

**Drug Utilization Review Board
Meeting Minutes, Open Session
April 10, 2013**

<p>Drug Utilization Review Board Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital Room Topeka, KS</p>	<p>Members Present: Tim Heston, DO John Kollhoff, Pharm.D. Daniel Sutherland, RPh Roger Unruh, D.O. Kevin Waite, Pharm.D. Member Absent: Judy McDaniel Dowd, PA-C DHCF Staff Present: Brandy Allen Kelley Melton, Pharm.D. HP Enterprise Services Staff Present: Karen Kluczykowski, RPh Nancy Perry, R.N. HID Staff Present: Nicole Ellermeier, Pharm.D. MCO Staff Present: Tom Kaye RPh, MBA, FASHP: Sunflower State Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p>Representatives: Darcy Gill, Genentech Sam Smothers, MedImmune Risa Reusuher, Amgen Dave Sproat, Bristol-Myers Mike Hauger, Genentech Brad Clay, Amgen Russ Wilson, Johnson & Johnson, Jen Dabrowski, Allergan Jeff Knappen, Allergan Teresa Blair, Amgen Don Larsen, Forest Jerry Clewell, Abbvie Heather Jones, GSK Joe Summers, Novo Mark Weisz, Otsuka Sumar Bieda, Purdue Matthew Stafford, Merck Terry McCurren, Otsuka Sara Huff, Novartis David Crippen, Novartis Brian Strickland, Gilead Berend Koops, Merck Ted Sheedy, GSK</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>I. Call to Order</p>	<p>Dr. Waite called the meeting to order at 10:05 a.m.</p>	
<p>A. Announcements</p>	<p>Dr. Ellermeier advised the attendees that the parking spaces in the front of the building (east side) are available for the Board members and that there is additional parking on the west side of the HP office for visitors.</p> <p>Dr. Melton thanked the board for their attendance, and mentioned that due to technical issues, sound equipment would not be used at the meeting, so this will have to be taken into account when providing public comment.</p> <p>Dr. Melton introduced Brandy Allen as a new administrative assistant with the state, and announced that Shelly Liby had left the pharmacy program to join the Business Operations Team at Medicaid. Dr. Melton also introduced all 3 MCO Pharmacy Directors: Lisa Todd at Amerigroup, Jennifer Murff at United Healthcare, and Tom Kaye at Sunflower State Health</p>	

	Plan.	
II. Old Business A. Review and Approval of October 10, 2012 DUR Meeting Minutes	The minutes from the October DUR meeting were reviewed.	Dr. Unruh moved to approve the July DUR minutes. Dr. Heston seconded and it carried with a unanimous vote.
III. New Business A. KanCare Prior Authorization Criteria and Limitation Overview <ol style="list-style-type: none"> 1. Amerigroup 2. Sunflower 3. United Healthcare 	<p>Dr. Ellermeier stated that these presentations were being provided so that the board had an overview of what each of the current MCOs was using for PA criteria prior to approving any new criteria.</p> <p>Lisa Todd introduced herself as the pharmacy director at Amerigroup and presented an overview of Amerigroup’s pharmacy program. This included a general overview of the Amerigroup Kansas transition of care, basic benefit and plan design, clinical program, and help desk information.</p> <p>Tom Kaye, Sunflower State Health Plan, stated that in preparation for the meeting, some inaccuracies in some Sunflower process were identified, and had elected not to present until they got these processes rectified. Dr. Melton stated that Sunflower’s agenda items had been removed from this agenda, but that the state is committed to working with Sunflower to working through any issues and getting Sunflower’s information available for the July meeting.</p> <p>Jennifer Murff introduced herself as the Account Manager Pharmacist with United Healthcare in Kansas. She provided an overview of United’s clinical guidelines, quantity limits, diagnosis edits, gender edits, prior authorization processes, and the grievance and appeal processes. Dr. Waite asked if the online tool was available from the KanCare website, but Dr. Melton reported this link was not posted yet. Dr. Melton confirmed with Ms. Murff that only providers can initiate a PA in their online portal. Dr. Heston asked if there was a prior authorization processes to override gender-specific edits. Both Ms. Murff and Ms. Todd confirmed that clinical review would be required for patients who needed to bypass a gender limitation.</p>	
B. Fee-for-Service Criteria	Dr. Melton explained that because the MCOs have adopted and are using state criteria, the DUR Board will need to review revised fee-for-service criteria when there changes, such as updates to package inserts. The MCOs will then also adopt these revisions.	
1. Botulinum Toxins (Botox [®] (onabotulinumtoxinA), Dysport [®] (abobotulinumtoxinA), Myobloc [®] (rimabotulinumtoxinB),	<p><u>Background</u></p> <p>In January 2013 the Food and Drug Administration (FDA) expanded the labeled indications for Botox to include the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults who have an inadequate response to or are intolerant of an anticholinergic medication. Revised prior authorization criteria are being</p>	Dr. Heston made a motion to approve the revised Botox criteria. Mr. Sutherland seconded the

