

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
October 14, 2015**

<p><b>Drug Utilization Review Board</b> Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital Room Topeka, KS</p>	<p><b>DUR Board Members Present</b> James Backes, PharmD Tim Heston, D Lauren Morton, PharmD, BCPS Russell Scheffer, MD Mrs. Judy McDaniel Dowd, PA-C Roger Unruh, DO Moneeshindra Mittal, MD John Kollhoff, PharmD</p> <p><b>DUR Board Members Absent</b> LaTonyua Rice, PharmD, CGP</p> <p><b>DHCF Staff Present</b> Kelley Melton, PharmD. Liane Larson, PharmD Carol Arace, Sr. Administrative Assistant</p> <p><b>HP Enterprise Services Staff Present</b> Karen Kluczykowski, RPh Nancy Perry, R.N.</p> <p><b>HID Staff Present</b> Ariane Casey, PharmD (phone) Rachel Boyer, PharmD</p> <p><b>MCO Staff Present</b> Jonalan Smith, PharmD., FASCP: Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p><b>Representatives</b> Lexia Schultz: Midwestern University Jennifer Davis: Onyx Pharmaceuticals Amy Christensen: Novartis Lisa Tootle: BMS Chad Patel: BMS Scott Maurice: B.I. Christina Seltwedel: Amgen Julie McDavitt: B.I. Tom Shaughnessy: ARJ Haley Gola: Pfizer Eric Gardner: Vertex Jamie Tobbitt: Vertex Marla Wiedenmann: NovoNordisk Jim Baumann: Pfizer Brian Rose: Merck Valerie Collins: BMS Paul Hueseman: Astra Zeneca Uzma Fareed: KU Angie Zhou: Sunflower John Omick: Lundbeck Sanket Bhavra: Sunflower Cassandra Johnson: Alkermes Mary Jo Defloro: J&amp;J Nikki Moon: Abbvie Jennifer Stoffel: Janssen Phil King: Pfizer Jim Buntz: KU Amanda Clough: KU Stacy Cassat: KU Tyler Tush: KU Sydney Mibedeax: KU Nancy Zogelman: Pfizer</p>
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<b>TOPIC</b>	<b>DISCUSSION</b>	<b>DECISION AND/OR ACTION</b>
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	The meeting was called to order by DUR Board Chair Dr. Russell Scheffer at 10:10 a.m.	
A. Announcements	<p>Dr. Melton made an announcement about parking outside of HP's offices. She introduced Dr. Rachel Boyer, a pharmacist with Health Information Designs, who typically works with Maryland Medicaid but is working with Kansas in the absence of Dr. Ariane Casey. She also introduced Dr. Lauren Morton, a new pharmacist on the DUR Board who works at Wesley Medical Center in Wichita. Finally, Dr. Melton announced that the Peer Education Resource Council (PERC) Committee would be joining the DUR Board once they conclude business as their meeting.</p> <p>All state staff, HP &amp; HID staff, MCO staff, and DUR board members introduced themselves.</p>	
II. Old Business A. Review and Approval of July 8, 2015 DUR Meeting Minutes	The minutes from the July 8, 2015 DUR Board meeting were reviewed by the board.	<p>Motion to approve: Dr. Kollhoff            Seconded: Dr. Mittal            The minutes from July 8, 2015 were approved unanimously.</p>
B. Opana® (oxymorphone)	<p><b>Background</b>            Opana is an opioid analgesic that is indicated for acute pain (immediate-release tablets) and chronic pain (extended-release tablets). In July 2015, information was presented to the DUR board of the increased abuse that was evident with this medication. The DUR board was open to being proactive for a change in criteria to potentially decrease the abuse through the prior authorization process. Proposed criteria options are being presented to monitor utilization of Opana.</p>	<p>Dr. Kollhoff moved to approve the criteria as written.</p> <p>Mrs. Dowd seconded.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL APPROVAL</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Patient has one of the following: <ul style="list-style-type: none"> <li>○ Patient has a diagnosis of cancer, or</li> <li>○ Patient is terminally ill, or</li> <li>○ Must meet all of the following: <ul style="list-style-type: none"> <li>▪ The patient has not taken another long-acting opioid (see attached table) in the past 3 months or there is documentation of discontinuation of previous agent</li> <li>▪ All narcotic analgesics are written by a single KMAP or MCO enrolled prescriber or practice</li> <li>▪ The patient has a signed opioid treatment agreement with the prescriber</li> <li>▪ Prescriber has reviewed the patient’s K-TRACS profile (information regarding K-TRACS [The Kansas Prescription Drug Monitoring Program], may be found on the Kansas Board of Pharmacy web site)</li> <li>▪ Provider is a specialist in pain management <ul style="list-style-type: none"> <li>• Routine urine drug screening must be included in treatment plan</li> </ul> </li> <li>▪ Patient does not have any of the following: <ul style="list-style-type: none"> <li>• Moderate or severe hepatic impairment</li> <li>• Significant respiratory depression</li> <li>• Acute or severe bronchial asthma or hypercarbia</li> <li>• Known or suspected paralytic ileus</li> </ul> </li> </ul> </li> </ul> </li> <li>• Patient does not have a diagnosis of opioid or other substance abuse</li> <li>• Patient is at least 18 years old</li> <li>• Dosage does not exceed drug limitation of 124 tablets per 28 days</li> <li>• Patient is not pregnant</li> </ul> <p><b>CRITERIA FOR RENEWAL</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Patient must meet initial criteria for renewals</li> <li>• No more than one early refill attempt in the past 3 months unless there is documentation of dose titration from the prescriber.</li> <li>• Provider provides documentation that the patient has been assessed for abuse, addiction, misuse, and oversedation with each approval</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 3 months</p> <p>Dr. Boyer introduced the proposed criteria for Opana® (oxymorphone).</p> <p>Dr. Melton explained that this topic was being re-introduced from the previous DUR Board meeting because Opana utilization was being reviewed as a potential public health issue due to a HIV/AIDs outbreak in Southern Indiana that had been traced to needle sharing specific to Opana use.</p> <p>Dr. Kollhoff asked if Kansas’ utilization data was available.</p> <p>Dr. Boyer reported that there were 944 claims in the past year with 165 patients.</p> <p><b>Public Comment</b></p>	

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	<p>None</p> <p><b>Board Discussion</b> Dr. Kollhoff asked if the risk for HIV infection was the sole consideration for applying PA to Opana, in light of attempting to minimize the number of PA criteria.</p> <p>Dr. Melton stated that the criteria today is being presented in conjunction with removing it from the current long acting opiate criteria, so in any case, Opana will require PA. She stated that the criteria proposed specifically for Opana will just be more stringent.</p>	
<p>III. New Business</p> <p>A. New Preferred Drug List (PDL) Classes</p> <p>1. Opioid-Induced Constipation Agents</p> <p>i. Non-preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b> At the September 2015 PDL meeting, the committee approved the addition of Opioid-Induced Constipation Agents 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><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	<p>Dr. Kollhoff moved to accept the criteria as written.</p> <p>Dr. Mittal seconded.</p> <p>The criteria were approved unanimously.</p>
<p>2. Inhaled Long-Acting Beta Agonists/Anticholinergics</p> <p>i. Non-preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b> At the September 2015 PDL meeting, the committee approved the addition of Inhaled Long-Acting Beta Agonists/Anticholinergic Agents 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><b>Public Comment</b> Julie McDavitt, Boehringer-Ingelheim, stated her availability for any questions on Stiolto.</p> <p><b>Board Discussion</b> None</p>	<p>Mrs. Dowd made a motion to approve.</p> <p>Dr. Backus seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>3. Anaphylaxis Agents</p> <p>i. Non-preferred PDL PA Criteria</p>	<p><b>Background</b> At the September 2015 PDL meeting, the committee approved the addition of a fourth PDL criteria for Anaphylaxis Agents, stating that a patient established/training on one device does not necessarily need to switch to a new device. Standard non-preferred prior authorization</p>	<p>Dr. Kollhoff moved to approve with the changes noting auto-injector pens.</p>

