

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
January 12, 2011**

<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 Dennis Grauer, Ph.D. John Kollhoff, Pharm.D. Daniel Sutherland, R.Ph. Kevin Waite, Pharm.D. <b>Members Absent:</b> Judy McDaniel Dowd, PA-C Roger Unruh, D.O. <b>KHPA Staff Present:</b> LeAnn Bell, Pharm.D. Shelly Liby Marlene Shellenberger <b>HP Enterprise Services Staff Present:</b> Deb Quintanilla, R.N. Lisa Todd, R.Ph. <b>HID Staff Present:</b> Nicole Churchwell, Pharm.D.</p>	<p><b>Representatives:</b> Barbara Belcher, Merck Grant Cale, BMS Jim Graves, BMS Phil King, Pfizer Rob Pearson, GSK Julie Graham, Centocor Terry Rehmus, Centocor Jeff Knappen, Allergan Laura Nichols, GSK Teresa Blair, Amgen Susan Zalenski, J &amp; J Chet Steckler, Purdue Joe Summers, Takeda Carol Curtis, AstraZeneca Mike LaFond, Abbott Tyler Hunter, Gilead</p>
<b>TOPIC</b>	<b>DISCUSSION</b>	<b>DECISION AND/OR ACTION</b>
<p>I. Call to Order</p>	<p>Dr. Burke, Board Chair, called the meeting to order at 10:12 a.m.</p>	
<p>II. Announcements</p>	<p>Dr. Bell announced that Dr. Robert Moser had requested to withdraw his recent nomination to the DUR Board, as he had been named to serve as a member of the Governor's Cabinet. Follow-up will be made with the Kansas Medical Society to obtain another nomination, representing the medical associations.</p> <p>Dr. Bell asked the members of the general public to complete a conflict of interest form if they intended to provide public comments to the Board and advised the group of the five-minute limitation. Dr. Bell also advised the group of the appropriate parking location, which is on the west side of the HP facility.</p>	
<p>III. Old Business A. Review and Approval of October 13, 2010 Meeting Minutes</p>	<p>There were no revisions to the meeting minutes.</p>	<p>Dr. Kollhoff moved to approve the minutes as written. Mr. Sutherland seconded the motion. Motion carried unanimously.</p>

<p>B. Neurontin® (gabapentin)</p> <ol style="list-style-type: none"> <li>i. Diagnosis Restrictions</li> <li>ii. Public Comment</li> <li>iii. Board Discussion/Action</li> </ol>	<p><u>Background:</u> Dr. Bell advised a request had been made by Dr. Kollhoff at the October 2010 DUR meeting, to schedule a review of Gabapentin at the next DUR meeting. She advised that the DUR Board held discussions in early 2008 regarding the diagnosis restrictions placed on Gabapentin due to off-label marketing and use, whether those restrictions should remain or be removed, or if restrictions should be placed on all adjunct anti-epileptics. In May 2008, the Board subsequently approved to remove all diagnosis code restrictions on the adjunct anti-epileptics while maintaining current quantity and PA restrictions on Lyrica. Dr. Bell continued that, since all new/revised policies with fiscal impact to the Kansas Medicaid Program are reviewed by the agency's internal policy team, that team had determined that implementing this policy change would be too costly and did not approve. The DUR Board discussed this issue again at the July 2009 meeting, at which time members were advised additional utilization data was being compiled. Dr. Bell reported that, at the current time, the policy is still pending until a more refined cost estimate impact can be developed.</p> <p><u>Public Comment:</u> There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Kollhoff added he thought that the diagnosis code restriction placed on Gabapentin was because of the initial high cost of the product but that now the price has decreased considerably and that Lyrica is more expensive. Dr. Bell suggested that the fiscal impact may be improved if the policy was revised to remove the restrictions for only Gabapentin, if the Board would want to consider that option. Dr. Burke recommended that the Board table this discussion until the next meeting, requested this item be reflected on the next meeting agenda as follow-up discussion to a prior DUR action, and asked that copies of the past DUR minutes relating to this discussion be forwarded to the Board members.</p>	<p>Dr. Kollhoff moved to table the gabapentin discussion until the next DUR meeting, when the claims analysis is available. Dr. Grauer seconded the motion. Motion carried unanimously.</p>
<p>IV. New Business</p> <p>A. Botulinum Toxins (Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA), Myobloc® (rimabotulinumtoxinB), Xeomin® (incobotulinumtoxinA))</p> <ol style="list-style-type: none"> <li>i. Revised Clinical PA Criteria</li> <li>ii. Public Comment</li> <li>iii. Board Discussion/Action</li> </ol>	<p><u>Background:</u> Recently the FDA approved a new indication for onabotulinumtoxinA and a new agent in the botulinum toxin class, incobotulinumtoxinA. The botulinum toxins currently require prior authorization and revisions are being proposed to follow the current package inserts for each agent in the class.</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>  <i>IncobotulinumtoxinA (Xeomin®)</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>Prophylaxis of headaches in patients with chronic migraines (≥ 15 days per month with headache lasting 4 hours a day or longer).</i></li> <li>• <i>Treatment of upper limb spasticity in elbow, wrist or finger flexors.</i></li> <li>• <i>Treatment of cervical dystonia</i></li> </ul>	<p>Dr. Waite moved to accept the revised PA criteria. Dr. Kollhoff seconded the motion. Motion carried unanimously.</p>