<p>Xeomin[®] (incobotulinumtoxinA));</p> <ol style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>proposed to include this new indication.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR ONABOTULINUMTOXINA: (must meet one of the following)</p> <ul style="list-style-type: none"> • Prophylaxis of headaches in patients with chronic migraines (≥15 days per month with a headache lasting 4 hours a day or longer) • Treatment of upper limb spasticity in elbow, wrist, or finger flexors • Treatment of cervical dystonia • Treatment of severe primary auxiliary hyperhidrosis that is inadequately managed with topical agents • Treatment of blepharospasm or strabismus • Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency or urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury or multiple sclerosis) who have an inadequate response to or are intolerant to an anticholinergic medication <p>CRITERIA FOR ABOBOTULINUMTOXINA AND RIMABOTULINUMTOXINB: (must meet the following)</p> <ul style="list-style-type: none"> • Treatment of cervical dystonia <p>CRITERIA FOR INCOBOTULINUMTOXINA: (must meet one of the following)</p> <ul style="list-style-type: none"> • Treatment of cervical dystonia • Treatment of blepharospasm in adults previously treated with onabotulinumtoxinA <p>Initial authorization will be approved for 6 months. Subsequent authorizations will be granted for up to 2 injections in 6 months, injections must be at least 12 weeks apart.</p> <p>Note: Use of Botulinum Toxins will NOT be approved for cosmetic purposes.</p> </div> <p><u>Public Comments:</u></p> <p>Jennifer Dabrowski, pharmacist with Allergan, stated that the indication is as stated in the package insert and offered to answer any questions during the process today.</p> <p><u>No Board Discussion</u></p>	<p>motion.</p> <p>The motion passed unanimously.</p>
<ol style="list-style-type: none"> 2. Prolia[®] (denosumab) <ol style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comments iii. Board Discussion 	<p><u>Background</u></p> <p>In September 2012 the FDA expanded the labeled indications for Prolia to include treatment to increase bone mass in men with osteoporosis at high risk for fracture or for patients who have failed or are intolerant to other available osteoporosis therapy. Revised prior authorization criteria are being proposed to include this new indication.</p>	<p>Dr. Unruh made a motion to accept Prolia prior authorization criteria</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>

	<p>CRITERIA FOR OSTEOPOROSIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of osteoporosis • Patient is postmenopausal OR a male • Patient must have either: <ul style="list-style-type: none"> ○ A history of osteoporotic fracture ○ Multiple risk factors for fracture (examples of risk factors: low BMI, chronic corticosteroid use, excessive alcohol intake, cigarette smoking, eating disorders, etc.) ○ Failed or are intolerant to at least one other available osteoporosis therapy (examples: alendronate, risedronate, ibandronate, or zoledronic acid) • Maximum of 1 injection every 6 months <p>CRITERIA FOR BONE LOSS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient is at a high risk for fractures • Patient must have either: <ul style="list-style-type: none"> ○ A diagnosis of nonmetastatic prostate cancer and is receiving androgen-deprivation therapy (examples: leuprolide, goserelin, flutamide, nilutamide, or bicalutamide) ○ A diagnosis of breast cancer and is receiving adjuvant aromatase inhibitor therapy (examples: anastrozole, letrozole, or exemestane) <p>LENGTH OF APPROVAL 12 months</p> <p>Note: All patients receiving denosumab should receive 1,000mg of calcium daily and at least 400 IU of vitamin D daily.</p> <p><u>Public Comments</u></p> <p>Brad Clay, PharmD and Medical liaison with Amgen Scientific Affairs stated that osteoporosis does affect men as well, with 27-30% of major osteoporotic fractures occurring in men and with worse mortality in men after a hip fracture. In addition, 1 out of 2 osteoporotic women, if untreated, will experience a major osteoporotic fracture, while this occurs at a rate of 1 out of 3 in men. Dr. Clay also stated that this indication was approved in September, and that the indication was based on a phase 3 trial that showed a statistically significant improvement in lumbar spine bone mineral density compared to placebo.</p> <p>Dr. Heston asked why there was no age limit on the males, but there was on females. Dr. Clay explained that the clinical trial that led to the approval of the indication included men ages 30-85, with a mean age of 65, and that age is a risk factor. Dr. Heston clarified that the package insert appears to limit use of this drug to post-menopausal women. Dr. Clay said that in men a determination of their bone mineral density might be used to determine if therapy was needed.</p> <p><u>No Board Discussion</u></p>	
<p>3. Actemra® (tocilizumab)</p> <ol style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comments iii. Board Discussion 	<p><u>Background</u></p> <p>In October 2012 the indication for rheumatoid arthritis was revised. Actemra is currently indicated for adult patients with moderate to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs. Revised</p>	<p>Mr. Sutherland made a motion to approve Actemra PA criteria.</p> <p>Dr. Unruh seconded the motion.</p>

