

**Drug Utilization Review Board
Meeting Minutes, Open Session
April 14, 2010 (amended 10-13-10)**

<p>Drug Utilization Review Board Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital / Cedar Crest Room Topeka, KS</p>	<p>Members Present: Michael Burke, M.D., Ph.D., Chair John Kollhoff, Pharm.D. Judy McDaniel Dowd, PA-C Brenda Schewe, M.D. Daniel Sutherland, R.Ph. Roger Unruh, D.O. Kevin Waite, Pharm.D. Dennis Grauer, Ph.D. KHPA Staff Present: LeAnn Bell, Pharm.D. Aimee Grubb, Recorder Shelly Liby Margaret Smith, M.D., M.P.H., M.H.S.A. HP Enterprise Services Staff Present: Deb Quintanilla, R.N. Lisa Todd, R.Ph. HID Staff Present Nicole Churchwell, Pharm.D.</p>	<p>Representatives: Mike LaFond, Abbott Jeff Knappen, Allergan Mary Deane, AMAG Teresa Blair, Amgen Charles Dahm, Amgen Nick Boyer, AstraZeneca Carol Curtis, AstraZeneca Cyndee Davies, AstraZeneca Jim Graves, BMS Joe Busby, Eli Lilly Patty Minear, Eli Lilly Dana Evans, Genetech William Dozier, Gilead Susan Zalenski, J & J Todd Paulsen, Novo Nordisk Mary Shefchyk, Novo Nordisk Mark Weisz, Otsuka Jim Baumann, Pfizer Phil King, Pfizer</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Burke, Chair called the meeting to order at 10:01 a.m.	
II. Announcements	Dr. Bell asked the public to fill out the conflict of interest forms if they wanted to speak to the board. There is a limit of five minutes per drug. Also, the public was asked to note on the sign in sheet whether or not they'd like to be on an email distribution list to receive meeting notifications.	
III. Old Business A. Review and Approval of 1/13/10 Meeting Minutes	No changes made.	Dr. Kollhoff moved to approve the minutes. Dr. Unruh seconded and it carried with a unanimous vote.
IV. New Business A. Rituxan [®]	<p>The DUR Board approved clinical prior authorization criteria in January 2010. In February 2010 Rituxan[®] received approval for a new indication, Chronic Lymphocytic Leukemia. This has been added to the clinical PA criteria for approval.</p> <p>MANUAL GUIDELINES: <i>The following drug requires prior authorization: Rituximab (Rituxan[®])</i></p> <p>Criteria for Non-Hodgkin's Lymphoma (NHL) or Chronic Lymphocytic Leukemia (CLL): <i>(must meet all of the following)</i></p>	<p>Ms. Dowd moved to accept changes to the PA criteria for Rituxan[®].</p> <p>Dr. Kollhoff seconded. The motion passed 7-1. Dr. Grauer abstained.</p>

	<ul style="list-style-type: none"> • Patient must be 18 years of age or older • Patient must have a diagnosis of Non-Hodgkin’s Lymphoma or Chronic Lymphocytic Leukemia • Must be prescribed by an oncologist or hematologist <p>Renewal Criteria for NHL or CLL: (must meet initial prior authorization criteria in addition to the following)</p> <ul style="list-style-type: none"> • Documentation of appropriate lab testing (CBC and Platelets) <p>Criteria for Rheumatoid Arthritis(RA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be 18 years of age or older. • Patient must have a diagnosis of moderate to severe, active Rheumatoid Arthritis. • Must be prescribed by a Rheumatologist. • Must be given in combination with methotrexate. • Must have documentation of inadequate response to one or more TNF antagonist therapies. • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA. <p>Renewal Criteria for RA: (must meet initial prior authorization criteria in addition to the following)</p> <ul style="list-style-type: none"> • Documentation of appropriate lab testing (CBC and Platelets) <p>Warnings: This drug carries a Black Box Warning. Fatal infusion reactions, tumor lysis syndrome, severe mucocutaneous reactions, and progressive multifocal leukoencephalopathy may occur.</p> <p>Lab Recommendations: CBC and platelets should be monitored at two to four month intervals during rituximab therapy for Rheumatoid Arthritis. In patients with lymphoid malignancies, during treatment with rituximab monotherapy CBC and platelets should be monitored prior to each course. During treatment with rituximab and chemotherapy, obtain CBC and platelets at weekly to monthly intervals and more frequently in patients who develop cytopenias.</p> <p>Prior Authorization will be approved for six (6) months.</p> <p>Dana Evans, Genentech, said the PA criteria are consistent with the package insert.</p> <p>No board discussion.</p>	
B. Actemra®	Actemra® is a recently approved Targeted Immune Modulator for the treatment of Rheumatoid Arthritis. The other agents in this class require prior authorization.	Dr. Waite moved to accept the PA criteria for Actemra®.

