

**Drug Utilization Review Board
Meeting Minutes, Open Session
April 13, 2016**

<p>Drug Utilization Review Board HP Enterprise Services, Capital Room 6700 SW Topeka Blvd, Bldg. 283 J, Topeka, KS 66619</p>	<p>DUR Board Members Present Lauren Morton, Pharm.D., BCPS, Chair Tim Heston, DO Roger Unruh, DO</p> <p>DUR Board Members Absent Russell Scheffer, MD Judy McDaniel Dowd, PA-C</p> <p>DHCF Staff Present Liane Larson, Pharm.D.</p> <p>HP Enterprise Services Staff Present Nancy Perry, R.N.</p> <p>HID Staff Present Ariane Casey, Pharm.D.</p> <p>MCO Staff Present Jonalan Smith, Pharm.D., FASCP: Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p>Representatives Mackenzie Andra, KDHE/KU Pharmacy; Amy Christensen, Novartis; Kirby Consier, Novartis; Jeff Knappen, Allergan; Mary Jo Defloio, Janssen; Corinne Copeland, Eisai Inc; Joel Meyer, Novartis; Doug Wood, Viv; Melissa Basil, Abbvie; Laura Hill, Abbvie; Valerie Collins, BMS; Melissa Lauvie, BMS; Patrick Mumme, Alexion; Rich McKenna, Alexion; Angie Zhou, Sunflower; Marla Wiedenmann, NovoNordisk; Brent Hildebrand, Gilead; Sue Lewis, MHAH; Colin Thomasset, ACMHCK; Brian Rose, Merck; Michael Ferrarl, Merck; Berend Koops, Merck; Brett Maret, BMS; Julie McDavitt, BI; Haley Gish, Pfizer; Michele Puyear, Gilead; Jennifer Stoffel, Janssen; Monica Johnson, Sunflower; Terry McCurren, Otsuka; Marc Ramby, Grifols; Scott Maurice, BI; Donna Osterland, Genzyme</p>
---	---	---

TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Morton called the meeting to order at 10:06am.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
A. Announcements	Dr. Larson provided the general parking announcement, thanked Dr. Morton for sitting in as Chair, and reminded the public to fill out and turn in the conflict of interest form should they wish to speak.	
II. Old Business A. Review and Approval of the January 13, 2016 DUR Meeting Minutes	Board Discussion None	Dr. Backes moved to accept the minutes as presented. Dr. Rice seconded the motion. The January 13, 2016 minutes were accepted as presented.
III. New Business A. New Preferred Drug List (PDL) Classes 1. Topical Testosterone Agents i. Non-Preferred PDL PA Criteria	Background: At the March 2016 PDL meeting, the committee approved the addition of the Topical Testosterone Agents to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. Public Comment Laura Hill with Abbvie spoke on behalf of AndroGel. Board Discussion None	Dr. Mittal moved to approve as written. Dr. Backes seconded the motion. The criteria were approved unanimously.
A. New Preferred Drug List (PDL) Classes 2. Cannabinoid Antiemetics i. Non-Preferred PDL PA Criteria	Background: At the March 2016 PDL meeting, the committee approved the addition of the Cannabinoid Antiemetics to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. Public Comment: None Board Discussion None	Dr. Backes moved to approve as written. Dr. Mittal seconded the motion. The criteria were approved unanimously.
A. New Preferred Drug List (PDL) Classes 3. Ophthalmic Anti-Infective/Steroid Combinations i. Non-Preferred PDL PA Criteria	Background At the March 2016 PDL meeting, the committee approved the addition of the Ophthalmic Anti-Infective/Steroid Combinations to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. Public Comment None Board Discussion None	Dr. Backes moved to approve as written. Dr. Rice seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>A. New Preferred Drug List (PDL) Classes</p> <p>4. Ophthalmic Beta-Blockers</p> <p>i. Non-Preferred PDL PA Criteria</p>	<p>Background</p> <p>At the March 2016 PDL meeting, the committee approved the addition of the Ophthalmic Beta Blockers to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.</p> <p>Public Comment</p> <p>None</p> <p>Board Discussion</p> <p>None</p>	<p>Dr. Heston moved to approve as written.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>A. New Preferred Drug List (PDL) Classes</p> <p>5. Ophthalmic Alpha Adrenergic Agonists</p> <p>i. Non-Preferred PDL PA Criteria</p>	<p>Background</p> <p>At the March 2016 PDL meeting, the committee approved the addition of the Ophthalmic Alpha Adrenergic Agonists to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.</p> <p>Public Comment</p> <p>None</p> <p>Board Discussion</p> <p>None</p>	<p>Dr. Mittal moved to approve as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>A. New Preferred Drug List (PDL) Classes</p> <p>6. Platelet Aggregation Inhibitors (Stroke)</p> <p>i. Non-Preferred PDL PA Criteria</p>	<p>Background</p> <p>At the March 2016 PDL meeting, the committee approved the addition of the Platelet Aggregation Inhibitors for Stroke to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.</p> <p>Public Comment</p> <p>None</p> <p>Board Discussion</p> <p>None</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>A. New Preferred Drug List (PDL) Classes</p> <p>7. Platelet Aggregation Inhibitors (Secondary Cardiac Prevention)</p> <p>i. Non-Preferred PDL PA Criteria</p>	<p>Background</p> <p>At the March 2016 PDL meeting, the committee approved the addition of the Platelet Aggregation Inhibitors for Secondary Cardiac Prevention to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.</p> <p>Public Comment</p> <p>Michael Ferrari with Merck spoke on behalf of Zontivity XR.</p> <p>Board Discussion</p> <p>Dr. Larson noted that this is to be able to group these particular agents in this one class.</p>	<p>Dr. Mittal moved to approve as written.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p>	<p>Background</p> <p>Actemra is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the</p>	<p>Dr. Backes moved to approve as written.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>1. Actemra® (tocilizumab)</p> <p>i. Revised PA Criteria</p>	<p>DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p> <div style="border: 1px solid black; padding: 10px;"> <p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA) (SUBQ & IV FORMULATIONS): (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, 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) (IV FORMULATIONS ONLY): (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 12 months</p> </div> <p>Public Comment None</p> <p>Board Discussion None</p>	<p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>2. Cimzia® (certolizumab)</p>	<p>Background</p> <p>Cimzia is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Rice seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>i. Revised PA Criteria</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 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 • 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 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 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 