prior authorization criteria are being proposed to include this new indication.

The motion passed unanimously.

<p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following)</p> <ul style="list-style-type: none">• Patient must have a diagnosis of rheumatoid arthritis• Must be prescribed by a rheumatologist• Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval• Patient must be 18 years of age or older• Patient has not taken another biologic agent (see attached table) in the past 30 days• Must have documentation of inadequate response to one or more TNF antagonist therapies• Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one Disease-Modifying Anti-Rheumatic Drug (DMARD) (see attached table)• Prior to initiation of therapy patient must have an absolute neutrophil count (ANC) $\geq 2,000$ cells/mm³• Prior to initiation of therapy patient must have a platelet count $\geq 100,000$ cells/mm³• Prior to initiation of therapy patient must have normal liver function tests (LFTs) (ALT or AST)<ul style="list-style-type: none">○ 1.5 times the upper limit of normal (ULN) is considered abnormal for tocilizumab therapy initiation <p>RENEWAL CRITERIA FOR RA: (must meet initial criteria in addition to all of the following)</p> <ul style="list-style-type: none">• Documentation of ANC, platelets and LFTs every 4-8 weeks• Documentation of lipid parameters 4-8 weeks after initiation of therapy and then every 24 weeks <p>CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA): (must meet all of the following)</p> <ul style="list-style-type: none">• Patient must have a diagnosis of juvenile idiopathic arthritis• Must be prescribed by a rheumatologist• Evaluation for latent TB with TB skin test prior to initial prior authorization approval• Patient must be 2 years of age or older• Patient has not taken another biologic agent (see attached table) in the past 30 days• Prior to initiation of therapy patient must have an ANC $\geq 2,000$ cells/mm³• Prior to initiation of therapy patient must have a platelet count $\geq 100,000$ cells/mm³• Prior to initiation of therapy patient must have normal LFTs (ALT or AST)<ul style="list-style-type: none">○ 1.5 times the upper limit of normal (ULN) is considered abnormal for tocilizumab therapy initiation <p>RENEWAL CRITERIA FOR JIA: (must meet initial criteria in addition to all of the following)</p> <ul style="list-style-type: none">• Documentation of ANC, platelets and LFTs beginning with the second infusion, then every 2-4 weeks• Documentation of lipid parameters 4-8 weeks after initiation of therapy and then every 24 weeks <p>LENGTH OF APPROVAL 6 months</p>

Public Comments

Darcy Gill, a medical liaison with Genentech, stated that the indication was as presented in the PA criteria, but reminded the board that Actemra is a human monoclonal antibody against the IL-6 receptor, so it does have a novel mechanism of action that is different than a TNF-Inhibitor. It was initially approved to treat rheumatoid arthritis following the failure of a TNF-Inhibitor, but in October 2012, this indication was expanded to include patients who had failed on a DMARD. Ms. Gill reported that the most common DMARDs used are methotrexate, sulfasalazine, and leflunomide. The indication is reflective of the patient population seen in phase 3 and 4 clinical trials, as the majority of patients were refractory to