	<ul style="list-style-type: none"> <li>• Treatment of severe primary auxiliary hyperhidrosis that is inadequately managed with topical agents.</li> <li>• Treatment of blepharospasm or strabismus.</li> </ul> <p><b>CRITERIA for AbobotulinumtoxinA and RimabotulinumtoxinB:</b> (must meet the following)</p> <ul style="list-style-type: none"> <li>• Treatment of cervical dystonia.</li> </ul> <p><b>CRITERIA for IncobotulinumtoxinA:</b> (must meet the following)</p> <ul style="list-style-type: none"> <li>• Treatment of cervical dystonia.</li> <li>• Treatment of blepharospasm in adults previously treated with onabotulinumtoxinA.</li> </ul> <p><b>NOTES:</b> Use of Botulinum Toxins will <b>NOT</b> be approved for cosmetic purposes.</p> <p><b>Prior Authorization will be approved for six (6) months.</b> Subsequent authorizations granted for up to two (2) injections in six (6) months and no injections less than three (3) months apart.</p> <p><u>Public Comment:</u> There were no public comments.</p> <p><u>Board Discussion:</u> The proposed PA criteria were briefly reviewed, noting the new criteria added for incobotulinumtoxinA. Dr. Grauer questioned how the new criteria related to the limitation of “.....15 days per month....” would be documented. Dr. Churchwell responded medical documentation would be used.</p>	
<p>B. Kalbitor® (ecallantide)</p> <ol style="list-style-type: none"> <li>New Clinical PA Criteria</li> <li>Public Comment</li> <li>Board Discussion/Action</li> </ol>	<p><u>Background:</u> Kalbitor was recently approved for the treatment of acute attacks of hereditary angioedema. The two other agents used for hereditary angioedema, Cinryze and Berinert require prior authorization. For consistency across the class, a proposal is being made to add a prior authorization to this agent.</p> <p><b>MANUAL GUIDELINES:</b> The following drug(s) require prior authorization: Ecallantide (Kalbitor®)</p> <p><b>CRITERIA for Ecallantide:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must be 16 years of age or older.</li> <li>• Patient must have a diagnosis of hereditary angioedema (HAE).</li> <li>• Must be used for the treatment of an acute attack of HAE.</li> <li>• Must be administered by a healthcare professional.</li> </ul> <p><b>Prior authorization will be approved for 6 (six) months.</b></p>	<p>Dr. Kollhoff moved to approve the new criteria. Dr. Waite seconded the motion. Motion carried unanimously.</p>