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 <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	<p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>3. Enbrel® (etanercept)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Enbrel is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p>	<p>Dr. Mittal moved to approve as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 (JIA): • Patient must be 2 years of age or older • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Must be prescribed by a rheumatologist • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA) OR ANKYLOSING SPONDYLITIS (AS): Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Rheumatoid Arthritis (RA) or Ankylosing Spondylitis (AS) • Patient must be 18 years of age or older • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Must be prescribed by a rheumatologist • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR PSORIATIC ARTHRITIS: Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Psoriatic Arthritis • Patient must be 18 years of age or older • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Must be prescribed by a rheumatologist or dermatologist • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR PLAQUE PSORIASIS: Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Plaque psoriasis • Patient must be 18 years of age or older • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Must be prescribed by a rheumatologist or dermatologist • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has taken oral agents for the treatment of plaque psoriasis (see attached table) or patient is a candidate for systemic therapy or phototherapy <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>4. Entyvio® (vedolizumab)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Entyvio is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p>	<p>Dr. Backes moved to approve as amended.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 moderately to severely active ulcerative colitis • Patient must be 18 years of age or older • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Must be prescribed by or in consultation with a gastroenterologist • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient had one of the following: <ul style="list-style-type: none"> ○ An inadequate response with, lost response to, or was intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator ○ An inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids <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 moderately to severely active Crohn's disease • Patient must be 18 years of age or older • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Must be prescribed by or in consultation with a gastroenterologist • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient had one of the following: <ul style="list-style-type: none"> ○ An inadequate response with, lost response to, or was intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator ○ An inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	<p>unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>5. Humira® (adalimumab)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Humira is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p>	<p>Dr. Backes moved to approve as amended.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 2 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 	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 PEDIATRIC 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 6 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate <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>CRITERIA FOR HIDRADENITIS SUPPURATIVA (HS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or III or Acne Inversa Severity Index [AIS] score of ≥ 10) • 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>LENGTH OF APPROVAL 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>6. Ilaris® (canakinumab)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Ilaris is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p> <div style="border: 1px solid black; padding: 5px;"> <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 CAPS, including: <ul style="list-style-type: none"> ○ Familial Cold Autoinflammatory Syndrome (FCAS) ○ Muckle-Wells Syndrome (MWS) • Patient must be 4 years of age or older • Patient must have an evaluation for latent tuberculosis (TB) with a TB skin test prior to initial prior authorization approval • Patient must not be taking another IL-1 blocking agent or biologic agent (see attached table) within 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 active, systemic juvenile idiopathic arthritis • Must be prescribed by or in consultation with a rheumatologist or dermatologist • Patient must have an evaluation for latent TB with a 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 <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment None</p> <p>Board Discussion None</p>	<p>Dr. Backes moved to table this item.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>7. Kineret® (anakinra)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Kineret is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p>	<p>Dr. Backes moved to approve as written</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>8. Orencea® (abatacept)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Orencea is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</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 <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 <p>LENGTH OF APPROVAL: 12 months</p>	<p>Dr. Rice moved to approve as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>9. Remicade® (infliximab)</p> <p>i. Revised PA Criteria</p>	<p><u>Background</u> Remicade is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p> <p><u>CRITERIA FOR RHEUMATOID ARTHRITIS (RA):</u> (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has a diagnosis of rheumatoid arthritis • The patient is 18 years of age or older • The prescriber is a rheumatologist • Must be taken in combination with methotrexate • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent (see attached table) in the past 30 days <p><u>CRITERIA FOR ANKYLOSING SPONDYLITIS (AS):</u> (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has a diagnosis of ankylosing spondylitis • The patient is 18 years of age or older • The prescriber is a rheumatologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent (see attached table) in the past 30 days <p><u>CRITERIA FOR PSORIATIC ARTHRITIS:</u> (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has a diagnosis of psoriatic arthritis • The patient is 18 years of age or older • The prescriber is a dermatologist or rheumatologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent (see attached table) in the past 30 days 	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR ULCERATIVE COLITIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has a diagnosis ulcerative colitis • The patient is 6 years of age or older • The prescriber is a gastroenterologist • The patient has used conventional ulcerative colitis therapies (see attached table) or there is documentation of inadequate response, contraindication, allergy or intolerable side effects to conventional ulcerative colitis therapies (see attached table) • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR CROHN’S DISEASE: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has a diagnosis of Crohn’s Disease • The patient is 6 years of age or older • The prescriber is a gastroenterologist • The patient has used conventional Crohn’s Disease therapies (see attached table) or there is documentation of inadequate response, contraindication, allergy or intolerable side effects to conventional Crohn’s Disease therapies (see attached table) • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR PLAQUE PSORIASIS: Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of plaque psoriasis • The patient is 18 years of age or older • The prescriber is a dermatologist or rheumatologist • The patient has taken oral agents for the treatment of plaque psoriasis (see attached table) or patient is a candidate for systemic therapy or phototherapy • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>10. Simponi® (golimumab)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Simponi is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 moderate to severe, active rheumatoid arthritis • Must be given in combination with methotrexate, unless patient has a contraindication to methotrexate • Must be prescribed by or in consultation with a rheumatologist • Patient must have an evaluation for latent tuberculosis (TB) with a 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 PSORIATIC ARTHRITIS (PsA) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of active psoriatic arthritis • Must be prescribed by or in consultation with a rheumatologist or dermatologist • Patient must have an evaluation for latent TB with a 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 active Ankylosing spondylitis • Must be prescribed by or in consultation with a rheumatologist • Patient must have an evaluation for latent TB with a 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 ULCERATIVE COLITIS (UC) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of moderate to severe, active ulcerative colitis • Patient must meet one of the following <ul style="list-style-type: none"> ○ Patient has had an inadequate response to or failed to tolerate one of the following <ul style="list-style-type: none"> ▪ oral aminosalicylates ▪ oral corticosteroids ▪ azathioprine ▪ 6-mercaptopurine ○ Patient has an inability to taper corticosteroids without a return of the symptoms of UC (i.e., patient is corticosteroid dependent) • Patient must have an evaluation for latent TB with a 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>LENGTH OF APPROVAL 12 months</p>	<p>unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>11. Stelara® (ustekinumab)</p> <p>i. Revised PA Criteria</p>	<p><u>Background</u></p> <p>Stelara is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PLAQUE PSORIASIS: (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 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 • Patient must be a candidate for systemic therapy or phototherapy • Dose must not exceed 45 mg per injection. If prescriber is seeking 90 mg per dose, documentation of the patient’s weight is required and/or that 45 mg has not been efficacious <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 • Dose must not exceed 45 mg per injection. If prescriber is seeking 90 mg per dose, documentation of patient’s weight and coexisting moderate to severe plaque psoriasis is submitted <p>LENGTH OF APPROVAL 12 months</p> </div> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	<p>Dr. Rice moved to approve as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>12. Cosentyx® (secukinumab)</p> <p>i. Revised PA Criteria</p>	<p><u>Background</u></p> <p>Cosentyx is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months. Prior authorization criteria were initially approved in April 2015. Since that time, two new FDA indications have been approved: psoriatic arthritis and ankylosing spondylitis. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p>	<p>Dr. Mittal moved to approve as written.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR MODERATE TO SEVERE PLAQUE PSORIASIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of moderate to severe plaque psoriasis • Patient must be 18 years or older • Patient must be a candidate for systemic therapy or phototherapy • Must be prescribed by or in consultation with a Dermatologist or Rheumatologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent in the past 30 days <p>CRITERIA FOR ACTIVE PSORIATIC ARTHRITIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of active psoriatic arthritis • Patient must be 18 years or older • Must be prescribed by or in consultation with a Dermatologist or Rheumatologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent in the past 30 days <p>CRITERIA FOR ACTIVE ANKYLOSING SPONDYLITIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of active ankylosing spondylitis • Patient must be 18 years or older • Must be prescribed by or in consultation with a Rheumatologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent in the past 30 days <p>LENGTH OF APPROVAL: 12 MONTHS</p> <p>Public Comment Amy Christensen spoke on behalf of Novartis.</p> <p>Board Discussion None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>13. Xeljanz® (tofacitinib)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Xeljanz is an immunomodulator. At the January 2016 DUR meeting, it was suggested by the DUR board to extend the duration of approval for all immunomodulators from 6 months to 12 months. Prior authorization criteria were initially approved in July 2013. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Xeljanz XR.</p>	<p>Dr. Backes moved to approve as amended.