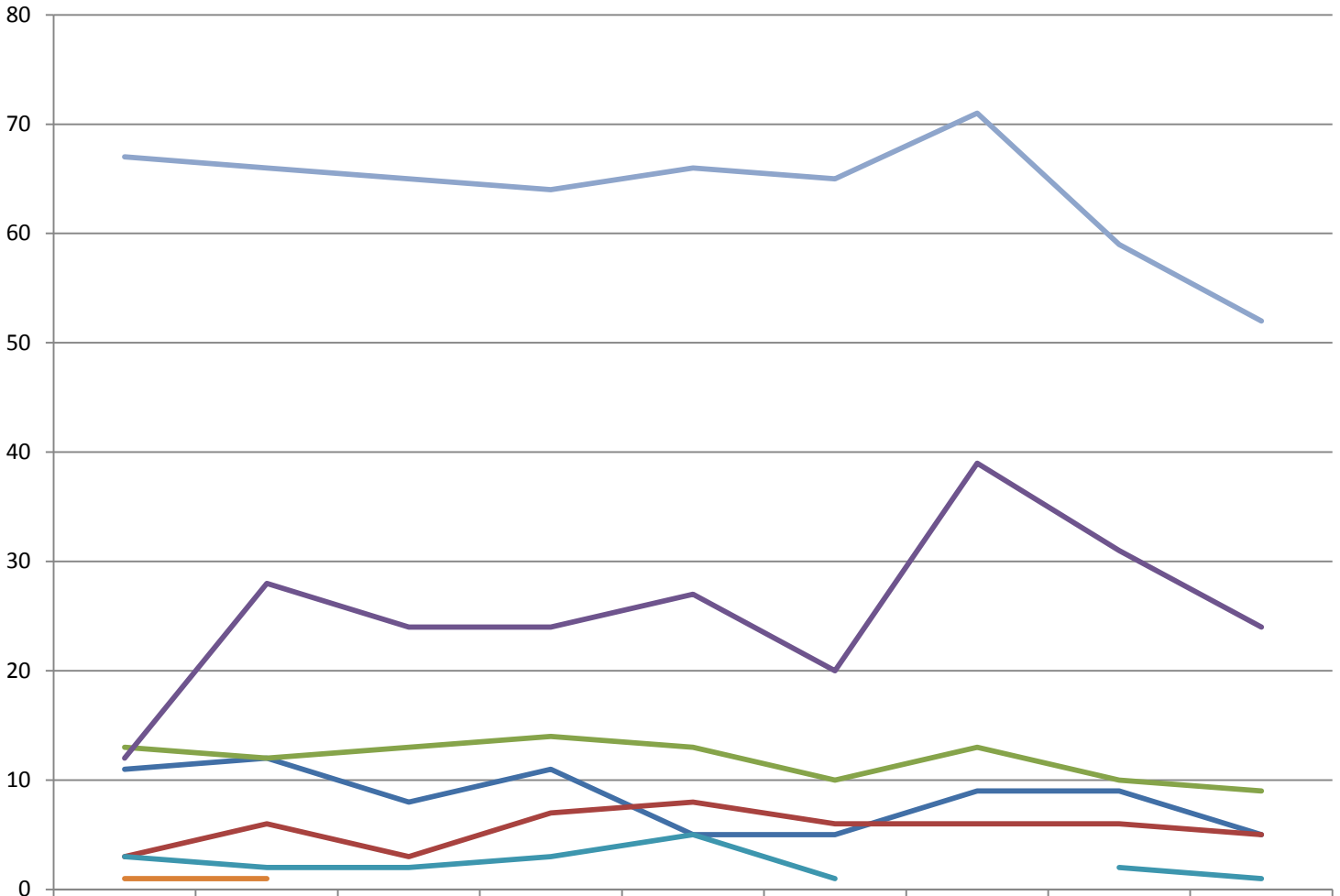
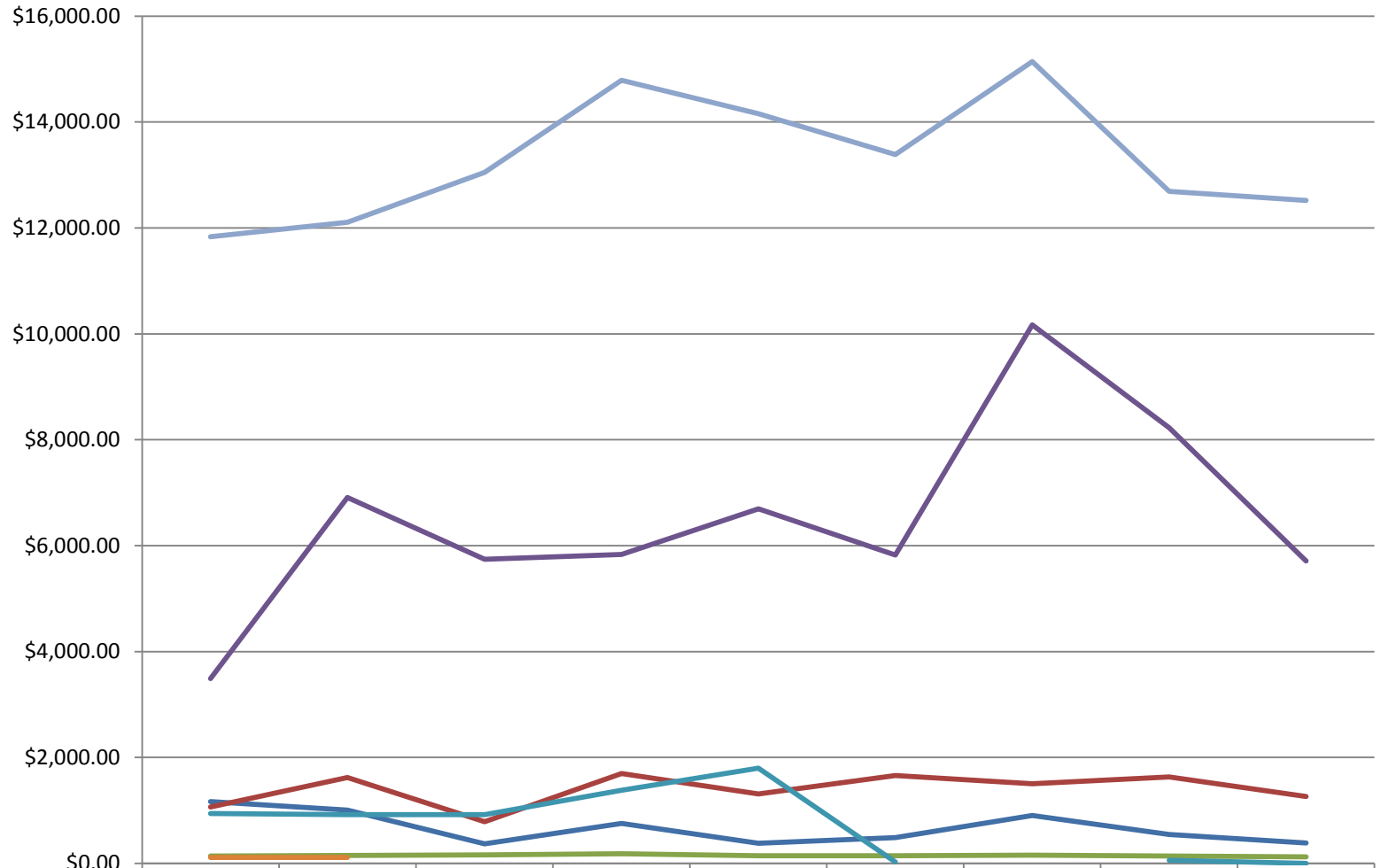
Buprenorphine Utilization by Claim Count



	201304	201305	201306	201307	201308	201309	201310	201311	201312
BUPRENORPHINE HCL	11	12	8	11	5	5	9	9	5
BUPRENORPHINE HCL/NALOXON	3	6	3	7	8	6	6	6	5
BUTORPHANOL TARTRATE	13	12	13	14	13	10	13	10	9
BUTRANS	12	28	24	24	27	20	39	31	24
NALBUPHINE HCL	3	2	2	3	5	1		2	1
PENTAZOCINE/NALOXONE HCL	1	1		2			1		
SUBOXONE	67	66	65	64	66	65	71	59	52

Buprenorphine Utilization by Pharmacy Paid Amt



	201304	201305	201306	201307	201308	201309	201310	201311	201312
BUPRENORPHINE HCL	$1,168.94	$1,004.86	$372.15	$757.09	$381.18	$488.11	$906.74	$544.95	$386.01
BUPRENORPHINE HCL/NALOXON	$1,066.27	$1,624.28	$786.86	$1,694.53	$1,313.08	$1,659.76	$1,505.49	$1,631.23	$1,263.90
BUTORPHANOL TARTRATE	$141.75	$151.05	$162.14	$182.34	$147.30	$143.96	$156.02	$137.25	$125.16
BUTRANS	$3,492.26	$6,910.88	$5,743.35	$5,833.39	$6,698.64	$5,826.32	$10,167.93	$8,226.99	$5,713.28
NALBUPHINE HCL	$943.79	$921.00	$921.00	$1,381.50	$1,797.46	$29.62		$59.24	$2.25
PENTAZOCINE/NALOXONE HCL	$113.99	$113.99		$309.86			$133.48		
SUBOXONE	$11,832.53	$12,107.36	$13,051.32	$14,791.08	$14,154.39	$13,388.44	$15,140.58	$12,690.03	$12,517.97

DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID
DRUG USE REVIEW (DUR) BOARD
PROPOSED PRIOR AUTHORIZATION CRITERIA

Suboxone® (buprenorphine/naloxone) and Subutex® (buprenorphine) are a covered benefit of Nevada Medicaid for recipients who meet the following criteria for coverage.

1. Coverage and Limitations:
Authorization will be given if the following criteria are met and documented:

Requests for Suboxone® (buprenorphine/naloxone)

1. Must have ALL of the following:
    a. The recipient has a diagnosis of opioid dependence.
    AND
    The recipient is 16 years of age or older.
    AND
    The medication is being prescribed by a physician with a Drug Addiction Treatment Act (DATA) of 2000 waiver who has a unique "X" DEA number.
    AND
    There is documentation (name of specific substance abuse program) that formal substance abuse counseling/treatment is in place or, if the prescriber is a psychiatrist or certified addiction specialist, they may confirm that they personally render the counseling.
    AND
    There is documentation that the patient has honored all of their office visits and counseling sessions in a compliant manner.

Requests for Subutex® (buprenorphine)

2. Must have ALL of the following:
    b. The recipient has a diagnosis of opioid dependence.
    AND
    The recipient is 16 years of age or older.
    AND
    The medication is being prescribed by a physician with a Drug Addiction Treatment Act (DATA) of 2000 waiver who has a unique "X" DEA number.
    AND
    There is documentation (name of specific substance abuse program) that formal substance abuse counseling/treatment is in place or, if the prescriber is a psychiatrist or certified addiction specialist, they may confirm that they personally render the counseling.
    AND
    There is documentation that the patient has honored all of their office visits and counseling sessions in a compliant manner.
    AND
    There is documentation that the recipient is pregnant.
    OR
    There is documentation the recipient is breastfeeding an infant who is dependent on methadone or morphine.

2. PA Guidelines:
Prior authorization approval will be for 1 year

3. Quantity Limitations:
Suboxone® 2 mg/0.5 mg sublingual tablet/film: 3 tablets/film per day
Suboxone® 4 mg/1 mg sublingual film: 1 film per day
Suboxone® 8 mg/2 mg sublingual tablet/film: 2 tablets/film per day
Suboxone® 12 mg/3 mg sublingual tablet/film: 1 film per day
Subutex® 8 mg sublingual tablet: 2 tablets per day
Subutex® 2 mg sublingual tablet: 3 tablets per day

Therapeutic Class Overview
Epinephrine for Anaphylaxis Agents

Therapeutic Class

- **Overview/Summary:** Anaphylaxis, a potentially fatal disorder, is an acute, multisystem syndrome resulting from a sudden release of mast cell- and basophil-derived mediators into circulation.[1] Most commonly it results from immunologic reactions to foods, medications and insect stings. In humans the heart, vasculature system and lungs are predominately affected during an anaphylactic reaction, and fatalities can result from circulatory collapse and respiratory arrest.[1,2] Epinephrine is essential for the treatment of anaphylaxis. It is recognized as the treatment of choice because the benefits associated with epinephrine are greater than any other available pharmacologic intervention (e.g., antihistamines, bronchodilators, glucocorticoids). Epinephrine is the only agent that prevents and reverses airflow obstruction in the upper and lower respiratory tracts, as well as cardiovascular collapse. The therapeutic actions of epinephrine result from α1, β1 and β2 adrenergic receptor agonist effects and include increased vasoconstriction, increased peripheral vascular resistance, decreased mucosal edema, increased inotropy, increased chronotropy, increased bronchodilation and decreased release of mediators of inflammation from mast cells and basophils.[3]

  The epinephrine for anaphylaxis agents (Adrenaclick®, Auvi-Q®, EpiPen® and EpiPen Jr®) which are all Food and Drug Administration approved for the emergency treatment of severe allergic reactions. All agents are available as single use, auto-injectors to be administered as an intramuscular or subcutaneous injection into the anterolateral aspect of the thigh.[4-7] Based on clinical trial data, intramuscular administration is preferred as it consistently provides a more rapid increase in the plasma and tissue concentrations of epinephrine.[2,8,9] These agents are intended for immediate administration in patients with a history of anaphylactic reactions. Furthermore, these agents are designed for emergency supportive therapy and are not intended to substitute immediate medical care. In conjunction with the administration of one of these agents, patients should seek the appropriate medical care. Differences among the various agents are minimal and include specific packaging and administration requirements. Auvi-Q® is the first epinephrine auto-injector with audio instructions that directs patients and caregivers through the injection process.[4-7] Each agent is available as a 0.15 and 0.3 mg injection. Generic epinephrine for anaphylaxis agents are currently available.

Table 1. Current Medications Available in the Therapeutic Class[4-7]

Generic (Trade Name)	Food and Drug Administration Approved Indications	Dosage Form/Strength	Generic Availability
Epinephrine (Adrenaclick®*, Auvi-Q®, EpiPen®, EpiPen Jr®)	Emergency treatment of severe allergic reactions (Type 1) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants), biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as anaphylaxis to unknown substances (idiopathic anaphylaxis) or exercise-induced anaphylaxis	Injection: 0.15 mg/0.15 mL (Adrenaclick®*, Auvi-Q®*, epinephrine*) 0.15 mg/0.3 mL (EpiPen Jr®*) 0.3 mg/0.3 mL (Adrenaclick®*, Auvi-Q®*, epinephrine*, EpiPen®*)	✔

*Generic available in at least one dosage form and/or strength.

Evidence-based Medicine

- It has been noted that controlled clinical trials evaluating epinephrine for this indication will never be performed, due to ethical considerations in a disease that can kill within minutes and mandates

prompt epinephrine administration.[3] As noted in the Food and Drug Administration-approved package labeling of the various agents, epinephrine is essential for the treatment of anaphylaxis.[4-7]

Key Points within the Medication Class

- According to Current Clinical Guidelines:
  - Epinephrine is the first drug that should be used in the emergency management of a child having a potentially life-threatening allergic reaction.
  - Epinephrine injection is available in a number of self-administration delivery devices.
  - There are no contraindications to the use of epinephrine for a life-threatening allergic reaction.
  - In patients who have had anaphylactic reactions, it is recommended that epinephrine be given at the start of any reaction occurring in conjunction with exposure to a known or suspected allergen.
  - In situations where there has been a history of a severe cardiovascular collapse to an allergen, the physician may advocate that epinephrine be administered immediately after an insect sting or ingestion of the offending food and before any reaction has begun.
  - Epinephrine should be kept in locations that are easily accessible and not in locked cupboards or drawers.
- Other Key Facts:
  - Generic products are available.
  - Auvi-Q® is the first epinephrine auto-injector with audio instructions that directs patients and caregivers through the injection process.[4-7]

References

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4. Adrenaclick® [package insert]. Horsham (PA): Amedra Pharmaceuticals LLC.; 2013 Apr.
5. Epinephrine [package insert]. Horsham (PA): Lineage Therapeutics; 2013 Apr.
6. EpiPen®, EpiPen Jr® [package insert]. Basking Ridge (NJ): Mylan Specialty L.P.; 2012 Aug.
7. Auvi-Q® [package insert]. Bridgewater (NJ): Sanofi-Aventis.; 2012 Sep.
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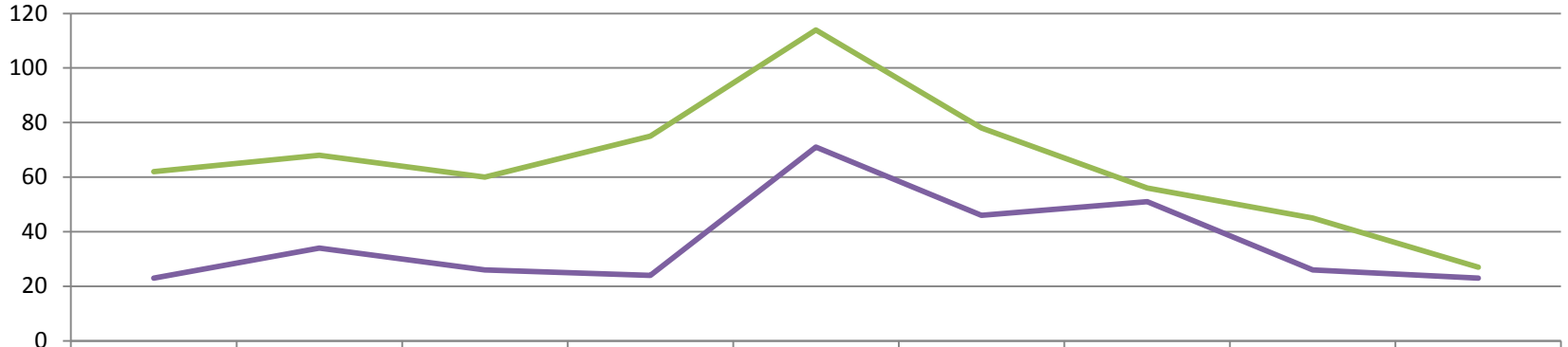
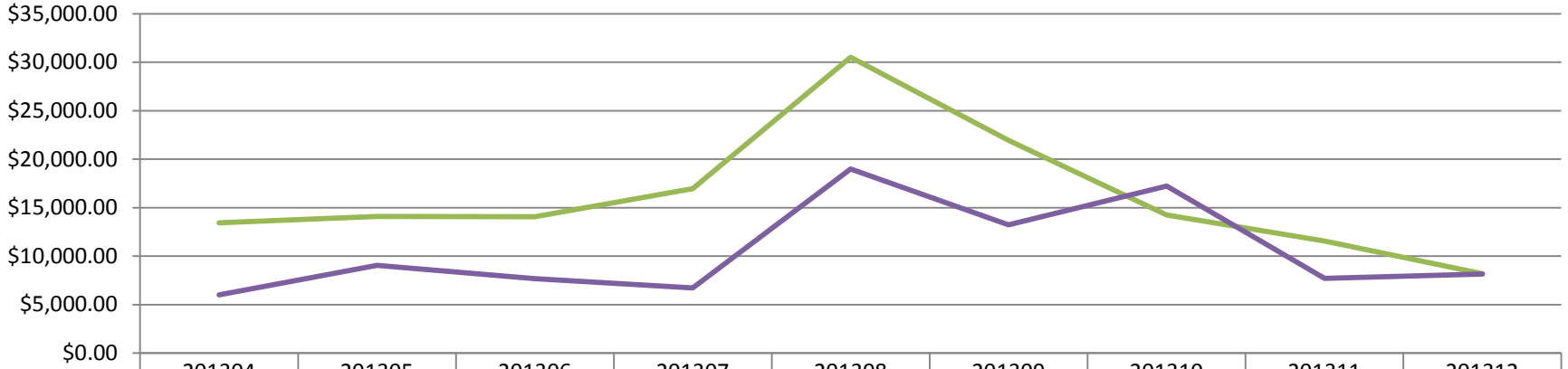
Epinephrine by Claim Count