	<p><u>Public Comment:</u> There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke asked if the three agents (Kalbitor, Cinryze, and Berinert) had separate PA criteria. Dr. Bell responded affirmatively and that the utilization was very low for these agents. Dr. Churchwell mentioned that these agents had slightly different indications, some indicated for treatment and others for prophylaxis which accounts for the differences in PA criteria as the board usually follows the package insert for the PA criteria.</p>	
<p>C. Qulaquin® (quinine)</p> <ol style="list-style-type: none"> <li>i. New Clinical PA Criteria</li> <li>ii. Public Comment</li> <li>iii. Board Discussion/Action</li> </ol>	<p><u>Background:</u> Qulaquin is the only FDA approved prescription quinine sulfate for the treatment of uncomplicated Plasmodium falciparum malaria. Quinine has historically been used for the treatment of leg cramps, but this is not an approved indication for this drug. Over the counter quinine remedies are still available. New prior authorization criteria are being proposed which follows the FDA indication as outlined in package insert.</p> <p><b>MANUAL GUIDELINES:</b> <i>The following drug(s) require prior authorization: Quinine (Qulaquin®)</i></p> <p><b>CRITERIA for Quinine:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must be 16 years of age or older.</i></li> <li>• <i>Patient must have a diagnosis of uncomplicated Plasmodium falciparum malaria.</i></li> </ul> <p><b>Prior authorization will be approved for 7 (seven) days.</b></p> <p><b>NOTE:</b> <i>Qulaquin is not approved for the treatment of severe or complicated P. falciparum, prevention of malaria, or the treatment or prevention of nocturnal leg cramps.</i></p> <p><u>Public Comment:</u> There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke stated that quinine has regularly been used off-label for treating leg cramps and that these PA criteria would only restrict the use of Qulaquin to follow the FDA indications.</p>	<p>Dr. Grauer moved to approve the new criteria. Mr. Sutherland seconded the motion. Motion carried unanimously.</p>
<p>D. Crinone® (progesterone)</p> <ol style="list-style-type: none"> <li>i. New Clinical PA Criteria</li> <li>ii. Public Comment</li> <li>iii. Board Discussion/Action</li> </ol>	<p><u>Background:</u> Crinone is a FDA approved for two indications: 1) use with assisted reproductive technology and 2) secondary amenorrhea. Fertility treatments are not a covered benefit under KS Medicaid, and prior authorization criteria is being proposed to ensure use of this product only for secondary amenorrhea.</p>	

	<p><b>MANUAL GUIDELINES:</b> <i>The following drug(s) require prior authorization: Progesterone (Crinone®)</i></p> <p><b>CRITERIA for Progesterone:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must be 18 years of age or older.</i></li> <li>• <i>Patient must have a diagnosis of secondary amenorrhea.</i></li> </ul> <p><b>Prior authorization will be approved for 6 (six) months.</b></p> <p><b>NOTE:</b> <i>Use of Crinone will NOT be approved for fertility purposes.</i></p> <p><u>Public Comment:</u> There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke reiterated that the FDA approved indication for this product did include fertility treatments and secondary amenorrhea but the proposed PA would specify the patient must have diagnosis of secondary amenorrhea as KS Medicaid does not cover fertility treatments.</p>	<p>Dr. Kollhoff moved to approve the new criteria. Mr. Sutherland seconded the motion. Motion carried unanimously.</p>
<p>E. Humira® (adalimumab)</p> <ol style="list-style-type: none"> <li>i. Revised Clinical PA Criteria</li> <li>ii. Public Comment</li> <li>iii. Board Discussion/Action</li> </ol>	<p><u>Background:</u> Humira currently requires prior authorization; the criteria currently require a patient have documentation of inadequate response to methotrexate or disease modifying antirheumatic drugs (DMARDs) for plaque psoriasis, which is inconsistent with the package insert. Revised prior authorization criteria are being proposed to more accurately match the package insert.</p> <p><b>MANUAL GUIDELINES:</b> <i>The following drug(s) require prior authorization: Adalimumab (Humira®)</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 prescribed by a Rheumatologist.</i></li> <li>• <i>Evaluation for latent tuberculosis 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 or Dermatologist.</i></li> <li>• <i>Evaluation for latent tuberculosis with TB skin test prior to initial PA.</i></li> </ul>	<p>Dr. Waite moved to accept the revised criteria. Dr. Kollhoff seconded the motion. Motion carried unanimously.</p>

- 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 with TB skin test prior to initial PA.
- Patient must be 18 years of age or older.

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

- Patient must have a diagnosis of moderate to severe, active juvenile idiopathic arthritis.
- Must be prescribed by a Rheumatologist.
- Evaluation for latent tuberculosis with TB skin test prior to initial PA.
- Patient must be 4 years of age or older.