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ii. *Public Comment  iii. Board Discussion	<p>criteria are being proposed for this new class to allow access to non-preferred agents.</p> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> Dr. Melton stated that, unlike other PDL PA criteria presented, if a patient were already trained on one of the products in the Anaphylaxis Agents class, they would be able to use that exception to continue to receive their medication if it were made non-preferred.</p> <p>Dr. Kollhoff also noted that the listed agents should specifically denote that they are ‘auto injector’ products. This change was made to the criteria.</p>	<p>Dr. Unruh seconded.</p> <p>With the noted changes made, the criteria were approved unanimously.</p>
4. Thrombopoietin (TPO) Receptor Agonists i. Non-preferred PDL PA Criteria ii. *Public Comment iii. Board Discussion	<p><b>Background</b> At the September 2015 PDL meeting, the committee approved the addition of Thrombopoietin (TPO) Receptor 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><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	<p>Mrs. Dowd made the motion to approve as written.</p> <p>Dr. Kollhoff seconded.</p> <p>The criteria were approved unanimously.</p>
5. PCSK9-inhibitors (Proprotein convertase subtilisin/kexin type 9) i. Non-preferred PDL PA Criteria ii. *Public Comment iii. Board Discussion	<p><b>Background</b> At the September 2015 PDL meeting, the committee approved the addition of PCSK9-inhibitors 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><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	<p>Mrs. Dowd moved to accept the criteria as written.</p> <p>Dr. Morton seconded.</p> <p>The criteria were approved as written.</p> <p>Dr. Backes recused himself from the vote.</p>
III. New Business B. Revised Prior Authorization (PA) Criteria 1. Xifaxan® (rifamixin)	<p><b>Background</b> Xifaxan is an anti-infective agent indicated for the treatment of hepatic encephalopathy and Traveler’s diarrhea, depending on the strength. Prior authorization criteria were last revised in July 2013. Since that time, Xifaxan has become FDA approved for the treatment of Irritable</p>	<p>Dr. Unruh moved to approve the criteria as written.</p> <p>Dr. Kollhoff seconded.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Bowel Syndrome (IBS) with diarrhea (IBS-D) in adults. The prior authorization criteria are being revised to ensure appropriate use.</p> <p><b>CRITERIA FOR HEPATIC ENCEPHALOPATHY:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of hepatic failure</li> <li>• Patient has had a previous episode of hepatic encephalopathy</li> <li>• Patient must be ≥ 18 years of age</li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p> <p><b>CRITERIA FOR TRAVELERS' DIARRHEA:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must be ≥ 12 years of age</li> <li>• Patient must have a positive culture and susceptibility for noninvasive strain(s) of <i>Escherichia coli</i></li> <li>• Patient does not have diarrhea complicated by fever or blood in the stool</li> <li>• Patient does not have diarrhea due to pathogens other than <i>E. coli</i></li> </ul> <p><b>LENGTH OF APPROVAL</b> 30 days</p> <p><b>CRITERIA FOR IRRITABLE BOWEL SYNDROME:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)</li> <li>• Patient must be ≥ 18 years of age</li> <li>• Patient must not be treated more than 3 times per year</li> </ul> <p><b>LENGTH OF APPROVAL</b> 14 days</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>• 200 mg tablets are approved for Traveler's diarrhea</li> <li>• 550 mg tablets are approved for hepatic encephalopathy and Irritable Bowel Syndrome (diarrhea predominant)</li> </ul> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	<p>The criteria were approved unanimously.</p>
<p>2. Breo Ellipta® (fluticasone/vilanterol)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Breo Ellipta is a respiratory inhalant combination (inhaled corticosteroid and long-acting beta-agonist) indicated to reduce exacerbations and for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). Prior authorization criteria were initially approved in January 2014. Since that time, Breo Ellipta has become FDA approved for the treatment of asthma 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 the criteria as written.</p> <p>Dr. Kollhoff seconded.</p> <p>The criteria were approved unanimously.</p>

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	<p><b>CRITERIA FOR BREO ELLIPTA: (must meet all of the following)</b></p> <ul style="list-style-type: none"> <li>• Patient must have one of the following diagnoses: <ul style="list-style-type: none"> <li>○ Chronic obstructive pulmonary disease (COPD)</li> <li>○ Asthma</li> </ul> </li> <li>• Patient must be 18 years of age or older</li> </ul> <p><b>LENGTH OF APPROVAL</b>    12 months</p> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> None</p>	
<p>3. Delatestryl® (testosterone enanthate injection)</p> <ul style="list-style-type: none"> <li>i. Revised PA Criteria</li> <li>ii. *Public Comment</li> <li>iii. Board Discussion</li> </ul>	<p><b><u>Background</u></b></p> <p>Delatestryl is an injectable testosterone indicated for hormone replacement. Prior authorization criteria were last revised in July 2013. When the medication is indicated for the treatment of delayed puberty in male adolescents, testosterone levels are not used for diagnostic testing. Revised prior authorization criteria are being proposed to include commonly used evaluations for the diagnosis of delayed puberty.</p>	<p>Mrs. Dowd moved to approve the criteria as written.</p> <p>Dr. Backes seconded.</p> <p>The criteria were approved unanimously.</p>

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	<p><b>CRITERIA FOR MALES:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must be a male</li> <li>• Patient must have one of the following diagnoses: <ul style="list-style-type: none"> <li>○ Primary hypogonadism (congenital or acquired) <ul style="list-style-type: none"> <li>▪ Primary hypogonadism (testicular failure) due to conditions such as (but not limited to) cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals</li> <li>▪ Patient must have serum testosterone &lt; 300 ng/dL</li> </ul> </li> <li>○ Hypogonadotropic hypogonadism (congenital or acquired) <ul style="list-style-type: none"> <li>▪ Hypogonadotropic hypogonadism due to (but not limited to) idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation</li> <li>▪ Patient must have serum testosterone &lt; 300 ng/dL</li> </ul> </li> <li>○ Delayed puberty <ul style="list-style-type: none"> <li>▪ Documented delay in bone age &gt; 2 years, Growth rate &lt; 3 cm/yr, Testicular volume &lt; 4 mL, and/or low serum gonadotropins (LH &lt; 0.1 IU/L; FSH &lt; 0.2 IU/L using ICMA sensitive testing)</li> </ul> </li> </ul> </li> </ul> <p><b>PATIENT MUST MEET INITIAL CRITERIA FOR RENEWALS</b></p> <p><b>LENGTH OF APPROVAL FOR HYPOGONADISM</b>                      12 months</p> <p><b>LENGTH OF APPROVAL FOR DELAYED PUBERTY</b>                      6 months</p> <p><b>CRITERIA FOR FEMALES:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient has a diagnosis of metastatic breast cancer</li> <li>• Patient must be a female</li> <li>• Must be prescribed by or in consultation with an oncologist or endocrinologist</li> </ul> <p><b>PATIENT MUST MEET INITIAL CRITERIA FOR RENEWALS</b></p> <p><b>LENGTH OF APPROVAL</b>                      12 months</p> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	