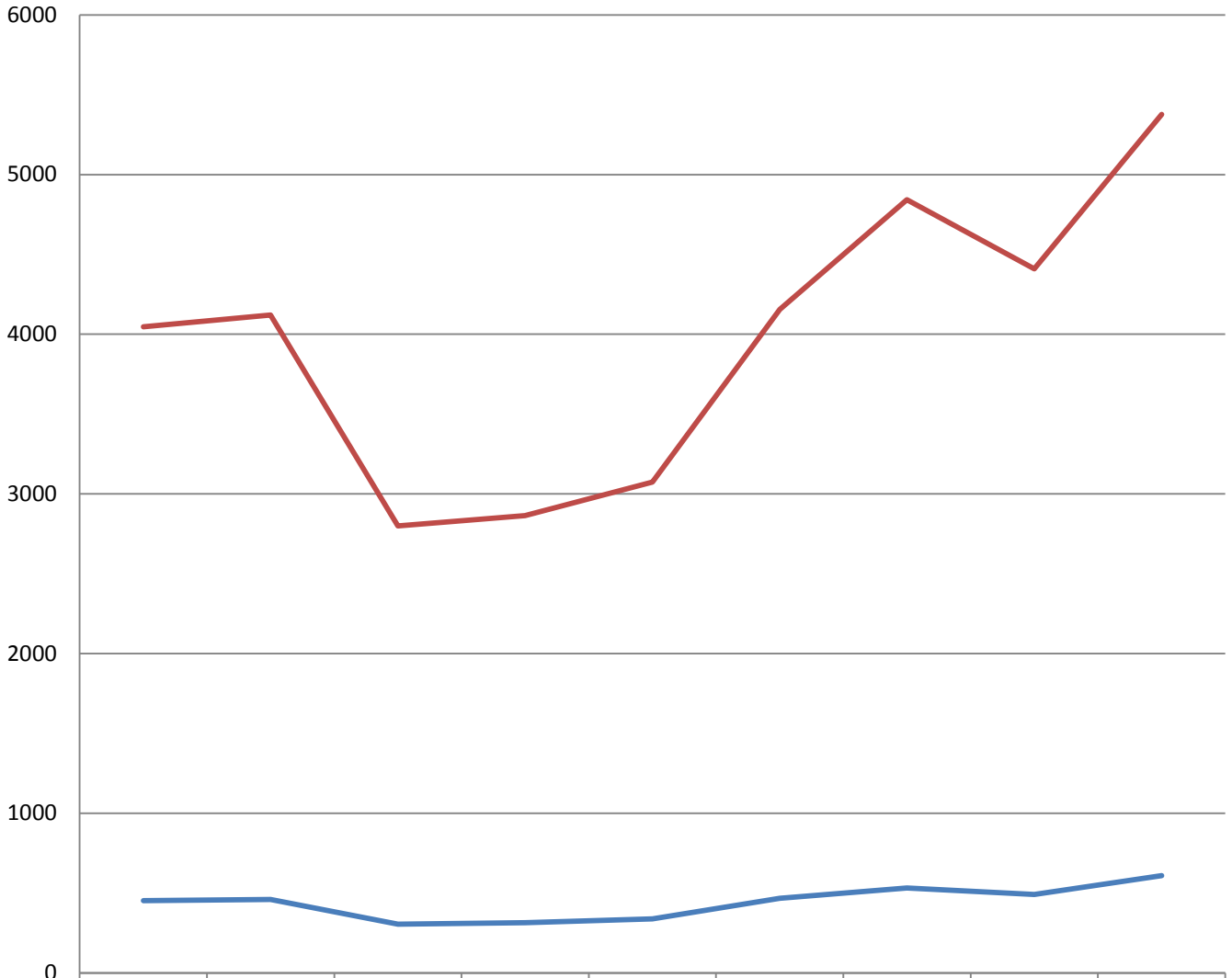
	201304	201305	201306	201307	201308	201309	201310	201311	201312
AUVI-Q		1		1		3		1	
EPINEPHRINE						1			
EPIPEN 2-PAK	62	68	60	75	114	78	56	45	27
EPIPEN-JR 2-PAK	23	34	26	24	71	46	51	26	23

Epinephrine by Pharmacy Paid Amt



	201304	201305	201306	201307	201308	201309	201310	201311	201312
AUVI-Q		$39.39		$47.35		$862.35		$25.00	
EPINEPHRINE						$18.10			
EPIPEN 2-PAK	$13,426.26	$14,105.47	$14,059.05	$16,962.13	$30,505.47	$21,957.67	$14,247.07	$11,558.44	$8,185.74
EPIPEN-JR 2-PAK	$6,015.42	$9,059.33	$7,666.29	$6,727.66	$18,987.74	$13,244.21	$17,239.53	$7,709.54	$8,169.22

Promthazine with Codeine Utilization



	201304	201305	201306	201307	201308	201309	201310	201311	201312
PROMETHAZINE/CODEINE - Sum of Claim Count	454	460	306	315	339	467	532	491	609
PROMETHAZINE/CODEINE - Sum of Phr Due Amt	$4,046.41	$4,121.03	$2,800.69	$2,864.57	$3,075.19	$4,155.80	$4,843.12	$4,409.28	$5,376.32

Promethazine with Codeine Liquid Utilization
January 2013 - December 2013

Member ID Encrypted	Claims	Sum of Qty (ml)	Amount (ml) per Claim	Claims per Month	Number of Pharmacies	Number of Prescribers
25489055552	24	11,464	478	2.00	2	2
77771867851	24	10,809	450	2.00	6	2
66668781707	13	7,800	600	1.08	3	1
12425055556	16	7,680	480	1.33	1	1
11117135769	24	7,624	318	2.00	3	1
22222345714	12	7,200	600	1.00	1	1
33338382049	15	7,095	473	1.25	2	2
99994909910	17	6,883	405	1.42	1	2
33339398753	13	6,149	473	1.08	1	3
00004067698	11	6,120	556	0.92	4	2
66666678669	12	5,640	470	1.00	1	2
88888953630	18	5,400	300	1.50	7	1
00000023979	11	5,283	480	0.92	4	1
33338393155	11	5,273	479	0.92	2	3
68502511112	20	5,259	263	1.67	3	6
45256411112	11	4,991	454	0.92	3	2
22223262229	11	4,991	454	0.92	2	2
01518177770	15	4,858	324	1.25	1	1
66661764910	13	4,812	370	1.08	3	4
88882910147	11	4,800	436	0.92	2	1
76604600001	12	4,320	360	1.00	3	1
11113242683	18	4,320	240	1.50	1	1
33334338736	9	4,299	478	0.75	1	1
02540355556	9	4,200	467	0.75	1	3
66668663023	16	4,096	256	1.33	6	5
22228246871	17	4,080	240	1.42	3	2
25501244447	11	3,960	360	0.92	2	2
40009866667	13	3,900	300	1.08	1	1
14291466667	13	3,900	300	1.08	1	1
48329144445	13	3,900	300	1.08	1	2
48803288889	11	3,861	351	0.92	3	2
22224254551	12	3,600	300	1.00	1	1
00001064667	12	3,563	297	1.00	1	1
94271500002	8	3,520	440	0.67	2	1
33337449442	10	3,380	338	0.83	3	3
95751599990	10	3,373	337	0.83	1	2
69676822224	14	3,360	240	1.17	2	3
44447403747	18	3,360	187	1.50	1	2
00001090910	7	3,360	480	0.58	1	1
55559619573	7	3,325	475	0.58	1	2
45887388889	7	3,325	475	0.58	3	3
00004031723	11	3,315	301	0.92	4	4
66668749578	11	3,300	300	0.92	1	1
45051200003	9	3,266	363	0.75	3	1
99993925670	10	3,173	317	0.83	4	2
60869266667	10	3,125	313	0.83	4	4
11114108636	8	3,120	390	0.67	1	1
33334313823	13	3,120	240	1.08	2	1
15062633334	10	3,100	310	0.83	1	2
66668605171	20	3,000	150	1.67	3	1
88883819580	7	3,000	429	0.58	3	2
81816899990	10	2,940	294	0.83	3	7

44446435086	13	2,880	222	1.08	4	1
65549422223	8	2,880	360	0.67	1	2
76406022223	12	2,880	240	1.00	1	1
11113123595	12	2,880	240	1.00	3	1
71405888889	11	2,850	259	0.92	3	1
77777736517	12	2,760	230	1.00	4	1
85978599990	14	2,760	197	1.17	4	3
22224217697	7	2,753	393	0.58	2	1
33339383650	7	2,732	390	0.58	2	3
61031288881	11	2,640	240	0.92	1	1
88069222223	11	2,640	240	0.92	3	1
22224216878	13	2,600	200	1.08	3	1
77771882944	11	2,475	225	0.92	2	1
89651555556	9	2,400	267	0.75	2	1
66668694966	10	2,400	240	0.83	1	1
00002080992	8	2,400	300	0.67	2	1
33334398208	10	2,400	240	0.83	1	1
88881869505	7	2,360	337	0.58	1	3
11111104705	8	2,285	286	0.67	4	5
43955299994	10	2,280	228	0.83	2	2
81643899091	11	2,280	207	0.92	1	1
04619299990	7	2,273	325	0.58	5	1
98824644445	11	2,240	204	0.92	1	2
51123255556	9	2,220	247	0.75	6	4
11117192405	9	2,213	246	0.75	1	5
94378933334	7	2,206	315	0.58	2	3
20551577877	11	2,200	200	0.92	1	1
66660767657	12	2,190	183	1.00	8	4
88881862214	7	2,180	311	0.58	1	1
22933969667	11	2,160	196	0.92	2	5
57648677879	10	2,160	216	0.83	2	2
93082011215	10	2,160	216	0.83	2	2
11112243908	10	2,140	214	0.83	1	1
25957555656	10	2,040	204	0.83	4	2
55550645799	10	2,000	200	0.83	3	1
77771725830	8	1,950	244	0.67	1	1
22225233580	8	1,920	240	0.67	5	2
88889884483	8	1,920	240	0.67	1	2
39364666766	8	1,920	240	0.67	1	1
33333414011	8	1,920	240	0.67	1	1
00004133577	7	1,905	272	0.58	3	3
00005093229	9	1,890	210	0.75	4	5
33337488737	9	1,860	207	0.75	3	3
11111149201	9	1,850	206	0.75	2	2
11933177778	10	1,840	184	0.83	3	2
66666776606	7	1,810	259	0.58	2	6
67227500001	9	1,800	200	0.75	6	1
05938244445	9	1,800	200	0.75	1	1
99999092552	9	1,800	200	0.75	4	1
65027512211	9	1,800	200	0.75	1	1
50746700001	8	1,760	220	0.67	1	1
22228566667	8	1,740	218	0.67	4	1
44447589111	9	1,740	193	0.75	3	4
76171411112	8	1,700	213	0.67	2	1
97039499099	8	1,695	212	0.67	1	2

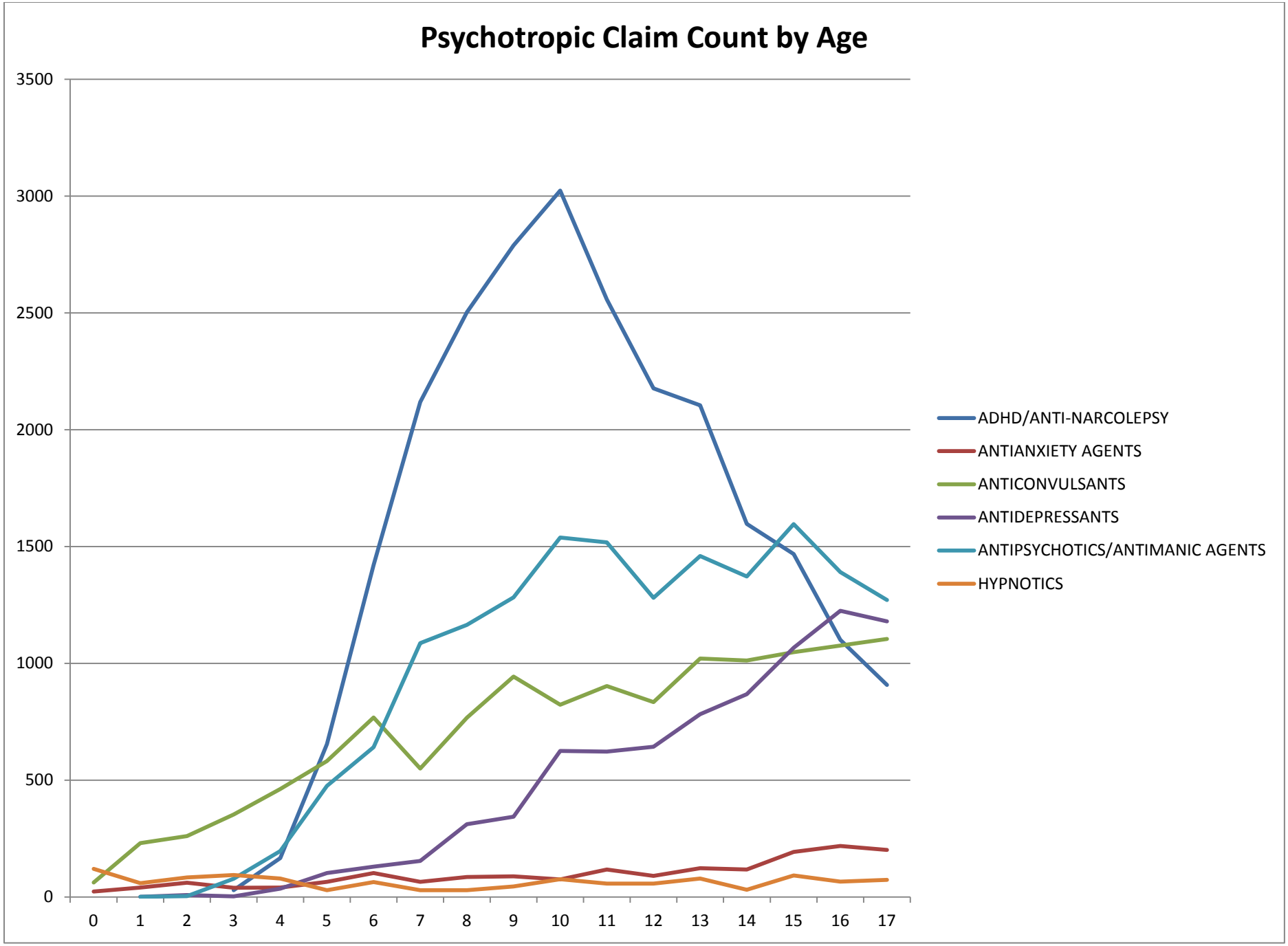
25993455558	9	1,690	188	0.75	3	2
27532422223	7	1,686	241	0.58	3	3
00005069109	7	1,680	240	0.58	1	1
22224303457	7	1,680	240	0.58	1	1
88882816421	7	1,680	240	0.58	1	1
48623244447	7	1,680	240	0.58	1	1
77778798383	7	1,680	240	0.58	2	1
33336387622	9	1,620	180	0.75	1	1
33333434604	7	1,620	231	0.58	1	2
47621570778	7	1,590	227	0.58	2	2
05396733334	9	1,560	173	0.75	1	1
55555604221	8	1,560	195	0.67	2	3
33339404421	7	1,560	223	0.58	2	3
22227285572	7	1,560	223	0.58	1	2
82292022223	12	1,560	130	1.00	1	2
99993012123	7	1,560	223	0.58	1	2
55556563064	7	1,560	223	0.58	1	1
47778111114	8	1,530	191	0.67	2	3
33336396118	7	1,410	201	0.58	1	3
45570922226	7	1,400	200	0.58	1	1
48320811113	7	1,340	191	0.58	2	2
20352966667	11	1,320	120	0.92	1	1
33337366688	7	1,280	183	0.58	1	5
30209344445	10	1,150	115	0.83	1	2
82651122223	7	1,020	146	0.58	1	1

Promethazine with Codeine Liquid Utilization
January 2013 to December 2013

Prescriber	Claims	Sum of Qty (ml)	Amt (ml) per Claim	Claims per month	Number of Pharmacies	Number of Recipients
1	253	50330	199	21	47	103
2	198	42530	215	17	3	143
3	169	35400	209	14	45	56
4	161	28630	178	13	13	131
5	158	61685	390	13	51	55
6	115	18520	161	10	48	61
7	109	23370	214	9	37	45
8	100	23503	235	8	27	33
9	80	24181	302	7	28	34
10	68	26098	384	6	22	21
11	65	32853	505	5	21	8
12	62	13200	213	5	19	43
13	60	7320	122	5	43	59
14	60	11940	199	5	15	22
15	59	13800	234	5	6	14
16	57	6940	122	5	17	53
17	56	13380	239	5	15	38
18	52	5660	109	4	11	50
19	47	13755	293	4	15	14
20	46	9220	200	4	13	21
21	45	16006	356	4	13	13
22	44	11000	250	4	10	11
23	44	12300	280	4	8	20
24	43	10800	251	4	17	16
25	41	15823	386	3	8	5
26	39	11224	288	3	3	2
27	39	3115	80	3	5	38
28	38	4720	124	3	5	30
29	38	16728	440	3	17	18
30	37	17181	464	3	25	22
31	37	6625	179	3	27	34
32	36	8160	227	3	10	4
33	35	8806	252	3	13	14
34	34	7773	229	3	17	22
35	31	9300	300	3	9	4
36	31	7486	241	3	18	16
37	30	5620	187	3	17	27
38	30	7400	247	3	3	24
39	30	8700	290	3	5	5
40	30	5980	199	3	16	15
41	29	4000	138	2	14	16
42	28	5240	187	2	18	23
43	26	11137	428	2	7	7
44	26	6360	245	2	8	24
45	26	7120	274	2	15	17
46	25	5450	218	2	6	6
47	25	3750	150	2	8	5
48	25	6679	267	2	4	23
49	24	5640	235	2	13	11
50	24	9310	388	2	14	16
51	23	5520	240	2	16	17
52	23	5498	239	2	10	13
53	22	7022	319	2	5	4

54	22	9120	415	2	3	3
55	22	1430	65	2	10	16
56	21	5336	254	2	12	11
57	20	135	7	2	1	20
58	20	2400	120	2	2	20
59	20	4080	204	2	1	13
60	20	4770	239	2	10	8
61	20	3905	195	2	15	14
62	20	2760	138	2	10	19
63	19	2910	153	2	15	19
64	19	4070	214	2	12	14
65	19	3300	174	2	10	16
66	19	4260	224	2	11	14
67	19	4200	221	2	11	6
68	18	8269	459	2	3	2
69	18	7560	420	2	8	10
70	18	5386	299	2	11	10
71	18	4320	240	2	5	3
72	18	1700	94	2	14	13
73	18	5806	323	2	13	12
74	17	4210	248	1	13	12
75	17	2900	171	1	8	12
76	17	3710	218	1	5	8
77	17	3400	200	1	11	10
78	17	3960	233	1	7	14
79	17	3705	218	1	6	5
80	17	3780	222	1	7	5
81	17	2660	156	1	15	17
82	17	4480	264	1	12	8
83	17	4980	293	1	8	7
84	17	3140	185	1	16	16
85	16	3840	240	1	2	9
86	16	1740	109	1	6	11
87	16	3600	225	1	5	13
88	15	3600	240	1	8	6
89	15	7123	475	1	11	11
90	15	4613	308	1	3	3
91	15	3759	251	1	8	5
92	15	5259	351	1	2	2
93	15	3480	232	1	5	4
94	14	3493	250	1	8	10
95	14	3180	227	1	7	3
96	14	3260	233	1	8	7
97	14	2640	189	1	6	7
98	14	2060	147	1	8	13
99	14	3360	240	1	1	2
100	14	3090	221	1	11	11
101	13	1913	147	1	8	9
102	13	990	76	1	7	13
103	13	3120	240	1	2	1
104	13	3865	297	1	8	9
105	12	2560	213	1	10	9
106	12	2880	240	1	7	9
107	12	2986	249	1	10	10
108	12	5040	420	1	9	5

109	12	1886	157	1	5	10
110	11	1320	120	1	1	1
111	11	2640	240	1	4	3
112	11	2398	218	1	7	11
113	11	4800	436	1	2	1
114	11	4532	412	1	6	5
115	11	2400	218	1	9	8
116	11	1320	120	1	11	11
117	11	2880	262	1	5	5
118	11	3480	316	1	6	4
119	11	1860	169	1	2	2
120	10	4751	475	1	3	1
121	10	1140	114	1	7	9
122	10	2580	258	1	5	5
123	10	1920	192	1	8	9
124	10	2936	294	1	4	5


Psychotropic Claim Count by Age
3500
3000
2500
2000
1500
1000
500
0
0
1
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17
ADHD/ANTI-NARCOLEPSY
ANTIANXIETY AGENTS
ANTICONVULSANTS
ANTIDEPRESSANTS
ANTIPSYCHOTICS/ANTIMANIC AGENTS
HYPNOTICS