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

- Patient must have a diagnosis of moderate to severe, active plaque psoriasis.
- Patient must be a candidate for phototherapy or systemic therapies.
- Documentation that other systemic therapies are medically less appropriate.
- Must be prescribed by a Rheumatologist or Dermatologist.
- Evaluation for latent tuberculosis with TB skin test prior to initial PA.
- Patient must be 18 years of age or older.

**CRITERIA for Crohn's Disease:** (must meet all of the following)

- Patient must have a diagnosis of moderate to severe, active Crohn's Disease.
- Documentation of inadequate response to conventional therapies. Conventional therapy for Crohn's Disease would include: 5-ASA (Mesalamine and Rowasa), Sulfasalazine, Corticosteroids (prednisone and others) and Budesonide (Entocort EC).
- Must be prescribed by a Gastroenterologist.
- Evaluation for latent tuberculosis with TB skin test prior to initial PA.
- Patient must be 18 years of age or older.

**WARNING:** This drug carries a Black Box Warning: Increased incidence of serious infections and tuberculosis.

**NOTE:** Humira® may be used as monotherapy or 1<sup>st</sup> line without regard to Methotrexate and Disease Modifying Antirheumatic Drugs (DMARD) for Adult RA, Psoriatic Arthritis, Ankylosing spondylitis, and Juvenile Idiopathic Arthritis.

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

	<p><u>Public Comment:</u> There were no public comments.</p> <p><u>Board Discussion:</u> . Dr. Churchwell noted that the removal of DMARDs information would follow the package insert. Dr. Waite questioned what type of documentation would need to be submitted to PA indicating medically less appropriate. Dr. Bell responded a letter from a physician indicating patient is allergic to Methotrexate, for example. Mr. Sutherland asked if the provider could submit a list of treatments the patient has tried which were not effective; but Dr. Bell responded that could not be required as that would be considered step therapy which is not allowed under the Kansas Medicaid Program but would be acceptable documentation for the PA.</p>	
<p>F. Amevive® (alefacept)</p> <p>i. Revised Clinical PA Criteria</p> <p>ii. Public Comment</p> <p>iii. Board Discussion/Action</p>	<p><u>Background:</u> Amevive currently requires prior authorization; revised prior authorization criteria are being proposed today to more accurately match the package insert. The current criteria require documentation of inadequate response to conventional therapies for plaque psoriasis, which is inconsistent with the package insert.</p> <p><b>MANUAL GUIDELINES:</b>     <i>The following drug(s) require prior authorization: Alefacept (Amevive®)</i></p> <p><b>CRITERIA for Alefacept:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient has a diagnosis of moderate to severe chronic plaque psoriasis.</i></li> <li>• <i>Patient must be a candidate for phototherapy or systemic therapy.</i></li> <li>• <i>Patient must be 18 years of age or older.</i></li> <li>• <i>Documentation of appropriate lab testing for renewal</i></li> <li>• <i>Prescribed by a Dermatologist or Rheumatologist.</i></li> </ul> <p><b><u>WARNINGS:</u></b> <i>Increased risk of lymphopenia, malignancies, and serious infections.</i></p> <p><i>Lab Recommendations: Monitor total lymphocyte and CD4 and T cell counts prior to initiation of therapy and prior to each dose. Withhold if CD4 and T-Lymphocyte counts are below 250 cells/ul. If counts remain below 250 cells/ul. For one month, then drug should be discontinued.</i></p> <p><i>Amevive is contraindicated if Beneficiary is HIV+.</i></p> <p><b><i>Prior Authorization will be approved for six (6) months.</i></b></p> <p><u>Public Comment:</u> There were no public comments.</p>	<p>Mr. Sutherland made motion to accept revised PA criteria with the changes made per Board discussion. Dr. Grauer seconded the motion. Motion carried unanimously.</p>