	<p>a DMARD and naïve to biologics.</p> <p><u>No Board Discussion</u></p>	
<p>4. Humira® (adalimumab)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>In November 2012 the FDA expanded the labeled indications for Humira to include inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressive agents. Revised prior authorization criteria are being proposed to include this new indication.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of rheumatoid arthritis • Must be prescribed by a rheumatologist • Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of juvenile idiopathic arthritis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 4 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR PSORIATIC ARTHRITIS (PSA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of psoriatic arthritis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR ANKYLOSING SPONDYLITIS (AS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of ankylosing spondylitis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days </div>	<p>Dr. Heston made a motion to approve Humira prior authorization criteria.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The motion passed unanimously.</p>

	<p>CRITERIA FOR CROHN'S DISEASE (CD): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Crohn's disease • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has used a conventional Crohn's disease therapy (see attached table) OR there is documentation of inadequate response, contraindication, allergy, or intolerable side effects to a conventional Crohn's disease therapy (see attached table) <p>CRITERIA FOR ULCERATIVE COLITIS (UC): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of ulcerative colitis • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has used a conventional ulcerative colitis therapy (see attached table) OR there is documentation of inadequate response, contraindication, allergy, or intolerable side effects to a conventional ulcerative colitis therapy (see attached table) <p>CRITERIA FOR PLAQUE PSORIASIS (Ps): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of plaque psoriasis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has taken an oral agent for the treatment of plaque psoriasis (see attached table) OR patient is a candidate for systemic therapy or phototherapy <p>LENGTH OF APPROVAL 6 months</p> <p><u>Public Comment</u></p> <p>Dr. Jerry Clewell, AbbVie, stated that the criteria are consistent with the current package labeling but that he is happy to answer any questions.</p> <p><u>No Board Discussion</u></p>	
<p>5. Kineret[®] (anakinra)</p> <ol style="list-style-type: none"> Revised PA Criteria *Public Comments Board Discussion 	<p><u>Background</u></p> <p>In December 2012 the FDA expanded the labeled indications for Kineret to include the treatment of neonatal-onset multisystem inflammatory disease. Revised prior authorization criteria are being proposed to include this new indication.</p>	<p>Dr. Unruh made a motion to approve the criteria for Kineret.</p> <p>The motion was seconded by the Dr. Kollhoff.</p> <p>The motion passed unanimously.</p>

	<p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of rheumatoid arthritis • Must be prescribed by a rheumatologist • Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • Must have a complete blood count, including neutrophil counts prior to initiation of therapy • Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one Disease-Modifying Anti-Rheumatic Drug (DMARD) (see attached table) <p>CRITERIA FOR CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient has not taken another biologic agent (see attached table) in the past 30 days • Must have a complete blood count, including neutrophil counts prior to initiation of therapy <p>RENEWAL CRITERIA: (must meet initial criteria for respective indication in addition to the following)</p> <ul style="list-style-type: none"> • Must have a complete blood count, including neutrophil count in the past 90 days if renewal is within the first year of therapy <p>LENGTH OF APPROVAL 6 months</p>	
<p>C. Managed Care Organization Criteria</p>	<p>Dr. Melton explained those agenda topics in Section C, which is the Managed Care Organization Criteria. She explained that each of the MCOs brought 7-8 topics that they'd like to take to DUR to an internal meeting, and the MCOs decided to collaborate and use each other's criteria. So, the MCO that initially proposed the topic will be presenting, but the other two have had the opportunity to review and approve the criteria. Should any of the 3 MCOs choose to put a presented drug on PA, the criteria presented at DUR are what they would use.</p> <p>Dr. Waite complimented the MCOs on their cooperation and stated that he appreciated their collaboration to make the process as smooth as possible.</p> <p>Dr. Melton also clarified that each drug will have to be taken through the legislative Rules & Regulations process, and stated that the state can keep the board informed throughout the DUR process as to which criteria each MCO chooses to adopt.</p>	
<p>1. Restasis® (cyclosporine)</p> <p>i. PA Criteria</p> <p>ii. *Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Lisa Todd presented the topic. Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Prior authorization criteria are</p>	<p>Dr. Heston made a motion to table the prior authorization criteria for Restasis.</p> <p>Dr. Unruh seconded the motion.</p>

being proposed to ensure appropriate use based on FDA-approved labeling information.

Dr. Ellermeier provided utilization data from the previous year and the first two months of KanCare in 2013. Dr. Waite noted that the usage of Restasis had increased substantially since the first of the year, and Dr. Ellermeier clarified that the utilization from the previous MCOs may be low because of how the data was provided.

CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)

- Diagnosis of keratoconjunctivitis sicca (dry eyes)
- Not currently using topical anti-inflammatory drugs (e.g. topical ophthalmic corticosteroids)
- Not currently using punctal plugs
- Does not currently have an active ocular infection
- 16 years of age or older
- Prescribed by an ophthalmologist or optometrist

CRITERIA FOR RENEWAL: (must meet the following)

- Patient must meet initial criteria for renewals

LENGTH OF APPROVAL 12 months

Public Comments

Dr. Jennifer Dabrowski, Allergan, stated that the use of topical anti-inflammatory and punctal plug criteria is in the package insert, but that these criteria are somewhat in conflict with international guidelines. She reported that package insert includes this information due to the study design of Restasis studies. Dr. Dabrowski stated that the international guidelines from the International Treatment Federation have levels of treatment. Level one is artificial tears, environmental modifications, and modifications of other medications. Level two is lubricants and anti-inflammatory agents such as topical steroids and/or cyclosporine. There are also add-on therapies as the levels go up, with punctal plugs at the next level. There is no restriction in the international guidelines that states that these products cannot be used together.

Dr. Dabrowski also stated that the active ocular infections criteria is not supported by the package insert, and noted that there are cases in the literature, for example in herpes keratitis infections, where Restasis may be used.

Dr. Dabrowski also added that in addition to optometrists and ophthalmologists prescribing, as required by the criteria, there may be other specialists such as rheumatologists who see a large number of patients with dry eye.

The motion passed unanimously.

Board Discussion

Dr. Heston asked Ms. Todd about the use of Restasis as a second-line therapy for blepharitis, and questioned how he'd be able to receive this medication for this indication. Ms. Todd stated that this indication could be added if the board determined this was appropriate. There was some discussion about the PA process, and the denial/appeal process.

Dr. Kollhoff asked Dr. Dabrowski about the statement from the package insert that 'increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs', but that he thought she had said the drug was not studied in those populations. Dr. Dabrowski clarified that the population included in the clinical trial were not allowed to use punctal plugs because this would be another method of increasing tear production. Thus, it served as exclusion criteria for trials and ended up in the package insert for this reason.

Dr. Kollhoff stated that the package insert makes it appear as though, when Restasis was used with punctal plugs, increased tear production was not seen. Dr. Dabrowski stated that the general consensus from the international guidelines is that a patient should first use tear products and then use topical steroids or something like Restasis.

Dr. Waite stated that he had received some unsolicited feedback from another provider who specifically cited Sjogrens patients as a case where either another anti-inflammatory drug or punctal plugs are used in conjunction with Restasis.

Dr. Waite stated that his concern with the criteria was related to the specialist requirement, as he stated that primary care providers may be prescribing this drug. Ms. Todd stated that there could be something added to the renewal criteria to allow for this. Dr. Waite suggested that 'in consultation with' language could be used. Dr. Melton mentioned that in the pre-DUR Conference Call with Dr. Waite, a question had come up about the vision provider networks for each of the MCOs, but these numbers had not been compiled for the meeting. She mentioned that if there was not a significant enough volume of these types of providers in their networks, this could present an access issue. Dr. Kollhoff stated that he does not have a problem with any provider prescribing this drug, and that he agrees that this should be removed from the criteria.

Mr. Sutherland mentioned that it seemed plausible that someone could receive punctal plugs as second mode of treatment, which could cause them to be denied use of Restasis. Dr. Kollhoff mentioned that he had a patient who had punctal plugs that were not sufficient, and who was given Restasis as add-on therapy.

Dr. Waite asked how common it was that a patient would continue on anti-inflammatory therapy while using Restasis. Dr. Dabrowski reported that this typically is an 'either/or' where patients will use an anti-inflammatory or an immunomodulator, of which Restasis is

the only product available. She also stated that there are a lot of side effects with a steroid drop that may not occur with Restasis, in addition to the fact that Restasis attacks the underlying condition. Someone that is up to date with the current literature would probably use one or the other, but the guidelines do not prohibit the use of both together, which is also the case with punctal plugs.

Dr. Waite stated that it appears that the criteria regarding anti-inflammatory drugs is appropriate, but that feedback he has received indicates that the use of punctal plugs with Restasis is common.