Psychotropic Utilization By Age
April 2013 to December 2013

Member Calc Age	Group Name	Claim Count	Member Count	Qty Disp	Days Supply	Pharmacy Paid Amt
0	ANTIANXIETY AGENTS	23	14	1,571.00	412	$ 364.82
0	HYPNOTICS	120	47	22,654.26	3,094	$ 3,369.63
0	ADHD/ANTI-NARCOLEPSY	5	4	240	100	$ 2,047.85
0	ANTICONVULSANTS	62	28	5,537.00	1,789	$ 2,246.06
1	ANTIANXIETY AGENTS	40	21	3,009.00	814	$ 400.31
1	ANTIDEPRESSANTS	1	1	30	30	$ 6.79
1	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1	1	120	30	$ 127.38
1	HYPNOTICS	59	26	15,485.00	1,350	$ 1,824.35
1	ANTICONVULSANTS	231	43	27,922.00	6,079	$ 36,841.50
2	ANTIANXIETY AGENTS	61	18	11,278.00	1,521	$ 1,314.76
2	ANTIDEPRESSANTS	8	4	405	240	$ 249.61
2	ANTIPSYCHOTICS/ANTIMANIC AGENTS	4	2	244.5	62	$ 258.72
2	HYPNOTICS	84	35	21,921.00	1,766	$ 2,842.18
2	ANTICONVULSANTS	261	61	38,118.55	7,094	$ 25,306.75
3	ANTIANXIETY AGENTS	39	17	5,029.00	822	$ 595.90
3	ANTIDEPRESSANTS	3	1	90	90	$ 17.22
3	ANTIPSYCHOTICS/ANTIMANIC AGENTS	78	23	4,522.00	2,048	$ 15,492.90
3	HYPNOTICS	94	23	34,005.30	1,932	$ 4,200.30
3	ADHD/ANTI-NARCOLEPSY	29	14	1,528.00	838	$ 5,124.36
3	ANTICONVULSANTS	353	59	54,034.00	10,054	$ 94,787.09
4	ANTIANXIETY AGENTS	40	14	8,929.00	875	$ 823.04
4	ANTIDEPRESSANTS	36	10	1,660.00	1,080	$ 595.51
4	ANTIPSYCHOTICS/ANTIMANIC AGENTS	197	55	10,087.50	5,486	$ 58,852.32
4	HYPNOTICS	79	26	31,271.50	1,693	$ 4,007.54
4	ADHD/ANTI-NARCOLEPSY	167	55	7,351.00	4,864	$ 28,145.63
4	ANTICONVULSANTS	462	78	98,933.00	13,652	$ 47,803.12
5	ANTIANXIETY AGENTS	65	21	10,983.00	1,371	$ 1,038.93
5	ANTIDEPRESSANTS	103	26	6,074.00	3,060	$ 2,004.38
5	ANTIPSYCHOTICS/ANTIMANIC AGENTS	475	123	21,298.00	13,475	$ 144,907.65
5	HYPNOTICS	29	13	4,249.50	452	$ 811.27
5	ADHD/ANTI-NARCOLEPSY	654	165	24,556.00	19,101	$ 116,919.99
5	ANTICONVULSANTS	582	102	109,885.00	17,238	$ 72,494.69
6	ANTIANXIETY AGENTS	103	26	18,961.00	2,485	$ 1,686.06

Psychotropic Utilization By Age
April 2013 to December 2013

Member Calc Age	Group Name	Claim Count	Member Count	Qty Disp	Days Supply	Pharmacy Paid Amt
6	ANTIDEPRESSANTS	130	38	4,293.00	3,880	$ 1,448.00
6	ANTIPSYCHOTICS/ANTIMANIC AGENTS	641	171	27,609.00	18,584	$ 176,868.25
6	HYPNOTICS	64	15	16,353.00	1,438	$ 1,692.52
6	ADHD/ANTI-NARCOLEPSY	1421	337	50,986.00	41,725	$ 235,212.74
6	ANTICONVULSANTS	768	111	167,860.00	22,215	$ 119,947.64
7	ANTIANXIETY AGENTS	65	33	9,643.00	1,438	$ 1,210.46
7	ANTIDEPRESSANTS	154	42	5,689.00	4,546	$ 1,923.23
7	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1086	249	49,483.50	31,183	$ 282,047.58
7	HYPNOTICS	29	15	1,491.50	522	$ 527.24
7	ADHD/ANTI-NARCOLEPSY	2118	456	78,260.00	62,560	$ 344,015.11
7	ANTICONVULSANTS	550	112	90,303.00	16,258	$ 53,123.90
8	ANTIANXIETY AGENTS	86	30	19,424.00	1,995	$ 1,951.04
8	ANTIDEPRESSANTS	312	81	12,428.00	9,109	$ 3,547.56
8	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1165	285	60,044.00	33,256	$ 317,037.85
8	HYPNOTICS	29	9	4,677.25	700	$ 1,362.82
8	ADHD/ANTI-NARCOLEPSY	2503	545	95,010.00	74,027	$ 428,581.92
8	ANTICONVULSANTS	767	131	145,823.00	22,489	$ 132,292.90
9	ANTIANXIETY AGENTS	88	38	12,285.00	2,174	$ 1,610.46
9	ANTIDEPRESSANTS	344	96	13,947.00	10,080	$ 5,478.95
9	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1282	312	64,693.00	37,074	$ 307,004.62
9	HYPNOTICS	45	15	9,194.00	1,108	$ 1,214.17
9	ADHD/ANTI-NARCOLEPSY	2789	590	102,542.00	82,795	$ 474,554.86
9	ANTICONVULSANTS	943	163	191,659.00	27,348	$ 129,336.06
10	ANTIANXIETY AGENTS	75	34	5,022.00	1,788	$ 753.45
10	ANTIDEPRESSANTS	625	145	23,947.00	18,330	$ 10,353.01
10	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1538	337	71,564.00	44,590	$ 389,873.84
10	HYPNOTICS	76	23	13,394.00	1,992	$ 6,973.13
10	ADHD/ANTI-NARCOLEPSY	3023	593	110,080.00	89,469	$ 552,612.44
10	ANTICONVULSANTS	823	155	146,694.75	24,438	$ 96,246.93
11	ANTIANXIETY AGENTS	118	36	12,438.00	2,937	$ 1,423.73
11	ANTIDEPRESSANTS	622	154	23,418.00	18,398	$ 7,896.38
11	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1518	332	72,722.00	43,997	$ 395,451.29
11	HYPNOTICS	57	20	18,069.00	1,534	$ 4,636.65

Psychotropic Utilization By Age
April 2013 to December 2013

Member Calc Age	Group Name	Claim Count	Member Count	Qty Disp	Days Supply	Pharmacy Paid Amt
11	ADHD/ANTI-NARCOLEPSY	2557	539	92,303.00	75,723	$ 448,039.79
11	ANTICONVULSANTS	903	153	154,254.50	26,270	$ 130,380.04
12	ANTIANXIETY AGENTS	90	41	11,046.00	2,056	$ 1,266.19
12	ANTIDEPRESSANTS	643	179	22,386.00	18,793	$ 6,491.05
12	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1280	305	56,963.00	37,025	$ 339,767.33
12	HYPNOTICS	57	17	5,573.00	1,464	$ 4,560.57
12	ADHD/ANTI-NARCOLEPSY	2177	488	79,283.00	64,270	$ 398,791.79
12	ANTICONVULSANTS	834	156	119,167.00	24,242	$ 127,849.08
13	ANTIANXIETY AGENTS	123	42	17,893.50	2,943	$ 1,891.67
13	ANTIDEPRESSANTS	782	205	29,256.50	23,124	$ 10,062.62
13	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1459	327	67,899.50	42,411	$ 407,806.62
13	HYPNOTICS	79	23	7,881.00	2,035	$ 2,735.76
13	ADHD/ANTI-NARCOLEPSY	2104	463	80,503.00	62,367	$ 387,264.62
13	ANTICONVULSANTS	1021	175	169,771.00	29,982	$ 123,379.03
14	ANTIANXIETY AGENTS	118	52	15,998.00	2,958	$ 1,505.09
14	ANTIDEPRESSANTS	868	251	31,405.00	25,548	$ 12,988.36
14	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1372	307	60,620.50	39,354	$ 321,592.84
14	HYPNOTICS	31	11	1,355.00	732	$ 1,113.32
14	ADHD/ANTI-NARCOLEPSY	1597	387	61,235.00	47,354	$ 301,506.35
14	ANTICONVULSANTS	1012	220	130,899.00	29,417	$ 68,452.64
15	ANTIANXIETY AGENTS	193	71	10,163.15	4,633	$ 1,514.90
15	ANTIDEPRESSANTS	1067	296	38,921.00	31,370	$ 15,530.80
15	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1596	363	75,421.00	45,819	$ 463,533.76
15	HYPNOTICS	92	23	5,438.50	2,379	$ 1,201.75
15	ADHD/ANTI-NARCOLEPSY	1468	349	55,057.00	43,681	$ 283,417.96
15	ANTICONVULSANTS	1048	207	153,620.50	29,706	$ 81,700.13
16	ANTIANXIETY AGENTS	218	91	10,481.50	5,096	$ 2,324.95
16	ANTIDEPRESSANTS	1225	311	43,994.00	36,049	$ 18,388.54
16	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1391	328	61,538.50	39,399	$ 401,746.69
16	HYPNOTICS	66	27	11,200.50	1,300	$ 1,659.78
16	ADHD/ANTI-NARCOLEPSY	1101	266	40,598.00	32,701	$ 210,497.48
16	ANTICONVULSANTS	1076	209	123,602.00	31,508	$ 95,844.31
17	ANTIANXIETY AGENTS	201	91	11,247.00	4,681	$ 1,966.47

Psychotropic Utilization By Age
April 2013 to December 2013

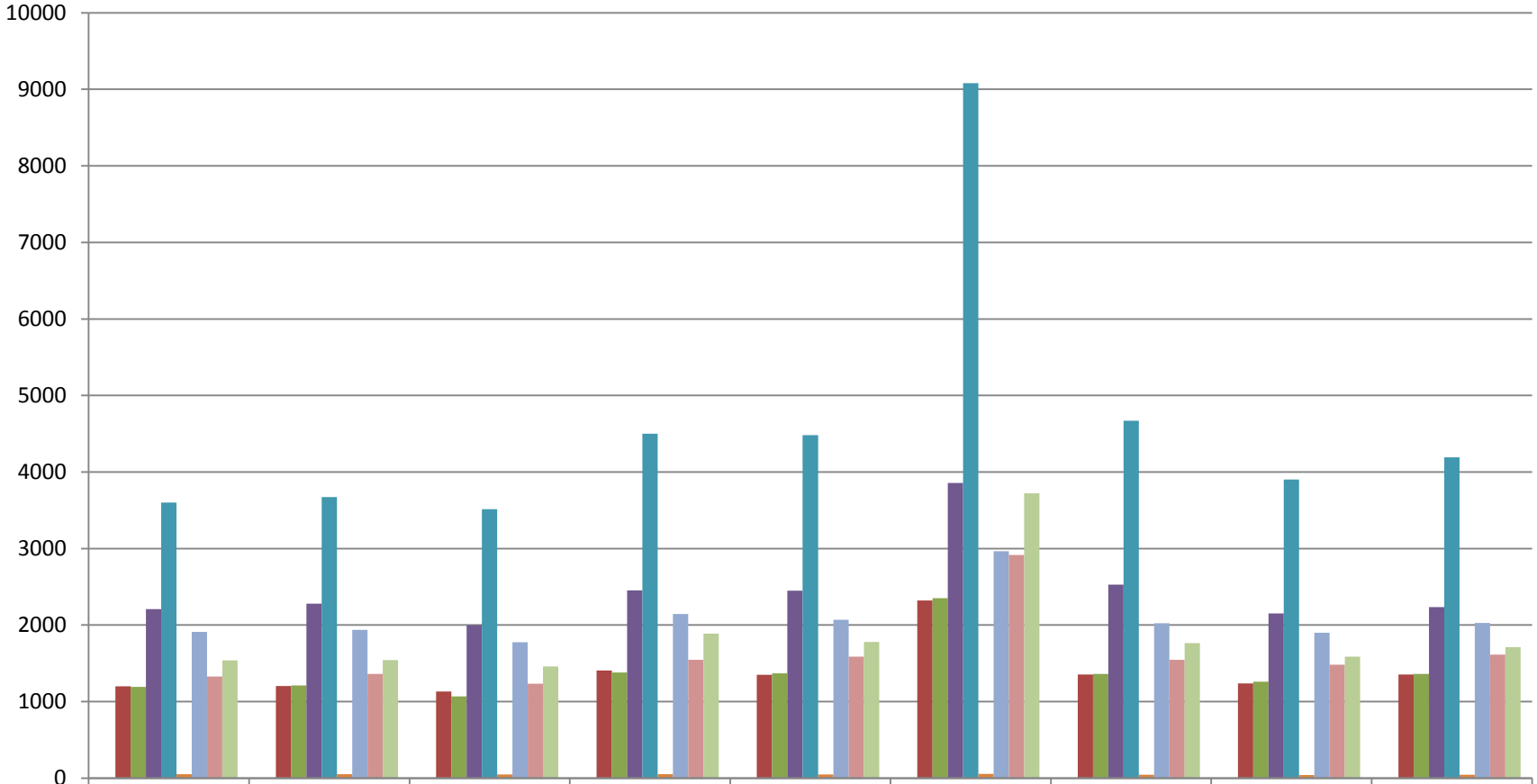
Member Calc Age	Group Name	Claim Count	Member Count	Qty Disp	Days Supply	Pharmacy Paid Amt
17	ANTIDEPRESSANTS	1180	320	44,879.00	34,820	$ 22,907.52
17	ANTIPSYCHOTICS/ANTIMANIC AGENTS	1271	309	53,755.50	36,603	$ 301,408.59
17	HYPNOTICS	73	31	5,784.00	1,850	$ 860.22
17	ADHD/ANTI-NARCOLEPSY	908	228	33,369.00	27,081	$ 170,813.98
17	ANTICONVULSANTS	1104	228	124,142.00	31,467	$ 74,383.68

State	DUR edits	PA requirements	Required Documentation for PA approval	Emergency supply allowance	Future direction
KS	*By law KS cannont restrict Mental Health medications				
WI		PA required for children age 6 and under; Prior auth requests for covered antipsychotic drugs for children 6 years of age and younger are approved at the ingredient level. An approved PA allows any covered NDC with the same active ingredient of the prior authorized drug to be covered with the same PA.	**Diagnosis**: appropriate indications for the use of antipsychotic medications in young children with certain diagnosis. Including autism spectrum disorders, psychotic disorders, tic disorders, and severe agitation or aggression that may accompany severe mood development disorders. **Prescriber credentials:** when reviewed, the prescriber's credential are considered as one's area of expertise that may or may not include familiarity with the antipsychotic class of medications. **Target symptoms**: the prescriber needs to carefully identify the primary target symptom so that the family, mental health clinicians, teachers, and all involved adults can help clarify and determint the efficacy of the medication. **Polypharmacy**: Requirement of notation of any psychoactive medication, concurrent medication as well as previous medication trials in the preceding 12 months. **Mental Health resources**: Noting involvement of resources (such as Birth to 3, in-home therapy, family therapy, child psychiatry consultation, outpatient contacts, hospitalization, acute/chronic medical needs. **Body mass index (BMI)**: due to effects of antipsychotic meds on weight, glucose, and lipids, the submission of a MBI measurement with each PA is required. **Foster placement**: must be indicated whether or not the child is in foster care placement. **Preferred Drug List (PDL)**: clinical justification must be made for use of a antipsychotic medication outside the PDL. PA requests for brand medically necessary must be submitted separately with clinical justification that the brand name is medically necessary.	A 14 days emergency supply is allowed and strongly encouraged for prescriptions for a covered drug with a PA restriction, the prescriber can not be reached to discuss drug options, and the pharmacist determines that the member should be taking the medication immediately.	

State	DUR edits	PA requirements	Required Documentation for PA approval	Emergency supply allowance	Future direction
DE		Atypical antipsychotic - 6 years ; Antidepressants -PA required for the following products for the pediatric patient under 6 years of age (Bupropion, Citaloprm, Fluoxetine, Fluvoxamine, Mirtazapine, Nefazodone, Paroxetine, Zoloft, Escitalopram, Venlafaxine, Duloxetine, Desyrel, Tricyclic antidepressants) CNS Stimulants - 6 years	For antidepressant treatment in under 6 years of age: 1.Psychiatric evaluation/therapy recommendations from psychiatrist or medical provider certified in pediatric mental health 2. For all new starts: Major depressive disorder: Fluoxetine only OCD: Fluoxetine, Fluvoxamine, Sertraline only 3. Requests for other medications will require documentation as to failure of FDA recommended product. 4. Clients currently receiving therapy will continue with documentation from the practitioner of evaluation of behavior with all dosage changes.		Looking into collaborative initiatives with state entities such as foster care department on better ways to track use in the under 18 yo population
CT	No restrictions				
OR	No restrictions				
RI	Members that fall below the indicated age that are on antipsychotics are reviewed at quarterly DUR board meeting.	PA for stimulants if member is over the age of 21 and drug is nonpreferred			
SC		PA for antipsychotics in children 6 or under			
AR					
FL		PA for any antipsychotice for children <6 years of age PA for any antipsychotic lacking an FDA indication or acceptable evidence-base for safety and efficacy for children age < 18 years PA for any high dose antipsychotic for children <18 years PA for any antidepressant for children < 6 years			
NY					
PA					
MN					
WY	**Prospective**: Must have ADHD diagnosis and be age 5 for all meds but Adderall/XR and generics which are allowed to 3 for ADHD. Dose limits apply to atypicals, ADHD meds, antidepressants and benzos **Retrospectiv**e: Children under the age of 5 on any psychotropic, on more than 5 concurrent psychotropics across all classes are identified and sent for a second opinion review by Seattle Children's Hospital	PA's are referred to Seattle Children's to specifically deal with pediatric use of psychotropics.			

State	DUR edits	PA requirements	Required Documentation for PA approval	Emergency supply allowance	Future direction
NV	Treatment of seizure disorders with following diagnosis on prescription (345, 780.3, 779.0) and treatment of ADHD with Abilify with the following ICD-9 codes of 299.00 or 299.01 (autistic disorder) written on the prescription.	PA for all psychotropic medications for recipients less than 18 years of age. To include antianxiety agents, anticonvulsants, antidepressants, Lithium preparations, sedatives, and antipsychotics.	**1.** Each medication prescribed must be independently treating a specific condition (diagnosis) **2**. To be considered for mulitple drug therapy for one diagnosis, treatment of unique symptoms, or treatment of side effects must be documented. **3**. Recipients must fail a trial of a single medication within the same class before treatment with multiple agents in the same class will be considered. **4**. Physician monitoring is required while the recipient is utilizing the medication(s). (monthly visits for recipients who are unstable or on initial therapy, and at least every three months for those considered stable in their therapy.) **5**. Psychotropic medication must be part of a comprehensive treatment plan that addressed the education, behavioral management, living home environment and psychotherapy.		