	<p><u>Board Discussion:</u> Dr. Burke noted the specific “Lab Recommendations” at bottom of the current criteria and added that these types of recommendations have been added to PA criteria to increase awareness about risks associated with the drug. He expressed some concern with the HIV statement on the current PA criteria. Dr. Kollhoff stated the HIV statement would be more appropriate on the PA approval form rather than the PA criteria sheet. Dr. Bell asked HP Pharmacy staff if the provider’s letter could be customized when a PA is approved. Ms. Quintanilla responded that customized remarks are usually added in the approval letter under “Analyst Remarks”. Discussion was held about removing the “Lab Recommendations” from the PA criteria, as providers are already being requested to submit lab results. Dr. Burke suggested reformatting the PA criteria to boldface “Warnings”, add bullets for the statement regarding increased risk of lymphopenia, for the statement about lab recommendations, and for the statement about the patient being HIV+.</p>	
<p>G. Remicade® (infliximab)</p> <ol style="list-style-type: none"> <li>i. Revised Clinical PA Criteria</li> <li>ii. Public Comment</li> <li>iii. Board Discussion/Action</li> </ol>	<p><u>Background:</u> Remicade currently requires prior authorization, along with the other agents in this class. To maintain consistency, the prescribing provider specialty type is being updated for this agent and the proposed revised criteria reflect this change.</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 or Dermatologist.</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>	<p>Dr. Waite moved to accept the revised criteria. Dr. Kollhoff seconded the motion. Motion carried unanimously.</p>

- Patient must have a diagnosis of moderate to severe, active Crohn’s Disease.
- 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 or Rheumatologist.
- 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 Comment: There were no public comments.

Board Discussion: Dr. Churchwell advised that this proposed criteria will add Dermatologists as a prescribing provider type for a patient with psoriatic arthritis and that Rheumatologists would be added as a prescribing provider type for a patient with plaque psoriasis.

- H. Simponi® (golimumab)
  - i. Revised Clinical PA Criteria
  - ii. Public Comment

Background: Simponi currently requires prior authorization, along with the other agents in this class. To maintain consistency, the prescribing provider specialty type is being updated for this agent and the proposed revised criteria reflect this change.

<p>iii. Board Discussion/Action</p>	<p><b>MANUAL GUIDELINES:</b> <i>The following drug(s) requires prior authorization: Golimumab (Simponi®)</i></p> <p><b>CRITERIA for Rheumatoid 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 moderate to severe, active rheumatoid arthritis.</i></li> <li>• <i>Must be given in combination with methotrexate, unless contraindicated.</i></li> <li>• <i>Must be prescribed by 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 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 Rheumatologist or Dermatologist.</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 old or older.</i></li> </ul> <p><b>CRITERIA for Ankylosing Spondylitis:</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 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 old or older.</i></li> </ul> <p><b><u>WARNINGS:</u></b> <i>Increased risk of invasive fungal infections, including histoplasmosis, coccidioidomycosis, pneumocystosis, and other opportunistic infections.</i></p> <p><b><u>Notes:</u></b> <i>Simponi may be used as monotherapy or 1<sup>st</sup> line without regard to Methotrexate and Disease Modifying Anti-Rheumatic Drugs (DMARD) for Psoriatic Arthritis and Ankylosing Spondylitis</i></p> <p><b><i>Prior Authorization will be approved for six (6) months.</i></b></p> <p><b><u>Public Comment:</u></b> There were no public comments.</p> <p><b><u>Board Discussion:</u></b> Dr. Churchwell advised that this proposed criteria will add Dermatologists as a prescribing provider type for a patient with psoriatic arthritis.</p>	<p>Dr. Grauer moved to accept the revised criteria. Mr. Sutherland seconded the motion. Motion carried unanimously.</p>
<p>I. Stelara® (ustekinumab)</p> <p>i. Revised Clinical PA Criteria</p> <p>ii. Public Comment</p>	<p><b><u>Background:</u></b> Stelara currently requires prior authorization, along with the other agents in this class. To maintain consistency, the prescribing provider specialty type is being updated for this agent and the proposed revised criteria reflect this change.</p>	

