

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

<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, D.O. John Kollhoff, PharmD. Jim Backes, PharmD. Russell Scheffer, MD Judy McDaniel Dowd, PA-C Kevin Waite, PharmD.</p> <p>DUR Board Members Absent</p> <p>DHCF Staff Present Kelley Melton, PharmD. Liane Larson, PharmD. Carol Arace, Administrative Assistant</p> <p>HP Enterprise Services Staff Present Karen Kluczykowski, RPh Nancy Perry, R.N.</p> <p>HID Staff Present Nicole Ellermeier, PharmD.</p> <p>MCO Staff Present Jonalan Smith, Pharm.D., FASCP: Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p>Representatives Mark Tiemann, Boehringer Ingelheim Ted Sheedy, GSK Eddilisa Martin, Abbvie Shelley Baugh, Celgene Jason Enders, Genzyme Marissa Clark, Clark Neuro Rehab Consultants Terry McCurren, Otsuka Scott Jones, Astra-Zeneca David Bloom, Astra-Zeneca Brent Hildebrand, Gilead Dave Sproat, Bristol-Myers Squibb Edie Dodson, Genzyme Jeff Haroldson, Intermune Deron Grothe, Teva Berend Koops, Merck Danielle Walters, Sanofi Patty Loughlin, Intermune</p>
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Waite called the meeting to order at 10:02am.	
A. Announcements	<p>Dr. Ellermeier offered a reminder as to where meeting guests should park.</p> <p>Dr. Waite reminded those that wanted to speak to fill out the disclosure form.</p>	
II. Old Business A. Review and Approval of October 8, 2014 and November 14, 2014 DUR Meeting Minutes		<p>Dr. Unruh made motion to accept the minutes as presented.</p> <p>Dr. Scheffer seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
		The minutes for October 8, 2014 and November 14, 2014 are approved as written.
<p>III. New Business</p> <p>A. Revised Prior Authorization (PA) Criteria</p> <p>1. Harvoni® (ledipasvir/sofosbuvir)</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background</p> <p>Prior authorization criteria for Harvoni was approved in November 2014, and at that time, a renewal timeline for treatment-naïve patients with cirrhosis was inadvertently left off of the criteria. The criteria is being revised to include renewals for treatment-naïve patients with cirrhosis for 12 weeks of total therapy with Harvoni.</p>	<p>Ms. Dowd made motion to accept the revised PA Criteria</p> <p>Dr. Kollhoff seconded the motion.</p> <p>Dr. Heston abstained due to late arrival.</p> <p>The criteria were approved.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 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®, Viekira™ or Sovaldi®) • Patient must not have been on a previous course of therapy with Sovaldi or Viekira • 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 • Patient must have one of the following: • Patient must have one of the following: <ul style="list-style-type: none"> ○ Advanced fibrosis (<u>Metavir F3</u>) ○ Compensated cirrhosis ○ Liver transplant ○ Type 2 or 3 essential mixed <u>cryoglobulinemia</u> with end-organ manifestations (eg, vasculitis) ○ Proteinuria ○ <u>Nephrotic syndrome</u> ○ <u>Membranoproliferative glomerulonephritis</u> <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-naïve, with cirrhosis – 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><u>Public Comment</u> <u>None</u> <u>Board Discussion</u> None</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>2. Humira® (adalimumab)</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background</p> <p>Prior authorization criteria for Humira was last revised in April 2013, and since that time, the indication for Juvenile Idiopathic Arthritis (JIA) has been reduced from patients 4 years of age and older to 2 years of age and older and there has been an expansion to include pediatric Crohn’s disease. The prior authorization criteria is being revised to include the current FDA-approved indications.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of rheumatoid arthritis • Must be prescribed by a rheumatologist • Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of juvenile idiopathic arthritis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 2 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR PSORIATIC ARTHRITIS (PsA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of psoriatic arthritis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR ANKYLOSING SPONDYLITIS (AS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of ankylosing spondylitis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days </div>	<p>Dr. Kollhoff made motion to accept the revised PA Criteria</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR CROHN'S DISEASE (CD): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Crohn's disease • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has used a conventional Crohn's disease therapy (see attached table) OR there is documentation of inadequate response, contraindication, allergy, or intolerable side effects to a conventional Crohn's disease therapy (see attached table) <p>CRITERIA FOR PEDIATRIC CROHN'S DISEASE (CD): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Crohn's disease • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 6 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has had an inadequate response to corticosteroids or <u>immunomodulators</u> such as azathioprine, 6-mercaptopurine, or methotrexate <p>CRITERIA FOR ULCERATIVE COLITIS (UC): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of ulcerative colitis • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has used a conventional ulcerative colitis therapy (see attached table) OR there is documentation of inadequate response, contraindication, allergy, or intolerable side effects to a conventional ulcerative colitis therapy (see attached table) <p>CRITERIA FOR PLAQUE PSORIASIS (Ps): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of plaque psoriasis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has taken an oral agent for the treatment of plaque psoriasis (see attached table) OR patient is a candidate for systemic therapy or phototherapy <p>LENGTH OF APPROVAL 6 months</p> <p>Public Comment <u>None</u></p> <p>Board Discussion</p> <p>Dr. Scheffer questioned where the age change originated either from the company requesting or was there a definition set. Dr. Ellermeier explained the younger age had been</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	approved. Dr. Waite noting that there had been more studies.	