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 moderate to severe, active rheumatoid arthritis • Patient must have had an inadequate response or intolerance to methotrexate • Must be prescribed by or in consultation with a rheumatologist • Patient must have an evaluation for latent tuberculosis (TB) with a TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken a biologic agent (see attached table) in the past 30 days • Patient must have had the following labs checked prior to initial prior authorization <ul style="list-style-type: none"> ○ lymphocyte count ○ absolute neutrophil count (ANC) ○ hemoglobin • The medication is limited to the following quantity limits: <ul style="list-style-type: none"> ○ Xeljanz 5 mg tablets 2 per day ○ Xeljanz XR 11 mg 1 per day <p>RENEWAL CRITERIA FOR RHEUMATOID ARTHRITIS (RA): Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have the following labs checked every 3 months <ul style="list-style-type: none"> ○ lymphocyte count ○ ANC ○ hemoglobin • The medication is limited to the following quantity limits: <ul style="list-style-type: none"> ○ Xeljanz 5 mg tablets 2 per day ○ Xeljanz XR 11 mg 1 per day <p>LENGTH OF INITIAL AND RENEWAL APPROVAL 12 months</p> <p>Public Comment None</p> <p>Board Discussion Dr. Backes ask to verify the length of approval. Dr. Casey change the 6 months to 12 months.</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>14. Botox® (onabotulinumtoxinA)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Botox is a botulinum toxin. Prior authorization criteria were last revised in October 2015. Since that time, Botox has become indicated for the treatment of lower limb spasticity in adults. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p>	<p>Dr. Mittal moved to approve as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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, finger, or thumb flexors • Treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle or toe 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 RIMABOTULINUMTOXINB: (must meet the following)</p> <ul style="list-style-type: none"> • Treatment of cervical dystonia <p>CRITERIA FOR ABOBOTULINUMTOXINA: (must meet one of the following)</p> <ul style="list-style-type: none"> • Treatment of cervical dystonia • Treatment of upper limb spasticity <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> <p>Public Comment None</p> <p>Board Discussion None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>15. Opdivo® (nivolumab)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Opdivo is a monoclonal antibody (antineoplastic) indicated for the treatment of melanoma. Prior authorization criteria were initially approved in October 2015. Since that time, the BRAF V600 mutations have become approved as a single agent or in combination with ipilimumab for either mutation; also a new indication of renal cell carcinoma has been added. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p>	<p>Dr. Backes and Dr. Unruh moved to approve as written.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR 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"> ○ Unresectable or metastatic melanoma <ul style="list-style-type: none"> ▪ Medication must be used as a single agent or in combination with ipilimumab ○ Metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy <ul style="list-style-type: none"> ▪ If EGFR or ALK mutation present, patient must have failure with a mutation specific medication prior to using Opdivo ○ Advanced renal cell carcinoma <ul style="list-style-type: none"> ▪ Patient must have received prior anti-angiogenic therapy • Must be prescribed by or in consultation with an oncologist • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>16. Pulmonary Hypertension Agents (Uptravi® [selexipag])</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Uptravi is a prostacyclin IP receptor agonist indicated for the treatment of pulmonary arterial hypertension (PAH). Prior authorization criteria for PAH agents were last revised in April 2014. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Uptravi.</p> <p>MANUAL GUIDELINES The following drug(s) require prior authorization:</p> <ul style="list-style-type: none"> Ambrisentan Tablets (Letairis®) Bosentan Tablets (Tracleer®) Epoprostenol Injection (Flolan®, Velettri®) Iloprost Inhalation Solution (Ventavis®) Macitentan (Opsumit®) Riociguat (Adempas®) Sildenafil Tablets, Oral Suspension, and Injection (Revatio®) Treprostinil Extended-Release Tablets (Orenitram®) Treprostinil Inhalation Solution (Tyvaso®) Treprostinil Injection (Remodulin®) Tadalafil Tablets (Adcirca®) Selexipag (Uptravi®) <p>Public Comment None</p> <p>Board Discussion</p>	<p>Dr. Mittal moved to approve as written.</p> <p>Mrs. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	None	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>17. Intravenous Immune Globulins (IVIGs)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Intravenous immune globulins are used for several FDA indications and several off-label uses. Prior authorization criteria were initially approved in January 2016. At the January 2016 DUR meeting, it was suggested by the DUR board members to extend the duration of approval. Since all indications were included, the diagnoses were separated into chronic and acute indications. The length of approval for chronic conditions requiring long-term IVIGs are 12 months and acute conditions requiring temporary use of IVIGs are 1 month.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR INTRAVENOUS IMMUNE GLOBULINS:</p> <p>Patient must have one of the following diagnoses for chronic use:</p> <ul style="list-style-type: none"> • Primary immune deficiency • Idiopathic thrombocytopenic purpura (ITP) • B-cell chronic lymphocytic leukemia • Chronic demyelinating polyneuropathy • Dermatomyositis • Bone marrow transplant • Human Immunodeficiency Virus (HIV) • Polymyositis • Autoimmune mucocutaneous blistering diseases • Multiple Sclerosis • Hemolytic anemia • Solid organ transplant • Lambert Eaton • Multifocal motor neuropathy <p>LENGTH OF APPROVAL: 12 months</p> </div>	<p>Dr. Unruh moved to approve as written.</p> <p>Mrs. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Patient must have one of the following diagnoses for acute treatment:</p> <ul style="list-style-type: none"> • Fetal or neonatal alloimmune thrombocytopenia • Sepsis treatment • Stevens Johnson • Toxic shock • Neonates (infection/sepsis prevention) • Rotavirus enterocolitis • Encephalitis (anti-NMDA or meningoencephalitis) • Guillain Barre Syndrome • Kawasaki Disease • Myasthenia gravis • Stiff man syndrome • Parvovirus B19 • Graves ophthalmopathy • Autoimmune uveitis • Neuropathy (paraprotein associated) <p>LENGTH OF APPROVAL: 1 month</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>18. Afinitor® (everolimus)</p> <p>i. Revised PA Criteria</p>	<p><u>Background</u></p> <p>Afinitor is a kinase inhibitor indicated for the treatment of several FDA indications. Prior authorization criteria were initially approved in January 2014. Since that time, a new FDA indication has been approved. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR ADVANCED HORMONE RECEPTOR-POSITIVE, HER2-NEGATIVE BREAST CANCER (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be postmenopausal • Patient must have a diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer (HR+ BC) • Must be used in combination with exemestane, after failure of treatment with letrozole or anastrozole • Patient must not be taking Afinitor Disperz concurrently <p>CRITERIA FOR ADVANCED NEUROENDOCRINE TUMORS OF PANCREATIC ORIGIN (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced or metastatic disease • Patient must not be taking Afinitor Disperz concurrently • Patient must not be pregnant <p>CRITERIA FOR ADVANCED RENAL CELL CARCINOMA (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of advanced renal cell carcinoma (RCC) • Patient must have failed treatment with sunitinib or sorafenib • Patient must not be taking Afinitor Disperz concurrently • Patient must not be pregnant <p>CRITERIA FOR RENAL ANGIOMYOLIPOMA WITH TUBEROUS SCLEROSIS COMPLEX (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery • Patient must not be taking Afinitor Disperz concurrently • Patient must not be pregnant <p>CRITERIA FOR SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) WITH TUBEROUS SCLEROSIS COMPLEX (TSC) (TABLETS & DISPERZ): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have tuberous sclerosis complex (TSC) with subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected • Patient must not be taking Afinitor tablets and Disperz concurrently • Patient must not be pregnant <p>CRITERIA FOR WALDENSTROM’S MACROGLOBULINEMIA (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Waldenstrom’s Macroglobulinemia (lymphoplasmcytic lymphoma) • Patient must not be taking Afinitor Disperz concurrently • Patient must not be pregnant <hr/> <p>CRITERIA FOR LUNG NEUROENDOCRINE TUMORS (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of lung neuroendocrine tumors • Patient must not be taking Afinitor Disperz concurrently • Patient must not be pregnant <p>CRITERIA FOR NEUROENDOCRINE TUMORS (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic • Patient must not be taking Afinitor Disperz concurrently • Patient must not be pregnant <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	None <u>Board Discussion</u> None	
B. Revised Prior Authorization (PA) Criteria 19. Gilenya® (fingolimod) i. Revised PA Criteria	<p>Background</p> <p>Gilenya is an immunomodulatory agent indicated for the treatment of multiple sclerosis (MS). Prior authorization criteria were initially approved in October 2012. Since that time, there have been post-marketing reports of progressive multifocal leukoencephalopathy (PML) due to the JC virus. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR APPROVAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple sclerosis • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a neurologist • Patient must not be on concurrent therapy with another disease-modifying MS agent: an interferon, natalizumab, mitoxantrone, or glatiramer • Patient must not have any of the following: <ul style="list-style-type: none"> ○ Myocardial infarction in past 6 months, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, and class III/IV heart failure ○ Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (unless a pacemaker is being used) ○ Baseline QTC interval ≥ 500 ms ○ Concurrent therapy with Class Ia or Class III anti-arrhythmic medications in the past 45 days • Patient must not be John Cunningham virus (JCV) positive • Dose must not exceed 1 capsule per day <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment</p> <p>Amy Christensen with Novartis responded to Dr. Todds' question concerning female patients. Noting there were currently 5. The additional information is to increase Physicians' awareness to issues that are unique to females.</p> <p>Board Discussion</p> <p>None</p>	<p>Dr. Heston moved to approve as written.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously.</p>
B. Revised Prior Authorization (PA) Criteria 20. Tecfidera® (dimethyl fumarate) i. Revised PA Criteria	<p>Background</p> <p>Tecfidera is an immunomodulatory agent indicated for the treatment of multiple sclerosis (MS). Prior authorization criteria were initially approved in July 2013. Since that time, there have been post-marketing reports of progressive multifocal leukoencephalopathy (PML) due to the JC virus. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>MANUAL GUIDELINES The following drug requires prior authorization: Dimethyl fumarate (Tecfidera®)</p> <p>CRITERIA FOR APPROVAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple sclerosis • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a neurologist • Patient must not be John Cunningham virus (JCV) positive • Dose must not exceed 1 capsule per day <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>21. Imbruvica® (ibrutinib)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Imbruvica is a tyrosine kinase inhibitor indicated for the treatment of chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), and Waldenström macroglobulinemia. Prior authorization criteria were initially approved in October 2015. Since that time, use in CLL is approved regardless of the patient’s treatment history. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p> <p>MANUAL GUIDELINES The following drug requires prior authorization: Imbruvica (ibrutinib)</p> <p>CRITERIA FOR INITIAL APPROVAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must be clinically diagnosed with one of the following diagnoses: <ul style="list-style-type: none"> ○ Chronic lymphoid leukemia ○ Chronic lymphoid leukemia with 17p chromosome deletion ○ Mantle cell lymphoma <ul style="list-style-type: none"> ▪ Patient has received at least one prior therapy ○ Waldenström macroglobulinemia • The medication is prescribed by or in consultation with an oncologist or hematologist <p>LENGTH OF APPROVAL: 6 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>22. Harvoni® (ledipasvir-</p>	<p>Background</p> <p>Harvoni is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis C infection. Prior authorization criteria were last revised in January 2016. The Hepatitis C</p>	<p>Dr. Mittal moved to approve as written.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>sofosbuvir) i. Revised PA Criteria</p>	<p>guidelines recommend holding treatment in pregnancy due to a lack of evidence supporting safety. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR INITIAL APPROVAL OF LEDIPASVIR/SOFOSBUVIR: (must meet all of the following)</p> <p><i>*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Sofosbuvir/Ledipasvir therapy total)*</i></p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C (CHC) • Patient must have genotype 1, 4, 5, or 6 hepatitis C • Patient must not have severe renal impairment (eGFR<30mL/min/1.73m²) or currently require hemodialysis • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Patient must not have been on previous or concurrent direct acting hepatitis C agents • If patient was on a previous course of treatment with Incivek or Victrelis it must have included an interferon-based regimen • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request • Dose must not exceed 1 capsule per day • Patient must have one of the following: <ul style="list-style-type: none"> ○ Advanced fibrosis (Metavir F3) ○ Compensated cirrhosis ○ Organ transplant ○ Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis) ○ Proteinuria ○ Nephrotic syndrome ○ Membranoproliferative glomerulonephritis • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with ledipasvir/sofosbuvir therapy <p>RENEWAL CRITERIA FOR LEDIPASVIR/SOFOSBUVIR:</p> <ul style="list-style-type: none"> • Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following: <ul style="list-style-type: none"> ○ Genotype 1 (one of the following) <ul style="list-style-type: none"> ▪ Treatment-naïve, without cirrhosis, and a pre-treatment HCV RNA < 6 million IU/mL – 8 weeks total therapy ▪ Treatment-naïve, with or without cirrhosis, and a pre-treatment HCV RNA ≥ 6 million IU/mL – 12 weeks total therapy ▪ Treatment-naïve, with cirrhosis– 12 weeks total therapy ▪ Treatment-experienced, without cirrhosis – 12 weeks total therapy ▪ Treatment-experienced, with cirrhosis: <ul style="list-style-type: none"> • 24 weeks total therapy alone • 12 weeks total therapy if used with Ribavirin ○ Genotype 4, 5, or 6 <ul style="list-style-type: none"> ▪ 12 weeks total therapy <p>LENGTH OF APPROVAL FOR LEDIPASVIR/SOFOSBUVIR: 4 weeks</p> </div> <p>Public Comment None</p> <p>Board Discussion</p>	<p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Dr. Casey provided examples of the verbiage used to show that the verbiage is consistent with other agents in the class.	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>23. Technivie (ombitasvir/paritaprevir/ritonavir)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Technivie is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis C infection. Prior authorization criteria were last revised in January 2016. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p> <div data-bbox="527 386 1619 1187" style="border: 1px solid black; padding: 5px;"> <p>MANUAL GUIDELINES The following drug requires prior authorization: ombitasvir/paritaprevir/ritonavir (Technivie®)</p> <p>CRITERIA FOR INITIAL APPROVAL (must meet all of the following): <i>*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of ombitasvir/paritaprevir/ritonavir therapy total)*</i></p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C (CHC) • Patient must have genotype 4 hepatitis C • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Must be used in combination with ribavirin, unless there is a contraindication and the patient is treatment-naïve • Patient must not have been on previous or concurrent direct acting hepatitis C agent • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request • Dose must not exceed 2 tablets per day • Patient must have a Metavir score of F3 • Patient must not have moderate or severe hepatic impairment or cirrhosis (Metavir score of F4 and Child-Pugh class B or C) • Patient must not be concurrently prescribed a moderate or strong CYP3A inducer • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Technivie and ribavirin combination therapy <p>CRITERIA FOR RENEWAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Prescriber must document adherence by patient of greater than or equal to 90% for both agents <p>LENGTH OF APPROVAL: 4 weeks for a total of 12 weeks of treatment</p> <p>Notes:</p> <ul style="list-style-type: none"> • The medication may be considered for administration without ribavirin for 12 weeks in patients who are treatment-naïve and cannot take or tolerate ribavirin </div> <p>Public Comment</p> <p>Laura Hill with AbbVie commented it is not contra-indicated in patients with cirrhosis, it's just not approved; it's not been studied.</p> <p>Board Discussion</p> <p>Dr. Casey apologized for miss-speaking and provided assurance to the board that the current verbiage is correct as is.</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>24. Daklinza® (daclatasvir)</p>	<p>Background</p> <p>Daklinza is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis C infection. Prior authorization criteria were initially approved in October 2015. Since that</p>	<p>Dr. Heston moved to approve as written.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>i. Revised PA Criteria</p>	<p>time, Daklinza has been approved for genotype 1; also, it has been established to be safe and effective in the decompensated cirrhosis and post liver transplant populations. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p> <div style="border: 1px solid black; padding: 5px;"> <p>MANUAL GUIDELINES The following drug requires prior authorization: Daclatasvir (Daklinza®)</p> <p>CRITERIA FOR INITIAL APPROVAL OF DACLATASVIR: (must meet all of the following): <i>*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of daclatasvir therapy total)*</i></p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C (CHC) • Patient must have genotype 1 or 3 hepatitis C • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Must be used in combination with Sovaldi® (sofosbuvir) • Patient must not have been on a previous or concurrent direct acting hepatitis C agent (except concurrent therapy with Sovaldi® according to acceptable treatment therapy options) • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request • Dose must not exceed 1 tablet per day • Patient must have a Metavir score of F3 or greater • Patient must not be concurrently prescribed a strong CYP3A inducer (e.g. phenytoin, carbamazepine, rifampin, St. John's wort) • Patient must not be on concurrent moderate CYP3A inducers (e.g. bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine) • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with daclatasvir combination therapy <p>CRITERIA FOR RENEWAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Prescriber must document adherence by patient of greater than or equal to 90% for both agents <p>LENGTH OF APPROVAL: 4 weeks for a total of 12 weeks of treatment</p> </div> <p>Public Comment Valerie Collins with Bristol-Myers Squibb spoke on behalf of Daklinza.</p> <p>Board Discussion Discussion on 12 weeks verses 24 weeks. The percentage of patients being so low and providers would know to appeal if necessary, the Board felt the criteria was reasonable to leave as proposed.