Dr. Kollhoff asked what ‘current utilization’ of a topical steroid would be defined as when reviewing Prior Authorizations. Ms. Todd clarified that claims from the last 30 days would be reviewed.

Dr. Ellermeier also mentioned to the board that e-mail feedback from providers had been given to the board.

Mr. Sutherland stated that a PA will frequently ask if a patient has received the alternatives to a product prior trying the drug. In this case, it seems as though the PA should be looking to see if the patient has tried the primary modes of treatment first. Dr. Melton stated that by statute, the state is not allowed to do step therapy unless it is labeled that way in the package insert. The Restasis package insert is not labeled this way, however. Mr. Sutherland stated that, as it stands, the PA criteria seem to be a way to deny Restasis. Dr. Melton stated that if there are parts of the criteria that seem to be an unnecessary barrier to entry that the DUR board can choose not to approve the criteria. Mr. Sutherland asked what the alternatives were for patients who are denied Restasis. Dr. Ellermeier stated that the point of the criteria was to ensure that use was clinically appropriate and following the package insert. The state will occasionally bring criteria for drugs that we know are being used off-label and are unsupported uses. Ms. Todd added that general Amerigroup criteria do have step therapy, and that the goal of the PA is to not have prescribers use Restasis as a first-line option. Mr. Sutherland mentioned that some diagnoses, such as blepharitis, appeared to be missing from the criteria. Ms. Todd stated that these could be added, but that ultimately step therapy cannot be done.

Dr. Kollhoff asked if the board is tied to the use of the package insert, given that blepharitis is an unlabeled indication. Dr. Ellermeier stated that information from DrugDex or one of the other compendia have been used if there is enough literature to support an off-label use. She also mentioned that this could be tabled to allow for the addition of other indications or more documentation. Dr. Heston agreed that this should be tabled and more information should be compiled on the ways that the drug is being used now. Dr. Melton mentioned that by July, we may be able to have more information on off-label use. Dr. Waite agreed that it may be good to see if there is ‘go to’ use of this drug ahead of less costly agents.

	<p>Dr. Kollhoff mentioned that there does not appear to be a lot of support in the package insert for the criteria regarding the use of anti-inflammatory drugs. Dr. Melton referenced the e-mails that Dr. Ellermeier had discussed previously, and stated that these letters did state that the anti-inflammatories were frequently used in conjunction with Restasis. Dr. Kollhoff mentioned again that the package insert doesn't show a lot of support to exclude the use of anti-inflammatories with Restasis.</p>	
<p>2. Zetia® (ezetimibe)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comments iii. Board Discussion 	<p><u>Background</u></p> <p>Ms. Todd presented the topic. Zetia inhibits the absorption of intestinal cholesterol and related phytosterol. It is indicated in patients with primary hyperlipidemia, mixed hyperlipidemia, homozygous familial hypercholesterolemia, or homozygous sitosterolemia. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have one of the following diagnoses: <ul style="list-style-type: none"> ○ Homozygous familial hypercholesterolemia (HoFH) ○ Homozygous sitosterolemia ○ Mixed hyperlipidemia ○ Primary hyperlipidemia • Patient must have a lipid panel within the previous 60 days with a LDL > 100 mg/dL • Patients with HoFH must be taking Zetia in combination with a HMG-CoA Reductase Inhibitor (statin) • Patients with mixed hyperlipidemia must be taking Zetia in combination with fenofibrate • Patient must be ≥ 10 years of age <p>LENGTH OF APPROVAL 12 months</p> </div> <p><u>Public Comment</u></p> <p>Matt Stafford, Merck, stated that he wanted to ask if a prior authorization for Zetia was needed, and asked the board to consider four points: 1. The current NCEP ATP guidelines; 2. How Zetia is most frequently used; 3. Clinical peer-reviewed journals and package labeling; 4. The consideration of whether prior authorization is really needed and whether this may offer an unneeded cost and administrative burden to the healthcare system.</p> <p>Stafford stated that Zetia is generally used in moderate- to high-risk patients who need to get to their NCEP goals of 100-70 mg/dl. The effect of Zetia on morbidity and mortality has not been established, and the contraindications are hypersensitivity to any component of Zetia or when used in combination with a statin, following the contraindications of the statin itself. Patients should be advised to promptly report muscle tenderness and weakness, and Zetia should not be used patients with moderate to severe hepatic impairment. The most common side effects are nasopharyngitis, myalgia, upper respiratory infection, arthralgia, and diarrhea.</p>	<p>Dr. Kollhoff made a motion to accept the Zetia prior authorization criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>