<p>iii. Board Discussion/Action</p>	<p><b>MANUAL GUIDELINES:</b> <i>The following drugs requires prior authorization: Ustekinumab (Stelara®)</i></p> <p><b>CRITERIA for plaque psoriasis:</b> <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> <li>• <i>Patient must be 18 years of age or older.</i></li> <li>• <i>Patient must have a diagnosis of moderate to severe plaque psoriasis.</i></li> <li>• <i>Patient must be a candidate for systemic therapy or phototherapy.</i></li> <li>• <i>Must be prescribed by a Dermatologist or Rheumatologist.</i></li> <li>• <i>Evaluation for latent tuberculosis infection with TB skin test prior to initial PA</i></li> </ul> <p><b><u>WARNINGS:</u></b> <i>Stelara should not be in combination with other immunosuppressive agents or phototherapy.</i></p> <p><i>Patients should not receive live vaccinations while being treated with Stelara.</i></p> <p><i>Stelara may increase the risk of infections and reactivation of latent infections.</i></p> <p><b><i>Prior Authorization will be approved for six (6) months.</i></b></p> <p><b><u>Public Comment:</u></b> There were no public comments.</p> <p><b><u>Board Discussion:</u></b> Dr. Churchwell advised that this proposed criteria will add Rheumatologists as a prescribing provider type for a patient with plaque psoriasis.</p>	<p>Dr. Waite moved to accept the revised criteria. Dr. Kollhoff seconded the motion. Motion carried unanimously.</p>
<p>J. Methadose® (Methadone)</p> <p>i. Public Comment</p> <p>ii. Board Discussion/Action</p>	<p><b><u>Background:</u></b> In October 2010 the DUR Board asked that restrictions be considered for methadone as all other opioids have restrictions approved by the DUR Board. Methadone’s unique pharmacokinetic profile means it does not have a linear morphine equianalgesic dose, making it difficult to include in the restrictions placed on short-acting opioids. Since it is available in limited strengths, inclusion in the dose-optimization policy with long-acting opioids is also difficult. The DUR Board is being asked to review utilization data and pharmacokinetic information to determine if/how to place restrictions on methadone.</p> <p><b>MANUAL GUIDELINES:</b> <i>The following drug(s) at doses above 200mg per day require prior authorization: Methadone</i></p> <p><b>CRITERIA:</b> <i>(Must meet one of the following)</i></p> <ol style="list-style-type: none"> <li>1. <i>Patient is terminally ill.</i></li> </ol> <p>OR</p> <ol style="list-style-type: none"> <li>2. <i>Patient has a diagnosis of cancer.</i></li> </ol>	<p>Mr. Sutherland moved to accept the proposed criteria as amended</p>

OR

3. *Must meet all of the following:*

- a. *Patient is taking no other long-acting opioid agents.*
- b. *All narcotic analgesics are prescribed by a single KMAP enrolled Prescriber or Practice.*
- c. *Patient does not have a diagnosis of opioid or other substance abuse within the past year.*
- d. *Patient has signed a treatment agreement with the Prescriber*

***RENEWAL CRITERIA:*** *(must meet initial prior authorization criteria in addition to the following)*

- *No more than one early refill in the prior three months unless proper documentation from the prescriber that the patient's dose was being titrated during this period is provided.*

***Prior Authorization will be approved for three (3) months.***

Upon discussion with Board members, Dr. Burke announced the Board would move into Executive Session for 15 minutes in order to review patient specific sensitive health information related to methadone usage in order to determine appropriate monitoring for this narcotic.

Upon resuming the Open Meeting, Dr. Burke advised that during Executive Session, utilization data had been reviewed which reflected the usage and diagnoses of those Medicaid beneficiaries who had a methadone prescription of over 200 mg per day. It was reported that only 2.4% of the Medicaid beneficiaries prescribed this product fell within that category (of above 200 mg). Dr. Burke stated that the purpose of the Board's review and discussion was not to restrict the use of methadone but rather to better monitor and assure safe usage.

Public Comment: There were no public comments.

Board Discussion: Dr. Churchwell reviewed the proposed PA criteria as well as the Renewal Criteria and added that these proposed revisions follow the current criteria for other opioids. Dr. Burke confirmed that, if a prescribing provider did not have a treatment agreement, an example agreement could be obtained from the Pharmacy PA staff. Dr. Churchwell agreed. Dr. Burke noted that, if a patient had been appropriately using opiate analgesics for a lengthy period of time and developed a tolerance, that could be coded as "opiate dependent" if the provider is using DSM-4 or DSM-5 diagnostic criteria. Since that same code is used when diagnosing an individual who is dependent but not abusing as well

with Board discussion. Dr. Kollhoff seconded the motion. Motion carried by unanimous vote.