</p>	<p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>C. New Prior Authorization (PA) Criteria</p> <p>1. Zepatier® (elbasvir/grazoprevir)</p> <p>i. Prior Authorization Criteria</p>	<p>Background Zepatier is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis C infection in genotype 1 and 4. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>MANUAL GUIDELINES The following drug requires prior authorization: Elbasvir/Grazoprevir (Zepatier®)</p> <p>CRITERIA FOR INITIAL APPROVAL (must meet all of the following): <i>*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of elbasvir/grazoprevir therapy total for most patients or 16 weeks for genotype 1a with baseline polymorphisms or genotype 4 IFN/RBV-experienced)*</i></p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C (CHC) • Patient must have genotype 1 or 4 hepatitis C • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Patient must not have been on previous or concurrent direct acting hepatitis C agent • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request • Dose must not exceed 1 tablet per day • Patient must have one of the following: <ul style="list-style-type: none"> ○ Advanced fibrosis (Metavir F3 or greater) ○ Compensated cirrhosis ○ Organ transplant ○ Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis) ○ Proteinuria ○ Nephrotic syndrome ○ Membranoproliferative glomerulonephritis • Patient must not have moderate or severe hepatic impairment (Child-Pugh class B or C) • Female patients on concurrent ribavirin must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during elbasvir/grazoprevir treatment • Patient must not be concurrently prescribed a strong CYP3A inducer, efavirenz, or OATP1B1/3 inhibitor • Patient must be tested for the presence of virus with NS5A resistance-associated polymorphisms prior to initiation of therapy <p>CRITERIA FOR RENEWAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Prescriber must document adherence by patient of greater than or equal to 90% for both agents <p>LENGTH OF APPROVAL: 4 weeks for a total of 12 weeks of treatment 4 weeks for a total of 16 weeks of treatment for patients with one of the following:</p> <ul style="list-style-type: none"> • Genotype 1a with baseline NS5A polymorphisms • Genotype 4 and Peg-Interferon/ribavirin experienced <p>Notes:</p> <ul style="list-style-type: none"> • OATP1B1 inhibitors include (but not limited to): cyclosporine, eltrombopag, lapatinib, lopinavir, rifampin, ritonavir • OATP1B3 inhibitors include (but not limited to): cyclosporine, lopinavir, rifampin, ritonavir • Strong CYP3A inducers include (but not limited to): phenytoin, carbamazepine, rifampin, St. John's wort <p>Public Comment Michael Ferrari spoke on behalf of Merck and Zepatier®.</p> <p>Board Discussion None</p>	
C. New Prior Authorization	Background	Dr. Mittal moved to approve as

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>(PA) Criteria</p> <p>2. Zurampic® (lesinurad)</p> <p>i. Prior Authorization Criteria</p>	<p>Zurampic is a uric acid transporter 1 inhibitor indicated for the treatment of hyperuricemia associated with gout (in combination with a xanthine oxidase inhibitor) in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.</p> <div style="border: 1px solid black; padding: 5px;"> <p>MANUAL GUIDELINES The following drug requires prior authorization: Lesinurad (Zurampic®)</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 hyperuricemia associated with gout • Patient must be 18 years of age or older • Patient must be taking medication in combination with a xanthine oxidase inhibitor (allopurinol or febuxostat) <ul style="list-style-type: none"> ○ Allopurinol dose must be at least 300 mg daily in patients with normal renal function or 200 mg in patients with CrCl 45-60 mL/min • Patient must have a serum uric acid level of 6 mg/dL or greater while on a xanthine oxidase inhibitor • Patient must not have any of the following: <ul style="list-style-type: none"> ○ Severe renal impairment (< 45 mL/min), end stage renal disease, kidney transplant recipient, or be on dialysis ○ Tumor lysis syndrome or Lesch-Nyhan syndrome • Dose must not exceed 200 mg per day <p>LENGTH OF APPROVAL: 6 months</p> <p>CRITERIA FOR RENEWAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must be taking medication in combination with a xanthine oxidase inhibitor (allopurinol or febuxostat) <ul style="list-style-type: none"> ○ Allopurinol dose must be at least 300 mg daily in patients with normal renal function or 200 mg in patients with CrCl 45-60 mL/min • Patient must not have any of the following: <ul style="list-style-type: none"> ○ Severe renal impairment (< 45 mL/min), end stage renal disease, kidney transplant recipient, or be on dialysis ○ Tumor lysis syndrome or Lesch-Nyhan syndrome • Dose must not exceed 200 mg per day • Patient must have one of the following: <ul style="list-style-type: none"> ○ Patient's serum uric acid levels must be < 6 mg/dL ○ If the patient's uric acid level is not at goal of < 6 mg/dL, patient must have a reduction of uric acid level from baseline and reduction in symptoms <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p> </div>	<p>written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>C. New Prior Authorization (PA) Criteria</p> <p>3. Kanuma® (sebelipase alfa)</p> <p>i. Prior Authorization</p>	<p>Background</p> <p>Kanuma is indicated for the treatment of patients with lysosomal acid lipase (LAL) deficiency. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the</p>	<p>Dr. Heston moved to approve as amended.</p> <p>Dr. Unruh seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
Criteria	<p>approved indication.</p> <div style="border: 1px solid black; padding: 5px;"> <p>MANUAL GUIDELINES The following drug requires prior authorization: Sebelipase alfa (Kanuma®)</p> <p>CRITERIA FOR APPROVAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Lysosomal Acid Lipase (LAL) deficiency • Prescriber must be a neonatologist, geneticist, gastroenterologist, endocrinologist, lipidologist, or hepatologist • Must be administered by a healthcare professional • Patient must be 1 month of age or older <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment Richard McKenna with Alexion spoke on behalf of Kanuma.</p> <p>Board Discussion The Board discussed possible infants diagnosed prior to 1 month of age. Treatment would not be declined. MCOs present noted that they could do expedited reviews. No adverse reactions were noted to this unique agent. Dr. Smith felt that any patient diagnosed would probably be in a hospital. The Board recommended amending the criteria by adding the list of qualified prescribers for this agent.</p>	The criteria were approved as unanimously as amended.