<p>4. Promacta® (eltrombopag)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Promacta is a small-molecule TPO-receptor agonist that interacts with the transmembrane domain of the human TPO-receptor and initiates signaling cascades that induce proliferation and differentiation from bone marrow progenitor cells. Prior authorization criteria were last revised in July 2015. Since that time, labeling has been revised to lower the age for use in chronic idiopathic thrombocytopenia (ITP) in children as young as one year old. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-</p>	<p>Dr. Kollhoff moved to accept the criteria as written.</p> <p>Dr. Unruh seconded.</p> <p>The criteria were approved unanimously.</p>

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	<p>approved labeling information.</p> <p><b>CRITERIA FOR APLASTIC ANEMIA:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of severe aplastic anemia</li> <li>• Patient must have had an inadequate response to immunosuppressive therapy</li> <li>• Patient must be 18 years of age or older</li> <li>• Must be prescribed by or consultation with a hematologist or oncologist</li> </ul> <p><b>CRITERIA FOR CHRONIC IMMUNE, IDIOPATHIC THROMBOCYTOPENIA (ITP):</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic immune, idiopathic thrombocytopenia</li> <li>• Patient must have had an inadequate response to one of the following: <ul style="list-style-type: none"> <li>○ Corticosteroids</li> <li>○ Immunoglobulins</li> <li>○ Splenectomy</li> </ul> </li> <li>• Patient must be 1 year of age or older</li> <li>• Must be prescribed by or in consultation with a hematologist or oncologist</li> </ul> <p><b>CRITERIA FOR THROMBOCYTOPENIA IN HEPATITIS C:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C with thrombocytopenia</li> <li>• Patient must be on interferon-based therapy</li> <li>• Patient must be 18 years of age or older</li> <li>• Must be prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist</li> </ul> <p><b>LENGTH OF APPROVAL</b>    6 months</p> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> Dr. Unruh asked what we considered to be the difference between severe aplastic anemia and non-severe aplastic anemia. He stated that aplastic anemia itself is bad, and asked what severe aplastic anemia denoted beyond this.</p> <p>Dr. Melton explained that this language was taken directly from the package insert, as it states ‘for treatment of patients with severe aplastic anemia’. Dr. Melton asked the MCOs how their PA reviewers would consider cases of aplastic anemia, and if a ‘severe’ designation was necessary.</p> <p>Dr. Smith of Sunflower stated that their reviewers would approved any aplastic anemia case,</p>	

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	<p>and both other MCO pharmacy directors concurred.</p> <p>It was decided to move forward with the ‘severe aplastic anemia’ language to be consistent with the package insert.</p> <p>Dr. Kollhoff questioned the need to require splenectomy prior to therapy with Promacta, but Dr. Scheffer pointed out that this was only one of three potential bullets that would qualify a patient for coverage. Dr. Melton also reported that this was taken directly from the drug’s package insert.</p>	
<p>5. Dysport® (abobotulinumtoxinA)</p> <ul style="list-style-type: none"> <li>i. Revised PA Criteria</li> <li>ii. *Public Comment</li> <li>iii. Board Discussion</li> </ul>	<p><b>Background</b></p> <p>Dysport is an acetylcholine release inhibitor and neuromuscular blocking agent indicated in the treatment of adults with cervical dystonia. Prior authorization criteria were last revised in October 2014. Since that time, labeling has been revised to include the indication of treatment of upper limb spasticity in adults to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p><b>CRITERIA FOR ONABOTULINUMTOXIN A:</b> (must meet one of the following)</p> <ul style="list-style-type: none"> <li>• Prophylaxis of headaches in patients with chronic migraines (≥15 days per month with a headache lasting 4 hours a day or longer)</li> <li>• Treatment of upper limb spasticity in elbow, wrist, or finger flexors</li> <li>• Treatment of cervical dystonia</li> <li>• Treatment of severe primary auxiliary hyperhidrosis that is inadequately managed with topical agents</li> <li>• Treatment of blepharospasm or strabismus</li> <li>• 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</li> </ul> <p><b>CRITERIA FOR RIMABOTULINUMTOXIN B:</b> (must meet the following)</p> <ul style="list-style-type: none"> <li>• Treatment of cervical dystonia</li> </ul> <p><b>CRITERIA FOR ABOBOTULINUMTOXIN A:</b> (must meet one of the following)</p> <ul style="list-style-type: none"> <li>• Treatment of cervical dystonia</li> <li>• Treatment of upper limb spasticity</li> </ul> <p><b>CRITERIA FOR INCOBOTULINUMTOXIN A:</b> (must meet one of the following)</p> <ul style="list-style-type: none"> <li>• Treatment of cervical dystonia</li> <li>• Treatment of blepharospasm in adults previously treated with onabotulinumtoxin A</li> </ul> <p><b>Initial authorization will be approved for 6 months.</b> Subsequent authorizations will be granted for up to 2 injections in 6 months; injections must be at least 12 weeks apart.</p> <p><b>Note:</b> Use of Botulinum Toxins will <b>NOT</b> be approved for cosmetic purposes.</p>	<p>Mrs. Dowd moved to accept the criteria as written.</p> <p>Dr. Morton seconded.</p> <p>The criteria were approved unanimously.</p>

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	<p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> None</p>	
<p>6. Ferriprox® (deferiprone)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b><u>Background</u></b>            Ferriprox is an iron-chelating agent used for transfusional iron overload. Prior authorization criteria were last revised in April 2013. Since that time, labeling has been revised to include information related to neutropenia. Prior authorization criteria are being proposed to ensure safe and appropriate use based upon the FDA-approved labeling information.</p> <p><b>CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD: (must meet all of the following)</b></p> <ul style="list-style-type: none"> <li>• Patient must be ≥ 18 years of age</li> <li>• Patient must have been transfused with at least 100 mL/kg of packed red blood cells (e.g., at least 20 units of packed red blood cells for a 40-kg person)</li> <li>• Patient must have a serum ferritin &gt; 1,000 mcg/L</li> <li>• Patient must have an absolute neutrophil count (ANC) &gt; 1.5 x 10<sup>9</sup>/L or 1500/mm<sup>3</sup></li> </ul> <p><b>LENGTH OF INITIAL APPROVAL</b>      3 months</p> <p><b>RENEWAL CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD: (must meet all of the following)</b></p> <ul style="list-style-type: none"> <li>• Serum ferritin is monitored monthly</li> <li>• Serum ferritin is consistently &gt; 500 mcg/L</li> </ul> <p><b>LENGTH OF RENEWAL APPROVAL</b>      6 months</p> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> None</p>	<p>Dr. Kollhoff made a motion to approve the criteria as written.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>7. Topical and Buccal Androgens</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b><u>Background</u></b>            Testosterone products (topical and buccal) are hormonal supplements approved for primary hypogonadism or hypogonadotropic hypogonadism. Prior authorization criteria were last revised in July 2014. Since that time, guidelines have recommended continuing treatment to maintain normal testosterone levels. Prior authorization criteria are being proposed to ensure appropriate continued use based upon the FDA-approved labeling information and national guidelines.</p>	<p>Mrs. Dowd moved to approve the criteria with the changes mentioned.