

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
October 13, 2010**

<p><b>Drug Utilization Review Board</b> Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital / Cedar Crest Room Topeka, KS</p>	<p><b>Members Present:</b> Michael Burke, M.D., Ph.D., Chair John Kollhoff, Pharm.D. Judy McDaniel Dowd, PA-C Daniel Sutherland, R.Ph. Roger Unruh, D.O. Kevin Waite, Pharm.D.</p> <p><b>Members Absent:</b> Dennis Grauer, Ph.D.</p> <p><b>KHPA Staff Present:</b> LeAnn Bell, Pharm.D. Shelly Liby Marlene Shellenberger</p> <p><b>HP Enterprise Services Staff Present:</b> Deb Quintanilla, R.N. Lisa Todd, R.Ph.</p> <p><b>HID Staff Present:</b> Nicole Churchwell, Pharm.D.</p>	<p><b>Representatives:</b> Jerry Clewell, Abbott Mike LaFond, Abbott Patrick Dors, Abbott Jeff Knappen, Allergan Michele Puyear, Amgen Teresa Blair, Amgen Nick Boyer, AstraZeneca Jim Graves, BMS Jennifer Murff, CMFHP Mark Veerman, J &amp; J Susan Zalenski, J &amp; J Catherine Fox, KUMC Nina Hicks, KUMC Patty Howard, Med Immune Sam Smethers, Med Immune Barbara Baner, Novartis Elex Scheels, Novartis Russ Wilson, OMJ Mark Weisz, Otsuka Phil King, Pfizer Jessie Bazi, Purdue Greg Hoke, Reckitt Benckiser Lon Lorey, Self Annie Palmer, Taro Pharma</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Burke, Chair called the meeting to order at 10:06 a.m.	
II. Announcements	<p>Dr. Bell announced that Dr. Robert Moser, MD. has recently joined the DUR Board following his nomination by the Kansas Medical Society. He is with the KU School of Medicine, Department of Family and Community Medicine in Wichita.</p> <p>Dr. Bell asked the public to fill out the conflict of interest forms if they intended to speak to the board and advised there was a limit of five minutes to speak.</p> <p>Dr. Bell also advised the group of the appropriate parking location, which is on the west side of the HP facility.</p>	
III. Health Information Designs Inc.	Dr. Churchwell presented highlights from the program assessment. Following the presentation the board was asked to select five topics for intervention for the Fiscal Year	

A. Program Assessment

2011 RetroDUR program.

*Program Assessment*

Yearly Totals

During the State Fiscal Year (SFY) of 2010 (July 1, 2009 through June 30, 2010), the Kansas Health Policy Authority (KHPA) Medical Programs paid over \$161 million (rebates not included) on over 2 million prescriptions for fee-for-service (FFS) beneficiaries. This was a \$13.2 million decrease in prescription expenditures from SFY 2009, when KHPA Medical Programs paid over \$175 million. While the total expenditure decreased from SFY 2009 to SFY 2010 the total number of claims increased by 56,086 and the average cost per claim decreased by \$8.64.

Total claims increased from SFY 2009 to SFY 2010 while total claims cost decreased, this can be attributed to three factors:

- Aggressive management of State Maximum Allowable Cost (SMAC); during SFY 2010 over 10,000 NDCs were placed on SMAC.
- The Third Party Liability (TPL) Cost Avoidance policy was implemented in January 2009.
- An increase in generic availability in many costly drug classes including anticonvulsants and proton-pump inhibitors.

In SFY 2010 KHPA Medical Programs had a total membership increase of over 3,700, a 1.4% increase from SFY 2009. While the total membership increased the average cost per member decreased by \$57 (8.8%) from SFY 2009. Total Users (defined as a member who received at least one prescription) increased by 2,700 (2.3%) while the average cost per user decreased by \$147 (9.8%) from SFY 2009.

Therapeutic Drug Class Reporting

Trends from SFY 2009 to SFY 2010 were reviewed by therapeutic class by both total number of claims and total claims cost. Amphetamines had the highest percent increase in the total number of claims (8.04%) and Penicillins had the highest percent decrease (2.23%). Amphetamines are considered a mental health drug class which, by state statute, are exempt from management.

The two most significant changes in total claims cost from SFY 2009 to SFY 2010 is the increase of 37.83% in the Miscellaneous CNS Agents and a 58.06% decrease in the Miscellaneous Anticonvulsants class. The Miscellaneous CNS Agents class includes drugs like Strattera® and Intuniv® (mental health medications). The Miscellaneous Anticonvulsants class had many agents that became generically available during SFY 2010.

The total number of claims for anticonvulsants did not change significantly from SFY 2009 to SFY 2010; therefore, it was concluded the release of generic products within this drug class reduced total claim costs. Agents that became generically available included: Keppra®, Depakote®, and Topamax®.

#### Conclusion

- There was an increase in total prescription claims while total claims cost decreased.
- Several therapeutic classes continue to be the top expenditure for KHPA Medical Programs. These classes include antipsychotic agents, antidepressants, opiate agonists, hemostatics and antiretrovirals.
- Several agents that appear on both the top drugs by total cost and total claims are used to treat mental health conditions. KHPA Medical Programs currently has no restrictions placed on these medications due to a statutory restriction.
- Generic availability in several classes, aggressive management of SMACs and TPL cost avoidance implementation had a significant impact in KHPA Medical Programs expenditures.