Black Box Warning Drugs by Claim



	201304	201305	201306	201307	201308	201309	201310	201311	201312
ASTRAMORPH		1			1		1		
CITALOPRAM	1200	1205	1131	1406	1351	2321	1356	1237	1355
CLONAZEPAM	1192	1212	1070	1381	1370	2352	1361	1260	1361
Ibuprofen	2210	2282	1998	2455	2449	3856	2529	2152	2237
Metformin	3603	3674	3513	4500	4482	9080	4670	3902	4191
Morphine	52	54	49	51	48	57	45	40	46
Risperidone	1911	1939	1775	2143	2070	2965	2025	1899	2028
Trazodone	1328	1363	1234	1546	1586	2917	1546	1483	1614
Zolpidem	1538	1544	1461	1889	1778	3721	1765	1589	1712

Top 10 Drug Class by Claim Count

Q2 2013

Class	Drug Class Name	Count of Claims	Pharmacy Paid
65	ANALGESICS - OPIOID*	55359	1917619.62
44	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	32602	2903318.67
72	ANTICONVULSANTS*	31738	1659190.99
58	ANTIDEPRESSANTS*	28586	633191.61
36	ANTIHYPERTENSIVES*	27373	321972.42
59	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	24640	5427590.23
39	ANTIHYPERLIPIDEMICS*	21338	637094.95
27	ANTIDIABETICS*	20309	1600256.36
57	ANTIANXIETY AGENTS*	20287	158145.83
82	HEMATOPOIETIC AGENTS*	18912	1478668.28

Q3 2013

Class	Drug Class Name	Count of Claims	Pharmacy Paid
65	ANALGESICS - OPIOID*	54043	1891480.22
72	ANTICONVULSANTS*	32145	1799563.79
44	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	31888	2890982.11
58	ANTIDEPRESSANTS*	28601	716446.28
36	ANTIHYPERTENSIVES*	27064	305280.37
59	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	24509	5741529.97
39	ANTIHYPERLIPIDEMICS*	20919	646438
57	ANTIANXIETY AGENTS*	20459	167366.01
27	ANTIDIABETICS*	20362	1821237.45
82	HEMATOPOIETIC AGENTS*	19964	1591278.68

Q4 2013

Class	Drug Class Name	Count of Claims	Pharmacy Paid
65	ANALGESICS - OPIOID*	51023	1931039.12
44	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	32936	3049663.6
72	ANTICONVULSANTS*	31379	2024089.13
58	ANTIDEPRESSANTS*	27699	668799.14
36	ANTIHYPERTENSIVES*	26053	306481.62
59	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	23797	5835600.45
39	ANTIHYPERLIPIDEMICS*	20464	616935.38
27	ANTIDIABETICS*	19225	1975813.68
57	ANTIANXIETY AGENTS*	18952	163619.19
49	ULCER DRUGS*	17997	782665.39

Top 10 Drug Class by Paid Amt

Q2 2013

Class	Drug Class Name	Count of Claims	Pharmacy Paid
59	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	24,640	$ 5,427,590.23
21	ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	3,733	$ 3,627,262.82
44	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	32,602	$ 2,903,318.67
85	HEMATOLOGICAL AGENTS - MISC.*	3,579	$ 2,343,034.23
12	ANTIVIRALS*	3,213	$ 1,997,836.71
65	ANALGESICS - OPIOID*	55,359	$ 1,917,619.62
61	ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	9,991	$ 1,727,161.66
72	ANTICONVULSANTS*	31,738	$ 1,659,190.99
27	ANTIDIABETICS*	20,309	$ 1,600,256.36
82	HEMATOPOIETIC AGENTS*	18,912	$ 1,478,668.28

Q3 2013

Class	Drug Class Name	Count of Claims	Pharmacy Paid
59	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	24,509	$ 5,741,529.97
44	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	31,888	$ 2,890,982.11
21	ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	3,636	$ 2,546,105.33
12	ANTIVIRALS*	3,223	$ 2,190,727.43
85	HEMATOLOGICAL AGENTS - MISC.*	3,444	$ 2,053,921.78
65	ANALGESICS - OPIOID*	54,043	$ 1,891,480.22
27	ANTIDIABETICS*	20,362	$ 1,821,237.45
72	ANTICONVULSANTS*	32,145	$ 1,799,563.79
61	ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	9,328	$ 1,722,022.59
82	HEMATOPOIETIC AGENTS*	19,964	$ 1,591,278.68

Q4 2013

Class	Drug Class Name	Count of Claims	Pharmacy Paid
59	ANTIPSYCHOTICS/ANTIMANIC AGENTS*	23,797	$ 5,835,600.45
85	HEMATOLOGICAL AGENTS - MISC.*	3,253	$ 3,954,943.63
44	ANTIASTHMATIC AND BRONCHODILATOR AGENTS*	32,936	$ 3,049,663.60
21	ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	3,200	$ 2,188,800.56
12	ANTIVIRALS*	3,323	$ 2,062,373.92
72	ANTICONVULSANTS*	31,379	$ 2,024,089.13
27	ANTIDIABETICS*	19,225	$ 1,975,813.68
65	ANALGESICS - OPIOID*	51,023	$ 1,931,039.12
61	ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREX	9,842	$ 1,833,080.99
30	ENDOCRINE AND METABOLIC AGENTS - MISC.*	11,657	$ 1,682,950.53

Top 10 Drug Classes by Paid Amt

Q2 2013

Drug Class	Drug Class Name	Count of Claims		Pharmacy Paid Amt
5925	QUINOLINONE DERIVATIVES**	3,682	$	2,426,495.95
8510	ANTIHEMOPHILIC PRODUCTS**	62	$	1,852,060.97
1210	ANTIRETROVIRALS**	1,948	$	1,709,832.89
4420	SYMPATHOMIMETICS**	21,031	$	1,661,177.22
5907	BENZISOXAZOLES**	7,186	$	1,289,440.55
6510	OPIOID AGONISTS**	22,579	$	1,271,706.82
8240	HEMATOPOIETIC GROWTH FACTOR	9,987	$	1,255,124.28
2710	INSULIN**	6,683	$	1,187,603.58
7260	ANTICONVULSANTS - MISC.**	21,602	$	1,166,781.22
5915	DIBENZAPINES**	8,412	$	1,080,941.33

Q3 2013

Drug Class	Drug Class Name	Count of Claims		Pharmacy Paid Amt
5925	QUINOLINONE DERIVATIVES**	3,644	$	2,622,286.98
1210	ANTIRETROVIRALS**	2,004	$	1,820,992.36
4420	SYMPATHOMIMETICS**	20,794	$	1,668,479.96
8510	ANTIHEMOPHILIC PRODUCTS**	75	$	1,626,857.99
8240	HEMATOPOIETIC GROWTH FACTOR	10,531	$	1,381,001.91
2710	INSULIN**	6,859	$	1,379,548.15
5907	BENZISOXAZOLES**	7,161	$	1,349,554.76
7260	ANTICONVULSANTS - MISC.**	21,879	$	1,289,254.54
6510	OPIOID AGONISTS**	21,447	$	1,231,452.39
5915	DIBENZAPINES**	8,443	$	1,067,444.60

Q4 2013

Drug Class	Drug Class Name	Count of Claims		Pharmacy Paid Amt
8510	ANTIHEMOPHILIC PRODUCTS**	86	$	3,604,951.09
5925	QUINOLINONE DERIVATIVES**	3,518	$	2,605,658.41
1210	ANTIRETROVIRALS**	2,022	$	1,836,744.62
4420	SYMPATHOMIMETICS**	21,855	$	1,715,136.30
2710	INSULIN**	6,391	$	1,489,382.04
5907	BENZISOXAZOLES**	6,866	$	1,430,137.88
7260	ANTICONVULSANTS - MISC.**	21,377	$	1,295,779.03
6510	OPIOID AGONISTS**	20,068	$	1,223,170.83
5915	DIBENZAPINES**	8,433	$	1,030,822.79
1950	MONOCLONAL ANTIBODIES**	366	$	1,019,473.10

Top 10 Drug Classes by Claim Count

Q2 2013

Drug Class	Drug Class Name	Count of Claims	Pharmacy Paid Amt
6599	OPIOID COMBINATIONS**	32,406	$ 583,243.39
6510	OPIOID AGONISTS**	22,601	$ 1,271,746.46
7260	ANTICONVULSANTS - MISC.**	21,605	$ 1,166,785.58
4420	SYMPATHOMIMETICS**	21,040	$ 1,661,194.81
5710	BENZODIAZEPINES**	16,830	$ 113,949.65
3940	HMG COA REDUCTASE INHIBITORS**	16,507	$ 263,424.13
6610	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS (NSAIDS)**	15,481	$ 200,161.49
5816	SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)**	14,723	$ 121,811.85
7510	CENTRAL MUSCLE RELAXANTS**	12,555	$ 176,502.14
3610	ACE INHIBITORS**	12,063	$ 59,102.16

Q3 2013

Drug Class	Drug Class Name	Count of Claims	Pharmacy Paid Amt
6599	OPIOID COMBINATIONS**	32,242	$ 589,052.08
7260	ANTICONVULSANTS - MISC.**	21,879	$ 1,289,254.54
6510	OPIOID AGONISTS**	21,445	$ 1,231,450.09
4420	SYMPATHOMIMETICS**	20,794	$ 1,668,479.96
5710	BENZODIAZEPINES**	16,865	$ 120,599.74
3940	HMG COA REDUCTASE INHIBITORS**	16,404	$ 278,808.34
6610	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS (NSAIDS)**	15,481	$ 236,025.59
5816	SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)**	14,692	$ 122,870.32
7510	CENTRAL MUSCLE RELAXANTS**	12,369	$ 197,892.68
3090	METABOLIC MODIFIERS**	12,338	$ 525,054.48

Q4 2013

Drug Class	Drug Class Name	Count of Claims	Pharmacy Paid Amt
6599	OPIOID COMBINATIONS**	30,603	$ 636,559.79
4420	SYMPATHOMIMETICS**	21,854	$ 1,715,082.58
7260	ANTICONVULSANTS - MISC.**	21,377	$ 1,295,779.03
6510	OPIOID AGONISTS**	20,068	$ 1,223,170.83
3940	HMG COA REDUCTASE INHIBITORS**	16,189	$ 280,488.32
5710	BENZODIAZEPINES**	15,523	$ 117,379.68
6610	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS (NSAIDS)**	14,826	$ 285,333.07
5816	SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)**	14,308	$ 122,820.01
7510	CENTRAL MUSCLE RELAXANTS**	12,114	$ 202,965.89
3610	ACE INHIBITORS**	11,287	$ 60,778.70

Top 50 Drugs by Amount - Q2 2013

Drug Code	Drug Name	Claim Count	Pharmacy Paid	Avg Qty/Rx	Avg Day Supply
5925001500	ARIPIPRAZOLE	3,682	$ 2,426,495.95	19	17
8510001025	ANTIHEMOPHILIC FACTOR RAHF-PFM	10	$ 1,007,150.31	22,039	9
4420990270	FLUTICASONE-SALMETEROL	3,598	$ 697,222.16	33	17
2125001040	ASPARAGINASE ERWINIA CHRYSANTHEMI	14	$ 647,801.72	98	1
5915307010	QUETIAPINE FUMARATE	5,277	$ 639,866.44	27	18
6510007510	OXYCODONE HCL	7,270	$ 551,336.21	63	15
8240157000	PEGFILGRASTIM	135	$ 541,816.27	1	3
5907005010	PALIPERIDONE PALMITATE	431	$ 525,452.56	1	19
9410003000	GLUCOSE BLOOD	4,607	$ 509,177.80	74	23
4420101010	ALBUTEROL SULFATE	13,726	$ 497,408.43	40	13
4927002510	ESOMEPRAZOLE MAGNESIUM	2,679	$ 459,416.61	21	19
2710400300	INSULIN GLARGINE	2,564	$ 457,371.28	9	18
6110990210	AMPHETAMINE-DEXTROAMPHETAMINE	2,821	$ 434,834.79	28	19
8510001510	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FAC	27	$ 407,322.72	5,611	8
1210990230	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARA	346	$ 375,896.08	20	20
8240102000	EPOETIN ALFA	9,483	$ 364,895.84	0	1
4410008010	TIOTROPIUM BROMIDE MONOHYDRATE	2,079	$ 345,811.58	17	17
5818002510	DULOXETINE HCL	1,821	$ 325,846.73	23	17
3010002000	SOMATROPIN	131	$ 325,816.58	4	17
6599170210	HYDROCODONE-ACETAMINOPHEN	22,068	$ 324,660.70	49	12
5940002310	LURASIDONE HCL	558	$ 320,937.93	20	16
0700007000	TOBRAMYCIN	61	$ 319,215.19	130	14
5907005000	PALIPERIDONE	450	$ 315,752.69	20	16
1910002010	IMMUNE GLOBULIN (HUMAN) IV	94	$ 302,501.91	480	2
6135303010	GUANFACINE HCL (ADHD)	1,435	$ 302,031.10	21	19
6140002010	METHYLPHENIDATE HCL	2,404	$ 301,666.94	28	19
6510005510	MORPHINE SULFATE	6,079	$ 293,338.58	25	10
8310102010	ENOXAPARIN SODIUM	957	$ 281,408.35	2	2
8580005000	ECULIZUMAB	13	$ 272,874.48	108	1
6240505000	NATALIZUMAB	41	$ 266,093.77	44	2
6240306045	INTERFERON BETA-1A	77	$ 263,440.10	2	14
2135307000	TRASTUZUMAB	75	$ 254,206.02	1	6
2135306000	RITUXIMAB	53	$ 243,931.43	60	1
5940008510	ZIPRASIDONE HCL	1,716	$ 236,782.63	29	17
1210990330	EFAVIRENZ-EMTRICITABINE-TENOFOVIR DISOPRO	147	$ 232,490.45	19	19
6110002510	LISDEXAMFETAMINE DIMESYLATE	1,354	$ 229,297.04	23	22
2110002800	OXALIPLATIN	45	$ 226,478.03	491	1
2133502000	BEVACIZUMAB	261	$ 226,351.02	6	1
5250504000	INFLIXIMAB	28	$ 225,428.93	97	2
5907007010	RISPERIDONE MICROSPHERES	366	$ 224,283.13	2	14
6599000220	OXYCODONE W/ ACETAMINOPHEN	8,434	$ 224,162.90	47	11
5915501510	ASENAPINE MALEATE	479	$ 212,791.05	21	14
2150000500	DOCETAXEL	71	$ 212,728.91	43	4
4530402000	DORNASE ALFA	91	$ 212,259.60	40	14
4440001500	BUDESONIDE (INHALATION)	620	$ 211,687.85	57	17
2710400200	INSULIN ASPART	1,299	$ 207,893.97	8	14
6510002500	FENTANYL	818	$ 200,745.83	4	11
4460306000	OMALIZUMAB	102	$ 199,755.44	38	18
3090685000	IDURSULFASE	6	$ 198,830.64	36	28
7260005700	PREGABALIN	1,314	$ 197,542.66	36	15

Top 50 Drugs by Amount - Q3 2013

Drug Code	Drug Name	Claim Count	Pharmacy Paid	Avg Qty/Rx	Avg Day Supply
5925001500	ARIPIPRAZOLE	3,644	$ 2,622,286.98	22	20
8510001025	ANTIHEMOPHILIC FACTOR RAHF-PFM	12	$ 789,087.10	16,251	8
4420990270	FLUTICASONE-SALMETEROL	3,447	$ 741,771.66	44	23
5915307010	QUETIAPINE FUMARATE	5,231	$ 619,505.18	30	20
5907005010	PALIPERIDONE PALMITATE	423	$ 588,390.41	1	19
8240157000	PEGFILGRASTIM	138	$ 574,048.11	1	2
4927002510	ESOMEPRAZOLE MAGNESIUM	2,875	$ 566,852.69	25	23
2710400300	INSULIN GLARGINE	2,641	$ 551,736.90	12	24
4420101010	ALBUTEROL SULFATE	14,047	$ 540,508.37	43	15
6510007510	OXYCODONE HCL	6,885	$ 530,145.53	78	19
9410003000	GLUCOSE BLOOD	4,446	$ 522,858.73	69	20
8510001510	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FAC	32	$ 455,048.86	4,426	7
0700007000	TOBRAMYCIN	80	$ 437,254.41	139	15
6110990210	AMPHETAMINE-DEXTROAMPHETAMINE	2,578	$ 412,853.22	28	19
5940002310	LURASIDONE HCL	657	$ 407,574.42	18	14
1210990230	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARA	347	$ 396,104.94	22	22
5818002510	DULOXETINE HCL	1,828	$ 388,847.36	29	22
4410008010	TIOTROPIUM BROMIDE MONOHYDRATE	1,998	$ 382,815.81	24	24
3010002000	SOMATROPIN	141	$ 344,188.69	3	14
8240102000	EPOETIN ALFA	10,019	$ 343,552.32	0	1
6135303010	GUANFACINE HCL (ADHD)	1,401	$ 333,200.82	22	20
6599170210	HYDROCODONE-ACETAMINOPHEN	22,068	$ 332,284.59	62	15
5907005000	PALIPERIDONE	417	$ 315,549.59	24	19
6240306045	INTERFERON BETA-1A	70	$ 295,156.52	2	18
6510005510	MORPHINE SULFATE	5,469	$ 284,089.20	32	13
6140002010	METHYLPHENIDATE HCL	2,200	$ 279,706.17	29	20
2135307000	TRASTUZUMAB	83	$ 267,068.42	1	5
6240505000	NATALIZUMAB	36	$ 259,748.02	47	3
8310102010	ENOXAPARIN SODIUM	833	$ 256,208.46	2	2
7260005700	PREGABALIN	1,397	$ 251,598.90	50	21
2710400200	INSULIN ASPART	1,304	$ 243,945.11	10	17
1210990330	EFAVIRENZ-EMTRICITABINE-TENOFOVIR DISOPRO	130	$ 236,627.10	22	21
6240003010	GLATIRAMER ACETATE	52	$ 236,601.00	0	10
8580005000	ECULIZUMAB	12	$ 235,999.44	100	1
4530402000	DORNASE ALFA	93	$ 235,020.71	41	14
7260003600	LACOSAMIDE	595	$ 228,016.23	60	16
6110002510	LISDEXAMFETAMINE DIMESYLATE	1,253	$ 227,780.20	23	23
6599000220	OXYCODONE W/ ACETAMINOPHEN	8,447	$ 227,490.52	58	13
2710400500	INSULIN LISPRO (HUMAN)	848	$ 225,446.29	12	21
5915501510	ASENAPINE MALEATE	484	$ 224,225.21	22	14
5940008510	ZIPRASIDONE HCL	1,574	$ 222,725.16	33	19
5907007010	RISPERIDONE MICROSPHERES	303	$ 215,116.36	1	15
6627001500	ADALIMUMAB	89	$ 211,708.65	1	13
8240152000	FILGRASTIM	211	$ 207,904.53	17	2
6629003000	ETANERCEPT	88	$ 205,988.38	2	13
1910002010	IMMUNE GLOBULIN (HUMAN) IV	71	$ 198,002.71	46,629	3
1210306010	RALTEGRAVIR POTASSIUM	209	$ 197,766.68	41	21
4420990241	BUDESONIDE-FORMOTEROL FUMARATE DIHYDRA	1,260	$ 194,951.96	8	24
2135306000	RITUXIMAB	33	$ 191,966.84	51	3
6510002500	FENTANYL	713	$ 189,363.27	5	14

Top 50 Drugs by Amount - Q4 2013

Drug Code	Drug Name	Claim Count		Pharmacy Paid	Avg Qty/Rx	Avg Day Supply
5925001500	ARIPIPRAZOLE	3,518.00	$	2,605,658.41	22	20
8510001025	ANTIHEMOPHILIC FACTOR RAHF-PFM	26.00	$	1,498,362.78	18,735	9
1950206000	PALIVIZUMAB	366.00	$	1,019,473.10	1	17
4420990270	FLUTICASONE-SALMETEROL	3,303.00	$	726,813.12	44	23
8510002620	COAGULATION FACTOR VIIA (RECOMBINANT)	1.00	$	704,110.76	78,000	6
5907005010	PALIPERIDONE PALMITATE	461.00	$	657,459.22	1	23
5915307010	QUETIAPINE FUMARATE	5,278.00	$	617,751.34	30	20
2710400300	INSULIN GLARGINE	2,502.00	$	603,462.10	13	24
4420101010	ALBUTEROL SULFATE	15,262.00	$	577,722.67	47	15
4927002510	ESOMEPRAZOLE MAGNESIUM	2,895.00	$	576,618.22	25	23
9410003000	GLUCOSE BLOOD	4,458.00	$	538,292.87	72	21
6510007510	OXYCODONE HCL	6,417.00	$	508,365.97	76	18
8510001510	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACT	30.00	$	500,642.52	6,756	9
5940002310	LURASIDONE HCL	692.00	$	479,505.91	18	15
6110990210	AMPHETAMINE-DEXTROAMPHETAMINE	2,774.00	$	446,919.27	29	20
0700007000	TOBRAMYCIN	75.00	$	418,421.97	146	15
4410008010	TIOTROPIUM BROMIDE MONOHYDRATE	1,940.00	$	414,755.23	25	25
8240157000	PEGFILGRASTIM	92.00	$	403,587.72	1	3
1210990230	EMTRICITABINE-TENOFOVIR DISOPROXIL FUMARAT	345.00	$	390,127.04	22	22
6135303010	GUANFACINE HCL (ADHD)	1,479.00	$	374,198.04	23	20
3030001000	CORTICOTROPIN	7.00	$	365,776.76	4	6
6599170210	HYDROCODONE-ACETAMINOPHEN	21,252.00	$	360,986.39	63	15
8510001000	ANTIHEMOPHILIC FACTOR (HUMAN)	2.00	$	356,450.56	128,475	15
5907005000	PALIPERIDONE	420.00	$	343,579.10	22	18
5818002510	DULOXETINE HCL	1,599.00	$	340,849.05	25	20
7250001010	DIVALPROEX SODIUM	3,804.00	$	327,971.67	56	19
3090685000	IDURSULFASE	18.00	$	318,529.68	19	10
6240306045	INTERFERON BETA-1A	66.00	$	311,432.72	2	18
3010002000	SOMATROPIN	126.00	$	311,038.52	3	14
8240102000	EPOETIN ALFA	7,335.00	$	309,096.33	0	1
6140002010	METHYLPHENIDATE HCL	2,269.00	$	292,186.05	28	18
7260005700	PREGABALIN	1,404.00	$	272,284.09	49	20
6510005510	MORPHINE SULFATE	4,860.00	$	269,264.14	35	14
8310102010	ENOXAPARIN SODIUM	730.00	$	266,338.38	2	3
6627001500	ADALIMUMAB	103.00	$	258,869.31	1	12
2710400200	INSULIN ASPART	1,133.00	$	254,062.80	11	18
6110002510	LISDEXAMFETAMINE DIMESYLATE	1,355.00	$	249,251.33	24	23
6599000220	OXYCODONE W/ ACETAMINOPHEN	7,594.00	$	243,217.23	56	13
4530402000	DORNASE ALFA	98.00	$	242,199.38	35	12
2710400500	INSULIN LISPRO (HUMAN)	858.00	$	242,166.65	11	20
8510001020	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	12.00	$	240,735.30	7,023	8
1910002010	IMMUNE GLOBULIN (HUMAN) IV	99.00	$	236,283.12	5,137	2
4440001500	BUDESONIDE (INHALATION)	722.00	$	233,560.30	52	17
1210990330	EFAVIRENZ-EMTRICITABINE-TENOFOVIR DISOPROX	128.00	$	231,451.18	26	26
2135307000	TRASTUZUMAB	78.00	$	229,949.28	1	4
7260003600	LACOSAMIDE	551.00	$	214,966.73	58	15
8580005000	ECULIZUMAB	14.00	$	214,224.48	77	1
4420990241	BUDESONIDE-FORMOTEROL FUMARATE DIHYDRAT	1,303.00	$	210,570.89	8	24
5940008510	ZIPRASIDONE HCL	1,491.00	$	209,038.70	36	21
2133502000	BEVACIZUMAB	188.00	$	207,064.28	7	1