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved with</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR PRIOR AUTHORIZATION:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient has one of the following diagnoses: <ul style="list-style-type: none"> <li>○ Primary hypogonadism (congenital or acquired) <ul style="list-style-type: none"> <li>▪ Primary hypogonadism (testicular failure) due to conditions such as (but not limited to) cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals</li> </ul> </li> <li>○ Hypogonadotropic hypogonadism (congenital or acquired) <ul style="list-style-type: none"> <li>▪ Hypogonadotropic hypogonadism due to (but not limited to) idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation</li> </ul> </li> </ul> </li> <li>• Patient must be a male</li> <li>• Patient must have serum testosterone &lt; 300 ng/dL</li> </ul> <p><b>LENGTH OF APPROVAL</b>    12 months</p> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> Dr. Boyer stated that criteria was previously included that required the patient's testosterone level to be below a certain level in order to qualify for a renewal. However, this was removed because patients who have attained therapeutic testosterone levels need to be able to continue on therapy. However, it will still have to be reviewed annually.</p> <p>Dr. Kollhoff asked if the length of the PA approval could just be lifetime? Dr. Melton explained that patients changing plans could cause issues with this, as a lifetime PA approved by Sunflower would not appear in Amerigroup's system, for example. Dr. Melton proposed that the criteria for initial and renewal approvals be the same, with the exception that the testosterone level bullet be removed for renewal criteria. The board agreed with this change.</p>	<p>changes.</p> <p>Dr. Heston abstained from the vote.</p>
<p>8. Harvoni® (ledipasvir/sofosbuvir)</p> <ul style="list-style-type: none"> <li>i. Revised PA Criteria</li> <li>ii. *Public Comment</li> <li>iii. Board Discussion</li> </ul>	<p><b><u>Background</u></b> Harvoni is a direct-acting antiretroviral indicated for the treatment of hepatitis C. Prior authorization criteria were last revised in January 2015. Since that time, the Hepatitis C guidelines have been revised to include patients with comorbid human immunodeficiency virus (HIV) infection to be treated with this medication. Prior authorization criteria are 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 made the motion to approve the criteria as amended.</p> <p>Dr. Morton seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL APPROVAL OF LEDIPASVIR/SOFOSBUVIR:</b> (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"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC)</li> <li>• Patient must have genotype 1 hepatitis C</li> <li>• Patient must not have severe renal impairment (eGFR&lt;30mL/min/1.73m<sup>2</sup>) or currently require hemodialysis</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• Patient must not have been on previous or concurrent direct acting hepatitis C agents</li> <li>• If patient was on a previous course of treatment with Incivek or Victrelis it must have included an interferon-based regimen</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request</li> <li>• Dose must not exceed 1 capsule per day</li> <li>• Patient must have one of the following: <ul style="list-style-type: none"> <li>○ Advanced fibrosis (Metavir F3)</li> <li>○ Compensated cirrhosis</li> <li>○ Organ transplant</li> <li>○ Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)</li> <li>○ Proteinuria</li> <li>○ Nephrotic syndrome</li> <li>○ Membranoproliferative glomerulonephritis</li> </ul> </li> </ul> <p><b>RENEWAL CRITERIA FOR LEDIPASVIR/SOFOSBUVIR:</b></p> <ul style="list-style-type: none"> <li>• 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"> <li>○ Treatment-naïve, without cirrhosis, and a pre-treatment HCV RNA &lt; 6 million IU/mL – <b>8 weeks total therapy</b></li> <li>○ Treatment-naïve, with or without cirrhosis, and a pre-treatment HCV RNA ≥ 6 million IU/mL – <b>12 weeks total therapy</b></li> <li>○ Treatment-naïve, with cirrhosis – <b>12 weeks total therapy</b></li> <li>○ Treatment-experienced, without cirrhosis – <b>12 weeks total therapy</b></li> <li>○ Treatment-experienced, with cirrhosis – <b>24 weeks total therapy</b></li> </ul> </li> </ul> <p><b>LENGTH OF APPROVAL FOR LEDIPASVIR/SOFOSBUVIR:</b> 4 weeks</p> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> There was discussion around clarifying requirements for previously-treated patients, whether with direct-acting agents or interferon-based regimens. Dr. Larson stated that the language was included to ensure that if a patient had done a prior course of therapy, that the regimen had been an appropriate therapy.</p>	
9. Sovaldi® (sofosbuvir)	<p><b><u>Background</u></b> Sovaldi is a direct-acting polymerase inhibitor (antiretroviral) indicated for the treatment of</p>	Dr. Mittal made the motion to approve the criteria with the

TOPIC	DISCUSSION	DECISION AND/OR ACTION
i. Revised PA Criteria ii. *Public Comment iii. Board Discussion	<p>Hepatitis C. Prior authorization criteria were last revised in April 2015. Since that time, the Hepatitis C guidelines have been revised and the medication has become FDA approved for use with another direct-acting antiretroviral, Daklinza. Prior authorization criteria are 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><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT:</b> (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 48 weeks of Sovaldi therapy total)*</i></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC)</li> <li>• Patient must have genotype 1, 2, 3, or 4 hepatitis C</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi</li> <li>• Patient must not have been on previous or concurrent direct acting hepatitis C agents</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• Dose must not exceed 1 capsule per day</li> <li>• Patient must have one of the following:               <ul style="list-style-type: none"> <li>○ Advanced fibrosis (as defined by a Metavir score of F3)</li> <li>○ Compensated cirrhosis</li> <li>○ Organ transplant</li> <li>○ Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)</li> <li>○ Proteinuria</li> <li>○ Nephrotic syndrome</li> <li>○ Membranoproliferative glomerulonephritis</li> </ul> </li> </ul> <p><b>LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT</b> 12 weeks</p> <p>Ribavirin and Peginterferon alfa are approved when using triple therapy with Sovaldi, if Sovaldi criteria are met.</p> <p><b>RENEWAL CRITERIA FOR ONE DIRECT ACTING AGENT:</b> (must meet one of the following)</p> <ul style="list-style-type: none"> <li>• Patient is infected with genotype 3 CHC (an additional 12 weeks of therapy will be approved for a max of 24 weeks if the patient is on an interferon-free regimen; Sovaldi plus ribavirin and interferon will only be approved for a max of 12 weeks.)</li> <li>• Patient is infected with genotype 1 CHC and is ineligible to receive interferon-based therapy (an additional 12 weeks of therapy will be approved for a max of 24 weeks)</li> <li>• Patient has a diagnosis of hepatocellular carcinoma and is awaiting a liver transplantation (an additional 36 weeks of therapy will be approved for a max of 48 weeks)</li> </ul>	<p>changes.