#### *State Fiscal Year 2010 RetroDUR Overview*

#### DUR Newsletters

Four newsletters were mailed to both prescribers and pharmacies, reporting on the following topics:

- Preferred Drug List Updates
- American Academy of Pediatrics Updated Synagis Guidelines
- 2009-2010 Influenza Season Update
- Understanding Bioequivalence
- Dispense as Written Prior Authorization process
- Asthma Treatment Guidelines
- FDA Safety Warning: Long-Acting Beta-Agonists
- Proper Storage of Antibiotics
- Head Lice Treatments Overview

#### Academic Detailing Visits

A total of sixty-one academic detailing visits were completed in SFY 2010.

- Twenty prescribers were visited as prescribers who received multiple intervention letters.
- Eleven prescribers were visited for having the highest overall prescribing volume.
- Thirty prescribers were visited to explain the new narcotic edit that will be

implemented, these prescribers were the highest prescribers of narcotics.

RetroDUR Profile Reviews

B. Fiscal Year 2011  
Intervention Selection

In SFY 2010 five interventions took place, the interventions focused on sedative hypnotics, atypical antipsychotic duplication, muscle relaxants, diabetes and dyslipidemia. There were a total of 522,308 criteria hits for FY2010. 3,962 profiles were reviewed resulting in 2,939 cases More than 3,000 letters were mailed with a response rate of 34%.

The board did not have any questions.

*State Fiscal Year 2011 Intervention Topic Selection*

Dr. Churchwell indicated that a total of five interventions will be selected by the board and completed in SFY 2011. The topics to choose from were:

- Increased risk of serotonin syndrome
- Bipolar disorders
- Appropriate ADD/ADHD treatment
- Increased risk of seizures
- Psychotropics in kids
- Appropriate narcotic utilization
- ACE inhibitors/ARBs
- Addictive sedation
- Appropriate Singulair® utilization
- History of drug abuse
- Appropriate antiulcer agent utilization

Dr. Burke inquired about results from previous interventions. Dr. Churchwell advised that the report from previous intervention would take six months from the last mailing, which was in June 2010, and should be ready around January 2011.

Board Discussion: Dr. Bell advised that Dr. Grauer, who was not able to attend the meeting, had submitted his five recommendations prior to the meeting. These were: Appropriate ADD/ADHD Treatment, Psychotropics in Kids, Additive Sedation, History of Drug Abuse, and Increased Risk of Seizures.

Dr. Waite recommended that Psychotropics In Kids be one of the topics selected, as this class continues to represent a large expenditure for KHPA. Ms. Dowd agreed and added that this class was last reviewed in 2005.

Dr. Waite also recommended reviewing Appropriate ADD/ADHD Treatment, noting the

	<p>increase in number of total claims and costs for the Therapeutic Class (which includes ADD/ADHD). Dr. Burke commented that the age range of those receiving this type of diagnoses and treatment should be a concern. Dr. Bell remarked that there have been several new agents recently added to this class.</p> <p>Both Mr. Sutherland and Dr. Kollhoff expressed interest in including Appropriate Narcotic Utilization for review and Mr. Sutherland asked how this would differ from the History of Drug Abuse topic. Dr. Churchwell responded that different criteria would be reviewed in each topic.</p> <p>Dr. Burke pointed out that HID included on the one-page summary for Appropriate Narcotic Utilization that "...several new narcotic limitations have just been approved by the DUR board and are in the process of implementation..." and asked if selecting one of these related topics now would be complementary or premature to the new DUR policy. The consensus of the group was that the selection of one or both of these topics would complement the recent DUR action on narcotic limitations.</p> <p>Ms. Dowd asked about the frequency of Serotonin Syndrome being seen in outpatients. Dr. Waite added that it is difficult to diagnose but this topic would tie into appropriate use of tramadol and also would flag prescribing patterns for other narcotics that are amiss. Dr. Bell added that, the Prescription Monitoring Program (PMP), which will be operational in Spring 2011, allows prescribers and pharmacists to review patients' profiles for all controlled drugs, regardless of who wrote the prescription and/or what pharmacy filled it.</p> <p>Dr. Kollhoff asked if a cost analysis or clinical evaluations had been completed for each of these intervention topics; Dr. Churchwell advised that these proposed topics were selected on the number of beneficiaries impacted.</p> <p>The five selections approved by the board members were:</p> <ol style="list-style-type: none"> <li>1. Increased Risk of Serotonin Syndrome</li> <li>2. Appropriate ADD/ADHD Treatment</li> <li>3. Psychotropics in Kids</li> <li>4. Appropriate Narcotic Utilization</li> <li>5. History of Drug Abuse</li> </ol>	<p>Dr. Unruh moved to approve the list of five intervention topics as listed in the minutes.</p> <p>Ms. Dowd seconded the motion.</p> <p>Motion carried unanimously.</p>
<p>IV. Old Business</p> <p>A. Review and Approval of 4/14/10 Meeting Minutes</p>	<p>Dr. Burke requested that, on Page 5 of the draft minutes, the first sentence of the fourth paragraph be amended to read: "Dr. Burke said the board has been trying to ..... discourage uncontrolled experimentation due to Medicaid resources being so limited....".</p>	<p>Ms. Dowd moved to approve the minutes as amended by Dr. Burke.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>Motion carried unanimously.</p>

B. Lidoderm®

**Background:** This agenda item was carried over from the April 2010 DUR Board meeting. Lidoderm® (lidocaine patches) is FDA approved for the treatment of post-herpetic neuralgia. Use of Lidoderm for the treatment of diabetic neuropathy is not FDA approved, but is supported in medical literature and is listed in DrugDex as an accepted use. Claims review has shown a significant amount of use without a diagnosis of post-herpetic neuralgia or diabetic neuropathy. In April 2010 the DUR Board was presented with proposed PA criteria, at that time they requested additional data.