	<p>MANUAL GUIDELINES: <i>The following drug requires prior authorization: Tocilizumab (Actemra®)</i></p> <p>Criteria for Rheumatoid Arthritis: <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> • <i>Patient must be 18 years of age or older.</i> • <i>Patient must have a diagnosis of moderate to severe, active Rheumatoid Arthritis.</i> • <i>Must be prescribed by a Rheumatologist.</i> • <i>Must have documentation of inadequate response to one or more TNF antagonist therapies.</i> • <i>Evaluation for latent tuberculosis infection with TB skin test prior to initial PA.</i> <p>Renewal Criteria: <i>(must meet all of the initial prior authorization criteria in addition to the following)</i></p> <ul style="list-style-type: none"> • <i>Documentation of appropriate lab testing (Neutrophils, Platelets and Liver Function Tests)</i> <p>Warnings: <i>This drug carries a Black Box Warning. Serious infections leading to hospitalization or death including tuberculosis, bacterial, invasive fungal, viral, and other opportunistic infections have occurred in patients receiving tocilizumab.</i></p> <p>Note: <i>Neutrophils, Platelets, and Liver Function Tests should be monitored every 4-8 weeks. Assessment of lipid parameters should be performed 4-8 weeks following initiation of tocilizumab therapy, then at approximately 6 month intervals.</i></p> <p>Prior Authorization will be approved for six (6) months.</p> <p>Dana Evans, Genentech, said the PA criteria are consistent with the package insert.</p> <p>No board discussion.</p>	<p>Mr. Sutherland seconded and it carried with a unanimous vote.</p>
<p>C. Arava®</p>	<p>Arava® currently requires prior authorization; initial approval of PA criteria was in April 2004.</p> <p>MANUAL GUIDELINES: <i>The following drugs requires prior authorization: Leflunomide (Arava®)</i></p> <p>CRITERIA: <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> • <i>Patient must have a diagnosis of active rheumatoid arthritis</i> • <i>Patient must be 18 years of age or older</i> • <i>Must be prescribed by a Rheumatologist</i> <p>RENEWAL CRITERIA: <i>(must meet all of the initial approval criteria in addition to the following)</i></p>	<p>Dr. Kollhoff moved to remove PA for Arava®</p> <p>Dr. Unruh seconded and it carried with a unanimous vote.</p>

	<ul style="list-style-type: none"> • <i>Documentation of appropriate lab testing (Platelet, white blood cell count, hemoglobin or hematocrit and ALTs)</i> <p><u>Warnings:</u> <i>FDA warning of hepatotoxicity – over 50 known cases of liver failure associated with leflunomide</i></p> <p><u>Recommendations:</u> <i>Pregnancy should be excluded <u>before</u> initiation of therapy</i></p> <p><i>Laboratory tests: Platelet, white blood cell count, hemoglobin or hematocrit and ALTs should be monitored at baseline and monthly for six months following initiation of therapy and every 6 to 8 weeks thereafter.</i></p> <p><i>Prior Authorization will be approved for six (6) months.</i></p> <p>No public comment.</p> <p>Dr. Kollhoff questioned the need for PA on this product. Dr. Bell asked Nancy Perry, PA Unit, how many PAs are received for this. She said a few. Dr. Bell said consistency needs to be maintained among all the drugs in the class. Dr. Kollhoff asked if methotrexate is on PA. Dr. Bell said no.</p>	
D. Lidoderm®	<p>Lidoderm® 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.</p> <p>MANUAL GUIDELINES: <i>The following drug(s) requires prior authorization: Lidoderm® (lidocaine patch 5%)</i></p> <p>CRITERIA: <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> • <i>Patient must be at least 18 years old.</i> • <i>Patient must have a diagnosis of post-herpetic neuralgia OR diabetic neuropathy.</i> <p><i>Prior Authorizations will be approved for 6 months.</i></p> <p>No public comment.</p> <p>Dr. Burke said 863 beneficiaries are receiving this product. 108 beneficiaries are receiving Lidoderm for postherpetic neuralgia or diabetic neuropathy, indications that are either FDA approved or recognized in DrugDex, one of the official compendia. The other 755 beneficiaries receiving Lidoderm do not have those diagnoses. Dr. Churchwell randomly</p>	<p>Dr. Schewe moved to table the discussion until next meeting.</p> <p>Dr. Grauer seconded and it carried with a unanimous vote.</p>

reviewed 203 of the 755 to see what other treatments they were receiving and what diagnoses they had. 12 out of the 203 were not receiving any other treatments.