<p>3. Interferons for Multiple Sclerosis (Plegridy™ [interferon beta-1a])</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>The prior authorization criteria for interferons for multiple sclerosis was initially approved in October 2012, and since that time, a new agent has been approved. The prior authorization criteria are being revised to include the new agent, Plegridy.</p> <div style="border: 1px solid black; padding: 5px;"> <p>MANUAL GUIDELINES: The following drug(s) require prior authorization:</p> <p><u>Avonex</u>® (interferon beta-1a)</p> <p><u>Betaseron</u>® (interferon beta-1b)</p> <p><u>Extavia</u>® (interferon beta-1b)</p> <p><u>Plegridy</u>® (interferon beta-1a)</p> <p><u>Rebif</u>® (interferon beta-1a)</p> <p>CRITERIA: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple sclerosis • Age >= 18. • Absence of concurrent therapy with another disease-modifying MS agent: a different interferon, glatiramer, natalizumab, or fingolimod. • Does not exceed the following quantity limits: <ul style="list-style-type: none"> ○ Betaseron (interferon beta-1b) – Quantity limit: 1 kit (of 14 units) per 28 days ○ Rebif (interferon beta-1a) – Quantity limit: 1 kit (of 12 units) per 28 days ○ Avonex (interferon beta-1a) – Quantity limit: 1 kit (of 4 vials/syringes/pens) per 28 days ○ Extavia (interferon beta-1b) – Quantity limit: 1 kit (15 units) per 30 days ○ Plegridy (interferon beta-1a) – Quantity limit: 1 kit (of 2 pens/syringes) per 28 days <p>Prior authorizations will be approved for 1 year.</p> </div> <p>Public Comment <u>None</u></p> <p>Board Discussion <u>None</u></p>	<p>Dr. Scheffer made motion to accept the revised PA Criteria</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>4. Otezla® (apremilast)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Prior authorization criteria for Otezla was initially approved in July 2014, and since that time, a new indication has been approved. Otezla is now approved for use in patients with moderate to severe plaque psoriasis. The prior authorization criteria is being revised to include this new indication.</p>	<p>Ms. Dowd made motion to accept the revised PA Criteria</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>MANUAL GUIDELINES The following drug requires prior authorization: Otezla (apremilast)</p> <p>CRITERIA FOR PSORIATIC ARTHRITIS (PSA) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of active psoriatic arthritis • Must be prescribed by a rheumatologist or dermatologist • Patient must be 18 years of age or older <p>CRITERIA FOR PLAQUE PSORIASIS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of moderate to severe plaque psoriasis • Must be prescribed by a rheumatologist or dermatologist • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment Shelly Vaughn, Manufacturer representative, offered overview of product, indications, dosage, and safety.</p> <p>Board Discussion None</p>	
<p>5. Methotrexate Subcutaneous Injections (Rasuvo™ [methotrexate])</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Prior authorization criteria for Otrexup™ (methotrexate subcutaneous injection) was initially approved in January 2014, and since that time, a new agent has been approved. Prior authorization criteria revisions are being proposed to include Rasuvo.</p>	<p>Dr. Heston made motion to accept the revised PA Criteria</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	<p>MANUAL GUIDELINES The following drug requires prior authorization: Otrexup® (methotrexate subcutaneous injection) Rasuvo® (methotrexate subcutaneous injection)</p> <p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of rheumatoid arthritis • Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one first line therapy (example: full dose non-steroidal anti-inflammatory agents) • Must be prescribed by or in consultation with a rheumatologist • Dose must be between 10mg and 25mg per week for Otrexup or 7.5mg and 30mg per week for Rasuvo <p>CRITERIA FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of polyarticular juvenile idiopathic arthritis • Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one first line therapy (example: full dose non-steroidal anti-inflammatory agents) • Must be prescribed by or in consultation with a rheumatologist • Dose must be between 10mg and 25mg per week for Otrexup or 7.5mg and 30mg per week for Rasuvo <p>CRITERIA FOR PSORIASIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of psoriasis • Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one other therapy (example: full dose non-steroidal anti-inflammatory agents) • Must be prescribed by or in consultation with a dermatologist • Dose must be between 10mg and 25mg per week for Otrexup or 7.5mg and 30mg per week for Rasuvo <p>LENGTH OF APPROVAL 6 months</p> <p>Public Comment <u>None</u></p> <p>Board Discussion <u>None</u></p>	