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF SOVALDI PLUS OLYSIO: (must meet all of the following)</b></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC) genotype 1</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• Dose must not exceed 1 capsule per day</li> <li>• Patient must not have been on previous or concurrent direct acting hepatitis C agents</li> <li>• Patient must have one of the following: <ul style="list-style-type: none"> <li>○ Advanced fibrosis (as defined by a Metavir score of F3)</li> <li>○ Compensated cirrhosis</li> <li>○ Organ transplant</li> <li>○ Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)</li> <li>○ Proteinuria</li> <li>○ Nephrotic syndrome</li> <li>○ Membranoproliferative glomerulonephritis</li> </ul> </li> <li>• Patient must not be on previous or concurrent therapy with Olysio unless the patient is interferon ineligible defined as one or more of the following: <ul style="list-style-type: none"> <li>○ Documented intolerance to IFN</li> <li>○ Autoimmune hepatitis or other autoimmune disorder</li> <li>○ Documented hypersensitivity to PEG or any of its components</li> <li>○ Decompensated hepatic disease</li> <li>○ Major uncontrolled depressive illness</li> <li>○ A baseline neutrophil count below 1500 a baseline platelet count below 90,000 or baseline hemoglobin below 10 g/dL</li> <li>○ A history of preexisting cardiac disease</li> </ul> </li> </ul> <p><b>LENGTH OF INITIAL APPROVAL</b>      4 weeks</p> <p><b>RENEWAL CRITERIA FOR SOVALDI PLUS OLYSIO: (must the following)</b></p> <ul style="list-style-type: none"> <li>• Prescriber must document adherence by patient of greater than or equal to 90% for both agents</li> </ul>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF SOVALDI PLUS DAKLINZA:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC) genotype 3</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• Dose must not exceed 1 capsule per day</li> <li>• Patient must not have been on previous or concurrent direct acting hepatitis C agents</li> <li>• Patient must have one of the following: <ul style="list-style-type: none"> <li>○ Metavir score of F2 or greater</li> <li>○ Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)</li> <li>○ Proteinuria]</li> </ul> </li> </ul> <hr/> <ul style="list-style-type: none"> <li>○ Nephrotic syndrome</li> <li>○ Membranoproliferative glomerulonephritis</li> <li>○ Organ transplant</li> </ul> <p><b>LENGTH OF INITIAL APPROVAL</b>     4 weeks</p> <p><b>RENEWAL CRITERIA FOR SOVALDI PLUS DAKLINZA:</b> (must the following)</p> <ul style="list-style-type: none"> <li>• Prescriber must document adherence by patient of greater than or equal to 90% for both agents</li> </ul> <p><b>LENGTH OF RENEWAL APPROVALS</b>     4 weeks for a <b>total of 12 weeks of treatment</b></p> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> There was some discussion of the recommendations included in the current hepatitis C guidelines around Sovaldi use for different genotypes, especially genotype 3. Dr. Melton stated that even regimens that are not recommended in the guidelines may still need to be covered if they are listed in a drug’s package insert.</p> <p>The criteria was also amended slightly for clarity.</p>	
<p>10. Olysio® (simeprevir)</p> <ul style="list-style-type: none"> <li>i. Revised PA Criteria</li> <li>ii. *Public Comment</li> <li>iii. Board Discussion</li> </ul>	<p><b><u>Background</u></b> Olysio is a direct acting Hepatitis C virus protease inhibitor initially approved in April 2014 for specific Hepatitis C genotypes according to drug information and package insert information. Revised prior authorization criteria is being proposed to simplify therapy options and update nomenclature based on newer treatments available.</p>	<p>Mrs. Dowd made the motion to approve the criteria with the amendments.</p> <p>Dr. Backes seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT:</b> (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 12 weeks of Olysio therapy total)*</i></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC)</li> <li>• Patient must have genotype 1 hepatitis C</li> <li>• If patient has subtype 1a they must have a negative test for NS3-Q80k polymorphism</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• Olysio must be used in combination with Peginterferon alfa and ribavirin or sofosbuvir</li> <li>• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Olysio</li> <li>• Patient must not have been on a previous or concurrent direct acting hepatitis C agent</li> <li>• Dose must not exceed 1 capsule per day</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• The patient must not have advanced and/or decompensated cirrhosis (moderate or severe hepatic impairment)</li> <li>• Patient must have one of the following: <ul style="list-style-type: none"> <li>○ Advanced fibrosis (as defined by a Metavir score of F3)</li> <li>○ Compensated cirrhosis</li> <li>○ Organ transplant</li> <li>○ Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)</li> <li>○ Proteinuria</li> <li>○ Nephrotic syndrome</li> <li>○ Membranoproliferative glomerulonephritis</li> </ul> </li> </ul> <p><b>LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT</b> 12 weeks</p> <p>Ribavirin and peg-interferon alfa are approved when using triple therapy with Olysio, if Olysio criteria are met.</p> <p><b>DISCONTINUATION CRITERIA FOR ONE DIRECT ACTING AGENT</b></p> <ul style="list-style-type: none"> <li>• Provider must submit HCV RNA level after treatment week 4, within 7 days, to prevent discontinuation of therapy</li> <li>• Therapy will be discontinued if the HCV RNA level is greater than or equal to 25IU/mL after treatment week 4</li> </ul>	<p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF TWO DIRECT ACTING AGENTS:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC) genotype 1</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• Dose must not exceed 1 capsule per day</li> <li>• Patient must not be on previous or concurrent therapy with a direct acting hepatitis C agent</li> <li>• The patient must not have advanced and/or decompensated cirrhosis (moderate or severe hepatic impairment)</li> <li>• Patient must have one of the following: <ul style="list-style-type: none"> <li>○ Advanced fibrosis (Metavir F3)</li> <li>○ Compensated cirrhosis</li> <li>○ Organ transplant</li> <li>○ Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)</li> <li>○ Proteinuria</li> <li>○ Nephrotic syndrome</li> <li>○ Membranoproliferative glomerulonephritis</li> </ul> </li> </ul> <p><b>LENGTH OF INITIAL APPROVAL</b> 4 weeks</p> <p><b>RENEWAL CRITERIA FOR TWO DIRECT ACTING AGENTS:</b> (must the following)</p> <ul style="list-style-type: none"> <li>• Prescriber must document adherence by patient of greater than or equal to 90% for both agents</li> </ul> <p><b>LENGTH OF RENEWAL APPROVALS</b> 4 weeks for a total of 12 weeks of treatment</p> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> Dr. Backes suggested that the criteria reference ‘Direct Acting Hepatitis C Agents’ instead of just ‘Direct Acting Agents’ and this change was agreed upon.</p>	
PERC Members Arrival: 11:10am		
<p>11. Viekira Pak™ (ombitasvir/paritaprevir/ritonavir/dasabuvir) Revised PA Criteria</p> <ul style="list-style-type: none"> <li>i. *Public Comment</li> <li>ii. Board Discussion</li> </ul>	<p><b>Background</b> Viekira Pak is a combination Hepatitis C treatment kit that was initially approved in January 2015 for specific Hepatitis C genotypes according to drug information and package insert information. Revised prior authorization criteria is being proposed to simplify therapy options and update nomenclature based on newer treatments available.</p>	<p>Dr. Mittal moved to approve the criteria with the changes noted.</p> <p>Dr. Morton seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL APPROVAL:</b> (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"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC)</li> <li>• Patient must have genotype 1 hepatitis C</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• 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</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• Dose must not exceed 1 daily dose pack per day (2 ombitasvir/paritaprevir/ritonavir and 2 dasabuvir tablets per day)</li> <li>• Patient must have one of the following: <ul style="list-style-type: none"> <li>○ Advanced fibrosis (Metavir F3)</li> <li>○ Compensated cirrhosis</li> <li>○ Organ transplant</li> <li>○ Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis)</li> <li>○ Proteinuria</li> <li>○ Nephrotic syndrome</li> <li>○ Membranoproliferative glomerulonephritis</li> </ul> </li> </ul> <p><b>RENEWAL CRITERIA:</b></p> <ul style="list-style-type: none"> <li>• 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"> <li>○ Genotype 1a with cirrhosis or mixed genotype with cirrhosis – <b>up to 24 weeks total therapy</b></li> <li>○ Liver transplant recipient with normal hepatic function and mild fibrosis (Metavir fibrosis score 2 or lower) – <b>24 weeks total therapy</b></li> <li>○ Genotype 1a without cirrhosis, mixed genotype without cirrhosis or genotype 1b with or without cirrhosis – <b>12 weeks total therapy</b></li> </ul> </li> </ul> <p><b>LENGTH OF APPROVAL FOR VIEKIRA PAK:</b> 4 weeks</p> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> Dr. Sweet asked if HIV specialists are excluded, and Dr. Melton clarified that they should be included under the ‘infectious disease’ specialist listing.</p>	