	<p>as those dependent and abusing the narcotic, there would need to be a clear distinction provided during the PA process to providers between abuse vs. dependence of this product. Dr. Kollhoff questioned the reasoning of the early refill attempt limitation outlined in the Renewal Criteria. Dr. Bell responded that, if a patient repeatedly requests an early refill, that could point to possible abuse; she clarified that the early refill alert is activated when 80% of the prescribed supply is used, such as needing to refill a 30-day supply after only 24 days have passed. Dr. Waite and Mr. Sutherland both asked how the early refill alert would work for those patients who simply drop off the prescription early for convenience of refilling with no indication of abuse; they also questioned if there is an override for a prescription which is lost or stolen. Ms. Quintanilla added that if a claim is sent by point-of-sale, and a patient is attempting an early refill, that pharmacy claim will be denied due to the early refill alert. Ms. Kluczykowski continued that, if the patient meets the criteria, the pharmacy provider could override that alert. Dr. Bell added that there is no provision for early refills for a lost or stolen prescription. Dr. Burke added that, since the number of beneficiaries in this category is very small, if there are repeated attempts made by a beneficiary to refill early, the PA staff could also do a manual review of that beneficiary’s history to see if there is anything that would point to abuse. Dr. Waite suggested removing “attempt” from the proposed Renewal Criteria and change “past” to “prior” to read “....No more than one early refill in the prior three months....”. Dr. Burke closed the discussion by reiterating that this revised criteria will affect very few Medicaid beneficiaries but that it will increase vigilance on appropriate usage of methadone.</p>	
<p>K. Rosiglitazone Products (Avandia® (rosiglitazone), Avandamet® (rosiglitazone/metformin), Avandaryl® (rosiglitazone/glimepiride))</p> <p>i. Public Comment ii. Board Discussion/Action</p>	<p><u>Background:</u> In September 2010 the FDA announced that rosiglitazone products should be significantly restricted for patients with Type 2 diabetes who cannot control their diabetes on other medications. These recommendations were in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with rosiglitazone. Based on the utilization trend, it appears no DUR action is needed at this time, but we will continue to monitor. This information is therefore an FYI only for Board members.</p> <p><u>Public Comment:</u> Rob Pearson with Glaxo Smith Kline (GSK) provided comments on the recent FDA announcement.</p> <p><u>Board Discussion:</u> Dr. Bell stated she wanted to make members aware of the recent FDA announcement and that, after reviewing related utilization data, there doesn’t appear to be a problem with overutilization of these products at this time and no Board action is needed.</p> <p>Dr. Burke noted that utilization data suggests that clinicians have dramatically reduced prescribing this drug since the September 2010 FDA announcement and agreed that no action was needed by the Board.</p>	<p>FYI topic - no Board action is needed.</p>
<p>L. Single-source prescription limit</p>	<p><u>Background:</u> Kansas Medicaid currently employs a “5 single-source drug limit.” This</p>	