Stafford also stated that there are two studies that have been published in the American Journal of Cardiology that show that Zetia is typically used in addition to a statin, which is consistent with the guidelines. One of these two studies compared atorvastatin titration from 20 mg to 40 mg versus adding Zetia to atorvastatin 20 mg. This study showed the incremental LDL reduction when Zetia was added to atorvastatin 20 mg was 27% compared to an 11% LDL reduction by titrating the statin. Additionally, 74% of those patients in the Zetia group achieved an LDL of 100 mg/dl or less, while only 32% of those in the titration group reached their goals. The second study compared the addition of Zetia to 40 mg of atorvastatin versus an atorvastatin titration from 40 mg to 80 mg in high-risk patients. Data from this study showed that 84% of patients got to their LDL goal when Zetia was added versus 49% of those patients in the titration group. The incremental LDL reductions when Zetia was added were 31% versus 11% in the titration group.

Stafford stated that because this drug is typically used in addition to statin, a prior authorization would simply be controlling for something that is naturally happening in the market. He stated that the data suggests that 80% of patients who start Zetia are either currently taking a statin or have recently been on a statin. In summary, Stafford stated that the NCEP guidelines continue to focus on LDL reduction, and the peer-reviewed literature shows that Zetia is superior to titrating statins, and where Zetia is used in the vast majority of patient is in addition to a statin, which may not necessitate a clinical prior authorization.

Dr. Heston asked Stafford if he had any concerns about the list of diagnoses on the criteria. Stafford stated that these were consistent with the label, but asked that an LDL of 70 be the threshold, as this is sometimes seen in high-risk patients. Dr. Ellermeier clarified that patients would have to meet just one of the diagnoses in addition to the other criteria, and that some of the diagnoses allow for monotherapy use of Zetia without a statin.

Board Discussion

Dr. Heston asked if, in a practical sense, patients only receive a hyperlipidemia diagnosis without getting in to more specific diagnoses.

Dr. Kollhoff asked about the status of the combination product. Dr. Melton stated that there is not a PA on Vytorin, so prescribing would potentially be driven to Vytorin. Dr. Kollhoff stated it might be possible to table this topic to look at Vytorin as well.

Dr. Waite stated that, from a diagnosis standpoint, a general hyperlipidemia diagnosis would allow a patient to receive the drug.

Dr. Waite asked for Lisa Todd's opinion on potentially driving usage to Vytorin. She stated that this was financially preferable.

Dr. Kollhoff suggested that the board adopt Stafford's recommendation that the LDL level

	in criteria be amended to 70.	
<p>3. Syprine[®] (trientine)</p> <p>i. PA Criteria</p> <p>ii. *Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Syprine is a chelating compound for removal of excess copper from the body. It is indicated in the treatment of patients with Wilson’s disease who are intolerant of penicillamine. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>CRITERIA FOR APPROVAL: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be ≥ 2 years of age • Patient must have a diagnosis of Wilson’s disease • Patient has an intolerance to penicillamine <p>LENGTH OF APPROVAL 3 months</p> </div> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>Dr. Waite stated that the criteria seemed to be pretty straight-forward, and that the patient population is very small.</p>	<p>Dr. Unruh made a motion to accept the Syprine prior authorization criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>4. Ferriprox[®] (deferiprone)</p> <p>i. PA Criteria</p> <p>ii. *Public Comments</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Ferriprox is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Unruh made a motion to accept the Ferriprox prior authorization criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The motion passed unanimously.</p>

	<p>CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be ≥ 2 years of age • Patient must have been transfused with at least 100 mL/kg of packed red blood cells (e.g., at least 20 units of packed red blood cells for a 40-kg person) • Patient must have a serum ferritin > 1,000 mcg/L • Patient must have an absolute neutrophil count (ANC) < 1.5 x 10⁹/L <p>LENGTH OF INITIAL APPROVAL 3 months</p> <p>RENEWAL CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD: (must meet all of the following)</p> <ul style="list-style-type: none"> • Serum ferritin is monitored monthly • Serum ferritin is consistently > 500 mcg/L <p>LENGTH OF RENEWAL APPROVAL 6 months</p>	
<p>5. Exjade® (deferasirox)</p> <ol style="list-style-type: none"> PA Criteria *Public Comments Board Discussion 	<p><u>Background</u></p> <p>Exjade is an iron chelating agent indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older and for patients 10 years of age or older with non-transfusion dependent thalassemia syndromes. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Heston made a motion to accept the Exjade prior authorization criteria.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The motion passed unanimously.</p>

