

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

Drug Utilization Review Board
HP Enterprise Services, Capital Room
6700 SW Topeka Blvd, Bldg. 283 J,
Topeka, KS 66619

DUR Board Members Present

Russell Scheffer, MD, Chair
Tim Heston, DO
John Kollhoff, Pharm.D.

James Backes, Pharm.D.
Judy McDaniel Dowd, PA-C
LaTonyua Rice, Pharm.D., CGP

DUR Board Members Absent

Roger Unruh, DO
Lauren Morton, Pharm.D., BCPS

Moneeshindra Mittal, MD

DHCF Staff Present

Liane Larson, Pharm.D.

Carol Arace, Sr. Administrative Assistant

HP Enterprise Services Staff Present

Karen Kluczykowski, RPh

Nancy Perry, R.N.

HID Staff Present

Ariane Casey, Pharm.D.

MCO Staff Present

Jonalan Smith, Pharm.D., FASCP: Sunflower Health Plan
Jennifer Murff, RPh: United Healthcare Community Plan
Lisa Todd, RPh, BBA: Amerigroup Kansas

Representatives

Jeff Cameron, Dyax
Larry Dollar
Kelli Amick, Takeda
Paul Hueseman, Astrazeneca
Marla Wiedenmann,
Novonordisk
Katherine Friedebach, Sunflower
Joel Meyer, Novartis
Jeff Knappen, Allergan
Janie Huff, Takeda
Kathy Brader, Lundbeck
Angie Zhou, Sunflower
Godfrey Archibong, Sunflower
Bethany Marks, Regeneron
Scott Maurice, BI
Shawna Williams, DK Pierce
Lisa Tootle, BMS
Melissa Laurie, BMS
Mina Allo, BMS
Laura Hill, Abbvie
Holly Weatherford, BMS
Melissa Basil, Abbvie
Michele Puyear, Gilead
Berend Koops, Merck
Brian Rose, Merck
Bram Svrganinanz, Merck
Kristin Monthye, Abbvie
Jeff Bender, KDHE
Katie Mispagel, KDHE
Tom Shaughuessy, ARJ
Terry McCurren
Eric Perry, Dyax
Hope Berry, USL
S. Skoynica, Sunflower

		Roberta Newirth, GSK Tyrone McBayne, Baxalta Carol Dagney, Grifols Mary Jo Deflorio, J&J Linda Sheppard, KHI Kim Koehler, KDHE
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Scheffer called the meeting to order at 10:09am.	
A. Announcements	Dr. Larson offered the general parking announcement, reminder of public comment is limited to five (5) minutes, and introduced Dr. Rice as a new member to the Kansas DUR Board.	
II. Old Business A. Review and Approval of the October 14, 2015 DUR Meeting Minutes	Board Discussion None	Dr. Kollhoff moved to approve the minutes as presented. Ms. Dowd seconded the motion The October 14, 2015 minutes were approved unanimously.
III. New Business A. Mental Health Medication Advisory Committee (MHMAC) 1. Use of Multiple Concurrent Benzodiazepines i. MHMAC PA Criteria	Prior to discussing the upcoming MHMAC recommendations, Dr. Larson gave a brief understanding for the board as to the review, approval, or rejection of the documents. Each document must be approved or rejected in full. If rejected, Dr. Larson would take any comments from the DUR back to the MHMAC for consideration. Background: At the October 2015 MHMAC meeting, the committee approved the benzodiazepine dosing limit criteria. Prior authorization criteria are being proposed to limit the number of individual benzodiazepines used concurrently within 30 days to a maximum of 2 medications before a prior authorization is required. <div style="border: 1px solid black; padding: 5px; margin-top: 10px;">CRITERIA FOR PRIOR AUTHORIZATION FOR PATIENTS RECEIVING MULTIPLE BENZODIAZEPINES CONCURRENTLY:<ul style="list-style-type: none">• Three or more different benzodiazepines used concurrently within 30 days will require a prior authorization:<ul style="list-style-type: none">○ Peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval○ Patients with documented seizure diagnosis will automatically be approvedLENGTH OF APPROVAL: 6 months</div> Public Comment None	Dr. Heston moved to approve as written. Dr. Backes seconded the motion. The criteria were approved unanimously.

	<p>Board Discussion</p> <p>The pharmacy would receive the message that a PA is required for three or more benzodiazepines. Dr. Larson provided data on the number of individuals that would meet this criteria request; 46 individuals within the first quarter of 2015.</p>	
<p>A. Mental Health Medication Advisory Committee (MHMAC)</p> <p>2. Use of Concurrent Multiple Antipsychotics</p> <p>i. MHMAC PA Criteria</p>	<p>Background:</p> <p>At the October 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent antipsychotics. 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 2 medications in the pediatric population before a prior authorization is required.</p> <div data-bbox="527 488 1629 829" style="border: 1px solid black; padding: 5px;"> <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> </div> <div data-bbox="527 865 1629 1146" style="border: 1px solid black; padding: 5px;"> <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"> • Two or more antipsychotics (including oral and long-acting injectable) 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, 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: 6 months</p> </div> <p>Public Comment:</p> <p>Dr. Shoyinka from Sunflower spoke of concerns with antipsychotic use in children.</p> <p>Board Discussion</p> <p>Dr. Casey clarified that the limit is 2 for adults and 1 for children before a PA would be required. Dr. Scheffer shared information on national standard for children being 2 mood stabilizers and feels this criteria goes against the national guidelines. Dr. Larson will take notes to the next MHMAC meeting.</p>	<p>Mrs. Dowd moved to reject as written.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were rejected unanimously.</p>