<ul style="list-style-type: none"> <li>i. Review Exemptions</li> <li>ii. Public Comment</li> <li>iii. Board Discussion/Action</li> </ul>	<p>limitation requires that the 6<sup>th</sup>, 7<sup>th</sup>, 8<sup>th</sup>, etc. single-source drug (primarily brand-name medications) a beneficiary fills in a calendar month be medically necessary. Medical necessity is documented on the prescription by the pharmacy and a point-of-sale override allows payment for the medication. KHPA received Legislative direction to reduce the number of allowed single-source drugs from 5 to 4, and to review the current limit exemptions for appropriateness. Current exemptions to the brand limitation are: Kan Be Healthy beneficiaries (anyone under 21 years of age), antiretroviral drugs, anti-rejection drugs used by transplant patients, chemotherapy drugs, antiemetics, interferon, immune globulins, drugs used to treat mental illness, antihemophilic drugs, all contraceptives, preferred drugs on the preferred drug list, and any product in the supplemental rebate program. Per Legislative direction, the DUR Board is to review the appropriateness of the current exclusions, with the exception of mental health drugs and preferred drugs, which were explicitly exempted from consideration by the DUR Board.</p> <p><u>Public Comment:</u> Barbara Belcher, Merck, provided historical background on the placement of specific classes on the exemption list, advising the intent was to make these drugs available to the population – who for the large part are very ill – without limitations.</p> <p><u>Board Discussion:</u> Dr. Bell reviewed an exclusion list of those drugs/classes which are exempt from the single-source limit and stated this list was not all-inclusive, that those listed were examples only. Dr. Burke noted the contraceptive class was listed and had been reviewed by the PDL committee in the past. Dr. Bell responded that the PDL Board reviewed this class in 2009 and determined all were clinically equivalent, mostly based on the individual components at similar dosage ranges. She added that the contraceptive class receives 90% federal match. Dr. Waite asked if there were many beneficiaries who encounter limitations with their drugs; Dr. Bell advised there were not many and that an estimated \$66,000 All Funds would be saved by decreasing the limit from five to four. Dr. Burke added that the limit can be overridden if medical necessity is documented. He suggested possibly removing antiemetics from the exemption list; Dr. Waite advised he would be hesitant to remove that class, due to the lack of availability of some generic drugs. He also remarked that the table of biologics should possibly be added to the exemption list at some later date.</p>	<p>Dr. Waite moved to approve reducing the number of allowed single-source drugs from 5 to 4, and that no changes be made to the classes which are currently exempted.</p> <p>Dr. Grauer seconded the motion.</p> <p>Motion carried unanimously.</p>
<p>M. Health Information Designs, Inc. (HID)</p> <ul style="list-style-type: none"> <li>i. Intervention Outcomes</li> <li>ii. Academic Detailing Visits</li> </ul>	<p><u>Background:</u> HID presented a summary of the Outcomes from SFY2010 Intervention letters. An appendix of the summary contained descriptions of each criteria number, which provided additional information regarding a particular alert message. In addition to reviewing the outcomes summary, the DUR Board will also be asked to provide input for which providers to target for Academic Detailing visits in SFY 2011.</p> <p><u>Public Comment:</u> There were no public comments.</p> <p style="text-align: center;"><b><u>Intervention Outcomes:</u></b></p> <p>Dr. Churchwell provided an overview of the SFY 2010 Intervention Outcomes of the</p>	

	<p>following five topics. These topics had been previously selected by the DUR Board for review in SFY 2010: 1) Sedative Hypnotics; 2) Muscle Relaxants; 3) Atypical Antipsychotic Duplication; 4) Dyslipidemia; and 5) Diabetes. For each topic, a summary was presented on the number of letters generated and mailed, prescriber responses, prescriber evaluations, cycle comparisons, and a summary of estimated cost savings.</p> <p>Dr. Burke commended HID on the work done with the Intervention Outcomes reporting as well as the improved response rate by providers when responding to the intervention letters.</p> <p>Dr. Kollhoff suggested that an additional followup should be made to those prescribers who change therapy for a patient, as a positive reinforcement. Dr. Bell responded she will forward that suggestion to the HID Office, as she is not sure if this type of follow-up service is typically provided by HID in other states.</p> <p style="text-align: center;"><b><u>Academic Detailing Visits:</u></b></p> <p>Dr. Churchwell reported Academic Detailing Visits were made with narcotic prescribers, those prescribers who received multiple intervention letters, and top Medicaid prescribers in SFY 2009 and SFY 2010. She asked Board members to provide recommendations for providers to target with these visits in the future.</p> <p>Dr. Grauer suggested contacting the PA unit as they might have useful suggestions for which additional prescribers to include. Dr. Grauer added it would be helpful to see sampling of provider feedback in the next report made for the Board. Dr. Burke agreed and suggested that a number of the handwritten comments from the intervention responses be added to the next presentation.</p> <p>Dr. Burke advised that no action was needed by Board on this item, as five intervention topics had already been selected for next year.</p> <p>A complete copy of the report is located on the KHPA website at the following address:  <a href="http://www.khpa.ks.gov/pharmacy/pharmacy_dur_program_interventions_outcomes.html">http://www.khpa.ks.gov/pharmacy/pharmacy_dur_program_interventions_outcomes.html</a></p>	<p>No action needed by Board.</p>
<p>V. Additional Public Comments</p>	<p>There were no additional public comments.</p>	
<p>VI. Adjournment</p>	<p>The meeting adjourned at 12:15 pm.  The DUR Board is scheduled to meet next on Wednesday, April 13, 2011, beginning at 10:00 am at the HP Enterprise Services Office.</p>	