

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
April 9, 2014**

<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> Judy McDaniel Dowd, PA-C Tim Heston, DO Russell Scheffer, MD Roger Unruh, D.O. Kevin Waite, Pharm.D.</p> <p><b>DUR Board Members Absent</b> John Kollhoff, Pharm.D. Daniel Sutherland, RPh</p> <p><b>DHCF Staff Present</b> F.E. Bustillo, III, MD Kelley Melton, Pharm.D.</p> <p><b>HP Enterprise Services Staff Present</b> Karen Kluczykowski, RPh Nancy Perry, R.N.</p> <p><b>HID Staff Present</b> Nicole Ellermeier, Pharm.D.</p> <p><b>MCO Staff Present</b> Jonalan Smith, Pharm.D., FASCP: Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p><b>Representatives</b> Sam Smothers, Med Immune Teresa Blair, Amgen Jeff Knappen, Allergan Bob Gustafson, Lundbeck John Omick, Lundbeck Risa Reuscher, Amgen James Osborne, GSK Faisal Riaz, Takeda Scott Maurice, Boehringer- Ingelheim Berend Koops, Merck Julie McDavitt, Boehringer- Ingelheim Ted Sheedy, GSK Jared Lurk, Novartis Mary Deane, Regeneron Molly Skelsey, Astra-Zeneca Jim Baumann, Pfizer Mark Weisz, Otsuka Michele Puyear, Gilead Mary Shefchyk, Novo Nordisk Inc. Brian Strickland, Gilead</p>
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<b>TOPIC</b>	<b>DISCUSSION</b>	<b>DECISION AND/OR ACTION</b>
I. Call to Order	Dr. Kevin Waite called the meeting to order at 10:09am.	
A. Announcements	<p>Dr. Ellermeier advised where individuals should park and the time limit of 5 minutes per presenter per topic.</p> <p>Dr. Melton introduced Dr. Bustillo, the new clinical director for DHCF and Jonalan Smith the new director of pharmacy for Sunflower Health Plan.</p>	
II. Old Business A. Review and Approval of		Dr. Unruh made motion to accept the minutes as

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January 8, 2013 DUR Meeting Minutes		<p>presented.</p> <p>Dr. Scheffer seconded the motion.</p> <p>The minutes were approved unanimously.</p>
<p>III. New Business</p> <p>A. New PDL Classes</p> <p>1. Oral Mesalamine Products</p> <p>i. PDL Non-Preferred PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>At the March 2014 PDL Meeting, the committee approved the addition of the Oral Mesalamine Products for Inflammatory Bowel Disease to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.</p> <div data-bbox="527 573 1633 899" style="border: 1px solid black; padding: 5px;"> <p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> <b>Patient has a medical intolerance to preferred drug.</b> Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p><input type="checkbox"/> <b>Patient has had an inadequate response to preferred drug.</b> Name of preferred agent patient tried: _____</p> <p><input type="checkbox"/> <b>An appropriate formulation or indication is not available as a preferred drug.</b> Please specify which formulation or indication is needed and information supporting the need: _____</p> </div> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> Ms. Dowd noted that she appreciated the new PDL form. Dr. Melton also confirmed that the criteria were consistent with that of other PDL classes.</p>	<p>Ms. Dowd made motion to accept the non-preferred PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>2. Carbonic Anhydrase Inhibitors</p> <p>i. PDL Non-Preferred PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>At the March 2014 PDL Meeting, the committee approved the addition of the Carbonic Anhydrase Inhibitors to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.</p>	<p>Dr. Heston made motion to accept the non-preferred PA criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> <b>Patient has a medical intolerance to preferred drug.</b> Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p><input type="checkbox"/> <b>Patient has had an inadequate response to preferred drug.</b> Name of preferred agent patient tried: _____</p> <p><input type="checkbox"/> <b>An appropriate formulation or indication is not available as a preferred drug.</b> Please specify which formulation or indication is needed and information supporting the need: _____</p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> None</p>	
<p>3. Hypertriglyceridemia</p> <p>i. PDL Non-Preferred PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>At the March 2014 PDL Meeting, the committee approved the addition of the Hypertriglyceridemia Agents to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.</p> <p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> <b>Patient has a medical intolerance to preferred drug.</b> Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p><input type="checkbox"/> <b>Patient has had an inadequate response to preferred drug.</b> Name of preferred agent patient tried: _____</p> <p><input type="checkbox"/> <b>An appropriate formulation or indication is not available as a preferred drug.</b> Please specify which formulation or indication is needed and information supporting the need: _____</p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> None</p>	<p>Ms. Dowd made motion to accept the non-preferred PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>4. Homozygous Familial Hypercholesterolemia Agents</p> <p>i. PDL Non-Preferred PA Criteria</p> <p>ii. *Public Comment</p>	<p><b>Background</b></p> <p>At the March 2014 PDL Meeting, the committee approved the addition of the HoFH agents to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.</p>	<p>Dr. Unruh made motion to accept the non-preferred PA criteria.</p> <p>Ms. Dowd seconded the motion.</p>

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iii. Board Discussion	<p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> <b>Patient has a medical intolerance to preferred drug.</b> Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p><input type="checkbox"/> <b>Patient has had an inadequate response to preferred drug.</b> Name of preferred agent patient tried: _____</p> <p><input type="checkbox"/> <b>An appropriate formulation or indication is not available as a preferred drug.</b> Please specify which formulation or indication is needed and information supporting the need: _____</p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> None</p>	The criteria were approved unanimously.