<p>A. Mental Health Medication Advisory Committee (MHMAC)</p> <p>3. Antipsychotics for Children Ages 13 and Younger</p> <p>i. MHMAC PA Criteria</p>	<p>Background</p> <p>At the October 2015 MHMAC meeting, the committee approved the age limit criteria for antipsychotics in children 13 years of age or younger. Prior authorization criteria are being proposed to limit the use to specific diagnoses and require appropriate monitoring.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR ANTIPSYCHOTICS PRESCRIBED TO CHILDREN AGES 6 OR YOUNGER: (must meet all of the following)</p> <ul style="list-style-type: none"> • Must be prescribed by or in consultation/collaboration with a psychiatrist, neurologist, or developmental-behavioral pediatrician • Must have a diagnosis of autistic disorder, mood disorder, psychotic disorder, tic disorder or Tourette’s syndrome • Documentation of plasma glucose, lipid screening, weight, height and waist circumference within the previous 3 months <p>LENGTH OF APPROVAL: 6 months*</p> <p>*A one-time 60 day override for this criteria requirement will be available to dispensing pharmacies through the Point-of-Sale PBM adjudication system.</p> </div>	<p>Dr. Kollhoff moved to approve as written.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>
---	---	---

DRAFT

	<p>CRITERIA FOR PRIOR AUTHORIZATION FOR ANTIPSYCHOTICS PRESCRIBED TO CHILDREN AGES 7-13: (must meet all of the following)</p> <ul style="list-style-type: none"> • Must have a diagnosis of Autistic Disorder, Hyperactive Behavior, Mood Disorder, Problem Behavior (Severe), Schizophrenia OR Tourette’s Syndrome • Documentation of plasma glucose, lipid screening, weight, height and waist circumference within the previous 3 months <p>LENGTH OF APPROVAL: 12 months*</p> <p>*A one-time 60 day override for this criteria requirement will be available to dispensing pharmacies through the Point-of-Sale PBM adjudication system.</p> <p>RENEWAL CRITERIA FOR ANTIPSYCHOTICS PRESCRIBED TO CHILDREN AGES 6 OR YOUNGER: (must meet all of the following)</p> <ul style="list-style-type: none"> • Must be prescribed by or in consultation/collaboration with a psychiatrist, neurologist, or developmental-behavioral pediatrician • Documentation of metabolic profile monitoring in accordance with AACAP/ADA guidelines • Patient must be receiving evidenced-based behavioral modification therapy concurrently with anti-psychotic therapy unless behavioral modification therapy is documented to be ineffective • Annual physical must be completed by a pediatrician, family practice physician, family nurse practitioner or physician assistant for continued approval <p>LENGTH OF RENEWAL APPROVAL: 12 months</p> <p>RENEWAL CRITERIA FOR ANTIPSYCHOTICS PRESCRIBED TO CHILDREN AGES 7-13: (must meet all of the following)</p> <ul style="list-style-type: none"> • Documentation of metabolic profile monitoring in accordance with AACAP/ADA guidelines • Patient must be receiving evidenced-based behavioral modification therapy concurrently with anti-psychotic therapy unless behavioral modification therapy is documented to be ineffective • Annual physical must be completed by a pediatrician, family practice physician, family nurse practitioner or physician assistant for continued approval <p>LENGTH OF RENEWAL APPROVAL: 12 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> Concerns of the low access to behavioral modification therapy and how that may affect PA outcome.</p>	
<p>A. Mental Health Medication Advisory Committee (MHMAC)</p> <p>4. Antipsychotic Dosing Limits</p> <p>i. MHMAC PA Criteria</p>	<p><u>Background</u></p> <p>At the October and December 2015 MHMAC meetings, the committee approved the criteria for antipsychotic dosing limits. Prior authorization criteria are being proposed to limit the maximum daily dose allowed before a prior authorization is required.</p>	<p>Dr. Heston moved to approve as written.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved</p>

	<p>CRITERIA FOR PRIOR AUTHORIZATION FOR ANTIPSYCHOTIC DOSING LIMITS:</p> <ul style="list-style-type: none"> • Doses exceeding those listed in Table 1 will require a prior authorization <ul style="list-style-type: none"> ○ Prior authorization will require a peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment None</p> <p>Board Discussion The burden of having to renew the PA every 12 months for long term care patients was discussed. Should the criteria become burdensome, this can be revisited for review.</p>	unanimously.
<p>A. Mental Health Medication Advisory Committee (MHMAC)</p> <p>5. Use of Multiple Concurrent Selective Serotonin Reuptake Inhibitors (SSRIs)</p> <p>i. MHMAC PA Criteria</p>	<p>Background At the December 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent selective serotonin reuptake inhibitors (SSRIs). Prior authorization criteria are being proposed to limit the number of individual SSRIs used concurrently for greater than 60 days to a maximum of 1 medication before a prior authorization is required.</p> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR PATIENTS RECEIVING MULTIPLE SSRIS CONCURRENTLY:</p> <ul style="list-style-type: none"> • Two or more different SSRIs used concurrently for greater than 60 days will require prior authorization: <ul style="list-style-type: none"> ○ Peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment None</p> <p>Board Discussion None</p>	<p>Dr. Kollhoff moved to approve as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>A. Mental Health Medication Advisory Committee (MHMAC)</p> <p>6. Use of Multiple Concurrent Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)</p> <p>i. MHMAC PA Criteria</p>	<p>Background At the December 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent serotonin-norepinephrine reuptake inhibitors (SNRIs). Prior authorization criteria are being proposed to limit the number of individual SNRIs used concurrently for greater than 60 days to a maximum of 1 medication before a prior authorization is required.</p> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR PATIENTS RECEIVING MULTIPLE SNRIS CONCURRENTLY:</p> <ul style="list-style-type: none"> • Two or more different SNRIs used concurrently for greater than 60 days will require prior authorization: <ul style="list-style-type: none"> ○ Peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment One member of the public expressed a concern regarding fibromyalgia and/or combination therapy to be appropriate. Dr. Larson stated that the MHMAC chose to add Savella even</p>	<p>Dr. Kollhoff moved to approve as written.</p> <p>Dr. Rice and Mrs. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>