Dr. Burke said there is broad off-label use, should use be redirected toward approved indications. Dr. Waite was concerned about driving patients toward more opioid use. Dr. Schewe said it helps many of her fibromyalgia patients.

Dr. Burke said it may be effective among a broad group of diagnoses.

Mr. Sutherland said the patches are individually packaged so the patient could get a week trial to see if it works before getting a box of 30 patches.

Dr. Burke said the board has been trying to direct treatments toward FDA approved indications and to discourage uncontrolled experimentation due to Medicaid resources being so limited. If the board approves the PA as it is written the patients who don't have a diagnosis of postherpetic neuralgia or diabetic neuropathy will be denied this drug and there will be no basis for an appeal. If the board decides not to put this drug on PA there is a \$600,000 per year budget for Lidoderm[®]. Dr. Grauer suggested having the patients try opioids first and then Lidoderm[®]. Dr. Bell said that is step therapy and that is not allowed by state statute.

Dr. Waite said it is expensive. Dr. Schewe said yes it is, but putting people on long-term narcotics has long-term consequences and cost.

Dr. Burke suggested adding a bullet to the PA that allows a two week trial to explore efficacy. Dr. Grauer asked what happens after those two weeks. Nancy Perry, PA Unit, said that would be a lot of administrative work.

Dr. Bell said from a PA management standpoint it is preferred to follow the FDA approved indications.

A question about cost savings was raised. Dr. Bell said we wouldn't save the \$500,000 that was spent, as those patients that were denied Lidoderm[®] would be switched to another drug.

Dr. Burke asked what third party payers are doing with this. Mr. Sutherland said they want to see treatment failure with something else before they will pay for Lidoderm[®].

Dr. Kollhoff asked if they are getting refills. Dr. Churchwell said the patients that are using it off-label are using it for a longer period of time. Dr. Kollhoff said the numbers average out to about three fills per year per patient. Dr. Waite said he would be interested in how that is distributed. Mr. Sutherland said patients can cut the patch to size so they may not use 30 patches in 30 days. Dr. Kollhoff said it would be interesting to see, based on diagnosis,

	<p>how long patients are receiving therapy.</p> <p>James Lieurance, Endo Pharmaceuticals, said there are a lot of different alternatives such as quantity limit for any off-label use.</p> <p>Dr. Waite suggested we table this until next meeting so more data can be gathered. Dr. Burke asked for more utilization data and would like to know what other states have done. Dr. Churchwell asked what type of utilization data should be provided for review. Dr. Grauer asked to see the number of claims, how many prescriptions per beneficiary, how many patients got refills and how many didn't, etc.</p>	
<p>E. Byetta®</p>	<p>In October 2009 Byetta® was approved for first line treatment of Type 2 Diabetes as an adjunct to diet and exercise to improve glycemic control. Revised criteria reflect the updated labeling as well as efficacy data from a trial published in Clinical Therapeutics comparing exenatide and insulin glargine, which indicates that for patients with a baseline HbA1c of >9.0%, exenatide monotherapy will not be sufficient to obtain therapeutic goal. For baseline HbA1c >9.0% the proposed criteria require concurrent use of oral diabetic therapy.</p> <p>Dr. Bell said previously it was for use after inadequate treatment with oral hypoglycemics now it is approved for first line. It needs to be on PA to prevent off-label use for weight loss.</p> <p>MANUAL GUIDELINES: <i>The following drug(s) requires prior authorization:</i> <i>Exenatide (Byetta®)</i></p> <p>CRITERIA: <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> • <i>Patient must be at least 18 years old.</i> • <i>Patient must have a diagnosis of Type 2 diabetes.</i> <ul style="list-style-type: none"> ○ <i>Diagnosis of Type 2 diabetes must be documented by HbA1c > 6.5%.</i> • <i>Patient must have a HbA1c between 6.5%-9.0%</i> <ul style="list-style-type: none"> ○ <i>Patients with an HbA1c above 9.0% may be approved for use in combination with other oral diabetic agents.</i> <p>RENEWAL CRITERIA: <i>(must meet one of the following)</i></p> <ul style="list-style-type: none"> • <i>Documented improvement of HbA1c from pretreatment levels.</i> • <i>Achievement or maintenance of therapeutic goals (HbA1c ≤ 6.5%).</i> <p><i>Prior Authorizations will be approved for 6 months.</i></p> <p>No public comment.</p> <p>Dr. Kollhoff said using Byetta® first line is not the most cost effective way of managing Type 2 diabetes. Patients should have inadequate response to metformin or sulfonylurea</p>	<p>Dr. Waite moved to accept the PA criteria for Byetta®.</p> <p>Mr. Sutherland seconded and it carried with a unanimous vote.</p>