**MANUAL GUIDELINES:** *The following drug(s) requires prior authorization:*

*Lidoderm® (lidocaine patch 5%)*

**CRITERIA:** *(must meet all of the following)*

- *Patient must be at least 18 years old.*
- *Patient must have a diagnosis of post-herpetic neuralgia OR diabetic neuropathy.*
- *Maximum quantity of 90 patches per month.*

**Prior Authorizations will be approved for 1 year.**

**Note:** *First prescription can be filled for a quantity of 30 without a prior authorization, subsequent fills will require a prior authorization with a maximum quantity of 90.*

**Public Comment:** None.

**Board Discussion:** Members reviewed utilization data for Lidoderm, noting that from January through June 2010. A total of 563 beneficiaries had been prescribed this agent for a total cost of approximately \$304,000, and 495 of those beneficiaries did not have a diagnosis of post-herpetic neuralgia or diabetic neuropathy; meaning that about 85% were being prescribed Lidoderm for other indications. It was also noted that most states use a PA process for Lidoderm and require a diagnosis of post-herpetic neuralgia on their criteria.

Dr. Burke advised he had recently spoken with a colleague from a Wichita pain management clinic who agreed that this product could be effectively used by patients with chronic pain such as lower back or fascia pain.

Dr. Waite added that it seems to be frequently prescribed for post-operative pain as well. This would be a short-term use of the agent.

Mr. Sutherland moved to accept the PA criteria for Lidoderm®

Dr. Waite seconded the motion.

Motion carried unanimously.

	<p>Discussion was held to amend the proposed PA by adding a quantity limit and allowing the first fill without a PA. For subsequent fill requests use would be limited to diagnoses of post-herpetic neuralgia or diabetic neuropathy.</p> <p>Dr. Burke cautioned that the DUR Board does not promote off-label use of a product, however there seemed to be evidence that this medication was useful in treating chronic pain conditions other than post-herpetic neuralgia or diabetic neuropathy.</p> <p>Mr. Sutherland asked what the process would be to allow this product for those Medicaid patients who do not have neuralgia or diabetes but for whom this product is effective with their pain condition; Dr. Bell responded those patients could request that an administrative level review of this product be done and provide a peer-review published journal or other supporting literature.</p>	
<p>V. New Business</p> <p>A. Preferred Drug List (PDL) Update</p>	<p><u>Background:</u> In June 2010 the Preferred Drug List (PDL) Committee approved new agents for inclusion in classes that have previously been reviewed by the PDL Committee. This was an information only agenda item and required no action by the DUR Board, as the non-preferred criteria for each of these classes had already been reviewed and approved by the Board:</p> <ol style="list-style-type: none"> <li>1) Actemra® (tocilizumab) was approved for inclusion in the Biologics class</li> <li>2) Exalgo® (hydromorphone) was approved for inclusion in the Long-Acting Opioids class</li> <li>3) Vimovo® (naproxen/esomeprazole) was approved for inclusion in the Oral Non-Steroidal Anti-Inflammatory class</li> <li>4) Edluar® (zolpidem sublingual) was approved for inclusion in the Drugs for Insomnia class.</li> </ol>	No action required by the DUR Board on this item.
<p>B. Ophthalmic Antihistamine/Mast Cell Stabilizer Combinations</p>	<p><u>Background:</u> In June 2010 the PDL Committee approved this drug class for inclusion on the PDL. Drugs in this class include: Alaway® (ketotifen), Refresh® (ketotifen), Zaditor® (ketotifen), Bepreve® (bepotastine), Elestat®, (epinastine), Optivar®, (azelastine), Pataday® (olopatadine), and Patanol® (olopatadine). The standard Non-Preferred PDL PA criteria were presented. These PA criteria will apply to all non-preferred agents in the class, which may change in the future as a result of pricing changes of agents in the class.</p> <p><u>Public Comment:</u> There were no public comments.</p>	See Agenda item F for Board action.
<p>C. Pancreatic Enzyme Replacement Products</p>	<p><u>Background:</u> In June 2010 the PDL Committee approved this drug class for inclusion on the PDL. Drugs in this class include: Creon® (pancrelipase), Zenpep® (pancrelipase), and Pancrease MT® (pancrelipase). The standard Non-Preferred PDL PA criteria were presented. These PA criteria will apply to all non-preferred agents in the class, which may change in the future as a result of pricing changes of agents in the class.</p>	