	<p>though it is for fibromyalgia.</p> <p>Board Discussion Board was reminded that it is over 60 days that would hit the PA.</p>	
<p>A. Mental Health Medication Advisory Committee (MHMAC)</p> <p>7. Use of Multiple Concurrent Antidepressants</p> <p>i. MHMAC PA Criteria</p>	<p>Background At the December 2015 MHMAC meeting, the committee approved the criteria for multiple concurrent antidepressants. Prior authorization criteria are being proposed to limit the number of individual antidepressants used concurrently for greater than 60 days to a maximum of 2 medications before a prior authorization is required.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR PATIENTS RECEIVING MULTIPLE ANTIDEPRESSANTS CONCURRENTLY:</p> <ul style="list-style-type: none"> • Three or more different antidepressants used concurrently for greater than 60 days will require a prior authorization: <ul style="list-style-type: none"> ○ Peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment None</p> <p>Board Discussion It was clarified that a PA would be required on 3 or more. MHMAC had removed some of the antidepressants that were used for a wider variety of conditions.</p>	<p>Mrs. Dowd moved to approve as written.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>8. LABA-Anticholinergic Combinations (Utibron Neohaler [indacaterol/glycopyrrolate], Stiolto Respimat [tiotropium/olodaterol])</p> <p>i. Revised PA Criteria</p>	<p>Background Prior authorization criteria for LABA-Anticholinergic Combinations (formerly named Anoro Ellipta, the only medication in the class at that time) were initially approved in October 2014. Since that time, two new agents have been approved. The prior authorization criteria is being revised to include the new agents, Utibron NeoHaler and Stiolto Respimat.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR INHALED LABA/ANTICHOLINERGIC COMBINATIONS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic obstructive pulmonary disease (COPD) • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment None</p> <p>Board Discussion None</p>	<p>Dr. Backes moved to approve as written.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>9. Eylea® (aflibercept)</p>	<p>Background Eylea is an intravitreal injection indicated for the treatment of macular edema and macular degeneration. Prior authorization criteria were initially approved in July 2014. Since that time, two new indications have been approved, diabetic macular edema and diabetic</p>	<p>Mrs. Dowd moved to approve as amended.</p> <p>Dr. Backes seconded the</p>

<p>i. Revised PA Criteria</p>	<p>retinopathy in patients with diabetic macular edema. The prior authorization criteria are being revised to ensure appropriate use.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR AFLIBERCEPT: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be 18 years of age or older • Patient must have one of the following: <ul style="list-style-type: none"> ○ Neovascular (wet) age-related macular degeneration (AMD) ○ Macular edema following central retinal vein occlusion (RVO) ○ Diabetic macular edema (DME) ○ Diabetic retinopathy (DR) in patients with DME • Patient must not have an active ocular or periocular infection • Must be prescribed and administered by an ophthalmologist <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment Bethany Marks, Regeneron, wanted clarification on the PA criteria. Dr. Scheffer verified that it had all the appropriate criteria.</p> <p>Board Discussion Must be prescribed and administered by a trained ophthalmologist. Given this is prescribed for chronic diseases, length of approval was changed from 6 months to 12 months.</p>	<p>motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>10. Hetlioz® (tasimelteon)</p> <p>i. Revised PA Criteria</p>	<p>Background Hetlioz is a melatonin receptor agonist indicated for the treatment of non-24 hour sleep-wake disorder. Prior authorization criteria were initially approved in January 2015. Efficacy of Hetlioz was only established in patients who were totally blind with no perception of light. The prior authorization criteria are being revised to ensure appropriate use.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR TASIMELTEON: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of non-24-hour sleep-wake disorder • Patient must be totally blind with no perception of light • Patient must be 18 years of age or older • Dose must not exceed 20mg per day <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment None</p>	<p>Dr. Kollhoff moved to approve as written.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>

	<p><u>Board Discussion</u> None</p>	
<p>B. Revised Prior Authorization (PA) Criteria 11. Humira® (adalimumab) i. Revised PA Criteria</p>	<p><u>Background</u> Humira is a tumor necrosis factor-alpha (TNF-α) blocker indicated as a biologic treatment in several diagnoses. Prior authorization criteria were last revised in January 2015. Since that time, a new indication has been approved, hidradenitis suppurativa. 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 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 </div>	<p>Mrs. Dowd moved to approve as amended.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>

CRITERIA FOR CROHN'S DISEASE (CD): (must meet all of the following)

- 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)

CRITERIA FOR PEDIATRIC CROHN'S DISEASE (CD): (must meet all of the following)

- 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

CRITERIA FOR ULCERATIVE COLITIS (UC): (must meet all of the following)

- 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 HIDRADENTITIS 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 6 months</p> <p>Public Comment Laura Hill suggested changes to the Hurley and AISI on the first bullet point.</p> <p>Board Discussion Dr. Larson provided the data information for AISI. The changes were made as suggested.</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>12. Stelara® (ustekinumab)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Stelara is an immunomodulator indicated for biologic treatment of plaque psoriasis and psoriatic arthritis. Prior authorization criteria were last revised in January 2014. Recommended dosing begins at 45 mg per injection, only to be increased based on weight, efficacy, and coexistent conditions. The prior authorization criteria are being revised to ensure appropriate use.</p>	<p>Mrs. Dowd moved to approve as amended.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