Top 50 Drugs by Claim Count - Q2 2013

Drug Code	Drug Name	Claim Count	Pharmacy Paid	Avg Qty/Rx	Avg Day Supply
6599170210	HYDROCODONE-ACETAMINOPHEN	22,068	$ 324,660.70	49	12
4420101010	ALBUTEROL SULFATE	13,726	$ 497,408.43	40	13
3610003000	LISINOPRIL	10,624	$ 51,757.61	22	20
8240102000	EPOETIN ALFA	9,483	$ 364,895.84	0	1
5710001000	ALPRAZOLAM	9,375	$ 76,211.77	39	16
3090504000	DOXERCALCIFEROL	9,237	$ 93,846.29	2	1
6599000220	OXYCODONE W/ ACETAMINOPHEI	8,434	$ 224,162.90	47	11
7260003000	GABAPENTIN	8,040	$ 132,595.33	53	17
2810001010	LEVOTHYROXINE SODIUM	7,795	$ 57,741.38	20	20
3400000310	AMLODIPINE BESYLATE	7,683	$ 32,347.76	18	17
3940007500	SIMVASTATIN	7,680	$ 40,557.76	19	19
6510007510	OXYCODONE HCL	7,270	$ 551,336.21	63	15
6610002000	IBUPROFEN	7,105	$ 41,506.99	42	11
2725005000	METFORMIN HCL	7,040	$ 45,080.52	39	19
6510005510	MORPHINE SULFATE	6,079	$ 293,338.58	25	10
5907007000	RISPERIDONE	5,784	$ 135,333.26	31	18
0120001010	AMOXICILLIN	5,566	$ 45,735.04	60	6
4450505010	MONTELUKAST SODIUM	5,450	$ 114,203.26	19	19
6020408010	ZOLPIDEM TARTRATE	5,440	$ 40,623.33	18	18
5025006505	ONDANSETRON HCL	5,415	$ 24,661.49	4	2
5915307010	QUETIAPINE FUMARATE	5,277	$ 639,866.44	27	18
4920002010	RANITIDINE HCL	4,886	$ 43,388.00	39	19
3720003000	FUROSEMIDE	4,646	$ 18,771.02	23	18
3320003010	METOPROLOL TARTRATE	4,628	$ 19,827.29	31	17
5812008010	TRAZODONE HCL	4,610	$ 31,971.25	25	18
9410003000	GLUCOSE BLOOD	4,607	$ 509,177.80	74	23
5816007010	SERTRALINE HCL	4,446	$ 33,539.32	24	19
6410001000	ASPIRIN	4,342	$ 15,187.12	20	20
3620101010	CLONIDINE HCL	4,336	$ 59,590.89	33	18
6510009510	TRAMADOL HCL	4,023	$ 33,660.70	51	13
4220003230	FLUTICASONE PROPIONATE (NASA	4,019	$ 83,846.54	10	18
5816002010	CITALOPRAM HYDROBROMIDE	3,992	$ 22,546.37	20	18
7210001000	CLONAZEPAM	3,987	$ 24,720.43	39	18
0340001000	AZITHROMYCIN	3,923	$ 57,359.66	7	3
4927006000	OMEPRAZOLE	3,921	$ 13,662.45	17	14
4155003000	LORATADINE	3,913	$ 26,713.75	32	22
5710006000	LORAZEPAM	3,904	$ 18,619.84	20	9
7250001010	DIVALPROEX SODIUM	3,850	$ 146,157.97	52	18
7510005010	CYCLOBENZAPRINE HCL	3,742	$ 26,618.82	42	18
5925001500	ARIPIPRAZOLE	3,682	$ 2,426,495.95	19	17
4420990270	FLUTICASONE-SALMETEROL	3,598	$ 697,222.16	33	17
5816004000	FLUOXETINE HCL	3,527	$ 33,247.32	26	19
3760004000	HYDROCHLOROTHIAZIDE	3,416	$ 14,720.56	21	20
4920003000	FAMOTIDINE	3,362	$ 21,919.35	24	15
5710004000	DIAZEPAM	3,348	$ 17,510.30	36	16
3940001010	ATORVASTATIN CALCIUM	3,344	$ 34,813.34	17	17
7510002000	CARISOPRODOL	3,300	$ 27,387.86	49	17
8230004800	IRON SUCROSE	3,251	$ 81,234.73	3	1
2210004500	PREDNISONE	3,170	$ 14,210.93	21	11
4155002010	CETIRIZINE HCL	3,128	$ 25,279.53	39	18

Top 50 Drugs by Claim Count - Q3 2013

Drug Code	Drug Name	Claim Count		Pharmacy Paid	Avg Qty/Rx	Avg Day Supply
6599170210	HYDROCODONE-ACETAMINOPHEN	22,068	$	332,284.59	62	15
4420101010	ALBUTEROL SULFATE	14,047	$	540,508.37	43	15
3610003000	LISINOPRIL	10,524	$	53,141.61	30	27
3090504000	DOXERCALCIFEROL	10,155	$	107,137.76	2	1
8240102000	EPOETIN ALFA	10,019	$	343,552.32	0	1
5710001000	ALPRAZOLAM	9,382	$	79,268.72	49	21
6599000220	OXYCODONE W/ ACETAMINOPHEN	8,447	$	227,490.52	58	13
7260003000	GABAPENTIN	8,280	$	143,987.01	70	22
3400000310	AMLODIPINE BESYLATE	7,658	$	34,341.36	26	25
2810001010	LEVOTHYROXINE SODIUM	7,576	$	60,193.06	29	29
3940007500	SIMVASTATIN	7,430	$	40,272.74	27	27
6610002000	IBUPROFEN	7,069	$	42,857.25	47	13
2725005000	METFORMIN HCL	7,029	$	47,176.10	53	26
6510007510	OXYCODONE HCL	6,885	$	530,145.53	78	19
5907007000	RISPERIDONE	5,876	$	142,101.72	35	21
6510005510	MORPHINE SULFATE	5,469	$	284,089.20	32	13
5025006505	ONDANSETRON HCL	5,296	$	24,526.53	4	2
6020408010	ZOLPIDEM TARTRATE	5,248	$	41,898.96	22	22
5915307010	QUETIAPINE FUMARATE	5,231	$	619,505.18	30	20
4450505010	MONTELUKAST SODIUM	5,178	$	105,644.02	22	22
0120001010	AMOXICILLIN	4,939	$	38,954.64	54	6
4920002010	RANITIDINE HCL	4,740	$	42,506.61	47	22
3320003010	METOPROLOL TARTRATE	4,648	$	20,466.80	40	22
6410001000	ASPIRIN	4,608	$	15,922.43	20	20
5812008010	TRAZODONE HCL	4,576	$	34,564.90	31	23
3720003000	FUROSEMIDE	4,563	$	19,429.07	29	23
5816007010	SERTRALINE HCL	4,512	$	34,220.13	29	23
9410003000	GLUCOSE BLOOD	4,446	$	522,858.73	69	20
3620101010	CLONIDINE HCL	4,211	$	51,648.38	38	21
6510009510	TRAMADOL HCL	4,156	$	33,495.80	66	17
5710006000	LORAZEPAM	4,078	$	22,396.29	23	10
5816002010	CITALOPRAM HYDROBROMIDE	4,053	$	23,045.41	24	23
7210001000	CLONAZEPAM	3,984	$	25,103.40	48	22
7250001010	DIVALPROEX SODIUM	3,904	$	145,455.72	53	18
7510005010	CYCLOBENZAPRINE HCL	3,794	$	27,061.61	48	21
4927006000	OMEPRAZOLE	3,763	$	14,171.78	30	26
5925001500	ARIPIPRAZOLE	3,644	$	2,622,286.98	22	20
3940001010	ATORVASTATIN CALCIUM	3,625	$	36,698.84	23	23
4155003000	LORATADINE	3,608	$	23,959.40	31	22
4220003230	FLUTICASONE PROPIONATE (NASAL)	3,517	$	74,409.51	12	22
0340001000	AZITHROMYCIN	3,500	$	47,145.27	7	4
4420990270	FLUTICASONE-SALMETEROL	3,447	$	741,771.66	44	23
3760004000	HYDROCHLOROTHIAZIDE	3,433	$	15,013.03	28	27
5816004000	FLUOXETINE HCL	3,430	$	31,974.02	29	22
8230004800	IRON SUCROSE	3,409	$	79,758.61	3	1
4920003000	FAMOTIDINE	3,374	$	22,960.08	28	18
5710004000	DIAZEPAM	3,240	$	17,653.65	46	19
2210004500	PREDNISONE	3,154	$	14,546.46	21	11
7510002000	CARISOPRODOL	3,035	$	25,731.68	65	23
4927002510	ESOMEPRAZOLE MAGNESIUM	2,875	$	566,852.69	25	23

Top 50 Drugs by Claim Count - Q4 2013

Drug Code	Drug Name	Claim Count	Pharmacy Paid	Avg Qty/Rx	Avg Day Supply
6599170210	HYDROCODONE-ACETAMINOPHEN	21252	360986.39	62.69007913	14.96136001
4420101010	ALBUTEROL SULFATE	15262	577722.67	47.07672446	14.6770814
3610003000	LISINOPRIL	9990	52160.35	30.92456154	27.94425305
5710001000	ALPRAZOLAM	9044	78412.24	51.20084019	21.71737576
7260003000	GABAPENTIN	8024	143656.58	68.62136009	21.85218395
6599000220	OXYCODONE W/ ACETAMINOPHEN	7594	243217.23	56.09972831	13.16413716
3400000310	AMLODIPINE BESYLATE	7484	34765.09	27.6578272	26.70658683
8240102000	EPOETIN ALFA	7335	309096.33	0.495877529	1.112823261
2810001010	LEVOTHYROXINE SODIUM	7294	64642.14	29.27618002	28.26454446
3090504000	DOXERCALCIFEROL	7238	95036.82	1.720543807	1.057539138
3940007500	SIMVASTATIN	7185	39691.27	27.30779646	27.2007221
6610002000	IBUPROFEN	6755	40841.39	46.05072077	12.80758142
2725005000	METFORMIN HCL	6671	52648.72	54.78168781	26.38433536
6510007510	OXYCODONE HCL	6417	508365.97	76.42985582	18.18766449
0120001010	AMOXICILLIN	6291	52812.33	64.03050037	6.190481249
5907007000	RISPERIDONE	5572	138272.16	35.13379062	20.5976292
0340001000	AZITHROMYCIN	5470	82251.85	8.062409227	3.808217308
5915307010	QUETIAPINE FUMARATE	5278	617751.34	29.82127488	19.78119957
4450505010	MONTELUKAST SODIUM	5130	123539.46	21.4778713	21.37985338
6020408010	ZOLPIDEM TARTRATE	4981	40283.06	23.23806809	22.97800945
6510005510	MORPHINE SULFATE	4860	269264.14	34.97026586	13.94657637
4920002010	RANITIDINE HCL	4677	42828.92	47.38087748	22.4749877
5812008010	TRAZODONE HCL	4612	34902.19	32.07900281	23.56039326
3320003010	METOPROLOL TARTRATE	4567	21041.55	40.56169142	22.18814886
9410003000	GLUCOSE BLOOD	4458	538292.87	72.43398302	21.30069161
5816007010	SERTRALINE HCL	4405	34064.72	27.95988464	22.33210977
6410001000	ASPIRIN	4336	15871.56	21.79032787	21.30180328
3720003000	FUROSEMIDE	4323	19194.88	31.05460896	24.13852445
5025006505	ONDANSETRON HCL	4239	30753.64	4.973227617	1.830622128
3620101010	CLONIDINE HCL	4207	53295.18	39.34780444	21.71911111
6510009510	TRAMADOL HCL	4059	34375.37	66.11201913	17.12696831
3940001010	ATORVASTATIN CALCIUM	3956	41836.11	24.0200476	23.81929696
7210001000	CLONAZEPAM	3908	24846.83	48.58914446	22.70087427
5816002010	CITALOPRAM HYDROBROMIDE	3861	22326.7	23.91465534	22.20119714
7250001010	DIVALPROEX SODIUM	3804	327971.67	56.24746769	18.86447782
7510005010	CYCLOBENZAPRINE HCL	3796	28060.82	43.2858871	19.16169355
4220003230	FLUTICASONE PROPIONATE (NASAL)	3650	79046.8	12.3546173	22.54014143
4155003000	LORATADINE	3577	24034.47	32.99195797	22.81535492
4927006000	OMEPRAZOLE	3521	13864.19	29.04995005	24.95584416
5925001500	ARIPIPRAZOLE	3518	2605658.41	22.20126459	19.56770428
5816004000	FLUOXETINE HCL	3424	32271.59	29.76854731	22.60439805
3760004000	HYDROCHLOROTHIAZIDE	3357	15237.62	25.22591672	25.04536979
4420990270	FLUTICASONE-SALMETEROL	3303	726813.12	43.86523248	23.06985889
2210004500	PREDNISONE	3239	16164.42	19.68810186	9.888508453
5710006000	LORAZEPAM	3217	21024.57	30.46441598	13.8089058
5710004000	DIAZEPAM	3124	16821.56	46.27991782	19.54776579
4920003000	FAMOTIDINE	3087	25142.72	32.46098861	20.34359099
4927002510	ESOMEPRAZOLE MAGNESIUM	2895	576618.22	25.02080555	23.36169645
3330000700	CARVEDILOL	2832	17722.4	48.35157952	24.42075163
7260004300	LEVETIRACETAM	2820	159093.89	124.4169479	19.68322083