	<p><u>Public Comment:</u> Public comments were provided by: 1) Catherine Fox, MS, RD, LD, with the KU Pediatric and Adult Cystic Fibrosis Clinic; and 2) Mark Veerman with Johnson &amp; Johnson.</p> <p>Ms. Fox requested that all Pancreatic Enzyme drugs be placed on the PDL to provide cystic fibrosis patients with all available options. She advised that there are only three FDA approved products available now, there had been five on the market but not all were approved by FDA.</p> <p>Dr. Burke commented that all agents are available through the PA process.</p> <p>Mr. Veerman advised that “Pancrease MT” is the same product and same formulation as “Pancreaze”. The slight change in brand name had been made due to a new drug application process required by the FDA. He also advised that not all these products are interchangeable and that FDA has information on its website about the therapeutic inequivalency of these agents.</p>	See Agenda item F for Board action.
D. Topical Non-Steroidal Anti-Inflammatory Agents	<p><u>Background:</u> In June 2010 the PDL Committee approved this drug class for inclusion on the PDL. Drugs in this class include: Flector® Patch (diclofenac), Voltaren® Gel (diclofenac), and Pennsaid® Solution (diclofenac). The standard non-preferred PDL PA criteria were presented. These PA criteria will apply to all non-preferred agents in the class, which may change in the future as a result of pricing changes of agents in the class.</p> <p><u>Public Comment:</u> There were no public comments.</p>	See Agenda item F for Board action.
E. Calcium Channel Blocker/Angiotensin II Receptor Blocker Combinations	<p><u>Background:</u> In January 2010 the PDL Committee approved this class for inclusion on the PDL. Drugs in this class include: Azor® (amlodipine/olmesartan), Twynsta® (amlodipine/telmisartan), and Exforge® (amlodipine/valsartan). The standard non-preferred PDL PA criteria were presented. These PA criteria will apply to all non-preferred agents in the class, which may change in the future as a result of pricing changes of agents in the class.</p> <p><u>Public Comment:</u> There were no public comments.</p>	See Agenda item F for Board action.
F. Intranasal Antihistamines	<p><u>Background:</u> In June 2010 the PDL committee approved this class for inclusion on the PDL. Drugs in this class include: Patanase® (olopatadine), Astelin® (azelastine), and Astepro® (azelastine). The standard non-preferred PDL PA criteria were presented. These PA criteria will apply to all non-preferred agents in the class, which may change in the future as a result of pricing changes of agents in the class.</p> <p><u>Public Comment:</u> There were no public comments.</p>	A motion was made by Dr. Kollhoff to approve the PDL Non-Preferred PA Criteria for these five classes: Ophthalmic Antihistamine/Mast Cell Stabilizer Combinations, Pancreatic Enzyme Replacement Products, Topical Non-Steroidal Anti-Inflammatory Agents, Calcium Channel Blocker/Angiotensin II Receptor

		<p>Combinations, and Intranasal Antihistamines.</p> <p>Dr. Unruh seconded the motion.</p> <p>Motion carried unanimously.</p>
<p>G. Long-Acting Opioids</p>	<p><b>Background:</b> In April 2010 the DUR board approved dose optimization limits for long-acting opioids to assist in the reduction of fraud and abuse and increase the cost-effectiveness of chronic narcotic use. A proposal is being made to add three additional agents for dose optimization: Duragesic® Patches (fentanyl), Exalgo® (hydromorphone), and Butrans® Patches (buprenorphine).</p> <p><b>MANUAL GUIDELINES:</b> <i>All long-acting formulations containing any of the following agents at units per day above DUR Board determined limit:</i></p> <p><i>Buprenorphine</i>  <i>Fentanyl</i>  <i>Hydromorphone</i>  <i>Morphine</i>  <i>Oxycodone</i>  <i>Oxymorphone</i>  <i>Tramadol</i></p> <p><b>CRITERIA:</b> <i>(Must meet one of the following)</i></p> <p>1. <i>Patient is terminally ill.</i></p> <p>OR</p> <p>2. <i>Patient has a diagnosis of cancer.</i></p> <p>OR</p> <p>3. <i>Must meet all of the following:</i></p> <p>a. <i>Patient is taking no other long-acting opioid agents.</i></p> <p>b. <i>All narcotic analgesics are prescribed by a single KMAP enrolled Prescriber or Practice.</i></p> <p>c. <i>Patient does not have a diagnosis of opioid or other substance abuse within the past year.</i></p> <p>d. <i>Patient has signed a treatment agreement with the Prescriber</i></p> <p><b>RENEWAL CRITERIA:</b> <i>(must meet initial prior authorization criteria in addition to the following)</i></p> <ul style="list-style-type: none"> <li><i>No more than one early refill attempt in the past three months unless proper documentation from the prescriber that the patient's dose was being titrated during</i></li> </ul>	<p>Mr. Sutherland moved to accept the updated PA criteria, to add the three additional agents for dose optimization limits for long-acting opioids.</p> <p>Dr. Waite seconded the motion.</p> <p>Motion carried unanimously.</p>