	<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 6 months</p> <p>Public Comment None</p> <p>Board Discussion Criteria updated to include patients weight and coexisting plaque psoriasis documentation. A question to change it to 12 months was discussed. Plan is to bring the biologics back at the next DUR meeting to change from 6months to 12 months for length of approval.</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>13. Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor Combinations (Invokamet [canagliflozin/metformin], Synjardy [empagliflozin/metformin], Xigduo XR [dapagliflozin/metformin])</p> <p>i. Revised PA Criteria</p>	<p>Background Prior authorization criteria for SGLT2 Inhibitor Combinations were initially approved in April 2015. Since that time, three new agents have been approved. The prior authorization criteria is being revised to include the new agents, Invokamet, Synjardy, and Xigduo XR.</p> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR SGLT2 INHIBITOR COMBINATIONS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of type II diabetes • Patient MUST NOT have a diagnosis of type I diabetes • Patient must be 18 years of age or older • Patient must have an <u>eGFR</u> above 45 ml/min/1.73m2 • Patient MUST NOT have any of the following contraindications: <ul style="list-style-type: none"> ○ End-stage renal disease ○ Currently on dialysis <p>LENGTH OF APPROVAL: 12 months</p>	<p>Dr. Kollhoff moved to table this item.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The criteria were tabled at this time.</p>

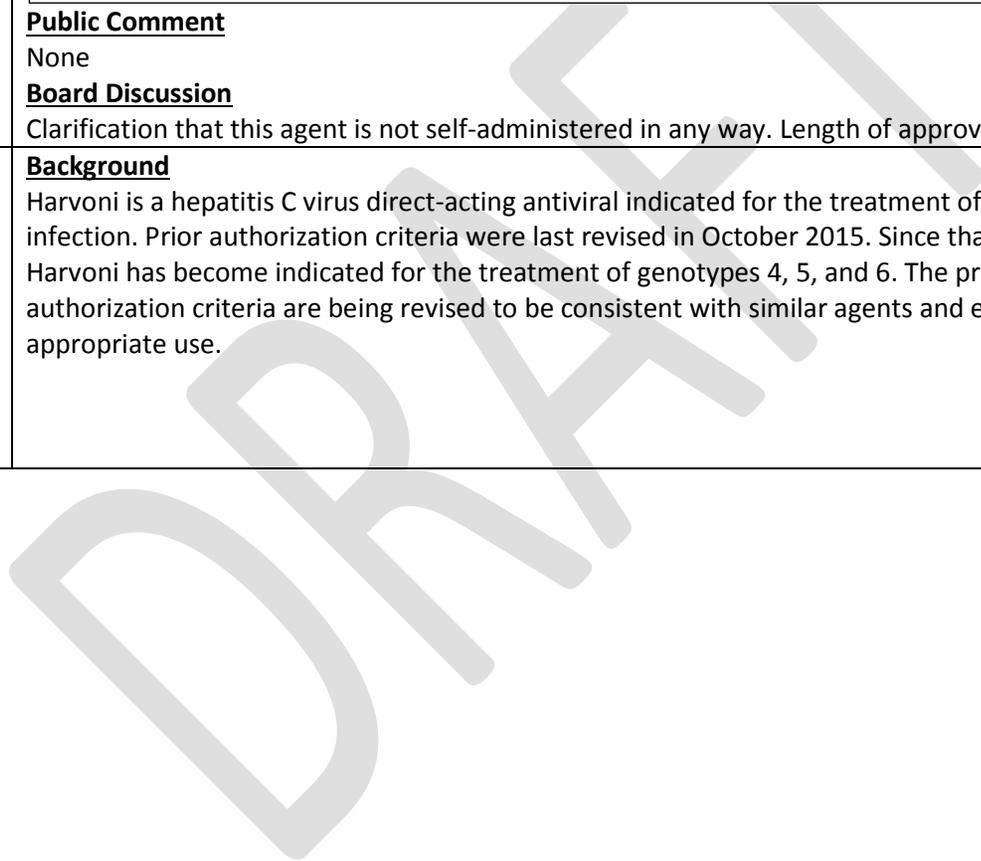
	<p>Public Comment None</p> <p>Board Discussion Thoughts around all 3 of these needing to be separated. Paul Hueseman from the audience provided information on differences. Rename the class or seperate the class? Tabled until additional information is obtained.</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>14. Topical Acne Medications</p> <p>i. Revised PA Criteria</p>	<p>Background Prior authorization criteria for Topical Acne Medications were last revised in October 2014. Since that time, a new agent has been approved and minimum ages have been established in several products. The prior authorization criteria is being revised to include the new agent, Epiduo Forte, and allow approval for appropriate ages based on medication. 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 ACNE VULGARIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of acne vulgaris • • For Epiduo and Epiduo Forte, patient must be 9 years of age or older • For Atralin, patient must be 10 years of age or older • For all other acne products, patient must be 12 years of age or older <p>CRITERIA FOR PLAQUE PSORIASIS (TAZORAC ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of plaque psoriasis • • For Tazorac 0.05% and 0.1% cream, patient must be 18 years of age or older • For Tazorac 0.05% and 0.1% gel, patient must be 12 years of age or older <p>CRITERIA FOR ROSACEA (FINACEA ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of inflammatory papules and pustules of mild to moderate rosacea • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment None</p> <p>Board Discussion Mrs. Dowd questioned why some of these agents require PA at all. Cost is significant. Dr. Larson noted that another way to manage these agents is through the PDL that does look at cost effectiveness.</p>	<p>Mrs. Dowd moved to approve as written and revisit through the PDL.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