DUR Conflict Code	Submitted Generic Name-10	History Generic Name-10	Total Claim Count	Total Alert Count	Alert Percentage	Original Paid Claim Count	Original Paid Claim Count Amount Due	Original Paid To Paid Claim Count	Original Paid To Paid Amount Due	Original Paid To Rejected Claim Count	Original Paid To Rejected Amount Due	Original Paid to Reversed Claim Count	Original Paid To Reversed Amount Due	Original Rejected Claim Count	Original Rejected to Paid Claim Count	Original Rejected to Paid Amount Due	Original Rejected to Rejected Claim Count	Original Rejected to Rejected Amount Due	Original Rejected to Reversed Claim Count	Original Rejected to Reversed Amount Due	Final Paid Count	Final Paid Count Amount Due	Final Reversed Count	Final Reversed Amount Due	Final Rejected Count	Final Rejected Amount Due	Prior Authorization Count	Professional Service Code Override	Total DUR Savings	Severity Level
COMPLIAN	ALBUTEROL SULFATE		18,521	4,038	21.80%	2645	$93,913.44	2389	$84,330.80	1	$8.76	255	$9,221.65	1393	413	$15,861.81	939	$44,357.17	41	$1,518.62	2802	$100,192.61	296	$10,740.27	940	$44,365.93	20	0	$55,106.20	0
COMPLIAN	LISINOPRIL		11,824	1,721	14.56%	1466	$7,099.37	1334	$6,401.68	0	$0.00	132	$698.16	255	126	$608.67	115	$672.76	14	$105.93	1460	$7,010.35	146	$804.09	115	$672.76	0	0	$1,476.85	0
COMPLIAN	IBUPROFEN		9,226	889	9.64%	805	$5,125.39	746	$4,684.05	1	$4.49	58	$436.01	84	49	$316.60	30	$204.77	5	$47.26	795	$5,000.65	63	$483.27	31	$209.26	0	0	$692.53	0
COMPLIAN	GABAPENTIN		8,843	1,061	12.00%	930	$13,550.01	836	$11,714.62	0	$0.00	94	$1,805.13	131	61	$798.08	59	$1,329.31	11	$326.73	897	$12,512.70	105	$2,131.86	59	$1,329.31	9	0	$3,461.17	0
COMPLIAN	LEVOTHYROXINE SODIUM		8,615	1,228	14.25%	1070	$7,567.49	985	$6,940.18	0	$0.00	85	$608.69	158	76	$620.69	65	$514.74	17	$184.22	1061	$7,560.87	102	$792.91	65	$514.74	19	0	$1,307.65	0
COMPLIAN	AMLODIPINE BESYLATE		8,358	1,299	15.54%	1090	$4,746.84	996	$4,309.27	0	$0.00	94	$439.96	209	113	$524.85	76	$396.18	20	$81.43	1109	$4,834.12	114	$521.39	76	$396.18	0	0	$917.57	0
COMPLIAN	SIMVASTATIN		8,121	1,317	16.22%	1055	$5,813.05	973	$5,391.97	2	$14.06	80	$405.91	262	146	$820.05	103	$730.55	13	$82.64	1119	$6,212.02	93	$488.55	105	$744.61	0	0	$1,233.16	0
COMPLIAN	METFORMIN HCL		7,501	1,185	15.80%	1064	$5,964.73	970	$5,376.03	0	$0.00	94	$594.84	121	43	$259.93	71	$587.92	7	$61.17	1013	$5,635.96	101	$656.01	71	$587.92	0	0	$1,243.93	0
COMPLIAN	OMEPRAZOLE		7,108	728	10.24%	547	$1,626.25	473	$1,462.47	0	$0.00	74	$181.06	181	63	$234.02	111	$1,282.73	7	$17.36	536	$1,696.49	81	$198.42	111	$1,282.73	55	0	$1,481.15	0
COMPLIAN	MONTELUKAST SODIUM		6,410	1,210	18.88%	1157	$24,358.48	1019	$20,631.52	0	$0.00	138	$3,728.42	53	15	$235.73	31	$699.18	7	$259.78	1034	$20,867.25	145	$3,988.20	31	$699.18	1	0	$4,687.38	0
DDI-DTMS	HYDROCODONE-ACETAMIN	BUPRENORPHINE	25,020	35	0.14%	2	$82.26	2	$82.26	0	$0.00	0	$0.00	33	27	$601.43	6	$153.00	0	$0.00	29	$683.69	0	$0.00	6	$153.00	0	0	$153.00	1
DDI-DTMS	HYDROCODONE-ACETAMIN	ISONIAZID	25,012	27	0.11%	2	$27.66	2	$27.66	0	$0.00	0	$0.00	25	16	$128.09	9	$111.51	0	$0.00	18	$155.75	0	$0.00	9	$111.51	0	0	$111.51	1
DDI-DTMS	HYDROCODONE-ACETAMIN	BUPRENORPHINE HCL-NALO	24,993	8	0.03%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	8	7	$270.66	0	$0.00	1	$33.57	7	$270.66	1	$33.57	0	$0.00	3	0	$33.57	1
DDI-DTMS	ALBUTEROL SULFATE	PROPRANOLOL HCL	14,663	180	1.23%	10	$370.95	7	$242.23	0	$0.00	3	$128.72	170	122	$4,656.09	37	$1,421.70	11	$500.24	129	$4,898.32	14	$628.96	37	$1,421.70	1	0	$2,050.66	1
DDI-DTMS	ALBUTEROL SULFATE	TIMOLOL MALEATE (OPHTH	14,519	36	0.25%	2	$100.34	2	$11.46	0	$0.00	0	$0.00	34	28	$1,359.79	5	$157.11	1	$3.30	30	$1,371.25	1	$3.30	5	$157.11	0	0	$160.41	1
DDI-DTMS	ALBUTEROL SULFATE	DORZOLAMIDE HCL-TIMOL	14,518	35	0.24%	2	$6.60	2	$6.60	0	$0.00	0	$0.00	33	19	$432.44	7	$285.40	7	$23.70	21	$439.04	7	$23.70	7	$285.40	0	0	$309.10	1
DDI-DTMS	ALBUTEROL SULFATE	BRIMONIDINE TARTRATE-T	14,516	33	0.23%	1	$14.35	1	$14.35	0	$0.00	0	$0.00	32	15	$477.89	16	$517.28	1	$45.44	16	$492.24	1	$45.44	16	$517.28	1	0	$562.72	1
DDI-DTMS	ALBUTEROL SULFATE	SOTALOL HCL	14,505	22	0.15%	1	$50.17	1	$50.17	0	$0.00	0	$0.00	21	12	$359.16	9	$313.05	0	$0.00	13	$409.33	0	$0.00	9	$313.05	0	0	$313.05	1
DDI-DTMS	ALBUTEROL SULFATE	NADOLOL	14,498	15	0.10%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	15	11	$317.50	4	$164.70	0	$0.00	11	$317.50	0	$0.00	4	$164.70	0	0	$164.70	1
DDI-DTMS	ALBUTEROL SULFATE	RASAGILINE MESYLATE	14,484	1	0.01%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	1	1	$3.30	0	$0.00	0	$0.00	1	$3.30	0	$0.00	0	$0.00	0	0	$0.00	1
DOSECHEK	HYDROCODONE-ACETAMIN		26,299	1,314	5.00%	827	$17,254.37	764	$15,861.37	5	$65.62	58	$1,302.44	487	140	$3,748.58	336	$7,732.01	11	$130.24	904	$19,609.95	69	$1,432.68	341	$7,797.63	41	0	$9,230.31	0
DOSECHEK	DOXERCALCIFEROL		15,702	13,534	86.19%	13500	$170,243.92	13457	$169,679.42	0	$0.00	43	$564.50	34	2	$408.03	32	$761.99	0	$0.00	13459	$170,087.45	43	$564.50	32	$761.99	0	0	$1,326.49	0
DOSECHEK	ALBUTEROL SULFATE		15,638	1,155	7.39%	830	$15,324.68	723	$12,597.09	1	$45.44	106	$2,535.00	325	166	$5,230.97	134	$5,582.13	25	$861.45	889	$17,828.06	131	$3,396.45	135	$5,627.57	0	0	$9,024.02	0
DOSECHEK	EPOETIN ALFA		13,771	3,078	22.35%	2613	$51,402.76	2607	$48,676.32	0	$0.00	6	$2,726.44	465	1	$3,351.64	464	$12,541.16	0	$0.00	2608	$52,027.96	6	$2,726.44	464	$12,541.16	21	0	$15,267.60	0
DOSECHEK	LISINOPRIL		10,805	702	6.50%	656	$241.94	405	$183.99	0	$0.00	251	$59.39	46	19	$105.52	25	$55.03	2	$25.46	424	$289.51	253	$84.85	25	$55.03	0	0	$139.88	0
DOSECHEK	ONDANSETRON HCL		10,048	1,482	14.75%	1418	$8,838.13	920	$7,022.95	0	$0.00	498	$3,792.93	64	24	$259.42	35	$349.83	5	$26.07	944	$7,282.37	503	$3,819.00	35	$349.83	1	0	$4,168.83	0
DOSECHEK	ALPRAZOLAM		9,277	28	0.30%	15	$242.01	15	$146.30	0	$0.00	0	$0.00	13	8	$351.04	5	$46.63	0	$0.00	23	$497.34	0	$0.00	5	$46.63	4	0	$46.63	0
DOSECHEK	OXYCODONE W/ ACETAMIN		8,948	124	1.39%	35	$578.16	32	$638.64	0	$0.00	3	$70.82	89	40	$2,354.92	47	$2,517.68	2	$104.66	72	$2,993.56	5	$175.48	47	$2,517.68	2	0	$2,693.16	0
DOSECHEK	IBUPROFEN		8,624	287	3.33%	257	$1,844.34	231	$1,602.69	0	$0.00	26	$243.44	30	16	$110.80	11	$52.88	3	$19.60	247	$1,713.49	29	$263.04	11	$52.88	0	0	$315.92	0
DOSECHEK	GABAPENTIN		8,550	768	8.98%	624	$6,213.81	550	$5,623.32	2	$41.26	72	$533.39	144	50	$792.77	92	$1,198.65	2	$12.08	600	$6,416.09	74	$545.47	94	$1,239.91	10	0	$1,785.38	0
DRUG_AGE	PROMETHAZINE HCL		2,734	30	1.10%	30	$318.61	29	$271.73	0	$0.00	1	$32.77	0	0	$0.00	0	$0.00	0	$0.00	29	$271.73	1	$32.77	0	$0.00	0	0	$32.77	1
DRUG_AGE	PROMETHAZINE W/CODEIN		1,209	5	0.41%	5	$36.71	4	$31.39	0	$0.00	1	$5.32	0	0	$0.00	0	$0.00	0	$0.00	4	$31.39	1	$5.32	0	$0.00	0	0	$5.32	1
DRUG_AGE	PROMETHAZINE-DM		1,072	57	5.32%	49	$314.94	44	$288.32	0	$0.00	5	$26.62	8	2	$16.99	4	$26.58	2	$14.08	46	$305.31	7	$40.70	4	$26.58	0	0	$67.28	1
DRUG_AGE	PROMETHAZINE & PHENYLE		53	1	1.89%	1	$8.21	1	$8.21	0	$0.00	0	$0.00	0	0	$0.00	0	$0.00	0	$0.00	1	$8.21	0	$0.00	0	$0.00	0	0	$0.00	1
DUPRX	HYDROCODONE-ACETAMIN		26,992	2,007	7.44%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	2007	46	$843.19	1957	$39,425.87	4	$113.98	46	$843.19	4	$113.98	1957	$39,425.87	4	0	$39,539.85	2
DUPRX	EPOETIN ALFA		17,570	6,877	39.14%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	6877	3	$504.25	6874	$352,936.04	0	$0.00	3	$504.25	0	$0.00	6874	$352,936.04	0	0	$352,936.04	2
DUPRX	ALBUTEROL SULFATE		15,635	1,152	7.37%	87	$1,381.72	70	$764.82	0	$0.00	17	$572.46	1065	295	$13,583.90	688	$32,750.64	82	$3,478.52	365	$14,348.72	99	$4,050.98	688	$32,750.64	6	0	$36,801.62	2
DUPRX	LISINOPRIL		11,159	1,056	9.46%	69	$263.83	37	$149.79	0	$0.00	32	$114.04	987	332	$2,249.86	592	$4,172.84	63	$451.25	369	$2,399.65	95	$565.29	592	$4,172.84	0	0	$4,738.13	2
DUPRX	ALPRAZOLAM		10,542	1,293	12.27%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	1293	20	$497.27	1272	$12,385.45	1	$9.34	20	$497.27	1	$9.34	1272	$12,385.45	1	0	$12,394.79	2
DUPRX	OXYCODONE W/ ACETAMIN		9,572	748	7.81%	1	$6.31	0	$0.00	0	$0.00	1	$6.31	747	26	$638.95	721	$24,538.94	0	$0.00	26	$638.95	1	$6.31	721	$24,538.94	5	0	$24,545.25	2
DUPRX	ONDANSETRON HCL		8,688	122	1.40%	23	$186.25	15	$34.09	0	$0.00	8	$1,108.69	99	6	$35.57	93	$198.78	0	$0.00	21	$69.66	8	$1,108.69	93	$198.78	0	0	$1,307.47	2
DUPRX	IBUPROFEN		8,625	288	3.34%	41	$64.99	37	$34.87	0	$0.00	4	$30.12	247	85	$612.75	150	$1,121.34	12	$99.06	122	$647.62	16	$129.18	150	$1,121.34	0	0	$1,250.52	2
DUPRX	GABAPENTIN		8,577	795	9.27%	39	$917.89	25	$487.07	0	$0.00	14	$430.82	756	237	$5,004.81	461	$11,126.48	58	$1,369.58	262	$5,491.88	72	$1,800.40	461	$11,126.48	1	0	$12,926.88	2
DUPRX	LEVOTHYROXINE SODIUM		8,024	637	7.94%	19	$100.22	11	$57.47	0	$0.00	8	$48.64	618	222	$2,561.52	346	$4,125.02	50	$749.61	233	$2,618.99	58	$798.25	346	$4,125.02	11	0	$4,923.27	2
DUPTHER	HYDROCODONE-ACETAMIN		32,309	7,324	22.67%	875	$2,999.67	596	$2,505.92	4	$32.48	275	$461.27	6449	3141	$52,825.06	3075	$57,507.05	233	$3,314.66	3737	$55,330.98	508	$3,775.93	3079	$57,539.53	217	0	$61,315.46	0
DUPTHER	ALBUTEROL SULFATE		21,541	7,058	32.77%	712	$15,895.85	565	$12,528.53	0	$0.00	147	$3,380.46	6346	3364	$129,743.70	2546	$118,534.83	436	$18,008.92	3929	$142,272.23	583	$21,389.38	2546	$118,534.83	26	0	$139,924.21	0
DUPTHER	EPOETIN ALFA		17,577	6,884	39.16%	11	$1,644.68	10	$1,376.93	0	$0.00	1	$267.75	6873	1	$173.43	6872	$352,862.53	0	$0.00	11	$1,550.36	1	$267.75	6872	$352,862.53	0	0	$353,130.28	0
DUPTHER	OXYCODONE W/ ACETAMIN		13,269	4,445	33.50%	1006	$4,323.68	635	$2,822.13	2	$119.68	369	$1,372.47	3439	2116	$57,540.26	1243	$33,950.67	80	$1,744.59	2751	$60,362.39	449	$3,117.06	1245	$34,070.35	174	0	$37,187.41	0
DUPTHER	LISINOPRIL		12,315	2,212	17.96%	361	$767.75	198	$559.60	0	$0.00	163	$208.17	1851	890	$5,193.80	832	$5,884.98	129	$831.00	1088	$5,753.40	292	$1,039.17	832	$5,884.98	0	0	$6,924.15	0
DUPTHER	ALPRAZOLAM		11,227	1,978	17.62%	179	$770.45	139	$732.90	0	$0.00	40	$37.41	1799	836	$7,112.12	923	$8,290.93	40	$430.21	975	$7,845.02	80	$467.62	923	$8,290.93	91	0	$8,758.55	0
DUPTHER	MORPHINE SULFATE		10,452	2,938	28.11%	1450	$5,981.28	882	$4,592.50	4	$31.30	564	$1,358.34	1488	939	$59,624.76	511	$27,806.41	38	$4,344.51	1821	$64,217.26	602	$5,702.85	515	$27,837.71	79	0	$33,540.56	0
DUPTHER	GABAPENTIN		9,585	1,803	18.81%	224	$2,549.88	141	$1,567.30	0	$0.00	83	$984.17	1579	768	$15,471.23	699	$17,248.15	112	$2,903.45	909	$17,038.53	195	$3,887.62	699	$17,248.15	13	0	$21,135.77	0
DUPTHER	OXYCODONE HCL		9,582	2,601	27.14%	168	$5,051.10	121	$4,328.17	2	$152.08	45	$551.48	2433	1554	$141,469.15	788	$59,213.39	91	$5,776.47	1675	$145,797.32	136	$6,327.95	790	$59,365.47	254	0	$65,693.42	0
DUPTHER	IBUPROFEN		8,906	569	6.39%	98	$138.20	84	$90.49	0	$0.00	14	$47.71	471	245	$1,619.74	201	$1,438.09	25	$204.76	329	$1,710.23	39	$252.47	201	$1,438.09	0	0	$1,690.56	0
TOO SOON	HYDROCODONE-ACETAMIN		25,365	380	1.50%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	380	12	$66.57	368	$8,861.48	0	$0.00	12	$66.57	0	$0.00	368	$8,861.48	0	0	$8,861.48	0
TOO SOON	HYDROCODONE-ACETAMIN		25,073	88	0.35%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	88	2	$2.75	86	$2,131.66	0	$0.00	2	$2.75	0	$0.00	86	$2,131.66	0	0	$2,131.66	2
TOO SOON	HYDROCODONE-ACETAMIN		25,061	76	0.30%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	76	0	$0.00	75	$1,739.54	1	$2.63	0	$0.00	1	$2.63	75	$1,739.54	0	0	$1,742.17	1
TOO SOON	ALBUTEROL SULFATE		14,747	264	1.79%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	264	5	$325.83	259	$12,298.74	0	$0.00	5	$325.83	0	$0.00	259	$12,298.74	0	0	$12,298.74	0
TOO SOON	ALBUTEROL SULFATE		14,534	51	0.35%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	51	0	$0.00	51	$2,761.34	0	$0.00	0	$0.00	0	$0.00	51	$2,761.34	0	0	$2,761.34	1
TOO SOON	ALBUTEROL SULFATE		14,527	44	0.30%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	44	1	$57.98	43	$2,289.49	0	$0.00	1	$57.98	0	$0.00	43	$2,289.49	0	0	$2,289.49	2
TOO SOON	EPOETIN ALFA		10,698	5	0.05%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	5	0	$0.00	5	$789.54	0	$0.00	0	$0.00	0	$0.00	5	$789.54	0	0	$789.54	0
TOO SOON	EPOETIN ALFA		10,694	1	0.01%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	1	0	$0.00	1	$60.98	0	$0.00	0	$0.00	0	$0.00	1	$60.98	0	0	$60.98	2
TOO SOON	EPOETIN ALFA		10,694	1	0.01%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	1	0	$0.00	1	$123.06	0	$0.00	0	$0.00	0	$0.00	1	$123.06	0	0	$123.06	1
TOO SOON	LISINOPRIL		10,311	208	2.02%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	208	4	$26.10	204	$1,500.50	0	$0.00	4	$26.10	0	$0.00	204	$1,500.50	0	0	$1,500.50	0