	<p><i>this period.</i></p> <p><i>Length of Prior Authorization: 3 months</i></p> <p><u>Public Comment:</u> There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Kollhoff referred to the utilization handout and questioned why methadone is not included in this chart. Dr. Churchwell responded that the drugs listed in the handout are available in multiple strengths and methadone comes in limited strengths which does not allow for inclusion of methadone in a dose optimization edit. Dr. Bell added that the Board could have an upper daily limitation added for methadone. Dr. Burke stated that the methadone discussion would be tabled for now but that the Board should consider including methadone in the narcotic edits at a future date. Lisa Todd cautioned that currently the claims processing system could not override the quantity-per-day limitation on individual strengths so for methadone the Board may want to recommend a different type of restriction.</p>	
<p>H. Suboxone® and Subutex®</p>	<p><u>Background:</u> Suboxone® (buprenorphine/naltrexone) &amp; Subutex (buprenorphine) currently require PA. The current maximum daily dose is 40mg, the package insert recommends doses of 4-24mg for maintenance.</p> <p>Dr. Bell advised that, following information shared at a recent conference regarding usage of these products, proposed changes were made to the current PA to reduce the daily dosing to 24 mg rather than 40 mg; add separate criteria for Subutex; and add renewal criteria.</p> <p><b>MANUAL GUIDELINES:</b> <i>The following drug(s) requires prior authorization:</i></p> <p style="text-align: center;"><i>Buprenorphine/Naloxone (Suboxone® SL Tablet &amp; SL Film) and Buprenorphine (Subutex®)</i></p> <p><b>CRITERIA for Suboxone (buprenorphine/naloxone):</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must have a diagnosis of opioid dependence.</i></li> <li>• <i>Patient must be actively involved in addiction treatment.</i></li> <li>• <i>Qualified prescribing physician (under Drug Addiction Treatment Act of 2000) must provide confirmation of their waiver from SAMHSA.</i></li> <li>• <i>Prescribing provider must practice in Kansas or Border City and be a Kansas Medicaid Provider.</i></li> <li>• <i>Daily dosing is not to exceed 24mg.</i></li> </ul> <p><b>CRITERIA for Subutex (buprenorphine):</b> <i>(must meet all criteria for Suboxone and one of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must be pregnant.</i></li> <li>• <i>Patient must have a documented medical allergy to Naloxone.</i></li> </ul>	<p>Ms. Dowd moved to accept the revised PA criteria for Suboxone and Subutex, with amendments by the Board as noted.</p> <p>Mr. Sutherland seconded the motion.</p>

	<p><b>RENEWAL CRITERIA:</b> (must meet all initial criteria and the following)</p> <ul style="list-style-type: none"> <li>• Patient has not received any other narcotic agents since last PA approval.</li> </ul> <p><b>Prior Authorization will be approved for 3 (three) months.</b></p> <p><u>Public Comment:</u> : Greg Hoke with Reckitt Benckiser provided comments on the proposed criteria.</p> <p><u>Board Discussion:</u> Dr. Burke suggested that “...sublingual tablet and film...” be added under “Manual Guidelines”, as Dr. Churchwell reported that a sublingual film was now available in addition to sublingual tablets. Dr. Burke also reported he had discussed the updated PA criteria with a colleague in Sedgwick County who is currently a specialist in addiction treatments and that his colleague was comfortable with the amended PA criteria.</p> <p>On a related note, Dr. Burke asked if a review could be done of the PA criteria used within the managed care organizations to coordinate the criteria used, as apparently the Medicaid MCOs are using different criteria. Dr. Bell responded that she would follow-up on this request.</p> <p>Dr. Kollhoff indicated some reservation on limiting Subutex use to only beneficiaries who are pregnant or have an allergy to Naloxone, as this drug is dramatically more cost-effective than Suboxone. He stated he was aware of the risk of abusing this product but expressed hesitation on limiting a product that would provide cost-savings for the state.</p> <p>Dr. Bell remarked that, according to the utilization data provided to the Board, there hadn’t been any usage of Subutex at all for previous six months and that there were only 23 beneficiaries who were using Suboxone. Dr. Burke added that there didn’t seem to be a big issue of over-utilization of either product right now and that the amendments proposed to the PA criteria were within the package insert guidelines.</p> <p>Dr. Waite commented that with the added restrictions to the PA criteria, it would further discourage abuse or addiction which could result in even further overall cost savings.</p> <p>The Board decided to add “...patient must have documented medical allergy to Naloxone...” to the Subutex criteria.</p>	<p>Motion carried with a unanimous vote.</p>
<p>I. Soma® (carisoprodol)</p>	<p><u>Background:</u> Soma is approved for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults. The recommended maximum duration of Soma use is up to two or three weeks. The recommended dose of Soma is 250-350mg four times a day. A review of KMAP utilization data shows beneficiaries using Soma at higher doses and</p>	

durations longer than recommended by the package insert. Soma has abuse potential and has been known to be abused along with other agents to potentiate euphoria from narcotics. The proposed limit is four tablets a day for 21 days, once a year. Additional courses of therapy will require prior authorization.

**MANUAL GUIDELINES:** *The following drug(s) require prior authorization:*  
*Carisoprodol (Soma®)*  
*Carisoprodol/Aspirin (Soma Compound®)*  
*Carisoprodol/Aspirin/Codeine (Soma Compound with Codeine®)*

**CRITERIA for carisoprodol containing products:** *(must meet one of the following)*

- *Patient is being tapered off of carisoprodol.*
  - *Taper schedule must be included with PA request. Taper must be complete within 21 days.*

*OR*

- *Patient has had new muscle injury resulting in the necessity of additional days supply of carisoprodol.*
  - *Documentation of new muscle injury must be included with PA request.*

**Prior Authorization will be approved for one fill (maximum of 21 days supply).**

Public Comment: None.

Board Discussion: Dr. Burke advised this product is placed on the non-preferred list because the PDL Committee could not locate efficacy data on this product at a previous meeting and could not approve for placement on the preferred drug list. He added that, although the product is inexpensive, there is high potential for abuse and for safety reasons this PA criteria has been proposed to place stricter yearly limitations on these agents.