5. Inhaled Tobramycin Products i. PDL Non-Preferred PA Criteria ii. *Public Comment iii. Board Discussion	<p><b>Background</b>            At the March 2014 PDL Meeting, the committee approved the addition of the Inhaled Tobramycin Products to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.</p> <p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> <b>Patient has a medical intolerance to preferred drug.</b> Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p><input type="checkbox"/> <b>Patient has had an inadequate response to preferred drug.</b> Name of preferred agent patient tried: _____</p> <p><input type="checkbox"/> <b>An appropriate formulation or indication is not available as a preferred drug.</b> Please specify which formulation or indication is needed and information supporting the need: _____</p> <p><b>Public Comment:</b> Jared Lurk, Novartis, provided information on Tobi Podhaler.</p> <p><b>Board Discussion:</b> None</p>	Dr. Scheffer made motion to accept the PA criteria.  Dr. Unruh seconded the motion.  The criteria were approved unanimously.
6. COX II Inhibitors i. PDL Non-Preferred PA Criteria ii. *Public Comment iii. Board Discussion	<p><b>Background</b>            At the March 2014 PDL Meeting, the committee approved the addition of the COX II Inhibitors to the PDL. Non-preferred prior authorization criteria consistent with other classes on the PDL are being presented for approval.</p>	Ms. Dowd made motion to accept the PA criteria.  Dr. Unruh seconded the motion.  The criteria were approved

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	<p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> <b>Patient has a medical intolerance to preferred drug.</b> Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p><input type="checkbox"/> <b>Patient has had an inadequate response to preferred drug.</b> Name of preferred agent patient tried: _____</p> <p><input type="checkbox"/> <b>An appropriate formulation or indication is not available as a preferred drug.</b> Please specify which formulation or indication is needed and information supporting the need: _____</p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> None</p>	<p>unanimously.</p>
<p>B. Revised Prior Authorization Criteria</p> <p>1. Pulmonary Hypertension Agents (Adempas® (riociguat) &amp; Orenitram® (treprostinil))</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Prior authorization criteria for pulmonary arterial hypertension agents were initially approved in April 2013. Since the last revision in January 2014, two new agents have been approved. Prior authorization criteria revisions are being proposed to include Adempas and Orenitram.</p>	<p>Ms. Dowd made motion to accept the PA criteria.</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Pulmonary Arterial Hypertension Agents</p> <p><b>PROVIDER GROUP</b> Pharmacy Professional</p> <p><b>MANUAL GUIDELINES</b> The following drug(s) require prior authorization:  <u>Ambrisentan Tablets (Letairis®)</u>  <u>Bosentan Tablets (Tracleer®)</u>  <u>Epoprostenol Injection (Flolan®, Veletri®)</u>  <u>Iloprost Inhalation Solution (Ventavis®)</u>  <u>Macitentan (Opsumit®)</u>  <u>Riociguat (Adempas®)</u>  <u>Sildenafil Tablets, Oral Suspension, and Injection (Revatio®)</u>  <u>Treprostinil Extended-Release Tablets (Orenitram®)</u>  <u>Treprostinil Inhalation Solution (Tyvaso®)</u>  <u>Treprostinil Injection (Remodulin®)</u>  <u>Tadalafil Tablets (Adcirca®)</u></p> <p><b>CRITERIA FOR INITIAL APPROVAL (ALL AGENTS):</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of pulmonary arterial hypertension (PAH)</li> <li>• Must be prescribed by or in consultation with a pulmonologist, cardiologist, or specialized treatment center</li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p> <p><b>CRITERIA FOR INITIAL APPROVAL (ADEMPAS ONLY):</b> (must meet all of the following)</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of pulmonary arterial hypertension (PAH) OR chronic thromboembolic pulmonary hypertension (CTEPH)</li> <li>• Must be prescribed by or in consultation with a pulmonologist, cardiologist, or specialized treatment center</li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> A question was raised about the ability of mid-level practitioner specialists to prescribe these medications. It was determined that they would fall under the designation of ‘specialized treatment center’ and that their prescribing would be preserved as in previous criteria.</p>	