<p>C. New Prior Authorization (PA) Criteria</p> <p>1. Daklinza® (daclatasvir)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Daklinza is a direct-acting antiviral agent indicated for combination therapy with sofosbuvir (Sovaldi®) for the treatment of chronic hepatitis C virus in adults with genotype 3 virus. Prior authorization criteria are 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. Mittal moved to approve the criteria with noted changes.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL APPROVAL OF DACLATASVIR:</b> (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"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC)</li> <li>• Patient must have genotype 3 hepatitis C</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• Must be used in combination with Sovaldi® (sofosbuvir)</li> <li>• 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)</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request</li> <li>• Dose must not exceed 1 tablet per day</li> <li>• Patient must not have decompensated cirrhosis</li> <li>• Patient must have a Metavir score of F2 or greater</li> <li>• Patient must not be a liver transplant recipient</li> <li>• Patient must not be concurrently prescribed a strong CYP3A inducer (e.g. phenytoin, carbamazepine, rifampin, St. John's wort)</li> <li>• Patient must not be on concurrent moderate CYP3A inducers (e.g. bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine)</li> <li>• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with daclatasvir combination therapy</li> </ul> <p><b>CRITERIA FOR RENEWAL</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Prescriber must document adherence by patient of greater than or equal to 90% for both agents</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 4 weeks for a total of 12 weeks of treatment for genotype 3 without cirrhosis  4 weeks for a total of up to 24 weeks of treatment for genotype 3 with cirrhosis</p> <p><b>Public Comment</b>  Valerie Collins with Bristol Meyer Squibb gave an overview of Daklinza.</p> <p><b>Board Discussion</b>  The board discussed including alcohol use disorder versus alcohol abuse in the criteria, no changes were made. The board made one change to criteria after discussion pertaining to length of treatment for genotype 3 patients with cirrhosis; length of approval is now 4 weeks at a time for a total of 24 weeks.</p>	
<p>2. Technivie®  (ombitasvir/paritaprevir/ritonavir)  i. PA Criteria</p>	<p><b>Background</b>  Technivie is a direct-acting antiviral agent indicated for combination therapy with Ribavirin for the treatment of chronic hepatitis C virus in adults with genotype 4 virus without cirrhosis. Prior authorization criteria are 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 the criteria as written.</p> <p>Dr. Morton seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
ii. *Public Comment  iii. Board Discussion	<p><b>CRITERIA FOR INITIAL APPROVAL</b> (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 12 weeks of ombitasvir/paritaprevir/ritonavir therapy total)*</i></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C (CHC)</li> <li>• Patient must have genotype 4 hepatitis C</li> <li>• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist</li> <li>• Patient must be 18 years of age or older</li> <li>• Must be used in combination with ribavirin, unless there is a contraindication and the patient is treatment-naive</li> <li>• Patient must not have been on previous or concurrent direct acting hepatitis C agent</li> <li>• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months</li> <li>• Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request</li> <li>• Dose must not exceed 2 tablets per day</li> <li>• Patient must not have cirrhosis or severe hepatic impairment (Child-Pugh score of C or D)</li> <li>• Patient must not be concurrently prescribed a moderate or strong CYP3A inducer</li> <li>• 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</li> </ul> <p><b>CRITERIA FOR RENEWAL</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Prescriber must document adherence by patient of greater than or equal to 90% for both agents</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 4 weeks for a total of 12 weeks of treatment</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• The medication may be considered for administration without ribavirin for 12 weeks in patients who are treatment-naïve and cannot take or tolerate ribavirin</li> </ul> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> None</p>	<p>The criteria were approved unanimously.</p>
3. Kadcyla® (ado-trastuzumab emtansine) i. PA Criteria ii. *Public Comment iii. Board Discussion	<p><b><u>Background</u></b></p> <p>Kadcyla is an antineoplastic agent indicated as a single agent for the treatment of HER2-positive, metastatic breast cancer. Prior authorization criteria are 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 made the motion to approve the criteria as written.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR METASTATIC BREAST CANCER</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of HER2-positive metastatic breast cancer</li> <li>• Patient must have previously received trastuzumab and a taxane, separately or in combination</li> <li>• Patient must have one of following: <ul style="list-style-type: none"> <li>○ Prior therapy for metastatic disease, OR</li> <li>○ Development of disease recurrence during or within six months of completing adjuvant therapy</li> </ul> </li> <li>• Patient must be 18 years of age or older</li> <li>• Must be prescribed by or in consultation with an oncologist</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 12 months</p> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> None</p>	
<p>4. CFTR therapy</p> <ul style="list-style-type: none"> <li>i. PA Criteria</li> <li>ii. *Public Comment</li> <li>iii. Board Discussion</li> </ul>	<p><b><u>Background</u></b></p> <p>Orkambi (lumacaftor/ivacaftor) and Kalydeco (ivacaftor) are cystic fibrosis transmembrane regulator (CFTR) protein potentiators indicated for the treatment of cystic fibrosis. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information regarding genetic polymorphisms.</p>	<p>Dr. Kollhoff made the motion to approve the criteria as written.</p> <p>Mrs. Dowd seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR KALYDECO:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must be at least 2 years old.</li> <li>• Patient must have a diagnosis of cystic fibrosis.</li> <li>• Patient must have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H</li> <li>• Patient must not be homozygous for the <i>F508del</i> mutation in the CFTR gene.</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 12 months</p> <p> </p> <p><b>CRITERIA FOR ORKAMBI:</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of Cystic Fibrosis.</li> <li>• Patient must be homozygous for <i>F508del</i> mutation in the CFTR gene.</li> <li>• Patient must 12 years of age or older.</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 12 months</p> <p><b>*Note:</b> Providers may be referred to the Cystic Fibrosis Foundation website for information regarding genetic testing to patients with a confirmed diagnosis of cystic fibrosis:  <a href="http://www.cff.org/treatments/Therapies/Kalydeco/#Is_Kalydeco_only_for_G551D">http://www.cff.org/treatments/Therapies/Kalydeco/#Is_Kalydeco_only_for_G551D</a>.</p> <p><b>Public Comment</b>  Jamie Tobbitt with Vertex Pharmaceuticals offered to answer an board questions regarding Kalydeco or Orkambi</p> <p><b>Board Discussion</b>  Dr. Melton notified the board that there were two letters included for their consideration; one from KU and the other from the Cystic Fibrosis Foundation.</p> <p>Board discussion around the age limit of 12 and possibility of prescribing at a younger age. Discussed bringing the criteria back for review if the drug is approved for a younger population.</p>	