	before being prescribed Byetta®. Dr. Bell said that is step therapy and by state statute is unallowable.									
F. Victoza®	<p>Victoza® was recently approved for the treatment of Type 2 Diabetes. It is the 2nd agent in the incretin mimetic class. The other incretin mimetic, exenatide (Byetta®), requires prior authorization; establishment of prior authorization criteria for liraglutide will maintain consistency across the class.</p> <p>MANUAL GUIDELINES: <i>The following drug(s) requires prior authorization: Liraglutide (Victoza®)</i></p> <p>CRITERIA: <i>(must meet all of the following)</i></p> <ul style="list-style-type: none"> • <i>Patient must be at least 18 years old.</i> • <i>Patient must have a diagnosis of Type 2 diabetes.</i> <ul style="list-style-type: none"> ○ <i>Diagnosis of Type 2 Diabetes must be documented by HbA1c > 6.5%</i> • <i>Pretreatment documented inadequate glycemic control (HbA1c ≥ 6.5%) with therapy of:</i> <ul style="list-style-type: none"> ○ <i>Maximum tolerated doses of metformin, unless contraindicated, and/or</i> ○ <i>Maximum tolerated doses of sulfonylurea, unless contraindicated.</i> <p>RENEWAL CRITERIA: <i>(Must meet one of the following)</i></p> <ul style="list-style-type: none"> • <i>Documented improvement of HbA1c from pretreatment levels.</i> • <i>Achievement or maintenance of therapeutic goals (HbA1c ≤ 6.5%).</i> <p>Prior Authorizations will be approved for 6 months.</p> <p>Todd Paulsen, Novo Nordisk, said Victoza® is indicated for Type 2 diabetes as adjunct to exercise and diet. It is indicated for monotherapy, but is not first line. It can be given once daily and can be taken any time of day regardless of meals.</p> <p>No board discussion.</p>	<p>Ms. Dowd moved to accept the changes to the PA criteria for Victoza®.</p> <p>Dr. Grauer seconded and it carried with a unanimous vote.</p>								
G. High Dose Short-Acting Opioids	<p>In January 2010 the DUR Board approved prior authorization criteria for high doses of short-acting opioids. The criteria have been revised with an expanded list of opioids as well as more specific criteria to reduce opioid abuse.</p> <p>MANUAL GUIDELINES: <i>All short-acting formulations containing any of the following agents or combination of agents at morphine equivalents greater than 200 mg per day require prior authorization:</i></p> <table style="margin-left: auto; margin-right: auto;"> <tr> <td><i>Hydromorphone</i></td> <td><i>Fentanyl</i></td> </tr> <tr> <td><i>Morphine</i></td> <td><i>Tramadol</i></td> </tr> <tr> <td><i>Oxymorphone</i></td> <td><i>Meperidine</i></td> </tr> <tr> <td><i>Oxycodone</i></td> <td><i>Tapentadol</i></td> </tr> </table>	<i>Hydromorphone</i>	<i>Fentanyl</i>	<i>Morphine</i>	<i>Tramadol</i>	<i>Oxymorphone</i>	<i>Meperidine</i>	<i>Oxycodone</i>	<i>Tapentadol</i>	<p>Mr. Sutherland moved to accept the updated PA criteria for high dose short-acting opioids.</p> <p>Dr. Kollhoff seconded and it carried with a unanimous vote.</p>
<i>Hydromorphone</i>	<i>Fentanyl</i>									
<i>Morphine</i>	<i>Tramadol</i>									
<i>Oxymorphone</i>	<i>Meperidine</i>									
<i>Oxycodone</i>	<i>Tapentadol</i>									

*Hydrocodone
Codeine
Propoxyphene*

*Opium
Pentazocine*

CRITERIA: (Must meet one of the following)

1. Patient is terminally ill.

OR

2. Patient has a diagnosis of cancer.

OR

3. Must meet all of the following:

a. All narcotic analgesics are prescribed by a single KMAP enrolled Prescriber or Practice.

b. Patient does not have a diagnosis of opioid or other substance abuse within the past year.

c. Concurrent therapy with a long-acting opioid.

o If beneficiary had a documented inability to tolerate long-acting opioids, concurrent therapy is not required

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 attempt in the past three months unless proper documentation from the prescriber that the patient's dose was being titrated during this period.