<p>B. Revised Prior Authorization (PA) Criteria</p> <p>15. Zyvox® (linezolid)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Zyvox is an anti-infective agent indicated for the treatment of gram positive bacteria. Prior authorization criteria were initially approved in May 2009. Dependent upon the infection, the recommended duration of treatment is typically 10-14 days and up to 28 days for certain infections. The prior authorization criteria are being revised to ensure appropriate use and to approve for a recommended duration of therapy.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR LINEZOLID: (must meet all of the following)</p> <ul style="list-style-type: none"> • Prior authorization may be approved for one of the following: <ul style="list-style-type: none"> a) Patient is infected with methicillin in-resistant staphylococcus aureus (MRSA) or vancomycin-resistant enterococcus (VRE) documented by culture and sensitivity results; OR b) Prescribed by an infectious disease specialist for FDA approved indications documented by culture and sensitivity results. If culture and sensitivity is not obtainable, documentation must be provided that supports treatment plan. • Treatment for infections caused by Gram-negative strains will not be approved. If a concomitant Gram-negative pathogen is documented or suspected, it is critical that specific Gram-negative therapy be initiated at the same time. • A baseline CBC must be obtained with weekly CBCs for the duration of the treatment. • Prior authorizations may be approved and renewed (one time) for two weeks (14 days) each. <ul style="list-style-type: none"> ○ Additional renewals must be approved by the pharmacy program manager. <p>LENGTH OF APPROVAL: 2 weeks</p> </div> <p>Public Comment</p> <p>None</p> <p>Board Discussion</p> <p>MCOs requested this to lower PA requests.</p>	<p>Dr. Heston 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>16. Beriner® (C1 esterase inhibitor, human)</p> <p>i. Revised PA Criteria</p>	<p>Background</p> <p>Beriner is a protein C1 inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in October 2010. Since that time, a new specification has been approved, laryngeal attack. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p>	<p>Dr. Kollhoff moved to approve as amended.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

	<p>CRITERIA FOR PRIOR AUTHORIZATION FOR C1 ESTERASE INHIBITOR: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for the treatment of an acute abdominal, facial, or laryngeal attack of HAE • Patient must be 13 years of age or older • Must be administered by a healthcare professional <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment Jeff Cameron/Dyax spoke on behalf of Kalbitor and asked the Board to consider 12 months for length of approval.</p> <p>Board Discussion Board agreed if the diagnosis is verified, that 12 months would be appropriate.</p>	
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>17. Cinryze® (C1 esterase inhibitor, human)</p> <p>i. Revised PA Criteria</p>	<p>Background Cinryze is a protein C1 inhibitor indicated for the prophylaxis of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in July 2009. Since that time, the medication has been approved for ages 13 years and older. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to include ages 13-17 years for this indication, to be consistent with similar agents, and to ensure appropriate use.</p> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR C1 ESTERASE INHIBITOR: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for routine prophylaxis against angioedema attacks in patients with HAE • Patient must be 13 years of age or older • Must be initially administered by a health care professional in an outpatient or home health setting with subsequent administration by only specific persons trained who have demonstrated competence <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment Jeff Cameron/Dyax noted that <i>angioedema</i> should read <i>hereditary angioedema</i>.</p> <p>Board Discussion Board agreed and the change was made along with length of approval.</p>	<p>Mrs. Dowd moved to approve as amended.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>18. Ruconest® (C1 esterase inhibitor, recombinant)</p> <p>i. Revised PA Criteria</p>	<p>Background Berinert is a protein C1 inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in October 2014. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p>	<p>Mrs. Dowd moved to approve as amended.</p> <p>Dr. Kollhoff seconded the motion.</p>

	<p>CRITERIA FOR PRIOR AUTHORIZATION FOR C1 ESTERASE INHIBITOR: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for the treatment of an acute attack of HAE • Must not be used for the treatment of a laryngeal HAE attack • Patient must be 13 years of age or older • Dose must not exceed 4200 units per dose, 2 doses per day • Must be initially administered by a health care professional in an outpatient or home health setting with subsequent administration by only specific persons trained who have demonstrated competence <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment Jeff Cameron/Dyax asked again about the 12 month length of approval.</p> <p>Board Discussion Board noted the length of approval change.</p>	<p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>19. Firazyr® (icatibant)</p> <p>i. Revised PA Criteria</p>	<p>Background Firazyr is a bradykinin inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in July 2012. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</p> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR ICATIBANT: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for the treatment of an acute attack of HAE • Patient must be 18 years of age or older • Dose must not exceed 90 mg (3 doses) per 24 hours • Must be initially administered by a health care professional in an outpatient or home health setting with subsequent administration by only specific persons trained who have demonstrated competence <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment None</p> <p>Board Discussion Comparison of wording between the previous agent and this one. This one is correct as is.</p>	<p>Mrs. Dowd moved to approve as amended.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>20. Kalbitor® (ecallantide)</p>	<p>Background Kalbitor is a kallikrein inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were initially approved in July 2012. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor</p>	<p>Mrs. Dowd moved to approve as amended.</p> <p>Dr. Kollhoff seconded the</p>

<p>i. Revised PA Criteria</p>	<p>levels. 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 PRIOR AUTHORIZATION FOR ECALLANTIDE: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for the treatment of an acute attack of HAE • Patient must be 12 years of age or older • Dose must not exceed 60 mg per 24 hours • Must be administered by a healthcare professional <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment None</p> <p>Board Discussion Clarification that this agent is not self-administered in any way. Length of approval issue.</p>	<p>motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>21. Harvoni® (ledipasvir/sofosbuvir)</p> <p>i. Revised PA Criteria</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 October 2015. Since that time, Harvoni has become indicated for the treatment of genotypes 4, 5, and 6. 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 amended.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>



CRITERIA FOR INITIAL APPROVAL OF LEDIPASVIR/SOFOSBUVIR: (must meet all of the following)

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)

- 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:
 - 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

RENEWAL CRITERIA FOR LEDIPASVIR/SOFOSBUVIR:

- Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following:
 - Genotype 1 (one of the following)
 - 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:
 - **24 weeks total therapy alone**
 - **12 weeks total therapy if used with Ribavirin**
 - Genotype 4, 5, or 6
 - **12 weeks total therapy**

LENGTH OF APPROVAL FOR LEDIPASVIR/SOFOSBUVIR: 4 weeks

Public Comment

Michele Puyear of Gilead, spoke on Harvoni; offering per package insert information about the 12 weeks with Ribavirin added.

Board Discussion

Board kept the criteria as written, but added the 12 week therapy option.