<p>2. Mekinist®(trametinib)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Mekinist is a kinase inhibitor indicated as a single agent or in combination with dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Prior authorization criteria were initially approved in October 2013 and in January 2014 Mekinist received approval for use in combination with dabrafenib. Prior</p>	<p>Ms. Dowd made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>authorization criteria are being revised to include all FDA-approved indications.</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p style="text-align: center;">CRITERIA FOR PRIOR AUTHORIZATION</p> <p style="text-align: right;">Mekinist® (trametinib)</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Trametinib (Mekinist)</p> <p><b>CRITERIA FOR MEKINIST SINGLE AGENT TREATMENT</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of unresectable or metastatic melanoma</li> <li>• Patient must have a mutation of BRAF V600E or V600K</li> <li>• Patient must not have received previous treatment with a BRAF-inhibitor</li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p> <p><b>CRITERIA FOR MEKINIST COMBINATION TREATMENT</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of unresectable or metastatic melanoma</li> <li>• Patient must have a mutation of BRAF V600E or V600K</li> <li>• Must be used in combination with dabrafenib</li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p> </div> <p><b>Public Comment:</b> James Osborne, GSK, stated that he was available for questions.</p> <p><b>Board Discussion:</b> None</p>	<p>The criteria were approved unanimously.</p>
<p>3. Tafinlar®(dabrafenib) i. Revised PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p><b>Background</b> Tafinlar is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or in combination with trametinib for patients with BRAF V600E or V600K mutations. Prior authorization criteria were initially approved in October 2013 and in January 2014 Tafinlar received approval for use in combination with trametinib. Prior authorization criteria are being revised to include all FDA-approved indications.</p>	<p>Dr. Scheffer made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	<p style="text-align: center;">CRITERIA FOR PRIOR AUTHORIZATION</p> <p style="text-align: right;">Tafinlar® (dabrafenib)</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization; Dabrafenib (Tafinlar)</p> <p><b>CRITERIA FOR TAFINLAR SINGLE AGENT TREATMENT</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of unresectable or metastatic melanoma</li> <li>• Patient must have a mutation of BRAF V600E</li> <li>• Patient must be 18 years of age or older</li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p> <p><b>CRITERIA FOR TAFINLAR COMBINATION TREATMENT</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of unresectable or metastatic melanoma</li> <li>• Must be used in combination with trametinib</li> <li>• Patient must have a mutation of BRAF V600E or V600K</li> <li>• Patient must be 18 years of age or older</li> </ul> <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. Weight Loss Drugs</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Weight loss drugs prior authorization criteria were initially approved in September 2007 and were last revised in October 2012. Xenical® (orlistat) recently received approval to reduce the risk for weight gain after prior weight loss. Prior authorization criteria are being revised to include all FDA-approved indications.</p>	<p>Ms. Dowd made motion to accept the PA criteria.</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Weight Loss Drugs</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drug(s) require prior authorization:  Lorcaserin (Belviq®)  Orlistat (Xenical® &amp; Alli®)  Phentermine (Adipex-P®)  Phentermine/Topiramate (Qsymia®)</p> <p><b>CRITERIA FOR INITIAL APPROVAL (ALL AGENTS):</b> (must meet all of the following)</p> <ol style="list-style-type: none"> <li>1. The patient is not pregnant or breastfeeding</li> <li>2. The treatment plan includes a nutritionally balanced, reduced-calorie diet, exercise, and behavioral counseling</li> <li>3. Must meet all bullets under a, b, c, d, or e <ol style="list-style-type: none"> <li>a. The claim is for lorcaserin <ul style="list-style-type: none"> <li>▪ The patient has a BMI ≥ 30 <b>OR</b> is in the 95<sup>th</sup> percentile <b>OR</b> BMI ≥ 27 <b>AND</b> has at least one comorbidity (diabetes, hypertension, dyslipidemia, or cardiovascular disease)</li> <li>▪ The patient must be 18 years of age or older</li> <li>▪ Dose must be ≤ 20mg per day (10mg twice daily)</li> </ul> </li> <li>b. The claim is for orlistat for weight loss <ul style="list-style-type: none"> <li>▪ The patient has a BMI ≥ 30 <b>OR</b> is in the 95<sup>th</sup> percentile <b>OR</b> BMI ≥ 27 <b>AND</b> has at least one comorbidity (diabetes, hypertension, dyslipidemia, or cardiovascular disease)</li> <li>▪ The patient has not taken more than 180 days of orlistat in the past 12 months</li> <li>▪ The patient must be 12 years of age or older</li> <li>▪ The patient has not had a history of cholestasis or chronic intestinal malabsorption in the past 12 months</li> </ul> </li> <li>c. The claim is for orlistat to reduce the risk of weight regain (<b>Xenical ONLY</b>) <ul style="list-style-type: none"> <li>▪ The patient is using Xenical to reduce the risk of weight regain after prior weight loss</li> <li>▪ The patient has a documented history of BMI ≥ 30 <b>OR</b> was in the 95<sup>th</sup> percentile <b>OR</b> BMI ≥ 27 <b>AND</b> has at least one comorbidity (diabetes, hypertension, dyslipidemia, or cardiovascular disease)</li> <li>▪ The patient must be 12 years of age or older</li> <li>▪ The patient has not had a history of cholestasis or chronic intestinal malabsorption in the past 12 months</li> </ul> </li> <li>d. The claim is for phentermine <ul style="list-style-type: none"> <li>▪ The patient has a BMI ≥ 30 <b>OR</b> is in the 95<sup>th</sup> percentile <b>OR</b> BMI ≥ 27 <b>AND</b> has at least one comorbidity (diabetes, hypertension, dyslipidemia, or cardiovascular disease)</li> <li>▪ The patient has not taken phentermine in the past 12 months</li> <li>▪ The patient must be 17 years of age or older</li> <li>▪ The patient has not taken a Monoamine Oxidase Inhibitor (MAOI) in the past 14 days (see attached table)</li> <li>▪ The patient has not had a history of uncontrolled hypertension, unstable cardiovascular disease, or cardiac arrhythmia in the past 12 months</li> </ul> </li> </ol> </li> </ol> <p style="text-align: right;">Page 1 of 3</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>e. The claim is for phentermine/topiramate</p> <ul style="list-style-type: none"> <li>▪ The patient has a BMI <math>\geq 30</math> <b>OR</b> is in the 95<sup>th</sup> percentile <b>OR</b> BMI <math>\geq 27</math> <b>AND</b> has at least one comorbidity (diabetes, hypertension, dyslipidemia, or cardiovascular disease)</li> <li>▪ The patient must be 18 years of age or older</li> <li>▪ The patient has not taken a Monoamine Oxidase Inhibitor (MAOI) in the past 14 days (see attached table)</li> <li>▪ The patient has not had a history of uncontrolled hypertension, unstable cardiovascular disease, or cardiac arrhythmia in the past 12 months</li> <li>▪ Dose must be <math>\leq 15\text{mg}/92\text{mg}</math> daily</li> <li>▪ Quantity limit for 3.75mg/23mg and 11.25mg/69mg strengths is <math>\leq 14</math> capsules</li> </ul> <p>LENGTH OF APPROVAL FOR PHENTERMINE 21 days ONLY</p> <p>LENGTH OF APPROVAL FOR LORCASERIN, ORLISTAT, AND PHENTERMINE/TOPIRAMATE 3 months</p> <p>RENEWAL CRITERIA FOR LORCASERIN: (must meet all of the following)</p> <ol style="list-style-type: none"> <li>1. The patient has lost a total of 5% of pretreatment weight within 3 months of initiating lorcaserin and maintains the 5% weight loss</li> <li>2. Dose must be <math>\leq 20\text{mg}</math> per day (10mg twice daily)</li> <li>3. The patient has not received lorcaserin for more than two calendar years</li> </ol> <p>LENGTH OF RENEWAL APPROVAL FOR LORCASERIN 3 months</p> <p>RENEWAL CRITERIA FOR ORLISTAT FOR WEIGHT LOSS: (must meet all of the following)</p> <ol style="list-style-type: none"> <li>1. The patient has lost a total of 5% of pretreatment weight within 3 months of initiating orlistat and maintains the 5% weight loss</li> <li>2. The patient has not received orlistat for more than four calendar years</li> </ol> <p>LENGTH OF RENEWAL APPROVAL FOR ORLISTAT FOR WEIGHT LOSS 3 months</p> <p>RENEWAL CRITERIA FOR ORLISTAT TO REDUCE THE RISK OF WEIGHT REGAIN: (must meet all of the following)</p> <ol style="list-style-type: none"> <li>1. The patient has maintained their weight loss</li> <li>2. The patient has not received orlistat for more than four calendar years</li> </ol> <p>LENGTH OF RENEWAL APPROVAL FOR ORLISTAT TO REDUCE THE RISK OF WEIGHT REGAIN 3 months</p> <p>RENEWAL CRITERIA FOR PHENTERMINE/TOPIRAMATE: (must meet all of the following)</p> <ol style="list-style-type: none"> <li>1. The patient has lost a total of 3% of pretreatment weight within 3 months of initiating phentermine/topiramate and maintains the 3% weight loss</li> <li>2. The patient has lost a total of 5% of pretreatment weight within 6 months of initiating phentermine/topiramate and maintains the 5% weight loss</li> <li>3. Dose must be <math>\leq 25\text{mg}/92\text{mg}</math> per day</li> <li>4. The patient has not received phentermine/topiramate for more than one calendar year</li> </ol> <p>LENGTH OF RENEWAL APPROVAL FOR PHENTERMINE/TOPIRAMATE 3 months</p> <p><b>Public Comment:</b> None</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<b>Board Discussion:</b> None	