Length of Prior Authorization: 3 months

No public comment.

Dr. Schewe asked how bullet 3a works. Dr. Churchwell said the PA Unit will look at past claims.

Dr. Burke had a concern with bullet 3b because of patients that have gone through detox for substance abuse. Dr. Churchwell said they will be able to get low dose opioids, this PA criteria is for greater than 200mg morphine equivalent.

Dr. Grauer asked how the early refill attempts are being checked. Dr. Bell said the claims engine will show an attempt to fill even it was denied.

Dr. Burke asked about bullet 3d; are there any treatment agreements on file to fax to prescribers that don't have them? Dr. Churchwell said yes, they are easy to find. Dr. Schewe asked if providers will be required to fax it in. Dr. Bell said yes.

	<p>Mr. Sutherland asked if a patient seeks outside of their primary doctor will it reject the claim. Dr. Churchwell said it won't reject, but it will be caught on renewal if they are doctor shopping.</p> <p>Dr. Schewe asked if this will create a lot of work for the PA Unit. Nancy Perry responded that there is an expected increase in PAs in the first few months after implementation but there would also be an expected decrease in PAs after the initial requests.</p>	
<p>H. Long-Acting Opioids</p>	<p>Reduction of fraud and abuse and increase in cost-effective management of chronic pain has been discussed in recent DUR meetings and has been an area of interest for the Kansas Legislature. We are proposing implementation of a dose optimization/dose limitation program for long acting opioids. Of note, one long-acting opioid already has a dosing limitation in place. In May 2002 the DUR board placed a twice daily dosing and 480mg/day limit on OxyContin. Currently the package insert for OxyContin states the medication should be used every 12 hours but the American Pain Society's "Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain" state that in some cases the dosing interval may be decreased for certain long-acting opioids.</p> <p>MANUAL GUIDELINES: <i>All long-acting formulations containing any of the following agents at units per day above determined limit:</i> <i>Morphine</i> <i>Oxycodone</i> <i>Oxymorphone</i> <i>Tramadol</i></p> <p>CRITERIA: <i>(Must meet one of the following)</i></p> <ul style="list-style-type: none"> • <i>Patient is terminally ill.</i> <p>OR</p> <ul style="list-style-type: none"> • <i>Patient has a diagnosis of cancer.</i> <p>OR</p> <ul style="list-style-type: none"> • <i>Must meet all of the following:</i> <ul style="list-style-type: none"> ○ <i>All narcotic analgesics are prescribed by a single KMAP enrolled Prescriber or Practice.</i> ○ <i>Patient does not have a diagnosis of opioid or other substance abuse within the past year.</i> ○ <i>Patient has signed a treatment agreement with the Prescriber</i> <p>RENEWAL CRITERIA: <i>(must meet initial prior authorization criteria in addition to the following)</i></p> <ul style="list-style-type: none"> • <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 this period.</i> 	<p>Dr. Kollhoff moved to accept the PA criteria for long-acting opioids.</p> <p>Mr. Sutherland seconded and it carried with a unanimous vote.</p> <p>Dr. Kollhoff requested having a table created to provide as guidance for pharmacies and clinicians.</p> <p>Dr. Grauer suggested putting this topic in the newsletter.</p>

	<p><i>Length of Prior Authorization: 3 months</i></p> <p>No public comment.</p> <p>Dr. Burke asked why methadone is not included. Dr. Bell said it can be included but in previous discussions it was removed from the list. Dr. Waite asked what the limit would be. There is a limited availability of strengths so it's common for someone to get 8-10 tablets at a time. Dr. Burke suggested leaving Methadone off the list because of the limited strengths available.</p> <p>Mr. Sutherland asked why fentanyl patches aren't included. Dr. Bell said this is currently only for oral long acting opioids. Dr. Waite asked if the PA should say long-acting <u>oral</u> opioids. Dr. Bell said that change can be made.</p> <p>Dr. Churchwell said the criteria are similar to short-acting opioids with the exception of requiring concurrent therapy.</p>	
V. Executive Session	The public was excused for executive session.	
VI. Adjourn	<p>Dr. Schewe turned in her resignation for both the DUR Board and PDL Advisory Committee.</p> <p>The meeting was adjourned at 11:55 a.m.</p>	<p>Dr. Schewe moved to adjourn the meeting.</p> <p>Mr. Sutherland seconded and it carried with a unanimous vote.</p>