B. Revised Prior Authorization (PA) Criteria

Background

Viekira Pak is a hepatitis C virus direct-acting antiviral indicated for the treatment of hepatitis

Mrs. Dowd moved to approve as written.

<p>22. Viekira Pak® (ombitasvir/paritaprevir/ritonavir and dasabuvir)</p> <p>i. Revised PA Criteria</p>	<p>C infection. Prior authorization criteria were last revised in October 2015. Since that time, a contraindication for use in patients with Child-Pugh class B has been added. This is due to the risk of serious liver injury in those with underlying advanced liver disease. 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: (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 Viekira Pak 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 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 patient has genotype 1b • Patient must not have been on a 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 • Dose must not exceed 1 daily dose pack per day (2 ombitasvir/paritaprevir/ritonavir and 2 dasabuvir tablets per day) • Patient must not have underlying moderate to severe hepatic impairment (Child-Pugh class B or C) • 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 <p>RENEWAL CRITERIA:</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 1a with cirrhosis or mixed genotype with cirrhosis – up to 24 weeks total therapy ○ Liver transplant recipient with normal hepatic function and mild fibrosis (Metavir fibrosis score 2 or lower) – 24 weeks total therapy ○ Genotype 1a without cirrhosis, mixed genotype without cirrhosis or genotype 1b with or without cirrhosis – 12 weeks total therapy <p>LENGTH OF APPROVAL FOR VIEKIRA PAK: 4 weeks</p> <p>Public Comment None</p> <p>Board Discussion None</p> </div>	<p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>23. Technivie® (ombitasvir/paritaprevir/ritonavir)</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 initially approved in October 2015. Since that time, a contraindication for use in patients with Child-Pugh class B has been added. This is due to the risk of serious liver injury in those with underlying advanced liver disease. The</p>	<p>Dr. Kollhoff moved to approve as written.</p> <p>Mrs. Dowd and Dr. Rice seconded the motion.</p>

<p>i. Revised PA Criteria</p>	<p>prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.</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 not have moderate or severe hepatic impairment or cirrhosis (Child-Pugh class B, C or D) • 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 <p>Public Comment None</p> <p>Board Discussion None</p>	<p>The criteria were approved unanimously.</p>
<p>C. New Prior Authorization (PA) Criteria</p> <p>1. Neurokinin 1 (NK₁) Antagonists</p> <p>i. Prior Authorization Criteria</p>	<p>Background</p> <p>NK₁ inhibitors are indicated for the prevention of nausea and vomiting associated with cancer chemotherapy. 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>CRITERIA FOR PRIOR AUTHORIZATION FOR NEUROKININ 1 (NK-1) ANTAGONISTS/NK-1 ANTAGONIST COMBINATION: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of cancer • Patient must be on oral or intravenous (IV) chemotherapy <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment</p>	<p>Dr. Heston moved to approve as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

	<p>None</p> <p><u>Board Discussion</u></p> <p>None</p>	
<p>C. New Prior Authorization (PA) Criteria</p> <p>2. Emend® (aprepitant)</p> <p>i. Prior Authorization Criteria</p>	<p><u>Background</u></p> <p>Emend Oral is a neurokinin 1 (NK₁) inhibitor indicated for the prevention of nausea and vomiting associated with cancer chemotherapy or for prevention of postoperative nausea and vomiting. 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>CRITERIA FOR PRIOR AUTHORIZATION FOR NAUSEA/VOMITING ASSOCIATED WITH CHEMOTHERAPY: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of cancer • Patient must be on oral or intravenous (IV) chemotherapy <p>LENGTH OF APPROVAL: 12 months</p> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR POSTOPERATIVE NAUSEA/VOMITING: (must meet all of the following)</p> <ul style="list-style-type: none"> • Must be used for prevention of postoperative nausea and vomiting (PONV) • MUST NOT be used for treatment of PONV <p>LENGTH OF APPROVAL: 1 capsule for 1 fill</p> </div> <p><u>Public Comment</u></p> <p>None</p> <p><u>Board Discussion</u></p> <p>None</p>	<p>Dr. Kollhoff moved to approve as written.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>C. New Prior Authorization (PA) Criteria</p> <p>3. Ninlaro® (ixazomib)</p> <p>i. Prior Authorization Criteria</p>	<p><u>Background</u></p> <p>Ninlaro is a proteasome inhibitor indicated for the treatment of multiple myeloma, in combination with lenalidomide and dexamethasone, in adult patients who have received at least 1 prior therapy. 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. Heston moved to approve as amended.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>

	<p>CRITERIA FOR PRIOR AUTHORIZATION FOR IXAZOMIB: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple myeloma (MM) • Patient must have received at least 1 prior therapy • Must be used in combination with lenalidomide and dexamethasone • Patient must be 18 years of age or older • Must be prescribed by, or in consultation with, an oncologist or hematologist • Patient must not be on concurrent strong CYP3A inducers • Patient must not be pregnant or breastfeeding <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment None</p> <p>Board Discussion No requirement for success or failure of therapy was added to the notes for this agent.</p>	
<p>C. New Prior Authorization (PA) Criteria</p> <p>4. Empliciti® (elotuzumab)</p> <p>i. Prior Authorization Criteria</p>	<p>Background Empliciti is an antineoplastic monoclonal antibody indicated for the treatment of multiple myeloma, in combination with lenalidomide and dexamethasone, in adult patients who have received 1-3 prior therapies. 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>CRITERIA FOR PRIOR AUTHORIZATION FOR ELOTUZUMAB: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple myeloma (MM) • Patient must have received 1-3 prior therapies • Must be used in combination with lenalidomide and dexamethasone • Patient must be 18 years of age or older • Must be prescribed by, or in consultation with, an oncologist or hematologist • Patient must not be pregnant or breastfeeding <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment Nina Allo spoke on behalf of Bristol Myers Squibb.</p> <p>Board Discussion None</p>	<p>Mrs. Dowd moved to approve as written.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>C. New Prior Authorization</p>	<p>Background</p>	<p>Mrs. Dowd moved to approve as</p>