<p>5. PCSK9 inhibitors [Praluent® (alirocumab), Repatha® (evolocumab)]</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p>	<p><b>Background</b>  Praluent and Repatha are human monoclonal antibodies that binds to proprotein convertase subtilisin kexin type 9 (PCSK9) indicated for the adjunctive treatment of hyperlipidemia in adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-cholesterol. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p>	<p>Dr. Heston made the motion to approve with changes noted.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved with Dr. Backes recusing.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
iii. Board Discussion	<p><b>CRITERIA FOR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HoFH)</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of homozygous familial hypercholesterolemia. This must be evidenced by: <ul style="list-style-type: none"> <li>○ Genotyping; or</li> <li>○ Clinical diagnosis based on a history of untreated LDL-C &gt; 500 mg/dl and one of the following: <ul style="list-style-type: none"> <li>▪ Xanthoma prior to the age of 10 years</li> <li>▪ Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents</li> </ul> </li> </ul> </li> <li>• Patient must be at least 13 years old</li> <li>• Must be used as adjunct to diet</li> <li>• Must be used as adjunct to other LDL-lowering therapy (maximally tolerated stable therapy, or patient must have a contraindication or allergic reaction to other therapy)</li> <li>• Must be prescribed by or in consultation with a cardiologist or lipidologist</li> <li>• Prescribed drug is evolocumab (Repatha®) <ul style="list-style-type: none"> <li>○ Dose must not be greater than 140 mg every 14 days</li> </ul> </li> </ul> <p><b>CRITERIA FOR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HeFH)</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of heterozygous familial hypercholesterolemia. This must be evidenced by: <ul style="list-style-type: none"> <li>○ Genotyping; or</li> <li>○ Clinical criteria using either the Simon Broome or WHO/Dutch Lipid Network criteria</li> </ul> </li> <li>• Must be at least 18 years old</li> <li>• Must be used as adjunct to diet</li> <li>• Must be used as adjunct to maximally tolerated stable, daily statin therapy (or patient must have a contraindication or allergic reaction to statins)*</li> <li>• Must be prescribed by or in consultation with a cardiologist or lipidologist</li> <li>• Prescribed drug is: <ul style="list-style-type: none"> <li>○ Evolocumab (Repatha®) <ul style="list-style-type: none"> <li>▪ Dose must not be greater than 140 mg every 14 days</li> </ul> </li> <li>○ Alirocumab (Praluent®) <ul style="list-style-type: none"> <li>▪ Dose must not be greater than 150 mg every 14 days</li> </ul> </li> </ul> </li> </ul>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR PRIMARY HYPERLIPIDEMIA (must meet all of the following):</b></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of clinical atherosclerotic cardiovascular disease (diagnosis of CVD, MI, unstable angina, or previous ACS) and require additional lowering of LDL-cholesterol</li> <li>• Must be at least 18 years old</li> <li>• Must be used as adjunct to diet</li> <li>• Must be used as adjunct to maximally tolerated stable, daily statin therapy (or patient must have a contraindication or allergic reaction to statins)*</li> <li>• Must be prescribed by or in consultation with a cardiologist or lipidologist</li> <li>• Prescribed drug is: <ul style="list-style-type: none"> <li>○ Evolocumab (Repatha®) <ul style="list-style-type: none"> <li>▪ Dose must not be greater than 140 mg every 14 days</li> </ul> </li> <li>○ Alirocumab (Praluent®) <ul style="list-style-type: none"> <li>▪ Dose must not be greater than 150 mg every 14 days</li> </ul> </li> </ul> </li> </ul> <p><b>LENGTH OF INITIAL APPROVAL: 3 months</b></p> <p><b>CRITERIA FOR RENEWAL (must meet all of the following):</b></p> <ul style="list-style-type: none"> <li>• Documentation that lipid lowering has occurred</li> <li>• Documentation of continued adjunct diet changes and pharmacotherapy from initial approval</li> <li>• Prescribed drug is: <ul style="list-style-type: none"> <li>○ Evolocumab (Repatha®) <ul style="list-style-type: none"> <li>▪ Dose must not be greater than 140 mg every 14 days</li> </ul> </li> <li>○ Alirocumab (Praluent®) <ul style="list-style-type: none"> <li>▪ Dose must not be greater than 150 mg every 14 days</li> </ul> </li> </ul> </li> </ul> <p><b>LENGTH OF RENEWAL APPROVAL: 6 months</b></p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>*Notes:</p> <ul style="list-style-type: none"> <li>• Clinical atherosclerotic cardiovascular disease includes, but is not limited to, a diagnosis of cardiovascular disease (CVD) or a previous acute coronary syndrome (ACS) (e.g., myocardial infarction, ischemic stroke, unstable angina)</li> <li>• For HeFH and Primary Hyperlipidemia patients who require adjunct therapy for High LDL Levels (LDL-C &gt; 160 mg/dl), a trial of a stable statin therapy and failure of multiple statins at maximum dose must be employed <ul style="list-style-type: none"> <li>○ Stable statin therapy is defined as the patient being at a stable dose for at least 4 weeks</li> <li>○ Combination therapy with covered alternative agent(s) is required if maximum statin dosage did not achieve efficacious level (e.g. ezetimibe, bile acid sequestrants, or other antilipemic agent or therapy)</li> <li>○ Baseline lab prior to any treatment and labs after all previous treatments showing inadequate control on statins</li> <li>○ For intolerance to statins, trial and failure of 2 statins at lower dose must be utilized. Specific intolerance must be documented and temporally related to statin treatment.   <ul style="list-style-type: none"> <li>▪ If intolerance is due to muscle pain, attach creatinine kinase labs checking for rhabdomyolysis.</li> </ul> </li> </ul> </li> <li>• For Repatha®, requests of 420mg every 28 days, clinical justification must be provided as to why the 140mg every 14 day dosing regimen was not sufficient/indicated.</li> </ul> <p><b><u>Public Comment</u></b> None</p> <p><b><u>Board Discussion</u></b> Board discussion pertaining to dosing guidelines and clinical studies. Current dosing options include 1 shot every 2 weeks or 3 shots once a month and comparable outcomes were seen with both schedules.</p> <p>The board discussed removing fibrin acid as a required adjunct therapy as well as apheresis. The board also added lipidologist to the allowed prescribers and made the initial PA length three months instead of two due to required follow up.</p> <p>Dr. Backes recused himself from the vote.</p>	
<p>6. Kyprolis® (carfilzomib)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b><u>Background</u></b> Kyprolis is an antineoplastic proteasome inhibitor indicated for the treatment of relapsed/refractory multiple myeloma. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p>	<p>Mrs. Dowd made the motion to approve the criteria as written.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>CRITERIA FOR INITIAL APPROVAL</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of multiple myeloma</li> <li>• Must be prescribed by or in consultation with an oncologist or hematologist</li> <li>• Patient must be at least 18 years old</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 1 year</p> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	unanimously.