	<p>CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be ≥ 2 years of age • Patient must have been transfused with at least 100 mL/kg of packed red blood cells (e.g., at least 20 units of packed red blood cells for a 40-kg person) • Patient must have a serum ferritin > 1,000 mcg/L <p>LENGTH OF INITIAL APPROVAL 3 months</p> <p>RENEWAL CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD: (must meet all of the following)</p> <ul style="list-style-type: none"> • Serum ferritin is monitored monthly • Serum ferritin is consistently > 500 mcg/L <p>LENGTH OF RENEWAL APPROVAL 6 months</p> <p>CRITERIA FOR NON-TRANSFUSIONAL IRON OVERLOAD: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be ≥ 10 years of age • Patient must have a serum ferritin > 300 mcg/L on at least 2 measurements one month apart • Patient must have a liver iron concentration (LIC) ≥ 5 mg Fe/g <u>dw</u> (milligrams of iron per gram of liver dry weight) <p>RENEWAL CRITERIA FOR NON-TRANSFUSIONAL IRON OVERLOAD (EXJADE ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Serum ferritin is monitored monthly • Serum ferritin > 300 mcg/L • LIC is monitored every 6 months • LIC > 3 mg Fe/g <u>dw</u> <p>LENGTH OF APPROVAL 3 months</p>	
	<p><u>Public Comment</u></p> <p>David Crippen, Reimbursement Manager for Novartis, stated that the criteria are consistent with package labeling.</p> <p><u>Board Discussion</u></p> <p>Dr. Waite commented that his own institution had just reviewed this for their sickle cell patients, and stated that the criteria seemed to be consistent.</p>	
<p>6. Pulmonary Arterial Hypertension Agents (Adcirca[®] (tadalafil), Flolan[®] (epoprostenol), Letairis[®] (ambrisentan), Remodulin[®] (treprostinil), Revatio[®] (sildenafil), Tracleer[®] (bosentan), Tyvaso[®] (treprostinil), Veletri[®] (epoprostenol), and Ventavis[®])</p>	<p><u>Background</u></p> <p>Pulmonary hypertension agents are used to improve exercise ability and delay clinical worsening in patients with pulmonary arterial hypertension. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Kollhoff made a motion to accept the PAH Agents prior authorization criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>

<p>(iloprost))</p> <p>i. PA Criteria</p> <p>ii. *Public Comments</p> <p>iii. Board Discussion</p>	<p>CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of pulmonary arterial hypertension (PAH) • Must be prescribed by or in consultation with a pulmonologist, cardiologist, or specialized treatment center <p>LENGTH OF APPROVAL 12 months</p> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>Dr. Heston stated that he appreciated the ‘in consultation’ statement for the prescriber criteria.</p> <p>Dr. Kollhoff asked if there were any criteria on these drugs currently. Dr. Ellermeier stated that there are diagnosis restrictions on the Revatio, but otherwise, there are no limitations. Dr. Kollhoff stated that he has noted some off-label use since the Revatio has been generic.</p> <p>Dr. Ellermeier provided utilization data, and it was noted that Revatio has the highest utilization.</p>	
<p>IV. *Open Public Comment</p>	<p>Dr. Melton mentioned that she had received questions about if manufacturers should be trying to work with the state or the MCOs for KanCare pharmacy questions and issues. Melton stated that each of the plan pharmacy directors had varying abilities to meet with manufacturers, so manufacturers can continue to work with the state. However, manufacturers should feel free to contact the MCOs as well.</p> <p>Dr. Melton also asked that if manufacturers are seeing any patients who are running in to issues receiving medications to make the state aware and they can work with the plans to resolve.</p>	
<p>V. Adjourn</p>	<p>The meeting was adjourned at 12:48 p.m.</p> <p>The next meeting will be on Wednesday July 10, 2013. It will begin at 10:00 am at the HP Enterprises Services Office.</p> <p>**LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS</p>	<p>Dr. Kollhoff made a motion to adjourn.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The motion passed unanimously.</p>