<p>(PA) Criteria</p> <p>5. Darzalex® (daratumumab)</p> <p>i. Prior Authorization Criteria</p>	<p>Darzalex is an antineoplastic monoclonal antibody indicated for the treatment of multiple myeloma in adult patients who have received at least 3 prior therapies, including a proteasome inhibitor and an immunomodulatory agent or who are double-refractory to a proteasome inhibitor and an immunomodulatory agent. 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>CRITERIA FOR PRIOR AUTHORIZATION FOR <u>DARATUMUMAB</u>: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple myeloma (MM) • Patient must have received at least 3 prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, OR is double-refractory to a PI and an immunomodulatory agent • Must be used in combination with a corticosteroid, antipyretic, and antihistamine • Patient must be 18 years of age or older • Must be prescribed by, or in consultation with, an oncologist or hematologist • Must be administered by a healthcare professional <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment None</p> <p>Board Discussion None</p>	<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>6. Tagrisso® (osimertinib)</p> <p>i. Prior Authorization Criteria</p>	<p>Background</p> <p>Tagrisso is a tyrosine kinase inhibitor indicated for the treatment of metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) in adult patients who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. 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>CRITERIA FOR PRIOR AUTHORIZATION FOR <u>OSIMERTINIB</u>: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of metastatic non-small cell lung cancer (NSCLC) • Patient must have documentation of a positive epidermal growth factor receptor (EGFR) T790M mutation • Patient must have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy • Patient must be 18 years of age or older • Must be prescribed by, or in consultation with, an oncologist or hematologist • Patient must not be pregnant or breastfeeding • Patient must have a baseline EKG • Patient must not be on concurrent strong CYP3A inhibitors or inducers <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment</p>	<p>Dr. Kollhoff moved to approve as amended.</p> <p>Dr. Rice seconded the motion.</p> <p>The criteria were approved unanimously.</p>

	<p>Paul Hueseman/AstraZeneca spoke on behalf of Tagrisso®. He advised the committee that recommendations for ‘or an appropriate in a pre-approved lab’ is available.</p> <p>Board Discussion</p> <p>Dr. Casey noted that if a package insert uses the word ‘avoid’, that information is usually put into the criteria. Concerns for the lab recommendation as to how far that pre-approved lab would be. The Board agreed to list the name of the test and include ‘patient must have documentation’.</p>	
<p>C. New Prior Authorization (PA) Criteria</p> <p>7. Onivyde® (irinotecan liposome)</p> <p>i. Prior Authorization Criteria</p>	<p>Background</p> <p>Onivyde is a DNA topoisomerase I inhibitor indicated for the treatment of metastatic adenocarcinoma of the pancreas, in combination with fluorouracil and leucovorin, after disease progression following gemcitabine-based therapy. 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>CRITERIA FOR PRIOR AUTHORIZATION FOR IRINOTECAN LIPOSOME: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of metastatic adenocarcinoma of the pancreas • Must be used in combination with fluorouracil (5-FU) and <u>leucovorin (LV)</u> • Patient must have progressed following gemcitabine-based therapy • Patient must be 18 years of age or older • Must be prescribed by, or in consultation with, an oncologist or hematologist • Patient must not be pregnant • Patient must have a baseline bilirubin less than 2 mg/dL • Patient must not be on concurrent strong CYP3A inhibitors or inducers <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment</p> <p>None</p> <p>Board Discussion</p> <p>Dr. Kollhoff asked if the last bullet should have ‘strong’ CYP3A inhibitors or inducers. The change was made.</p>	<p>Dr. Backes moved to approve as amended.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>C. New Prior Authorization (PA) Criteria</p> <p>8. Cotellic® (cobimetinib)</p> <p>i. Prior Authorization Criteria</p>	<p>Background</p> <p>Cotellic is a mitogen-activated extracellular kinase (MEK) inhibitor indicated for the treatment of unresectable or metastatic melanoma in adult patients with a BRAF V600E or V600K mutation, in combination with vemurafenib. 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. Kollhoff moved to approve as amended.</p> <p>Mrs. Dowd seconded the motion.</p>

	<p>CRITERIA FOR PRIOR AUTHORIZATION FOR <u>COBIMETINIB</u>: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of <u>unresectable</u> or metastatic melanoma • Patient must have a documented BRAF V600E or V600K mutation • Must be used in combination with <u>vemurafenib</u> • Patient must be 18 years of age or older • Must be prescribed by, or in consultation with, an oncologist or hematologist • Patient must not be on concurrent moderate or strong CYP3A inducers or inhibitors • Patient must not be pregnant <p>LENGTH OF APPROVAL: 12 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> Dr. Casey noted ‘moderate or strong’ was added to the criteria.</p>	<p>The criteria were approved unanimously.</p>
<p>C. New Prior Authorization (PA) Criteria</p> <p>9. Nucala® (mepolizumab)</p> <p>i. Prior Authorization Criteria</p>	<p><u>Background</u></p> <p>Nucala is a respiratory monoclonal antibody indicated for add-on maintenance treatment of severe asthma with an eosinophilic phenotype in adults and children 12 years and older. 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>CRITERIA FOR INITIAL PRIOR AUTHORIZATION FOR <u>MEPOLIZUMAB</u>: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of severe asthma • Patient must be 12 years of age or older • Patient must have blood eosinophils of greater than or equal to 150 cells/<u>mcl</u> • Must be prescribed by or in consultation with a pulmonologist, allergist, or immunologist • Patient must be taking and be compliant with a high-dose inhaled corticosteroid and a long-acting beta₂-agonist • Must be administered by a healthcare professional <p>CRITERIA FOR RENEWAL PRIOR AUTHORIZATION FOR <u>MEPOLIZUMAB</u>: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must demonstrate a decrease in frequency of exacerbations from baseline (defined as a reduction of oral/systemic corticosteroids and/or hospitalization and/or emergency department visits) <p>LENGTH OF APPROVAL: 6 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> Dr. Larson noted the third bullet is per package insert. The Board agreed to remain</p>	<p>Mrs. Dowd moved to approve as written.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