<p>5. Incivek®(telaprevir)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Incivek is a hepatitis C protease inhibitor indicated for the treatment of genotype 1 chronic hepatitis C. Prior authorization criteria were initially approved in 2013. The prior authorization criteria are being revised to be consistent with similar agents and to prevent concurrent use with other direct acting hepatitis C agents.</p> <div style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Direct Acting Hepatitis C Agents</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Telaprevir (Incivek®)</p> <p><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION</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 Incivek therapy total)*</i></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C</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>• Incivek must be used in combination with peginterferon alfa and ribavirin</li> <li>• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Incivek</li> <li>• Patient must not have been on a previous or concurrent direct acting hepatitis C agent (i.e. concurrent therapy or previous trial with Victrelis, Incivek, Olysio, or Sovaldi)</li> <li>• Dose must not exceed 6 tablets per day</li> </ul> <p><b>LENGTH OF INITIAL APPROVAL</b> 12 weeks</p> <p>Ribavirin and Peginterferon alfa are approved when using triple therapy with Incivek if Incivek criteria are met</p> <p><b>DISCONTINUATION CRITERIA</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 above 1,000 IU/mL after treatment week 4</li> </ul> </div> <p><b>Public Comment:</b> None</p>	<p>Dr. Scheffer made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>Board Discussion:</b> Dr. Scheffer asked about concurrent use and if there was supporting literature for this. Dr. Melton responded that there was a study ongoing regarding the concurrent use of two agents but we felt it would be more appropriate to handle the requests for concurrent therapy on a case-by-case basis at this point.</p>	
<p>6. Olysio®(simeprevir)  i. Revised PA Criteria  ii. *Public Comment  iii. Board Discussion</p>	<p><b>Background</b>  Olysio is a hepatitis C protease inhibitor indicated for the treatment of genotype 1 chronic hepatitis C. Prior authorization criteria were initially approved in January 2014. The prior authorization criteria are being revised to be consistent with similar agents and to prevent concurrent use with other direct acting hepatitis C agents.</p> <div style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Direct Acting Hepatitis C Agents</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Simeprevir (Olysio®)</p> <p><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION:</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</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>• Olysio must be used in combination with Peginterferon alfa and ribavirin</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 (i.e. concurrent therapy or previous trial with Victrelis, Incivek, Olysio, or Sovaldi)</li> <li>• Dose must not exceed 1 capsule per day</li> </ul> <p><b>LENGTH OF INITIAL APPROVAL</b> 12 weeks</p> <p>Ribavirin and peginterferon alfa are approved when using triple therapy with Olysio, if Olysio criteria are met.</p> <p><b>DISCONTINUATION CRITERIA</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> </div> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> None</p>	<p>Dr. Heston made motion to accept the PA criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>7. Victrelis®(boceprevir)</p>	<p><b>Background</b></p>	<p>Dr. Scheffer made motion to</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
i. Revised PA Criteria ii. *Public Comment iii. Board Discussion	<p>Victrelis is a hepatitis C protease inhibitor indicated for the treatment of genotype 1 chronic hepatitis C. Prior authorization criteria were initially approved in 2013. The prior authorization criteria are being revised to be consistent with similar agents and to prevent concurrent use with other direct acting hepatitis C agents.</p> <div style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Direct Acting Hepatitis C Agents</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Boceprevir (Victrelis®)</p> <p><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION</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 44 weeks of Victrelis therapy total)*</i></p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic hepatitis C</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>• Victrelis must be used in combination with peginterferon alfa and ribavirin</li> <li>• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Victrelis</li> <li>• Patient must not have been on a previous or concurrent direct acting hepatitis C agent (i.e. concurrent therapy or previous trial with Victrelis, Incivek, Olysio, or Sovaldi)</li> <li>• Dose must not exceed 12 capsules per day</li> </ul> <p><b>LENGTH OF INITIAL APPROVAL</b> 44 weeks</p> <p>Ribavirin and Peginterferon alfa are approved when using triple therapy with Victrelis if Victrelis criteria are met</p> <p><b>DISCONTINUATION CRITERIA</b></p> <ul style="list-style-type: none"> <li>• Provider must submit HCV RNA level after treatment week 12 and 24 within 7 days to prevent discontinuation of therapy</li> <li>• Therapy will be discontinued if the HCV RNA level is above 100 IU/mL after treatment week 12 or if the HCV RNA level is detectable after treatment week 24</li> </ul> </div> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> A question was asked about a patient’s ability to get one direct-acting Hepatitis C agent after use of another. Dr. Melton clarified that if a patient saw no effect</p>	<p>accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>from one direct-acting agent, it would not be appropriate for them to try a second. However, if they discontinued the first direct-acting agent due to adverse effects, their PA for a second direct-acting agent might be initially denied, but could be appealed.</p>	