<p>7. Somavert® (pegvisomant)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Somavert is indicated for the treatment of acromegaly in adults. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p><b>CRITERIA FOR INITIAL APPROVAL</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of acromegaly</li> <li>• Patient must have an inadequate response to or not be a candidate for surgery or radiation therapy</li> <li>• Patient must be at least 18 years old</li> <li>• Must have documentation of baseline insulin-like growth factor-1 (IGF-1) <ul style="list-style-type: none"> <li>○ Level must be <math>\geq</math> 750 mcg/L, or</li> <li>○ Patient must have moderate to severe symptoms of growth hormone excess</li> </ul> </li> <li>• Must have documentation of baseline liver function tests (LFTs)</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 6 months</p> <p>Note:</p> <ul style="list-style-type: none"> <li>• The Endocrine Society Clinical Practice Guideline (2014 update) recommends a trial of cabergoline as initial adjuvant (after surgery or radiation) therapy for patients with modest elevations of serum IGF-1 (<math>&lt;</math> 750 mcg/L) and mild signs and symptoms of growth hormone excess.</li> </ul> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> Board discussion regarding the agents use after inadequate response to surgery or radiation.</p> <p>Dr. Kollhoff abstained from the vote.</p>	<p>Dr. Unruh made the motion to approve the criteria as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved with Dr. Kollhoff abstaining.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>8. Vantas® (histrelin)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Vantas is a gonadotropin-releasing hormone analog indicated for the treatment of advanced prostate cancer in adult males. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents within this class.</p> <p><b>CRITERIA FOR INITIAL APPROVAL</b> (must meet all of the following):</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of advanced prostate cancer</li> <li>• Patient must be male</li> <li>• Patient must be at least 18 years old</li> </ul> <p><b>LENGTH OF APPROVAL:</b> 1 implant (50 mg) for 12 months</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• The recommended dose of Vantas is one implant every 12 months. The implant should be removed after 12 months of therapy; at the time an implant is removed, another implant may be inserted to continue therapy.</li> </ul> <p><b>Public Comment</b></p> <p>None</p> <p><b>Board Discussion</b></p> <p>None</p>	<p>Dr. Heston made the motion to approve the criteria as written.</p> <p>Mrs. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>9. Cysteamine agents (Cystaran®, Procysbi®)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Cysteamine agents aid in the conversion of cysteine to soluble agents indicated in the treatment of corneal cysteine crystal accumulation and nephropathic cystinosis. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p><b>CRITERIA FOR NEPHROPATHIC CYSTINOSIS:</b></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of nephropathic <u>cystinosis</u></li> <li>• For <u>Cystaran</u> ophthalmic solution, patient must have corneal cysteine accumulation</li> <li>• For <u>Procysbi</u>, patient must be 2 years of age or older</li> </ul> <p><b>LENGTH OF APPROVAL</b> 1 year</p> <p><b>Public Comment</b></p> <p>None</p>	<p>Dr. Mittal made the motion to approve the criteria as written.</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>Board Discussion</b> None</p>	
<p>10. Imbruvica® (ibrutinib)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b> Imbruvica is a tyrosine kinase inhibitor indicated for treatment of chronic lymphoid leukemia, mantle cell lymphoma and Waldenstrom macroglobulinemia. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and current clinically accepted guidelines.</p> <p><b>INITIATION CRITERIA FOR IMBRUVICA (IBRUTINIB):</b></p> <ul style="list-style-type: none"> <li>• Patient must be clinically diagnosed with one of the following diagnoses: <ul style="list-style-type: none"> <li>○ Chronic lymphoid leukemia <ul style="list-style-type: none"> <li>▪ Patient has received at least one prior therapy <b>OR</b></li> <li>▪ Patient has a 17p chromosome deletion</li> </ul> </li> <li>○ Mantle cell lymphoma <ul style="list-style-type: none"> <li>▪ Patient has received at least one prior therapy</li> </ul> </li> <li>○ Waldenström macroglobulinemia</li> </ul> </li> <li>• The medication is prescribed by or in consultation with an oncologist or hematologist</li> </ul> <p><b>LENGTH OF APPROVAL: 6 months</b></p> <p><b>RENEWAL CRITERIA FOR IMBRUVICA (IBRUTINIB):</b></p> <ul style="list-style-type: none"> <li>• MUST MEET INITIATION CRITERIA FOR RENEWAL</li> </ul> <p><b>RENEWAL LENGTH OF APPROVAL: 12 months</b></p> <p>* Refer to most recent NCCN (National Comprehensive Cancer Network) Non-Hodgkin's Lymphomas Guidelines for NCCN accepted regimens.</p> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	<p>Dr. Kollhoff made the motion to approve the criteria as written.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>11. Opdivo® (nivolumab)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p>	<p><b>Background</b> Opdivo is a human programmed death receptor-1 (PD-1) blocking monoclonal antibody indicated in the treatment of metastatic and/or unresectable melanoma and metastatic non-small cell lung cancer. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other</p>	<p>Dr. Kollhoff made the motion to approve the criteria with noted changes made.</p> <p>Dr. Mittal seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>iii. Board Discussion</p>	<p>agents within this class.</p> <p><b>CRITERIA FOR OPDIVO (NIVOLUMAB):</b></p> <ul style="list-style-type: none"> <li>• Patient must have one of the following diagnoses: <ul style="list-style-type: none"> <li>○ Unresectable or metastatic melanoma <ul style="list-style-type: none"> <li>▪ If BRAF V600 mutation-positive, patient must have disease progression following treatment with Yervoy (ipilimumab) and a BRAF inhibitor (e.g. vemurafenib, dabrafenib)</li> <li>▪ If BRAF V600 mutation-negative (wild-type), may be used in combination with ipilimumab</li> </ul> </li> <li>○ Metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy <ul style="list-style-type: none"> <li>▪ If EGFR or ALK mutation present, patient must have failure with a mutation specific medication prior to using Opdivo</li> </ul> </li> </ul> </li> <li>• Must be prescribed by or in consultation with an oncologist</li> </ul> <p><b>LENGTH OF APPROVAL: 12 months</b></p> <p>.</p> <p><b>Public Comment</b> Chad Patel with Bristol Meyer Squib provided an update regarding approved indications for Opdivo.</p> <p><b>Board Discussion</b> Board discussed inclusion of criteria regarding both unresectable or metastatic melanoma and metastatic non-small cell lung cancer. Criteria was updated based on board discussion.</p>	<p>The criteria were approved unanimously.</p>
<p>12. Viberzi® (eluxadoline)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b> Viberzi is a mu-opioid receptor agonist indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D). Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p><b>CRITERIA FOR IRRITABLE BOWEL SYNDROME WITH DIARRHEA: (must meet all of the following)</b></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of irritable bowel syndrome with diarrhea</li> <li>• Patient must be ≥18 years of age</li> </ul> <p><b>LENGTH OF APPROVAL 12 MONTHS</b></p> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b></p>	<p>Mrs. Dowd made the motion to approve the criteria as written.</p> <p>Dr. Mittal seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	None	
<p>13. Zelboraf® (vemurafenib)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b> Zelboraf is a kinase inhibitor indicated for the treatment of patients with unresectable and/or metastatic melanoma with a BRAF V600E mutation. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents within this class.</p> <p><b>CRITERIA FOR ZELBORAF (VEMURAFENIB): (MUST MEET ALL OF THE FOLLOWING)</b></p> <ul style="list-style-type: none"> <li>• Patient must have unresectable or metastatic melanoma <ul style="list-style-type: none"> <li>○ Documentation of a FDA-approved test indicating the presence of BRAF V600E mutation</li> </ul> </li> <li>• Must be prescribed by or in consultation with an oncologist</li> </ul> <p><b>LENGTH OF APPROVAL: <u>12 months</u></b></p> <p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	<p>Mrs. Dowd made the motion to approve the criteria as written.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>D. Miscellaneous Items</p> <p>1. Fee-for-Service Annual Program Assessment</p> <p>i. *Public Comment</p> <p>ii. Board Discussion</p>	<p><b>Background</b> The annual program assessment for the Medicaid fee-for-service population was presented to show drug trends over the past state fiscal year. Dr. Boyer presented highlights. Fee-for-service population only. Results do not include rebates or MCO data.</p> <p><b>Board Discussion</b> The board discussed MediKan coverage determination and Harvoni coverage, as well as ADAP program regarding federal cost sharing.</p> <p>The board was updated regarding the Mental Health Medication Advisory Committee</p>	
<p>IV. Open Public Comment</p>	<p><b>Public Comment</b> None</p> <p><b>Board Discussion</b> None</p>	
<p>V. Adjourn</p>	<p>The meeting was adjourned at 12:57pm.</p> <p>The next meeting will be on January 14, 2015. It will begin at 10:00am at the HP Enterprises</p>	<p>Dr. Kollhoff made a motion to adjourn</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Services Office.  <b>**LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS</b>	Dr. Unruh seconded the motion  The motion was approved unanimously