Dr. Waite added that, because of the highly addictive potential, he does not carry the product and works with his patients to find an alternative product.

Mr. Sutherland asked why this product was even being offered to Medicaid beneficiaries, since there are less-addictive products available. Dr. Bell responded that, if the manufacturer of a drug has signed a rebate agreement with CMS, then State Medicais are required to cover the product

The Board reviewed a suggested tapering schedule for this product which could be shared with prescribers. Discussion was held related to the length of time for the tapering schedule. Dr. Burke suggested amending the sentence in the criteria as follows: "Taper schedule must be included with PA request, not to exceed 21 days."

Dr. Waite moved to accept the amended PA criteria, to include Dr. Burke's amendment.

Dr. Unruh seconded the motion.

Motion carried unanimously.

J. Nucynta® (tapentadol)

Background: Nucynta® was approved in July 2009 as an opioid analgesic for the relief of

	<p>moderate to severe acute pain in adults. According to the package insert, daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days are not recommended. The proposed limit is 18,100mg per month ((600mg x 30days) + 100mg additional for first day = 18,100mg).</p> <p><u>Public Comment:</u> Mark Veerman with Johnson &amp; Johnson commented on the proposed criteria.</p> <p><u>Board Discussion:</u> Dr. Burke asked if this product was on the short-acting opioid list, and Dr. Churchwell confirmed that it was. She advised that this product had not been added with morphine equivalence from the package insert due to mechanism of action, it was added based on dosing in studies.</p> <p>It was clarified that there were no proposed PA criteria for this agenda item as the Board action today would be to simply limit the quantity and not to request a system override.</p>	<p>Dr. Kollhoff moved to accept the quantity limitations for this product.</p> <p>Mr. Sutherland seconded the motion.</p> <p>Motion carried unanimously.</p>
<p>K. Prolia® (denosumab)</p>	<p><u>Background:</u> Prolia® was recently approved for the treatment of osteoporosis in postmenopausal women at high risk for fracture or those who have failed or are intolerant to other osteoporosis treatments. Prolia is a human IgG2 monoclonal antibody with affinity and specificity for human RANKL (receptor activator of nuclear factor kappa-B ligand). Included in today's meeting packets were the package insert and proposed PA criteria.</p> <p><b>MANUAL GUIDELINES:</b> <i>The following drug(s) require prior authorization: Denosumab (Prolia®)</i></p> <p><b>CRITERIA:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must be postmenopausal.</i></li> <li>• <i>Patient must have a diagnosis of osteoporosis.</i></li> <li>• <i>Patient must have either:</i> <ul style="list-style-type: none"> <li>○ <i>A history of osteoporotic fracture or multiple risk factors for fracture.</i></li> <li>○ <i>Failed or are intolerant to other available osteoporosis therapies (examples: alendronate, risedronate, ibandronate, or zoledronic acid).</i></li> </ul> </li> <li>• <i>Patient recommended to take Calcium and Vitamin D concurrently.</i></li> <li>• <i>Maximum of 1 injection every 6 months.</i></li> </ul> <p><b>Prior authorization will be approved for 1 (one) year.</b></p>	<p>Ms. Dowd made motion to accept the PA criteria for this product, with the amendment as stated in the minutes.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>Motion carried unanimously.</p>

	<p><u>Public Comments:</u> None provided.</p> <p><u>Board Discussion:</u> Dr. Burke stated that the PA criteria had been taken from package insert and that each injection (maximum of 1 injection every 6 months) would require authorization.</p> <p>Ms. Dowd suggested amending the timeframe for PA approval on the criteria, changing to a 12-month period rather than six months.</p>	
<p>L. Botox®, Dysport®, &amp; Myobloc®</p>	<p><u>Background:</u> Recently the FDA approved a new indication for the treatment of spasticity in flexor muscles of the elbow, wrist and fingers for onabotulinumtoxinA as well as mandated a name change for the botulinum toxins to reduce medication errors.</p> <p><b>MANUAL GUIDELINES:</b>     <i>The following drug(s) require prior authorization:</i>  <i>OnabotulinumtoxinA (Botox®)</i>  <i>AbobotulinumtoxinA (Dysport®)</i>  <i>RimabotulinumtoxinB (Myobloc®)</i></p> <p><b>CRITERIA for OnabotulinumtoxinA:</b> <i>(must meet one of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment of Upper Limb Spasticity in elbow, wrist, or finger flexors, Cervical Dystonia, Primary Auxiliary Hyperhidrosis, Blepharospasm, or Strabismus.</i></li> </ul> <p><b>CRITERIA for AbobotulinumtoxinA and RimabotulinumtoxinB:</b> <i>(must meet the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment of Cervical Dystonia.</i></li> </ul> <p><b>NOTES:</b> <i>Use of Botulinum Toxins will NOT be approved for cosmetic purposes.</i></p> <p><b>Prior Authorization will be approved for six (6) months.</b> <i>Subsequent authorizations granted for up to two (2) injections in six (6) months and no injections less than three (3) months apart.</i></p> <p><u>Public Comments:</u> None provided. However Jeff Knappen with Allergan responded to an inquiry from Dr. Burke (see next paragraph).</p> <p><u>Board Discussion:</u> Dr. Churchwell reviewed the revised criteria for Botox which would now include the new indication, treatment of spasticity in flexor muscles of the elbow, wrist and fingers. She added that the criteria for Dysport and Myobloc had not changed and confirmed that the use of Botulinum Toxins would not be approved for cosmetic purposes.</p> <p>Dr. Burke asked which providers would be prescribing these products, noting that the</p>	<p>Mr. Sutherland made motion to accept the revised PA criteria for these products.</p> <p>Ms. Dowd seconded the motion.</p> <p>Motion carried unanimously.</p>