<p>8. Sovaldi®(sofosbuvir)  i. Revised PA Criteria  ii. *Public Comment  iii. Board Discussion</p>	<p><b>Background</b>  Sovaldi is a hepatitis C virus nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C. Prior authorization criteria were initially approved in January 2014. The prior authorization criteria are being revised to be consistent with similar agents and to prevent concurrent use with other direct acting hepatitis C agents.</p> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Direct Acting Hepatitis C Agent</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization:  Sofosbuvir (Sovaldi®)</p> <p><b>CRITERIA FOR INITIAL PRIOR AUTHORIZATION:</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>• Sovaldi must be used in combination with ribavirin</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 be on concurrent therapy with another direct acting hepatitis C agent (i.e. concurrent therapy with Victrelis, Incivek, or Olysio)</li> <li>• Dose must not exceed 1 capsule per day</li> </ul> <p><b>LENGTH OF INITIAL APPROVAL</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:</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 of therapy will be approved for a max of 24 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> </div> <p><b>Public Comment:</b> None</p>	<p>Dr. Heston made motion to accept the PA criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<b>Board Discussion:</b> None	
<p>C. New Prior Authorization Criteria</p> <p>1. Sodium Glucose Co-Transporter 2 Inhibitors (Farxiga®(dapagliflozin) &amp; Invokana®(canagliflozin))</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Farxiga and Invokana are SGLT2 Inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indications.</p> <div data-bbox="527 342 1614 992" style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: center;">Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drugs require prior authorization: Canagliflozin (Invokana®) Dapagliflozin (Farxiga®)</p> <p><b>CRITERIA FOR SGLT2 INHIBITORS</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of type II diabetes</li> <li>• Patient MUST NOT have a diagnosis of type I diabetes</li> <li>• Patient must be 18 years of age or older</li> <li>• Patient must have an eGFR above 60 mL/min/1.73m<sup>2</sup> for dapagliflozin OR above 45 mL/min/1.73m<sup>2</sup> for canagliflozin</li> <li>• Patient MUST NOT have any of the following contraindications: <ul style="list-style-type: none"> <li>○ Active bladder cancer</li> <li>○ End-stage renal disease</li> <li>○ Currently on dialysis</li> </ul> </li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p> </div> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> Dr. Scheffer raised the concern that this agent might be used in Type II diabetics who were also using insulin. Dr. Ellermeier stated that the package insert studies included this patient type. Molly Skelsey, Astra-Zeneca, confirmed that Farxiga had been studied in type II diabetics who were also using insulin, but not in type I diabetics.</p>	<p>Dr. Heston made motion to accept the PA criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>2. Sensipar® (cinacalcet)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Sensipar is a calcium-sensing receptor agonist indicated for secondary hyperparathyroidism (HPT) in patient with chronic kidney disease on dialysis, hypercalcemia in patients with parathyroid carcinoma, and severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy. Prior authorization criteria are being proposed to ensure use based upon FDA-approved indications.</p>	<p>Dr. Unruh made motion to accept the PA criteria.