	consistent with the package insert.	
<p>C. New Prior Authorization (PA) Criteria</p> <p>10. Belbuca® (buprenorphine)</p> <p>i. Prior Authorization Criteria</p>	<p>Background</p> <p>Belbuca is an opioid receptor agonist-antagonist analgesic indicated for the management of severe pain requiring daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 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; margin: 10px 0;"> <p>CRITERIA FOR PRIOR AUTHORIZATION FOR BUPRENORPHINE: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of severe pain, requiring around-the-clock, long-term opioid treatment • Patient MUST NOT have a diagnosis of opioid dependence • Alternative treatment options have been inadequate • Patient must be 18 years of age or older • Patient MUST NOT have any of the following: <ul style="list-style-type: none"> ○ Significant respiratory depression ○ Acute or severe bronchial asthma ○ Known or suspected gastrointestinal obstruction, including paralytic ileus ○ Personal or family history of Long QT Syndrome ○ QTc interval of 450 msec or more • Patient must not be on concurrent Class IA or III antiarrhythmic medication or other medication that prolongs the QT interval • Daily dose of buprenorphine must not exceed 1800 mcg (900 mcg every 12 hours) <p>LENGTH OF APPROVAL: 6 months</p> </div> <p>Public Comment</p> <p>None</p> <p>Board Discussion</p> <p>Adjustment was made to the QTc bullet point.</p>	<p>Mrs. Dowd moved to approve as amended.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>C. New Prior Authorization (PA) Criteria</p> <p>11. Intravenous Immune Globulins (IVIGs)</p> <p>i. Prior Authorization Criteria</p>	<p>Background</p> <p>Intravenous immune globulins are used for several FDA indications and several off-label uses. Prior authorization criteria is being proposed to ensure appropriate use based upon the available prescribing information and to remain consistent with other agents used for the approved indication.</p>	<p>Dr. Kollhoff moved to approve as written.</p> <p>Dr. Backes seconded the motion.</p> <p>Dr. Heston voted no.</p> <p>The criteria were approved.</p>

CRITERIA FOR PRIOR AUTHORIZATION FOR INTRAVENOUS IMMUNE GLOBULINS:

- Patient must have one of the following diagnoses:
 - Primary immune deficiency
 - Idiopathic thrombocytopenic purpura (ITP)
 - B-cell chronic lymphocytic leukemia
 - Kawasaki Disease
 - Chronic demyelinating polyneuropathy
 - Dermatomyositis
 - Fetal or neonatal alloimmune thrombocytopenia
 - Bone marrow transplant
 - Human Immunodeficiency Virus (HIV)
 - Polymyositis
 - Autoimmune mucocutaneous blistering diseases
 - Guillain Barre Syndrome
 - Myasthenia gravis
 - Multiple Sclerosis
 - Hemolytic anemia
 - Stiff man syndrome
 - Solid organ transplant
 - Parvovirus B19
 - Lambert Eaton
 - Stevens Johnson
 - Toxic shock
 - Multifocal motor neuropathy
 - Graves ophthalmopathy
 - Neuropathy (paraprotein associated)
 - Sepsis treatment

Public Comment

A representative from Baxalta questioned the 6 month length of approval.

Board Discussion

Discussion surrounding length of approval for chronic conditions.

IV. Open Public Comment

Public Comment

Dr. Kollhoff moved to reopen

	<p>Paul Heuseman asked about Tagrisso®.</p> <p>Board Discussion</p> <p>The Board reopened the Tagrisso agenda item by vote.</p>	<p>the Tagrisso agenda item.</p> <p>Dr. Heston seconded the motion.</p> <p>The Tagrisso agenda item was reopened.</p>
<p>V. New Prior Authorization (PA) Criteria Re-opened.</p> <p>1. Tagrisso® (osimertinib)</p> <p>i. Prior Authorization Criteria</p>	<p>Background</p> <p>Tagrisso is a tyrosine kinase inhibitor indicated for the treatment of metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) in adult patients who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. 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>CRITERIA FOR PRIOR AUTHORIZATION FOR OSIMERTINIB: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of metastatic non-small cell lung cancer (NSCLC) • Patient must have documentation of a positive epidermal growth factor receptor (EGFR) T790M mutation • Patient must have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy • Patient must be 18 years of age or older • Must be prescribed by, or in consultation with, an oncologist or hematologist • Patient must not be pregnant or breastfeeding • Patient must have a baseline EKG • Patient must not be on concurrent strong CYP3A inhibitors or inducers <p>LENGTH OF APPROVAL: 12 months</p> </div> <p>Public Comment</p> <p>Paul Hueseman/AstraZeneca offered webEx for the requirements.</p> <p>Board Discussion</p> <p>Discussion involved setting a baseline EKG. The baseline EKG bullet was added. The guidelines refer them back to a baseline.</p>	<p>Dr. Kollhoff moved to approve as amended and revisit at the next DUR meeting.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>VI. Open Public Comment (con't)</p>	<p>A member of the audience commented regarding premedication with Durzalex</p>	
<p>V. Adjourn</p>	<p>The meeting was adjourned at 1:15pm.</p> <p>The next meeting will be on April 13th at 10:00am at the HP Enterprises Services Office.</p> <p>**LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS</p>	<p>Dr. Kollhoff moved to adjourn.</p> <p>Dr. Backes seconded the motion.</p> <p>The meeting was adjourned at 1:15pm.</p>

DRAFT