	<p>criteria did not specify any provider. Mr. Knappen responded that prescribing providers could include ophthalmologists, dermatologists, neurologists, and rehabilitation specialists.</p>	
M. Xiaflex®	<p><b>Background:</b> Xiaflex® was recently approved by the FDA for the treatment of adult patients with Dupuytren’s contracture and a palpable cord. Due to the wide range of indications the drug manufacturer has explored and the cost of the medication, placement on prior authorization is proposed.</p> <p><b>MANUAL GUIDELINES:</b>     <i>The following drug(s) require prior authorization: Collagenase Clostridium Histolyticum (Xiaflex®)</i></p> <p><b>CRITERIA:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must have a diagnosis of Dupuytren’s Contracture with a palpable cord.</i></li> <li>• <i>Patient must be 18 years of age or older.</i></li> <li>• <i>Maximum of 3 injections per cord given at 4 week intervals.</i></li> </ul> <p><b>Prior Authorization will be approved for three (3) months. Subsequent authorizations may be granted for additional cords.</b></p> <p><b>Public Comments:</b> None.</p> <p><b>Board Discussion:</b> Dr. Burke stated that, although this product has a specific indication, there might be some motive to use off-label and that the Board is being proactive by considering these criteria.</p> <p>Dr. Churchwell clarified that the PA would be approved for only one cord (3 injections per cord) and that subsequent authorizations would be needed for additional cords.</p>	<p>Mr. Sutherland made motion to accept the PA criteria for this product.</p> <p>Dr. Unruh seconded the motion.</p> <p>Motion carried unanimously.</p>
Beriner®	<p><b>Background:</b> Beriner® is a plasma-derived C1 esterase inhibitor (human) indicated for the treatment of acute abdominal or facial attacks of hereditary angioedema. Currently, Cinryze® the only other C1 esterase inhibitor available is on PA for routine prophylaxis against angioedema attacks in patients with hereditary angioedema (HAE).</p> <p><b>MANUAL GUIDELINES:</b>     <i>The following drug(s) require(s) prior authorization: Beriner® (C1 Esterase Inhibitor (human))</i></p> <p><b>CRITERIA:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must have a diagnosis of Hereditary Angioedema (HAE).</i></li> <li>• <i>Must be used for the treatment of an acute abdominal or facial attack of HAE.</i></li> <li>• <i>Patient must be 13 years of age or older.</i></li> </ul>	<p>Dr. Kollhoff made motion to accept the PA criteria for this product.</p> <p>Ms. Dowd seconded the motion.</p> <p>Motion carried unanimously.</p>

	<ul style="list-style-type: none"> <li>• <i>Must be administered by a healthcare professional.</i></li> </ul> <p><b><i>Prior Authorization will be approved for six (6) months.</i></b></p> <p><u>Public Comments:</u> None.</p> <p><u>Board Discussion:</u> Dr. Burke stated that the Board typically treats all the drugs in a given class the same so these criteria are being proposed, and are consistent with the package insert.</p>	
O. Remicade®	<p><u>Background:</u> Remicade is a biologic approved for the treatment of Crohn’s Disease, Ulcerative Colitis, Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Plaque Psoriasis. The PA criteria for Ankylosing Spondylitis, Crohn’s Disease and Ulcerative Colitis have been revised to follow the current package insert..</p> <p><b>MANUAL GUIDELINES:</b>     <i>The following drug(s) require prior authorization: Infliximab (Remicade®)</i></p> <p><b>CRITERIA for Rheumatoid Arthritis (RA):</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must have a diagnosis of moderate to severe, active rheumatoid arthritis.</i></li> <li>• <i>Must be used in combination with Methotrexate</i></li> <li>• <i>Must be prescribed by a Rheumatologist.</i></li> <li>• <i>Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.</i></li> <li>• <i>Patient must be 18 years of age or older.</i></li> </ul> <p><b>CRITERIA for Psoriatic Arthritis:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must have a diagnosis of active Psoriatic Arthritis.</i></li> <li>• <i>Must be prescribed by a Rheumatologist.</i></li> <li>• <i>Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.</i></li> <li>• <i>Patient must be 18 years of age or older.</i></li> </ul> <p><b>CRITERIA for Ankylosing Spondylitis (AS):</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must have a diagnosis of active Ankylosing Spondylitis.</i></li> <li>• <i>Must be prescribed by a Rheumatologist.</i></li> <li>• <i>Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.</i></li> <li>• <i>Patient must be 18 years of age or older.</i></li> </ul> <p><b>CRITERIA for Crohn’s Disease:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must have a diagnosis of moderate to severe, active Crohn’s Disease.</i></li> </ul>	<p>Dr. Waite made motion to accept the revised PA criteria for this product. Dr. Kollhoff seconded. Motion carried unanimously.</p>