</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Sensipar® (cinacalcet)</p> <p><b>PROVIDER GROUP</b> Pharmacy Professional</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Cinacalcet (Sensipar)</p> <p><b>CRITERIA FOR TREATMENT OF SECONDARY HYPERPARATHYROIDISM</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of chronic kidney disease</li> <li>• Patient is on dialysis (hemodialysis or peritoneal dialysis)</li> <li>• Patient must be 18 years of age or older</li> <li>• Current serum calcium is <math>\geq 8.4</math>mg/dL (2.1 mmol/L)</li> <li>• Current iPTH (intact parathyroid hormone) levels are <math>\geq 300</math>pg/ml<sup>3</sup></li> </ul> <p><b>CRITERIA FOR TREATMENT OF HYPERCALCEMIA IN PATIENTS WITH PARATHYROID CANCER</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of parathyroid carcinoma</li> <li>• Patient must be 18 years of age or older</li> <li>• Patient must have hypercalcaemia</li> <li>• Current serum calcium levels <math>\geq 10.2</math>mg/dL</li> </ul> <p><b>CRITERIA FOR TREATMENT OF PRIMARY HYPERPARATHYROIDISM WITH SEVERE HYPERCALCEMIA</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient is unable to undergo parathyroidectomy</li> <li>• Patient must be 18 years of age or older</li> <li>• Current serum calcium is <math>\geq 12.5</math>mg/dL</li> </ul> <p><b>LENGTH OF APPROVAL FOR ALL INDICATIONS</b> 12 months</p> <p><b>Public Comment:</b> Risa Reuscher, Amgen, stated that she was available for questions.</p> <p><b>Board Discussion:</b> The criteria were revised to more closely follow package insert guidelines with respect to dialysis patients and serum calcium levels.</p>	<p>unanimously.</p>
<p>3. Constipation Agents (Amitiza® (lubiprostone) &amp; Linzess® (linaclotide))</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Amitiza and Linzess are both indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. Additionally, Amitiza is indicated for the treatment of opioid-induced constipation in adults with chronic, non-cancer pain. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.</p>	<p>Dr. Scheffer made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Constipation Agents</p> <p><b>PROVIDER GROUP</b> Pharmacy</p> <p><b>MANUAL GUIDELINES</b> The following drugs requires prior authorization; Linaclotide (Linzess®) Lubiprostone (Amitiza®)</p> <p><b>CRITERIA FOR CONSTIPATION AGENTS</b> Must meet the following criteria:</p> <ul style="list-style-type: none"> <li>• Patient must have one of the following diagnoses: <ul style="list-style-type: none"> <li>○ chronic idiopathic constipation</li> <li>○ irritable bowel syndrome (IBS) with constipation</li> <li>○ opioid-induced constipation with chronic, non-cancer pain <b>(Amitiza Only)</b></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>Public Comment:</b> Faisal Riaz, Takeda, stated that a lot of patients using Amitiza are treated by a surgeon or primary care provider. He also stated that they are only approved in patients 18 years and up, but currently have a pediatric trial.</p> <p><b>Board Discussion:</b> Dr. Heston also stated that many surgeons and primary care doctors used these agents, and that it would be difficult for a patient to get a gastroenterologist in 80% of the state. Dr. Waite stated that they see more use with surgeons than any other specialty. The criteria was amended to remove prescriber specialty requirements.</p>	<p>unanimously.</p>
<p>4. Lucentis® (ranibizumab)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Lucentis is an intravitreal injection indicated for the treatment of patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and diabetic macular edema. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.</p>	<p>Dr. Scheffer made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Intravitreal Injection</p> <p><b>PROVIDER GROUP</b> Pharmacy Professional</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Ranibizumab (Lucentis®)</p> <p><b>CRITERIA FOR LUCENTIS</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must be 18 years of age or older</li> <li>• Patient must have one of the following: <ul style="list-style-type: none"> <li>○ Neovascular (wet) age-related macular degeneration (AMD)</li> <li>○ Macular edema following retinal vein occlusion (RVO)</li> <li>○ Diabetic macular edema (DME)</li> </ul> </li> <li>• Patient must not have an active ocular or periocular infection</li> <li>• Must be prescribed by or in consultation with an ophthalmologist</li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> Dr. Scheffer suggested that it might be appropriate to include a physician specialty in the criteria. The criteria was amended to require that Lucentis be prescribed by or in consultation with an ophthalmologist.</p>	
<p>5. Jetrea® (ocriplasmin)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Jetrea is an intravitreal injection indicated for the treatment of symptomatic vitreomacular adhesion. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.</p>	<p>Ms. Dowd made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Intravitreal Injection</p> <p><b>PROVIDER GROUP</b> Pharmacy Professional</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Ocricplasmin (Jetrea®)</p> <p><b>CRITERIA FOR JETREA</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must be 18 years of age or older</li> <li>• Patient must have symptomatic vitreomacular adhesion (VMA)</li> <li>• Treatment for bilateral VMA must be done at least 7 days apart</li> <li>• Patient must not have received a prior intravitreal injection of ocricplasmin in the same eye</li> <li>• Must be prescribed by or in consultation with an ophthalmologist</li> </ul> <p><b>A SINGLE INTRAVITREAL INJECTION FOR ONE EYE WILL BE APPROVED AT A TIME</b></p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> Ophthalmologist prescriber specialty language was added to the criteria.</p>	