ProDUR Edits Q3 2013

DUR Conflict Code	Submitted Generic Name-10	History Generic Name-10	Total Claim Count	Total Alert Count	Alert Percentage	Original Paid Claim Count	Original Paid Claim Count Amount Due	Original Paid To Paid Claim Count	Original Paid To Paid Amount Due	Original Paid To Rejected Claim Count	Original Paid To Rejected Amount Due	Original Paid to Reversed Claim Count	Original Paid To Reversed Amount Due	Original Rejected Claim Count	Original Rejected to Paid Claim Count	Original Rejected to Paid Amount Due	Original Rejected to Rejected Claim Count	Original Rejected to Rejected Amount Due	Original Rejected to Reversed Claim Count	Original Rejected to Reversed Amount Due	Final Paid Count	Final Paid Count Amount Due	Final Reversed Count	Final Reversed Amount Due	Final Rejected Count	Final Rejected Amount Due	Prior Authorization Count	Professional Service Code Override	Total DUR Savings	Severity Level
COMPLIAN	ALBUTEROL SULFATE		20,374	4,671	22.93%	3980	$128,271.91	3696	$117,419.28	0	$0.00	284	$11,009.09	691	330	$12,762.91	340	$15,722.24	21	$849.56	4026	$130,182.19	305	$11,858.65	340	$15,722.24	29	0	$27,580.89	0
COMPLIAN	LISINOPRIL		15,698	2,336	14.88%	2062	$7,899.74	1938	$7,391.57	1	$8.68	123	$540.03	274	138	$791.85	121	$688.88	15	$69.36	2076	$8,183.42	138	$609.39	122	$697.56	0	0	$1,306.95	0
COMPLIAN	DOXERCALCIFEROL		15,378	4	0.03%	4	$21.85	4	$22.45	0	$0.00	0	$0.00	0	0	$0.00	0	$0.00	0	$0.00	4	$22.45	0	$0.00	0	$0.00	0	0	$0.00	0
COMPLIAN	AMLODIPINE BESYLATE		12,213	1,883	15.42%	1683	$5,792.30	1579	$5,307.89	0	$0.00	104	$505.91	200	109	$495.38	83	$460.17	8	$48.91	1688	$5,803.27	112	$554.82	83	$460.17	0	0	$1,014.99	0
COMPLIAN	GABAPENTIN		11,648	1,499	12.87%	1402	$15,397.73	1291	$13,129.46	0	$0.00	111	$2,284.60	97	48	$732.35	41	$1,229.14	8	$106.72	1339	$13,861.81	119	$2,391.32	41	$1,229.14	11	0	$3,620.46	0
COMPLIAN	SIMVASTATIN		11,550	1,847	15.99%	1627	$6,599.83	1559	$6,226.12	0	$0.00	68	$406.12	220	121	$708.77	85	$625.26	14	$69.01	1680	$6,934.89	82	$475.13	85	$625.26	0	0	$1,100.39	0
COMPLIAN	LEVOTHYROXINE SODIUM		11,545	1,670	14.47%	1498	$8,746.58	1414	$8,015.21	0	$0.00	84	$744.91	172	72	$566.31	84	$843.84	16	$154.24	1486	$8,581.52	100	$899.15	84	$843.84	20	0	$1,742.99	0
COMPLIAN	IBUPROFEN		10,823	1,113	10.28%	1042	$5,292.42	970	$4,813.42	0	$0.00	72	$491.47	71	40	$287.04	25	$192.94	6	$43.66	1010	$5,100.46	78	$535.13	25	$192.94	0	0	$728.07	0
COMPLIAN	METFORMIN HCL		10,583	1,690	15.97%	1590	$8,325.51	1481	$7,663.37	1	$6.56	108	$699.78	100	47	$775.86	45	$371.89	8	$51.21	1528	$8,439.23	116	$750.99	46	$378.45	0	0	$1,129.44	0
COMPLIAN	OMEPRAZOLE		10,386	1,308	12.59%	1136	$2,363.18	1076	$2,181.21	0	$0.00	60	$211.64	172	71	$335.91	97	$991.16	4	$4.60	1147	$2,517.12	64	$216.24	97	$991.16	60	0	$1,207.40	0
DDI-DTMS	HYDROCODONE-ACETAM	BUPRENORPHINE	31,512	60	0.19%	15	$212.23	13	$211.74	0	$0.00	2	$0.54	45	35	$958.71	10	$177.85	0	$0.00	48	$1,170.45	2	$0.54	10	$177.85	0	0	$178.39	1
DDI-DTMS	HYDROCODONE-ACETAM	ISONIAZID	31,469	17	0.05%	1	$1.10	1	$1.15	0	$0.00	0	$0.00	16	9	$106.67	7	$335.63	0	$0.00	10	$107.82	0	$0.00	7	$335.63	0	0	$335.63	1
DDI-DTMS	HYDROCODONE-ACETAM	BUPRENORPHINE HCL-NALOX	31,468	16	0.05%	2	$1.37	2	$1.42	0	$0.00	0	$0.00	14	11	$120.99	2	$6.75	1	$1.15	13	$122.41	1	$1.15	2	$6.75	4	0	$7.90	1
DDI-DTMS	HYDROCODONE-ACETAM	BUPRENORPHINE HCL	31,455	3	0.01%	1	$1.10	1	$1.15	0	$0.00	0	$0.00	2	2	$2.30	0	$0.00	0	$0.00	3	$3.45	0	$0.00	0	$0.00	0	0	$0.00	1
DDI-DTMS	ALBUTEROL SULFATE	PROPRANOLOL HCL	15,945	242	1.52%	56	$938.46	53	$722.12	0	$0.00	3	$241.33	186	127	$5,002.48	52	$2,269.64	7	$374.62	180	$5,724.60	10	$615.95	52	$2,269.64	0	0	$2,885.59	1
DDI-DTMS	ALBUTEROL SULFATE	DORZOLAMIDE HCL-TIMOLOI	15,766	63	0.40%	35	$107.84	34	$112.80	0	$0.00	1	$0.64	28	22	$446.69	6	$104.88	0	$0.00	56	$559.49	1	$0.64	6	$104.88	0	0	$105.52	1
DDI-DTMS	ALBUTEROL SULFATE	TIMOLOL MALEATE (OPHTH)	15,739	36	0.23%	2	$6.80	2	$7.00	0	$0.00	0	$0.00	34	21	$1,194.15	9	$389.32	4	$122.96	23	$1,201.15	4	$122.96	9	$389.32	0	0	$512.28	1
DDI-DTMS	ALBUTEROL SULFATE	BRIMONIDINE TARTRATE-TIM	15,734	31	0.20%	2	$6.60	2	$7.00	0	$0.00	0	$0.00	29	11	$170.06	18	$286.09	0	$0.00	13	$177.06	0	$0.00	18	$286.09	1	0	$286.09	1
DDI-DTMS	ALBUTEROL SULFATE	NADOLOL	15,716	13	0.08%	7	$23.30	7	$24.50	0	$0.00	0	$0.00	6	4	$177.44	2	$7.00	0	$0.00	11	$201.94	0	$0.00	2	$7.00	0	0	$7.00	1
DDI-DTMS	ALBUTEROL SULFATE	SOTALOL HCL	15,716	13	0.08%	1	$3.30	1	$3.50	0	$0.00	0	$0.00	12	7	$473.25	3	$28.33	2	$7.00	8	$476.75	2	$7.00	3	$28.33	0	0	$35.33	1
DOSECHEK	EPOETIN ALFA		58,411	10,510	17.99%	9841	$884,310.69	9771	$793,131.10	0	$0.00	70	$91,179.59	669	0	$0.00	669	$290,031.26	0	$0.00	9771	$793,131.10	70	$91,179.59	669	$290,031.26	29	0	$381,210.85	0
DOSECHEK	DOXERCALCIFEROL		53,948	38,574	71.50%	38467	$517,410.13	38348	$513,496.66	0	$0.00	119	$3,913.87	107	3	$903.81	102	$6,205.89	2	$721.14	38351	$514,400.47	121	$4,635.01	102	$6,205.89	0	0	$10,840.90	0
DOSECHEK	HYDROCODONE-ACETAM		32,820	1,368	4.17%	1042	$14,636.40	1015	$14,236.68	0	$0.00	27	$417.54	326	98	$2,591.82	223	$6,076.71	5	$290.38	1113	$16,828.50	32	$707.92	223	$6,076.71	38	0	$6,784.63	0
DOSECHEK	ALBUTEROL SULFATE		16,849	1,146	6.80%	854	$14,456.51	733	$11,641.88	2	$32.76	119	$2,925.34	292	164	$5,732.90	105	$2,988.59	23	$1,447.10	897	$17,374.78	142	$4,372.44	107	$3,021.35	0	0	$7,393.79	0
DOSECHEK	LISINOPRIL		14,231	869	6.11%	840	$298.49	523	$209.52	0	$0.00	317	$80.89	29	11	$90.36	18	$56.41	0	$0.00	534	$299.88	317	$80.89	18	$56.41	0	0	$137.30	0
DOSECHEK	IRON SUCROSE		14,226	1,857	13.05%	1799	$303,945.49	1772	$301,601.11	0	$0.00	27	$2,344.38	58	2	$205.36	54	$34,381.90	2	$205.36	1774	$301,806.47	29	$2,549.74	54	$34,381.90	0	0	$36,931.64	0
DOSECHEK	ALPRAZOLAM		11,595	41	0.35%	33	$592.50	31	$481.12	0	$0.00	2	$111.73	8	6	$63.21	2	$141.56	0	$0.00	37	$544.33	2	$111.73	2	$141.56	6	0	$253.29	0
DOSECHEK	GABAPENTIN		11,203	1,054	9.41%	889	$6,070.81	791	$5,646.39	1	$6.47	97	$431.59	165	59	$1,436.46	100	$933.19	6	$37.93	850	$7,082.85	103	$469.52	101	$939.66	13	0	$1,409.18	0
DOSECHEK	OXYCODONE W/ ACETAM		11,053	179	1.62%	72	$1,139.74	68	$1,036.38	0	$0.00	4	$129.73	107	42	$1,934.66	61	$2,894.63	4	$155.48	110	$2,971.04	8	$285.21	61	$2,894.63	6	0	$3,179.84	0
DOSECHEK	AMLODIPINE BESYLATE		10,926	596	5.45%	520	$529.26	351	$438.48	0	$0.00	169	$88.89	76	21	$94.50	54	$191.09	1	$7.45	372	$532.98	170	$96.34	54	$191.09	0	0	$287.43	0
DRUG_AGE	PROMETHAZINE HCL		2,864	13	0.45%	13	$104.22	11	$78.54	0	$0.00	2	$20.57	0	0	$0.00	0	$0.00	0	$0.00	11	$78.54	2	$20.57	0	$0.00	0	0	$20.57	1
DRUG_AGE	PROMETHAZINE W/CODE		1,120	5	0.45%	4	$27.09	4	$27.09	0	$0.00	0	$0.00	1	1	$8.13	0	$0.00	0	$0.00	5	$35.22	0	$0.00	0	$0.00	0	0	$0.00	1
DRUG_AGE	PROMETHAZINE-DM		897	27	3.01%	25	$145.18	24	$141.18	0	$0.00	1	$4.00	2	1	$6.15	0	$0.00	1	$6.46	25	$147.33	2	$10.46	0	$0.00	0	0	$10.46	1
DRUG_AGE	DIPH-TETANUS TOX-ACEL		140	1	0.71%	1	$16.00	1	$16.00	0	$0.00	0	$0.00	0	0	$0.00	0	$0.00	0	$0.00	1	$16.00	0	$0.00	0	$0.00	0	0	$0.00	1
DRUG_AGE	DIPHTHERIA, ACELLULAR I		130	1	0.77%	1	$16.00	1	$16.00	0	$0.00	0	$0.00	0	0	$0.00	0	$0.00	0	$0.00	1	$16.00	0	$0.00	0	$0.00	0	0	$0.00	1
DRUG_SEX	BICALUTAMIDE		68	3	4.41%	2	$14.62	2	$27.37	0	$0.00	0	$0.00	1	1	$22.10	0	$0.00	0	$0.00	3	$49.47	0	$0.00	0	$0.00	0	0	$0.00	1
DUPRX	EPOETIN ALFA		69,870	21,969	31.44%	3	$25.32	3	$25.32	0	$0.00	0	$0.00	21966	1	$173.43	21965	$1,559,868.22	0	$0.00	4	$198.75	0	$0.00	21965	$1,559,868.22	0	0	$1,559,868.22	2
DUPRX	HYDROCODONE-ACETAM		33,430	1,978	5.92%	1	$1.10	1	$1.15	0	$0.00	0	$0.00	1977	43	$790.53	1933	$35,135.78	1	$41.94	44	$791.68	1	$41.94	1933	$35,135.78	8	0	$35,177.72	2
DUPRX	ALBUTEROL SULFATE		16,794	1,091	6.50%	96	$1,794.33	82	$1,116.23	0	$0.00	14	$682.55	995	289	$14,491.63	642	$30,913.89	64	$2,995.59	371	$15,607.86	78	$3,678.14	642	$30,913.89	4	0	$34,592.03	2
DUPRX	DOXERCALCIFEROL		15,448	74	0.48%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	74	1	$182.67	73	$3,066.05	0	$0.00	1	$182.67	0	$0.00	73	$3,066.05	0	0	$3,066.05	2
DUPRX	LISINOPRIL		14,447	1,085	7.51%	114	$280.55	91	$206.11	0	$0.00	23	$76.44	971	331	$2,302.77	568	$3,919.71	72	$540.36	422	$2,508.88	95	$616.80	568	$3,919.71	0	0	$4,536.51	2
DUPRX	ALPRAZOLAM		12,735	1,181	9.27%	2	$15.62	2	$15.62	0	$0.00	0	$0.00	1179	25	$208.75	1153	$10,143.37	1	$7.70	27	$224.37	1	$7.70	1153	$10,143.37	10	0	$10,151.07	2
DUPRX	IRON SUCROSE		12,433	64	0.51%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	64	0	$0.00	64	$34,555.70	0	$0.00	0	$0.00	0	$0.00	64	$34,555.70	0	0	$34,555.70	2
DUPRX	OXYCODONE W/ ACETAM		11,700	826	7.06%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	826	21	$487.77	805	$25,797.70	0	$0.00	21	$487.77	0	$0.00	805	$25,797.70	2	0	$25,797.70	2
DUPRX	GABAPENTIN		11,102	953	8.58%	104	$830.69	77	$308.68	1	$96.71	26	$426.80	849	260	$5,240.17	522	$12,050.67	67	$1,276.84	337	$5,548.85	93	$1,703.64	523	$12,147.38	3	0	$13,851.02	2
DUPRX	AMLODIPINE BESYLATE		10,988	658	5.99%	69	$151.84	58	$135.01	0	$0.00	11	$19.96	589	186	$1,128.76	361	$2,318.03	42	$287.20	244	$1,263.77	53	$307.16	361	$2,318.03	0	0	$2,625.19	2
DUPTHER	EPOETIN ALFA		69,875	21,974	31.45%	9	$711.05	7	$476.28	0	$0.00	2	$234.77	21965	4	$523.76	21961	$1,559,531.60	0	$0.00	11	$1,000.04	2	$234.77	21961	$1,559,531.60	0	0	$1,559,766.37	0
DUPTHER	HYDROCODONE-ACETAM		39,592	8,140	20.56%	1932	$4,165.53	1643	$3,930.49	2	$65.20	287	$289.71	6208	2913	$50,621.12	3140	$55,364.19	155	$2,594.27	4556	$54,551.61	442	$2,883.98	3142	$55,429.39	259	0	$58,313.37	0
DUPTHER	ALBUTEROL SULFATE		22,424	6,721	29.97%	901	$14,610.87	717	$11,483.55	0	$0.00	184	$3,367.63	5820	3286	$137,917.23	2178	$96,502.53	356	$16,709.41	4003	$149,400.78	540	$20,077.04	2178	$96,502.53	50	0	$116,579.57	0
DUPTHER	DOXERCALCIFEROL		17,539	2,165	12.34%	2086	$24,282.41	2077	$23,871.20	0	$0.00	9	$411.61	79	3	$903.81	74	$3,426.62	2	$721.14	2080	$24,775.01	11	$1,132.75	74	$3,426.62	0	0	$4,559.37	0
DUPTHER	LISINOPRIL		15,930	2,568	16.12%	666	$922.70	490	$810.21	0	$0.00	176	$123.03	1902	950	$5,825.56	818	$5,363.33	134	$888.75	1440	$6,635.77	310	$1,011.78	818	$5,363.33	0	0	$6,375.11	0
DUPTHER	OXYCODONE W/ ACETAM		15,591	4,717	30.25%	1610	$4,578.73	1294	$4,384.34	0	$0.00	316	$192.26	3107	1716	$51,482.80	1307	$35,904.89	84	$2,228.71	3010	$55,867.14	400	$2,420.97	1307	$35,904.89	134	0	$38,325.86	0
DUPTHER	ALPRAZOLAM		13,703	2,149	15.68%	448	$733.85	347	$672.92	0	$0.00	101	$70.25	1701	804	$6,107.66	857	$7,630.67	40	$413.40	1151	$6,780.58	141	$483.65	857	$7,630.67	68	0	$8,114.32	0
DUPTHER	IRON SUCROSE		12,485	116	0.93%	52	$2,693.00	51	$2,595.08	0	$0.00	1	$97.92	64	0	$0.00	64	$34,555.70	0	$0.00	51	$2,595.08	1	$97.92	64	$34,555.70	0	0	$34,653.62	0
DUPTHER	GABAPENTIN		12,395	2,246	18.12%	506	$1,915.70	392	$1,353.57	1	$96.71	113	$479.19	1740	816	$17,517.28	779	$20,055.83	145	$2,678.80	1208	$18,870.85	258	$3,157.99	780	$20,152.54	22	0	$23,310.53	0
DUPTHER	MORPHINE SULFATE		12,316	3,456	28.06%	1914	$6,146.12	1266	$4,864.96	0	$0.00	648	$1,309.77	1542	953	$60,122.00	533	$16,970.47	56	$9,166.49	2219	$64,986.96	704	$10,476.26	533	$16,970.47	99	0	$27,446.73	0
TOO SOON	EPOETIN ALFA		47,903	2	0.00%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	2	0	$0.00	2	$445.94	0	$0.00	0	$0.00	0	$0.00	2	$445.94	0	0	$445.94	0
TOO SOON	EPOETIN ALFA		47,902	1	0.00%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	1	0	$0.00	1	$111.86	0	$0.00	0	$0.00	0	$0.00	1	$111.86	0	0	$111.86	1
TOO SOON	HYDROCODONE-ACETAM		31,823	371	1.17%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	371	8	$168.37	362	$9,043.50	1	$32.65	8	$168.37	1	$32.65	362	$9,043.50	0	0	$9,076.15	0
TOO SOON	HYDROCODONE-ACETAM		31,540	88	0.28%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	88	0	$0.00	88	$2,226.06	0	$0.00	0	$0.00	0	$0.00	88	$2,226.06	0	0	$2,226.06	2
TOO SOON	HYDROCODONE-ACETAM		31,531	79	0.25%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	79	4	$109.14	75	$1,942.90	0	$0.00	4	$109.14	0	$0.00	75	$1,942.90	0	0	$1,942.90	1
TOO SOON	ALBUTEROL SULFATE		15,967	264	1.65%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	264	3	$158.32	260	$13,344.02	1	$50.17	3	$158.32	1	$50.17	260	$13,344.02	0	0	$13,394.19	0
TOO SOON	ALBUTEROL SULFATE		15,778	75	0.48%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	75	1	$57.98	73	$4,133.81	1	$57.98	1	$57.98	1	$57.98	73	$4,133.81	0	0	$4,191.79	2
TOO SOON	ALBUTEROL SULFATE		15,755	52	0.33%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	52	3	$203.73	49	$2,348.36	0	$0.00	3	$203.73	0	$0.00	49	$2,348.36	0	0	$2,348.36	1
TOO SOON	LISINOPRIL		13,569	207	1.53%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	207	3	$22.06	204	$1,550.57	0	$0.00	3	$22.06	0	$0.00	204	$1,550.57	0	0	$1,550.57	0
TOO SOON	LISINOPRIL		13,431	69	0.51%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	69	3	$19.66	66	$475.32	0	$0.00	3	$19.66	0	$0.00	66	$475.32	0	0	$475.32	2