- *Documentation of inadequate response to conventional therapies. Conventional therapy for Crohn’s Disease would include the following drugs: 5-ASA (Mesalamine and Rowasa), Sulfasalazine, Corticosteroids (prednisone, etc.), and Budesonide (Entocort EC).*
- *Must be prescribed by a Gastroenterologist.*
- *Evaluation of latent tuberculosis infection with TB skin test prior to initial PA.*
- *Patient must be 6 years of age or older.*

**CRITERIA for Ulcerative Colitis:** *(must meet all of the following)*

- *Patient must have a diagnosis of moderate to severe, active Ulcerative Colitis.*
- *Documentation of inadequate response to conventional therapies. Conventional therapy for Ulcerative Colitis would include the following drugs: Mesalamine, Sulfasalazine, and Corticosteroids (prednisone, etc.).*
- *Must be prescribed by a Gastroenterologist.*
- *Evaluation of latent tuberculosis infection with TB skin test prior to initial PA.*
- *Patient must be 18 years of age or older.*

**CRITERIA for Plaque Psoriasis:** *(must meet all of the following)*

- *Patient must have a diagnosis of chronic severe plaque psoriasis.*
- *Patients must be candidates for systemic therapy or phototherapy.*
- *Must be prescribed by a Dermatologist.*
- *Evaluation of for latent tuberculosis infection with TB skin test prior to initial PA.*
- *Patient must be 18 years of age or older.*

**NOTE:** *This drug carries a Black Box Warning for increased risk of lymphomas, tuberculosis, invasive fungal infections and other opportunistic infections.*

**Prior Authorization will be approved for six (6) months.**

Public Comments: None.

Board Discussion: Dr. Burke commented that the changes to the criteria include removal of a criterion from ankylosing spondylitis and addition of a criterion to Crohn’s disease and ulcerative colitis.

Dr. Bell confirmed that the changes are consistent with the package insert.

P. Enbrel®

Background: Enbrel is a biologic approved for the treatment of Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis and Juvenile Idiopathic

Arthritis. The PA criteria have been updated to follow the current package insert. Included in the meeting packets were the package insert and revised PA criteria.

Dr. Bell advised that the proposed revisions to this PA criteria is consistent with the criteria for other biologics.

**MANUAL GUIDELINES:** *The following drug(s) require prior authorization:  
Etanercept (Enbrel®)*

**CRITERIA for Rheumatoid Arthritis (RA):** *(must meet all of the following)*

- *Patient must have a diagnosis of moderate to severe, active rheumatoid arthritis.*
- *Must be prescribed by a Rheumatologist.*
- *Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.*
- *Patient must be 18 years of age or older.*

**CRITERIA for Psoriatic Arthritis:** *(must meet all of the following)*

- *Patient must have a diagnosis of active Psoriatic Arthritis.*
- *Must be prescribed by a Rheumatologist or Dermatologist.*
- *Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.*
- *Patient must be 18 years of age or older.*

**CRITERIA for Ankylosing Spondylitis (AS):** *(Must meet all of the following)*

- *Patient must have a diagnosis of active Ankylosing Spondylitis.*
- *Must be prescribed by a Rheumatologist.*
- *Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.*
- *Patient must be 18 years of age or older.*

**CRITERIA for Plaque Psoriasis:** *(must meet all of the following)*

- *Patient must have a diagnosis of chronic moderate to severe plaque psoriasis.*
- *Patients must be candidates for systemic therapy or phototherapy.*
- *Must be prescribed by a Rheumatologist or Dermatologist.*
- *Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.*
- *Patient must be 18 years of age or older.*

**CRITERIA for Juvenile Idiopathic Arthritis:** *(must meet all of the following)*

- *Patient must have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis.*
- *Must be prescribed by a Rheumatologist.*

Dr. Kollhoff made motion to accept the revised PA criteria for this product.

Ms. Dowd seconded the motion.

Motion carried unanimously.

	<ul style="list-style-type: none"> <li>• <i>Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.</i></li> <li>• <i>Patient must be 2 years of age or older.</i></li> </ul> <p><b><u>NOTE:</u></b>        <i>This drug carries a Black Box Warning for increased incidence of serious skin infections and tuberculosis.</i>  <i>Enbrel® (etanercept) may be used as monotherapy or first line without regard to Methotrexate and Disease Modifying Anti-Rheumatic Drugs (DMARDs).</i></p> <p><b><i>Prior Authorization will be approved for six (6) months.</i></b></p> <p><b><u>Public Comments:</u></b> Michelle Puyear from Amgen requested the Board consider adding “Dermatologist” back into the criteria for Psoriatic Arthritis.</p> <p>Susan Zalenski with Johnson and Johnson asked if plans were being made to change criteria for other Biologics.</p> <p><b><u>Board Discussion:</u></b> Dr. Burke suggested that “Rheumatologist” be added back into the criteria for Plaque Psoriasis. The Board agreed to both additions.</p> <p>Dr. Bell advised that Medicaid Pharmacy staff would review the criteria for other biologics to determine whether or not revisions were needed for other agents.</p>	
Adjourn	<p>Dr. Kollhoff requested that a review of gabapentin be placed on the DUR meeting agenda for next meeting. The meeting was adjourned at 1:00 p.m.</p> <p>The DUR Board is scheduled to meet next on Wednesday, January 12, 2011.</p>	