<p>C. New Prior Authorization (PA) Criteria</p> <p>4. Strensiq® (asfotase alfa)</p> <p>i. Prior Authorization Criteria</p>	<p>Background Strensiq is indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP). Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.</p>	<p>Dr. Unruh moved to approve as amended.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously as amended.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>MANUAL GUIDELINES The following drug requires prior authorization: Asfotase alfa (Strensiq®)</p> <p>CRITERIA FOR APPROVAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must have one of the following: <ul style="list-style-type: none"> a) Diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) <ul style="list-style-type: none"> ▪ Dose must not exceed 9 mg/kg/week b) Diagnosis of juvenile-onset hypophosphatasia (HPP) • Patient must have a baseline ophthalmology examination and renal ultrasound <p>LENGTH OF APPROVAL: 6 months</p> <p>CRITERIA FOR RENEWAL (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must have an ophthalmology examination and renal ultrasound at 6 months of treatment and then annually • For a diagnosis of perinatal/infantile-onset hypophosphatasia (HPP), the dose must not exceed 9 mg/kg/week <p>LENGTH OF APPROVAL: 12 months</p> <p>Notes:</p> <ul style="list-style-type: none"> • The recommended dosage for both indications is 6 mg/kg/week, given as either 2 mg/kg three times per weeks or 1 mg/kg six times per week. • Three times weekly dosing at 3 mg/kg is only recommended for a diagnosis of perinatal/infantile-onset HPP, after lack of efficacy at recommended dose. • Do not use the 80 mg/0.8 mL vial in pediatric patients weighing less than 40 kg (88 lbs) due to decreased systemic exposure than the other strength vials. <p>Public Comment Richard McKenna spoke on behalf of Strensiq, requesting the Length of Approval to be changed from 6 months to 12 months.</p> <p>Board Discussion The Board recommended adding criteria for the initial length of approval and provided criteria for the 12 month length of approval for a renewal.</p>	
<p>D. Mental Health Medication Advisory Committee (MHMAC)</p> <p>1. Use of Concurrent Multiple Antipsychotics</p> <p>i. MHMAC PA Criteria</p>	<p>Background At the October 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent antipsychotics. Then at the February 2016 meeting, the criteria was amended, at the request of the DUR board members. Prior authorization criteria are being proposed to limit the number of individual antipsychotics used concurrently for greater than 60 days to a maximum of 2 oral/injectable medications or 1 injectable formulation in adults; and greater than 120 days to a maximum of 2 medications in the pediatric population before a prior authorization is required.</p>	<p>Dr. Heston moved to approve as written.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR PRIOR AUTHORIZATION FOR PATIENTS ≥ 18 YEARS OF AGE RECEIVING MULTIPLE ANTIPSYCHOTICS CONCURRENTLY FOR 60 DAYS:</p> <ul style="list-style-type: none"> • Three or more antipsychotics used concurrently for greater than 60 days (includes oral and long-acting injectable): <ul style="list-style-type: none"> ○ Must be prescribed by or in consultation/collaboration with a psychiatrist ○ Peer-to-Peer consult with health plan psychiatrist, medical director, or pharmacy director must be completed for approval • Two or more concurrent long-acting injectable antipsychotics for greater than 60 days <ul style="list-style-type: none"> ○ Peer-to-Peer consult with health plan psychiatrist, medical director, or pharmacy director must be completed for approval <p>LENGTH OF APPROVAL: 12 months</p> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR PATIENTS < 18 YEARS OF AGE RECEIVING MULTIPLE ANTIPSYCHOTICS CONCURRENTLY FOR 120 DAYS:</p> <ul style="list-style-type: none"> • Two or more antipsychotics (including oral and long-acting injectable) used concurrently for greater than 120 days (includes oral and long-acting injectable): <ul style="list-style-type: none"> ○ Must be prescribed by or in consultation/collaboration with a psychiatrist, neurologist, or developmental-behavioral pediatrician ○ Peer-to-Peer consult with health plan psychiatrist, medical director, or clinical pharmacist must be completed for approval <p>LENGTH OF APPROVAL: 12 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> Discussion on the data of individuals on these agents. The Board was reassured as to the review process and clinical review process for a crisis situation.</p>	
<p>E. Miscellaneous Items 1. Managed Care Organization Annual Reports</p>	<p>Amerigroup, United Healthcare, and Sunflower will present their annual reports at the July 2016 DUR meeting.</p>	<p>MCO Reports will be presented at the July 2016 DUR Meeting.</p>
<p>IV. Open Public Comment</p>	<p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>V. Adjourn.</p>	<p>Dr. Mittal moved to adjourn. Dr. Heston seconded the motion.</p>	<p>Dr. Morton adjourned the April 2016 DUR Meeting at 11:25 am.</p>