

**Drug Utilization Review Board
Meeting Minutes, Open Session
November 14, 2014**

<p>Drug Utilization Review Board Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital Room Topeka, KS</p>	<p>DUR Board Members Present Tim Heston, DO Roger Unruh, DO John Kollhoff, PharmD Jim Backes, PharmD Kevin Waite, PharmD</p> <p>DUR Board Members Absent Judy McDaniel Dowd, PA-C Russell Scheffer, MD</p> <p>DHCF Staff Present F.E. Bustillo, III, MD Kelley Melton, PharmD Liane Larson, PharmD Carol Arace, Administrative Assistant</p> <p>HP Enterprise Services Staff Present Karen Kluczykowski, RPh Nancy Perry, RN</p> <p>HID Staff Present Nicole Ellermeier, PharmD</p> <p>MCO Staff Present Jonalan Smith, PharmD, FASCP: Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p>Representatives Berend Koops, Merck Marla Wiepenmann, NNI Terry McCurren, Otsuka Holly Weatherford, BRNS Brent Hildebrand, Gilead Sciences Marcos Valdes, Gilead Sciences Brian Rose, Merck Ashley Pochley, Dave Sproat, Debbie Dox, Michelle Puyear, Gilead Sciences Rick Pham</p>
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Waite called the meeting to order at 2:05pm.	
A. Announcements	Dr. Melton offered a reminder as to where meeting guests should park and for those present in the room to sign-in.	
II. Old Business A. Review and Approval of October 8, 2014 DUR Meeting Minutes	The board discussed tabling the minutes for the October 2014 DUR meeting until the next DUR meeting.	Dr. Heston made motion to table the minutes. Dr. Unruh seconded the motion. The minutes were tabled.
II. New Business A. New Prior Authorization Criteria	Background Harvoni is a recently approved direct acting agent for the treatment of chronic hepatitis C genotype 1 infection. Prior authorization criteria are being proposed to be in line with other	Dr. Kollhoff made motion to accept the PA Criteria

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<p>1. Harvoni® (ledipasvir/Sovaldi)</p> <p>i. New PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>direct acting hepatitis C agents, the criteria follow the FDA label information and national guidelines for the treatment of chronic hepatitis C to ensure appropriate use. .</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR INITIAL APPROVAL OF LEDIPASVIR/SOFOSBUVIR: (must meet all of the following)</p> <p><i>*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Sofosbuvir/Ledipasvir therapy total)*</i></p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C (CHC) • Patient must have genotype 1 hepatitis C • Patient must have stage 3 or 4 liver fibrosis • Patient must not have a co-infection with HIV • Patient must not have severe renal impairment (eGFR<30mL/min/1.73m²) or currently require hemodialysis • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Patient must not be taking concurrently with another direct acting hepatitis C agent (i.e. concurrent therapy with Incivek®, Victrelis®, Olysio® or Sovaldi®) • Patient must not have been on a previous course of therapy with Sovaldi • If patient was on a previous course of treatment with Incivek, Victrelis or Olysio it must have included an interferon-based regimen • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request • Dose must not exceed 1 capsule per day <p>RENEWAL CRITERIA FOR LEDIPASVIR/SOFOSBUVIR:</p> <ul style="list-style-type: none"> • Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following: <ul style="list-style-type: none"> ○ Treatment-naïve, without cirrhosis, and a pre-treatment HCV RNA < 6 million IU/mL – 8 weeks total therapy ○ Treatment-naïve, with or without cirrhosis, and a pre-treatment HCV RNA ≥ 6 million IU/mL – 12 weeks total therapy ○ Treatment-experienced, without cirrhosis – 12 weeks total therapy ○ Treatment-experienced, with cirrhosis – 24 weeks total therapy <p>LENGTH OF APPROVAL FOR LEDIPASVIR/SOFOSBUVIR: 4 weeks</p> <p>Public Comment Michelle Puyear from Gilead Sciences stated she was available for questions from the board and asked a question regarding the requirement that ‘if a patient was on a previous course of treatment with Incivek, Victrelis or Olysio it must have included an interferon-based regimen’. Dr. Ellermeier stated that the criteria was meant to catch patients that may have used other direct acting agents off-label without interferon and patients who may have previously tried Olysio and Sovaldi in combination. This criteria is in line with the labeled indication for Harvoni.</p> <p>Board Discussion There was no additional board discussion.</p> </div>	<p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>IV. Open Public Comment</p>	<p>Public Comment</p>	

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	<p>There were no additional public comments offered during this meeting.</p> <p><u>Board Discussion</u> None</p>	
V. Adjourn	<p>The meeting was adjourned at 2:16pm.</p> <p>The next meeting will be on January 14, 2015. It will begin at 10:00am at the HP Enterprises Services Office.</p> <p>**LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS</p>	<p>Dr. Heston made motion to adjourn the meeting.</p> <p>Dr. Backes seconded the motion.</p> <p>The motion was approved unanimously.</p>