DUR Conflict Code	Submitted Generic Name-10	History Generic Name-10	Total Claim Count	Total Alert Count	Alert Percentage	Original Paid Claim Count	Original Paid Claim Count Amount Due	Original Paid To Paid Claim Count	Original Paid To Paid Amount Due	Original Paid To Rejected Claim Count	Original Paid To Rejected Amount Due	Original Paid to Reversed Claim Count	Original Paid To Reversed Amount Due	Original Rejected Claim Count	Original Rejected to Paid Claim Count	Original Rejected to Paid Amount Due	Original Rejected to Rejected Claim Count	Original Rejected to Rejected Amount Due	Original Rejected to Reversed Claim Count	Original Rejected to Reversed Amount Due	Final Paid Count	Final Paid Count Amount Due	Final Reversed Count	Final Reversed Amount Due	Final Rejected Count	Final Rejected Amount Due	Prior Authorization Count	Professional Service Code Override	Total DUR Savings	Severity Level
COMPLIAN	ALBUTEROL SULFATE		19,159	4,188	21.86%	3554	$142,516.17	3219	$129,266.12	6	$222.60	329	$13,110.25	634	386	$13,867.82	209	$9,266.40	39	$1,724.29	3605	$143,133.94	368	$14,834.54	215	$9,489.00	35	0	$24,323.54	0
COMPLIAN	DOXERCALCIFEROL		13,317	5	0.04%	2	$528.76	2	$528.76	0	$0.00	0	$0.00	3	0	$0.00	3	$16.56	0	$0.00	2	$528.76	0	$0.00	3	$16.56	0	0	$16.56	0
COMPLIAN	LISINOPRIL		11,166	1,726	15.46%	1515	$7,825.06	1382	$7,158.82	1	$6.11	132	$659.09	211	106	$574.49	83	$533.36	22	$131.29	1488	$7,733.31	154	$790.38	84	$539.47	0	0	$1,329.85	0
COMPLIAN	IBUPROFEN		9,082	897	9.88%	802	$5,269.54	746	$4,876.06	0	$0.00	56	$392.67	95	54	$373.04	34	$270.95	7	$61.63	800	$5,249.10	63	$454.30	34	$270.95	0	0	$725.25	0
COMPLIAN	GABAPENTIN		8,568	1,139	13.29%	1019	$18,219.17	922	$16,627.82	1	$10.31	96	$1,356.74	120	62	$1,147.24	52	$934.97	6	$119.01	984	$17,775.06	102	$1,475.75	53	$945.28	13	0	$2,421.03	0
COMPLIAN	LEVOTHYROXINE SODIUI		8,173	1,172	14.34%	1028	$8,780.91	941	$8,057.50	1	$2.51	86	$710.54	144	87	$763.03	45	$583.55	12	$120.78	1028	$8,820.53	98	$831.32	46	$586.06	22	0	$1,417.38	0
COMPLIAN	AMLODIPINE BESYLATE		8,150	1,297	15.91%	1109	$5,550.22	1007	$5,030.60	1	$5.96	101	$506.14	188	88	$427.46	92	$532.66	8	$46.38	1095	$5,458.06	109	$552.52	93	$538.62	0	0	$1,091.14	0
COMPLIAN	SIMVASTATIN		7,435	1,298	17.46%	1083	$6,514.48	1001	$6,003.52	1	$7.94	81	$497.30	215	123	$700.59	76	$487.26	16	$106.43	1124	$6,704.11	97	$603.73	77	$495.20	0	0	$1,098.93	0
COMPLIAN	METFORMIN HCL		7,074	1,214	17.16%	1097	$8,329.48	977	$7,521.02	3	$23.02	117	$782.24	117	48	$306.48	60	$863.96	9	$63.57	1025	$7,827.50	126	$845.81	63	$886.98	1	0	$1,732.79	0
COMPLIAN	OMEPRAZOLE		6,407	695	10.85%	554	$1,864.03	502	$1,691.88	0	$0.00	52	$172.15	141	58	$636.08	79	$989.22	4	$20.85	560	$2,327.96	56	$193.00	79	$989.22	73	0	$1,182.22	0
DDI-DTMS	HYDROCODONE-ACETAN	BUPRENORPHINE	24,144	48	0.20%	8	$145.55	5	$144.74	0	$0.00	3	$0.81	40	28	$977.22	11	$210.26	1	$6.77	33	$1,121.96	4	$7.58	11	$210.26	0	0	$217.84	1
DDI-DTMS	HYDROCODONE-ACETAN	BUPRENORPHINE HCL-NALOX	24,117	21	0.09%	7	$2.47	4	$1.39	0	$0.00	3	$1.08	14	8	$130.87	6	$145.71	0	$0.00	12	$132.26	3	$1.08	6	$145.71	0	0	$146.79	1
DDI-DTMS	HYDROCODONE-ACETAN	ISONIAZID	24,115	19	0.08%	5	$26.21	5	$26.21	0	$0.00	0	$0.00	14	14	$412.50	0	$0.00	0	$0.00	19	$438.71	0	$0.00	0	$0.00	0	0	$0.00	1
DDI-DTMS	HYDROCODONE-ACETAN	BUPRENORPHINE HCL	24,099	3	0.01%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	3	2	$2.30	1	$1.15	0	$0.00	2	$2.30	0	$0.00	1	$1.15	0	0	$1.15	1
DDI-DTMS	ALBUTEROL SULFATE	PROPRANOLOL HCL	15,191	220	1.45%	46	$1,344.32	30	$1,058.19	2	$73.48	14	$212.65	174	131	$5,012.36	32	$1,385.34	11	$444.21	161	$6,070.55	25	$656.86	34	$1,458.82	0	0	$2,115.68	1
DDI-DTMS	ALBUTEROL SULFATE	DORZOLAMIDE HCL-TIMOLOL	15,008	37	0.25%	2	$52.88	2	$52.88	0	$0.00	0	$0.00	35	24	$881.22	9	$310.08	2	$100.34	26	$934.10	2	$100.34	9	$310.08	0	0	$410.42	1
DDI-DTMS	ALBUTEROL SULFATE	TIMOLOL MALEATE (OPHTH)	15,001	30	0.20%	4	$68.48	4	$68.48	0	$0.00	0	$0.00	26	20	$497.70	4	$194.69	2	$114.71	24	$566.18	2	$114.71	4	$194.69	0	0	$309.40	1
DDI-DTMS	ALBUTEROL SULFATE	BRIMONIDINE TARTRATE-TIM	14,986	15	0.10%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	15	13	$260.64	2	$95.61	0	$0.00	13	$260.64	0	$0.00	2	$95.61	0	0	$95.61	1
DDI-DTMS	ALBUTEROL SULFATE	NADOLOL	14,984	13	0.09%	4	$1.72	4	$1.72	0	$0.00	0	$0.00	9	5	$204.18	4	$14.00	0	$0.00	9	$205.90	0	$0.00	4	$14.00	0	0	$14.00	1
DDI-DTMS	ALBUTEROL SULFATE	SOTALOL HCL	14,976	5	0.03%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	5	4	$110.98	0	$0.00	1	$3.50	4	$110.98	1	$3.50	0	$0.00	0	0	$3.50	1
DOSECHEK	DOXERCALCIFEROL		48,425	35,113	72.51%	34949	$458,102.39	34825	$456,141.73	0	$0.00	124	$1,960.66	164	2	$454.40	162	$5,947.95	0	$0.00	34827	$456,596.13	124	$1,960.66	162	$5,947.95	0	0	$7,908.61	0
DOSECHEK	EPOETIN ALFA		35,165	6,599	18.77%	5834	$135,340.76	5792	$112,488.26	0	$0.00	42	$22,852.50	765	1	$418.47	764	$11,663.57	0	$0.00	5793	$112,906.73	42	$22,852.50	764	$11,663.57	3	0	$34,516.07	0
DOSECHEK	HYDROCODONE-ACETAN		24,973	877	3.51%	576	$13,573.40	546	$12,680.27	2	$121.07	28	$799.42	301	91	$3,319.56	198	$6,072.54	12	$145.97	637	$15,999.83	40	$945.39	200	$6,193.61	32	0	$7,139.00	0
DOSECHEK	ALBUTEROL SULFATE		16,391	1,420	8.66%	1063	$17,697.78	927	$14,479.40	0	$0.00	136	$3,018.51	357	191	$4,469.62	141	$3,398.25	25	$976.14	1118	$18,949.02	161	$3,994.65	141	$3,398.25	0	0	$7,392.90	0
DOSECHEK	IRON SUCROSE		14,189	1,863	13.13%	1836	$88,181.47	1790	$85,939.76	0	$0.00	46	$2,241.71	27	0	$0.00	27	$2,733.60	0	$0.00	1790	$85,939.76	46	$2,241.71	27	$2,733.60	0	0	$4,975.31	0
DOSECHEK	ONDANSETRON HCL		11,688	3,399	29.08%	3112	$10,325.39	2021	$8,734.31	1	$4.80	1090	$1,743.77	287	27	$250.52	256	$621.52	4	$44.99	2048	$8,984.83	1094	$1,788.76	257	$626.32	7	0	$2,415.08	0
DOSECHEK	LISINOPRIL		10,537	1,097	10.41%	871	$240.29	514	$166.05	0	$0.00	357	$75.94	226	8	$40.90	217	$43.71	1	$46.70	522	$206.95	358	$122.64	217	$43.71	0	0	$166.35	0
DOSECHEK	AMOXICILLIN		9,753	669	6.86%	586	$4,102.98	520	$3,733.68	1	$4.00	65	$453.59	83	31	$397.19	38	$363.00	14	$131.99	551	$4,130.87	79	$585.58	39	$367.00	0	0	$952.58	0
DOSECHEK	ALPRAZOLAM		9,094	30	0.33%	18	$459.49	13	$147.74	0	$0.00	5	$311.75	12	4	$34.32	8	$123.02	0	$0.00	17	$182.06	5	$311.75	8	$123.02	3	0	$434.77	0
DOSECHEK	MORPHINE SULFATE		8,854	583	6.58%	424	$2,805.55	313	$2,479.19	0	$0.00	111	$323.34	159	57	$1,928.91	99	$1,860.82	3	$47.72	370	$4,408.10	114	$371.06	99	$1,860.82	11	0	$2,231.88	0
DRUG_AGE	PROMETHAZINE HCL		2,603	12	0.46%	12	$96.54	12	$96.54	0	$0.00	0	$0.00	0	0	$0.00	0	$0.00	0	$0.00	12	$96.54	0	$0.00	0	$0.00	0	0	$0.00	1
DRUG_AGE	PROMETHAZINE-DM		1,618	64	3.96%	58	$320.38	57	$312.22	0	$0.00	1	$8.16	6	5	$51.48	1	$5.61	0	$0.00	62	$363.70	1	$8.16	1	$5.61	0	0	$13.77	1
DRUG_AGE	PROMETHAZINE W/ COD		1,586	7	0.44%	6	$43.52	2	$14.00	0	$0.00	4	$29.52	1	1	$7.57	0	$0.00	0	$0.00	3	$21.57	4	$29.52	0	$0.00	0	0	$29.52	1
DRUG_AGE	MULTIPLE VITAMIN		1,085	2	0.18%	1	$5.05	1	$5.05	0	$0.00	0	$0.00	1	0	$0.00	1	$5.05	0	$0.00	1	$5.05	0	$0.00	1	$5.05	0	0	$5.05	1
DRUG_AGE	PHENYLEPH-PROMETHA		133	2	1.50%	2	$86.54	2	$86.54	0	$0.00	0	$0.00	0	0	$0.00	0	$0.00	0	$0.00	2	$86.54	0	$0.00	0	$0.00	0	0	$0.00	1
DRUG_AGE	DIPHTHERIA, ACELLULAR		79	1	1.27%	1	$16.00	0	$0.00	0	$0.00	1	$16.00	0	0	$0.00	0	$0.00	0	$0.00	0	$0.00	1	$16.00	0	$0.00	0	0	$16.00	1
DRUG_SEX	BICALUTAMIDE		47	2	4.26%	1	$7.31	1	$7.31	0	$0.00	0	$0.00	1	1	$20.06	0	$0.00	0	$0.00	2	$27.37	0	$0.00	0	$0.00	0	0	$0.00	1
DUPRX	EPOETIN ALFA		44,451	15,885	35.74%	1	$42.17	1	$42.17	0	$0.00	0	$0.00	15884	2	$563.79	15882	$868,003.42	0	$0.00	3	$605.96	0	$0.00	15882	$868,003.42	0	0	$868,003.42	2
DUPRX	HYDROCODONE-ACETAN		26,054	1,958	7.52%	174	$74.79	139	$60.76	0	$0.00	35	$14.03	1784	46	$1,059.90	1736	$34,950.30	2	$50.11	185	$1,120.66	37	$64.14	1736	$34,950.30	2	0	$35,014.44	2
DUPRX	ALBUTEROL SULFATE		16,158	1,187	7.35%	106	$1,854.40	75	$816.43	0	$0.00	31	$1,041.97	1081	345	$16,643.29	638	$29,769.10	98	$4,536.79	420	$17,459.72	129	$5,578.76	638	$29,769.10	12	0	$35,347.86	2
DUPRX	DOXERCALCIFEROL		13,415	103	0.77%	1	$12.75	1	$12.75	0	$0.00	0	$0.00	102	1	$4.88	101	$1,181.37	0	$0.00	2	$17.63	0	$0.00	101	$1,181.37	0	0	$1,181.37	2
DUPRX	IRON SUCROSE		12,368	42	0.34%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	42	0	$0.00	42	$3,085.96	0	$0.00	0	$0.00	0	$0.00	42	$3,085.96	0	0	$3,085.96	2
DUPRX	LISINOPRIL		10,772	1,332	12.37%	137	$212.43	69	$86.14	1	$5.54	67	$120.75	1195	334	$2,398.42	803	$4,303.39	58	$381.53	403	$2,484.56	125	$502.28	804	$4,308.93	0	0	$4,811.21	2
DUPRX	ALPRAZOLAM		10,305	1,241	12.04%	33	$17.24	20	$16.40	0	$0.00	13	$0.84	1208	21	$202.08	1185	$10,531.32	2	$339.04	41	$218.48	15	$339.88	1185	$10,531.32	4	0	$10,871.20	2
DUPRX	AMOXICILLIN		9,296	212	2.28%	39	$75.42	32	$56.91	0	$0.00	7	$18.51	173	59	$497.57	84	$706.36	30	$280.70	91	$554.48	37	$299.21	84	$706.36	0	0	$1,005.57	2
DUPRX	OXYCODONE W/ ACETAN		9,079	932	10.27%	181	$46.71	128	$30.33	0	$0.00	53	$16.38	751	12	$574.79	739	$23,685.74	0	$0.00	140	$605.12	53	$16.38	739	$23,685.74	2	0	$23,702.12	2
DUPRX	MORPHINE SULFATE		8,879	608	6.85%	16	$27.66	9	$14.20	0	$0.00	7	$13.46	592	5	$167.58	587	$5,141.04	0	$0.00	14	$181.78	7	$13.46	587	$5,141.04	2	0	$5,154.50	2
DUPTHER	EPOETIN ALFA		44,373	15,807	35.62%	2	$922.94	1	$751.94	0	$0.00	1	$171.00	15805	1	$418.47	15804	$865,108.04	0	$0.00	2	$1,170.41	1	$171.00	15804	$865,108.04	0	0	$865,279.04	0
DUPTHER	HYDROCODONE-ACETAN		31,062	6,966	22.43%	1165	$3,571.17	824	$3,195.65	0	$0.00	341	$359.20	5801	2949	$60,664.60	2679	$55,934.09	173	$3,243.96	3773	$63,860.25	514	$3,603.16	2679	$55,934.09	245	0	$59,537.25	0
DUPTHER	ALBUTEROL SULFATE		20,093	5,122	25.49%	648	$11,308.08	460	$7,219.84	0	$0.00	188	$4,080.26	4474	2530	$95,777.61	1528	$67,098.11	416	$17,213.59	2990	$102,997.45	604	$21,293.85	1528	$67,098.11	40	0	$88,391.96	0
DUPTHER	DOXERCALCIFEROL		15,516	2,204	14.20%	2151	$25,894.66	2151	$25,894.66	0	$0.00	0	$0.00	53	3	$4,906.81	49	$568.94	1	$4,452.41	2154	$30,801.47	1	$4,452.41	49	$568.94	0	0	$5,021.35	0
DUPTHER	IRON SUCROSE		12,492	166	1.33%	135	$3,945.67	129	$3,407.11	0	$0.00	6	$538.56	31	0	$0.00	31	$2,099.69	0	$0.00	129	$3,407.11	6	$538.56	31	$2,099.69	0	0	$2,638.25	0
DUPTHER	OXYCODONE W/ ACETAN		11,992	3,845	32.06%	1078	$4,660.92	757	$3,725.00	0	$0.00	321	$869.29	2767	1631	$59,068.28	1042	$33,332.77	94	$3,666.92	2388	$62,793.28	415	$4,536.21	1042	$33,332.77	119	0	$37,868.98	0
DUPTHER	LISINOPRIL		11,678	2,238	19.16%	414	$563.72	231	$390.18	0	$0.00	183	$173.54	1824	883	$5,407.95	837	$5,594.04	104	$706.66	1114	$5,798.13	287	$880.20	837	$5,594.04	0	0	$6,474.24	0
DUPTHER	MORPHINE SULFATE		11,267	2,996	26.59%	1577	$5,815.39	924	$3,875.10	0	$0.00	653	$1,935.97	1419	889	$54,122.73	495	$14,561.91	35	$2,712.97	1813	$57,997.83	688	$4,648.94	495	$14,561.91	133	0	$19,210.85	0
DUPTHER	ALPRAZOLAM		10,858	1,794	16.52%	176	$413.39	120	$381.20	1	$6.62	55	$25.57	1618	723	$5,714.61	867	$8,541.82	28	$540.87	843	$6,095.81	83	$566.44	868	$8,548.44	57	0	$9,114.88	0
DUPTHER	GABAPENTIN		9,454	2,025	21.42%	290	$2,623.54	180	$1,978.14	0	$0.00	110	$628.46	1735	869	$20,947.30	774	$17,920.66	92	$1,935.36	1049	$22,925.44	202	$2,563.82	774	$17,920.66	12	0	$20,484.48	0
TOO SOON	EPOETIN ALFA		28,575	9	0.03%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	9	1	$173.43	8	$1,443.66	0	$0.00	1	$173.43	0	$0.00	8	$1,443.66	0	0	$1,443.66	0
TOO SOON	EPOETIN ALFA		28,568	2	0.01%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	2	0	$0.00	2	$290.64	0	$0.00	0	$0.00	0	$0.00	2	$290.64	0	0	$290.64	2
TOO SOON	HYDROCODONE-ACETAN		24,473	377	1.54%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	377	8	$135.61	369	$9,912.92	0	$0.00	8	$135.61	0	$0.00	369	$9,912.92	1	0	$9,912.92	0
TOO SOON	HYDROCODONE-ACETAN		24,172	76	0.31%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	76	1	$6.85	75	$1,998.79	0	$0.00	1	$6.85	0	$0.00	75	$1,998.79	0	0	$1,998.79	2
TOO SOON	HYDROCODONE-ACETAN		24,160	64	0.26%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	64	2	$26.41	62	$1,449.94	0	$0.00	2	$26.41	0	$0.00	62	$1,449.94	0	0	$1,449.94	1
TOO SOON	ALBUTEROL SULFATE		15,236	265	1.74%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	265	5	$277.53	260	$13,539.68	0	$0.00	5	$277.53	0	$0.00	260	$13,539.68	0	0	$13,539.68	0
TOO SOON	ALBUTEROL SULFATE		15,045	74	0.49%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	74	1	$9.56	73	$3,898.30	0	$0.00	1	$9.56	0	$0.00	73	$3,898.30	0	0	$3,898.30	2
TOO SOON	ALBUTEROL SULFATE		15,034	63	0.42%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	63	1	$50.17	62	$3,099.91	0	$0.00	1	$50.17	0	$0.00	62	$3,099.91	0	0	$3,099.91	1
TOO SOON	DOXERCALCIFEROL		13,313	1	0.01%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	1	0	$0.00	1	$339.62	0	$0.00	0	$0.00	0	$0.00	1	$339.62	0	0	$339.62	1
TOO SOON	LISINOPRIL		9,687	247	2.55%	0	$0.00	0	$0.00	0	$0.00	0	$0.00	247	2	$11.36	245	$2,035.28	0	$0.00	2	$11.36	0	$0.00	245	$2,035.28	0	0	$2,035.28	0

State of Nevada
Department of Health and Human Services
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Drug Use Review (DUR) Board

Results:

Member #1
- At time of provider notification, member was receiving 120 butalbital/acetaminophen/caffeine tablets for a 20 day supply indicating use six times per day.
- Provider documents that member has refused prophylactic therapy for migraine prophylaxis.
- Provider indicated that member will be contacted to re-assess the use of migraine prophylaxis.
- Provider rated usefulness of initiative as 7/10.
- Member continues to fill quantities of 100 to 110 tablets for an 18 day supply.
- No claims for migraine prophylaxis medications.

Member #2
- At time of provider notification, member was receiving 60 butalbital/acetaminophen/caffeine tablets for a 20 day supply indicating use twice daily.
- Provider documents that member receives Vimpat® (lacosamide) for migraine prophylaxis.
- Provider indicated that member will be contacted to re-assess the use of migraine prophylaxis.
- Provider rated usefulness of initiative as 7/10.
- Member does not have a paid claim butalbital/acetaminophen/caffeine since provider notification.
- Member continues to have paid claims for Vimpat® (lacosamide).

Member #3
- At time of provider notification, member was receiving 100 butalbital/acetaminophen/caffeine tablets for a 25 day supply indicating use four times per day.
- Provider documents that member is intolerant to most migraine prophylaxis medications.
- Provider indicates that practice does not take Medicaid and therefor there should not be claims for headache medications for this member.
- Provider rated usefulness of initiative as 5/10.
- Member continues to fill quantities of 100 to 110 tablets for a 25 day supply.
- Member continues to have paid claims for lamotrigine and other psychotropic medications; however, lamotrigine is not considered effective for migraine prophylaxis according to guidelines published by the American Academy of Neurology.

Member #4
- At time of provider notification, member was receiving 60 butalbital/acetaminophen/caffeine tablets for a 15 day supply indicating use four times per day.
- Provider documents that member is partially under his care; however, another provider is responsible for pain management for this member.
- Provider indicated that member will be contacted to re-assess the use of migraine prophylaxis.
- Provider notes that member complains of 3-4 migraines/week and also has tension headaches.

- Provider will advise member to lower use to butalbital/acetaminophen/caffeine to 30 tablets/month. Of note member was refused refills due to lack of follow-up therefore unclear why it is reported that member is receiving 60 tablets per month (NOTE: Member is receiving prescription from more than one prescriber).
- Provider rated usefulness of initiative as 10/10.
- Member continues to fill quantities of 60 tablets for a 15 day supply.
- No claims for migraine prophylaxis medications.

Member #5

- At time of provider notification, member was receiving 9 sumatriptan tablets per month indicating a frequency of migraine headaches more than twice per week.
- Provider indicated that member will be contacted to re-assess the use of migraine prophylaxis.
- Provider rated usefulness of initiative as 5/10.
- Member continues to fill quantities of 9 tablets for a 5 day supply.
- Paid claims for amitriptyline, suggesting patient is receiving migraine prophylaxis medications.

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Medical Condition	Zolpidem Dosing Recommendations for Insomnia
Rationale	• Insomnia is present when all three of the following criteria are met: o A complaint of difficulty initiating sleep, difficulty maintaining sleep, waking up too early or sleep that is chronically nonrestorative or poor in quality. o Sleep difficulty occurs despite adequate opportunity and circumstances for sleep. o The impaired sleep produces deficits in daytime function.[1] • A survey of primary care patients found that 69% reported insomnia. The insomnia was reported as occasional by 50% and chronic by 19%.[2] • Patients with insomnia cost their employers approximately $2,280 per year in lost productivity and a total of $63 billion dollars annually in the United States.[3] • According to guidelines for Evaluation and Management of Chronic Insomnia in Adults by the American Academy of Sleep Medicine, short-term hypnotic treatment should be utilized in addition to behavioral and cognitive therapies when possible.[4] • For patients with primary insomnia, the recommended medication trials include a short- or intermediate-acting benzodiazepine or benzodiazepine receptor agonist (zolpidem, eszopiclone, zaleplon or temazepam) or ramelteon.[4] • Zolpidem is available in various formulations including immediate-release tablet (Ambien®), extended-release tablet (Ambien CR®), sublingual tablet (Edluar®, Intermezzo®) and oral spray solution (Zolpimist®).[5] • In January 2013, the Food and Drug Administration (FDA) released new recommendations that the dose of zolpidem be lowered due to new data suggesting that blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. Women appear to be more susceptible, as they eliminate zolpidem more slowly than men.[6] • The FDA required the manufacturers of Ambien®, Ambien CR®, Edluar®, and Zolpimist® to lower the recommended dose. The recommended dose of zolpidem for women should be lowered from 10 to 5 mg for immediate-release products (Ambien®, Edluar®, and Zolpimist®) and from 12.5 to 6.25 mg for extended-release products (Ambien CR®). For men, the labeling should recommend that health care professionals consider prescribing the lower doses—5 mg for immediate-release products and 6.25 mg for extended-release products.[6]
DUR Intervention	• Members with ≥2 pharmacy claims for zolpidem products (Ambien®, Ambien CR®, Edluar®, and Zolpimist®) at doses suggestive of 10 or 12.5 mg (Ambien CR® only) or greater from May 1, 2013 to July 31, 2013.
Objective	• To assess the utilization of zolpidem at doses of 10 or 12.5 mg (Ambien CR® only) or greater and to evaluate the impact of a retrospective drug utilization review (RDUR) initiative on zolpidem dosing in accordance with the recent FDA guidance on zolpidem products.
Inclusion Criteria	• Members with ≥2 pharmacy claims for zolpidem products (Ambien®, Ambien CR®, Edluar®, and Zolpimist®) at does suggestive of 10 or 12.5 mg (Ambien CR® only) or greater from May 1, 2013 to July 31, 2013 (GPIs and quantities described below).
Exclusion Criteria	• Members with a primary payer other than Nevada Medicaid. • Members without continuous plan eligibility in the last 120 days.
Intervention	• Each unique prescriber of patients meeting the above criteria will be notified through formal patient-specific letters sent via regular mail. All letters will include a brief

Medical Condition	Zolpidem Dosing Recommendations for Insomnia
	introduction to the RDUR initiative, a summary of the recent FDA dosing recommendations for zolpidem as well as a summary of the patient's recent zolpidem fill history, including prescriber information. Feedback forms will be included with the letter inquiring about the following: • Confirmation that the patient is currently under the care of the prescriber, and if not, does the prescriber have a record of the current primary care physician (PCP). • Confirmation that the patient is currently or was previously taking zolpidem at doses of 10 or 12.5 mg (Ambien CR® only) or greater per day. • Confirmation that prescriber is aware of recent changes in FDA-approved zolpidem dosing. • Reason for zolpidem dosing of 10 or 12.5 mg (Ambien CR® only) or greater per day. o Member has experienced an inadequate response to lower doses of zolpidem. o Member has been stabilized on the current dose of zolpidem with a good response to treatment. • This member has been counseled regarding the risk of impairment in activities that require alertness, including driving, the morning following their nightly dose. • Future plan, if any, to reduce the use and/or daily dose of zolpidem. • Usefulness of RDUR information on a scale of 1-10.
Outcome Measure	**Possible outcome measures may include:** • Percentage of patients on zolpidem 10 or 12.5 mg (Ambien CR® only) for ≥2 of three months at baseline and ≥2 of three months after intervention. • Percentage of women with a dose reduction to recommended doses in ≥2 of three months following intervention. • Percentage of men with a dose reduction to recommended doses in ≥2 of three months following intervention. • Percentage change in patients on any zolpidem product for ≥2 of three months at baseline and ≥2 of three months following intervention. • Number of patients who switched medications used for the treatment of insomnia following intervention. • Number of patients who switched from generic zolpidem to brand name sedative hypnotics following intervention. • Change in quantity of zolpidem dispensed per patient from baseline and following intervention. • Percentage of prescribers who were unaware of the FDA-recommended dosing changes. • Percentage of prescribers who plan on re-evaluating the patient's therapeutic regimen. • Prescriber rated usefulness of RDUR information on a scale of 1-10.
Preliminary Results	• There were 810 patients that met the criteria prescribed by 450 practitioners. A total of 921 letters were sent as some patients were receiving prescriptions from more than one prescriber. • As of 1/10/14, 172 letters were returned because the prescriber was not at the address listed. • As of 1/10/14, 109 surveys were returned with the following results: o 18 returned surveys noted that the patient was not currently under the care of the prescriber contacted. o 2 returned surveys noted that the pharmacy claims were inaccurate for the patient.

Medical Condition	Zolpidem Dosing Recommendations for Insomnia
	o 52 returned surveys noted that the prescriber was aware of the FDA dosing recommendations. o 52 returned surveys noted that the patient had an inadequate response to lower doses of zolpidem. o 48 returned surveys noted that the patient was stabilized on the current dose of zolpidem with a good response. o 44 returned surveys noted that the patient was counseled regarding the risk of impairment in activities that require alertness, including driving the morning following their nightly dose. o 50 returned surveys noted that the prescriber plans to re-assess the patient and reduce the dose of zolpidem (down from 10 or 12.5 mg or greater per day). o 14 returned surveys noted that the prescriber plans to maintain this patient's current therapeutic regimen with the most common reason being stability. o The average utility rating of the survey was a 7 with the majority rating a 7 or higher (14% for a rating of 7, 10% for a rating of 8, 17% for a rating of 9, and 23% for a rating of 10).
References	1. Bonnet MH. Overview of insomnia. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2013 [cited 2013 Aug 5]. Available from: http://www.utdol.com/utd/index.do 2. Shochat T, Umphress J, Israel AG, Ancoli-Israel S. Insomnia in primary care patients. Sleep. 1999 May 1;22 Suppl 2:S359-65. 3. Kessler RC, Berglund PA, Coulouvrat C, Hajak G, Roth T, Shahly V, et al. Insomnia and the performance of US workers: results from the America insomnia survey. Sleep. 2011 Sep 1;34(9):1161-71. 4. Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. J Clin Sleep Med. 2008 Oct 15;4(5):487-504. 5. Drug Facts and Comparisons 4.0 [database on the Internet]. St. Louis: Wolters Kluwer Health, Inc.; 2013 [cited 2013 Aug 5]. Available from: http://online.factsandcomparisons.com. 6. FDA Drug Safety Communication: Risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist) [press release on the Internet]. Rockville (MD): Food and Drug Administration (US); 2013 Jan 1 [cited 2013 Aug 7]. Available from: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01587.html.