<p>6. Elelyso® (taliglucerase alfa)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><b>Background</b></p> <p>Elelyso is indicated for long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type 1 Gaucher disease. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indication.</p> <p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Enzyme Replacement Therapy</p> <p><b>PROVIDER GROUP</b> Pharmacy Professional</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Taliglucerase Alfa (Elelyso®)</p> <p><b>CRITERIA FOR ELELYSO</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of Type 1 Gaucher disease</li> </ul> <p><b>LENGTH OF APPROVAL</b> 12 months</p>	<p>Dr. Unruh made motion to table the PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were tabled unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><b>Public Comment</b> Jim Baumann asked the committee consider tabling the Elelyso criteria until the next DUR board meeting and addressing all enzyme replacement therapy for Type 1 Gaucher disease together. Other agents include Cerezyme® and VPRIV®.</p> <p><b>Board Discussion:</b> None</p>	
<p>7. Xofigo® (radium Rx 223 dichloride) i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p><b>Background</b> Xofigo is indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.</p> <div data-bbox="527 548 1623 1084" style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Xofigo® (radium Ra 223 dichloride)</p> <p><b>PROVIDER GROUP</b> Pharmacy Professional</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Radium Ra 223 dichloride (Xofigo)</p> <p><b>CRITERIA FOR XOFIGO</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must be 18 years of age or older</li> <li>• Patient must have a diagnosis of castration-resistant prostate cancer with symptomatic bone metastases</li> <li>• Patient must NOT have known visceral metastatic disease</li> <li>• Planned course of therapy is for up to 6 injections given at 4 week intervals</li> <li>• Must be prescribed by or in consultation with an oncologist</li> </ul> <p><b>LENGTH OF APPROVAL</b> 6 months</p> </div> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> Dr. Waite stated that it seemed as though the window for the use of this agent is small. Dr. Heston questioned why oncologists were not listed as potential prescribers. The criteria was amended to this effect.</p>	<p>Dr. Unruh made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>8. Provenge® (sipuleucel-T) i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p><b>Background</b> Provenge is indicated for the treatment of asymptomatic or minimally symptomatic metastatic castration-resistant (hormone refractory) prostate cancer. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information.</p>	<p>Ms. Dowd made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p style="text-align: center;"><b>CRITERIA FOR PRIOR AUTHORIZATION</b></p> <p style="text-align: right;">Provenge® (sipuleucel-T)</p> <p><b>PROVIDER GROUP</b> Pharmacy Professional</p> <p><b>MANUAL GUIDELINES</b> The following drug requires prior authorization: Sipuleucel-T (Provenge)</p> <p><b>CRITERIA FOR PROVENGE</b> Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Patient must have a diagnosis of asymptomatic or minimally symptomatic metastatic castration-resistant (hormone refractory) prostate cancer.</li> <li>• Treatment must not exceed 3 complete doses</li> <li>• Must be prescribed by or in consultation with an oncologist</li> </ul> <p><b>LENGTH OF APPROVAL</b> 3 months</p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> The criteria was amended to include oncologist prescribing/consultation.</p>	unanimously.
<p>D. Miscellaneous Items</p> <p>1. Managed Care Organization Annual Reports</p> <p>i. Overall MCO Utilization</p> <p>ii. Amerigroup Individual Report</p> <p>iii. United Healthcare Individual Report</p> <p>iv. Sunflower Individual Report</p> <p>v. *Public Comment</p> <p>vi. Board Discussion</p>	<p><b>Background</b></p> <p>Amerigroup, United Healthcare, and Sunflower will present reports detailing utilization trends and provider education efforts for 2013.</p> <p><b>Public Comment:</b> None</p> <p><b>Board Discussion:</b> None</p>	
<p>IV. Open Public Comment</p>	<p><b>Public Comment:</b> None</p>	
<p>V. Adjourn</p>	<p>The meeting was adjourned at 11:53am.</p> <p>The next meeting will be on Wednesday July 9, 2014. It will begin at 10:00am at the HP Enterprises Services Office.</p>	<p>Dr. Heston made motion to adjourn the meeting.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion was approved</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<b>**LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS</b>	unanimously.