<p>6. Opioid Induced Constipation Agents (Relistor® [methylnaltrexone] & Movantik™ [naloxegol])</p> <ol style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Prior authorization criteria for Relistor was initially approved in September 2008. Since that time, Relistor was approved for a new indication and a new agent was approved. The prior authorization criteria is being revised to include the new indication for Relistor and the new agent, Movantik.</p>	<p>Dr. Kollhoff made motion to accept the revised PA Criteria</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>MANUAL GUIDELINES: The following drug requires prior authorization: Relistor® (methylnaltrexone) Movantik® (naloxegol)</p> <p>CRITERIA for Patients with Chronic Non-Cancer Pain (All Agents): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be 18 years of age or older • Patient must have opioid-induced constipation • Patient must have chronic non-cancer pain • Patient must have been on chronic opioid therapy for at least 4 weeks • Patient does not have known or suspected mechanical gastrointestinal obstruction • Dose must not exceed 12mg/day for Relistor or 25mg/day for Movantik <p>CRITERIA for Patients Receiving Palliative Care (RELISTOR ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be 18 years of age or older • Patient must have opioid-induced constipation with advanced illness and be receiving palliative care • Documentation of current opioid therapy • Patient's response to standard laxative therapy has not been sufficient • Patient does not have known or suspected mechanical gastrointestinal obstruction <p>LENGTH OF APPROVAL: 6 months</p> <p>Public Comment David Blume, Manufacturer, offered general information</p> <p>Board Discussion Board discussion around why cancer pain is excluded. There was not enough data available to include this as an indication for product use; therefore, package insert was not able to reflect use for that condition. Physician can use appeal process for this condition.</p>	
<p>7. Weight Loss Drugs (Contrave ER® [naltrexone/bupropion])</p> <ol style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Prior authorization criteria for the weight loss agents was brought before the DUR board in April 2014, and since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Contrave ER.</p>	<p>Dr. Scheffer made motion to accept the revised PA Criteria</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously with change.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)</p> <ul style="list-style-type: none"> • The patient is not pregnant or breastfeeding • The treatment plan includes a nutritionally balanced, reduced-calorie diet, exercise, and behavioral counseling • The patient has a BMI ≥ 30 OR is in the 95th percentile OR BMI ≥ 27 AND has at least one comorbidity (diabetes, hypertension, dyslipidemia, or cardiovascular disease) OR if patient is taking <u>orlistat</u> to reduce the risk of weight regain after prior weight loss the patient has a documented history of BMI ≥ 30 OR was in the 95th percentile OR BMI ≥ 27 AND has at least one comorbidity (diabetes, hypertension, dyslipidemia, or cardiovascular disease) • Dose must not be above the approved limits for agent in table 1 • Patient must meet age limits in table 2 • If patient is taking <u>orlistat</u> for weight loss, they have not taken more than 180 days of <u>orlistat</u> in the past 12 months • The patient does not have any contraindication to therapy (table 3) • For phentermine patient has not taken phentermine in the past 12 months AND has not taken a Monoamine Oxidase Inhibitor (MAOI) in the past 14 days (table 4) • For phentermine/<u>topiramate</u> ER the patient has not taken a MAOI in the past 14 days (table 4) AND is not taking above the quantity limit for 3.75mg/23mg and 11.25mg/69mg strengths of ≤ 14 capsules • For naltrexone/bupropion ER the patient has not taken a MAOI in the past 14 days (table 4) AND patient must not be taking another bupropion-containing product concurrently AND patient must not be on chronic opioids <p>LENGTH OF APPROVAL FOR PHENTERMINE 21 days ONLY</p> <p>LENGTH OF APPROVAL FOR ALL OTHER AGENTS 3 months</p> <p>RENEWAL CRITERIA FOR <u>LORCASERIN</u>, <u>ORLISTAT</u> FOR WEIGHT LOSS AND <u>NALTREXONE/BUPROPION</u>: (must meet all of the following)</p> <ul style="list-style-type: none"> • The patient has lost a total of 5% of pretreatment weight within 3 months of initiating therapy <u>lorcaserin</u> and maintains the 5% weight loss • Dose must not exceed limit in table 1 <p>LENGTH OF RENEWAL APPROVAL 3 months</p> <hr/> <p>RENEWAL CRITERIA FOR <u>ORLISTAT</u> TO REDUCE THE RISK OF WEIGHT REGAIN: (must meet all of the following)</p> <ul style="list-style-type: none"> • The patient has maintained their weight loss <p>LENGTH OF RENEWAL APPROVAL FOR <u>ORLISTAT</u> TO REDUCE THE RISK OF WEIGHT REGAIN 3 months</p> <p>RENEWAL CRITERIA FOR <u>PHENTERMINE/TOPIRAMATE</u> ER: (must meet all of the following)</p> <ul style="list-style-type: none"> • The patient has lost a total of 3% of pretreatment weight within 3 months of initiating phentermine/<u>topiramate</u> ER and maintains the 3% weight loss • The patient has lost a total of 5% of pretreatment weight within 6 months of initiating phentermine/<u>topiramate</u> ER and maintains the 5% weight loss <p>LENGTH OF RENEWAL APPROVAL FOR <u>PHENTERMINE/TOPIRAMATE</u> ER 3 months</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Public Comment <u>None</u></p> <p>Board Discussion Change made to weight loss maintenance threshold within three months of initiating therapy</p>	
<p>8. Long-Acting Opioids (Butrans® [buprenorphine patch], Targiniq™ ER [oxycodone/naloxone] & Hysingla™ ER [hydrocodone])</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Limitations and override criteria for the long-acting opioids was last revised in July 2014, and since that time, two new agents have been approved by the FDA. In addition to the new agents, a new strength of Butrans has been approved and is being added to the limitations for long-acting opioids. Limitations are being proposed for the new agents and the override criteria is being revised to include both Targiniq ER and Hysingla ER.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA for long-acting opioids: (must meet one of the following)</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of cancer. 2. The patient is terminally ill. 3. Must meet all of the following: <ul style="list-style-type: none"> a. 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. b. The patient does not have a diagnosis of opioid or other substance abuse. c. All narcotic analgesics are written by a single KMAP enrolled prescriber or practice. d. The patient has a signed opioid treatment agreement with the prescriber. e. 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) <p>RENEWAL CRITERIA for long-acting opioids: (must meet all of the following)</p> <ol style="list-style-type: none"> 1. No more than one early refill attempt in the past 3 months unless there is documentation of dose titration from the prescriber. <p>LENGTH OF APPROVAL 3 months</p> </div> <p>Public Comment <u>None</u></p> <p>Board Discussion Board Discussion around the product containing an abuse deterrent.</p>	<p>Ms. Dowd made motion to accept the revised PA Criteria</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. New Prior Authorization (PA) Criteria</p> <ol style="list-style-type: none"> 1. Viekira Pak™ (ombitasvir, paritaprevir, ritonavir & dasabuvir co-packaged) 	<p>Background Viekira Pak is a recently approved chronic hepatitis C medication. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.</p>	<p>Dr. Scheffer made motion to accept the PA Criteria</p> <p>Dr. Backes seconded the</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
i. PA Criteria ii. *Public Comment iii. Board Discussion	<p>CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)</p> <p><i>*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Viekira Pak therapy total)*</i></p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C (CHC) • Patient must have genotype 1 hepatitis C • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Must be used in combination with ribavirin unless patient has genotype 1b without cirrhosis • Patient must not have been on a previous or concurrent direct acting hepatitis C agent (i.e. past or concurrent therapy with Incivek®, Victrelis®, Olysio®, Sovaldi®, or Harvoni®) • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Dose must not exceed 1 daily dose pack per day (2 ombitasvir/paritaprevir/ritonavir and 2 dasabuvir tablets per day) • Patient must have one of the following: <ul style="list-style-type: none"> ○ Advanced fibrosis (<u>Metavir F3</u>) ○ Compensated cirrhosis ○ Liver transplant ○ Type 2 or 3 essential mixed <u>cryoglobulinemia</u> with end-organ manifestations (eg, vasculitis) ○ Proteinuria ○ <u>Nephrotic syndrome</u> ○ <u>Membranoproliferative glomerulonephritis</u> <p>RENEWAL CRITERIA:</p> <ul style="list-style-type: none"> • Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following: <ul style="list-style-type: none"> ○ Genotype 1a with cirrhosis or mixed genotype with cirrhosis – up to 24 weeks total therapy ○ Liver transplant recipient with normal hepatic function and mild fibrosis (<u>Metavir</u> fibrosis score 2 or lower) – 24 weeks total therapy ○ Genotype 1a without cirrhosis, mixed genotype without cirrhosis or genotype 1b with or without cirrhosis – 12 weeks total therapy <p>LENGTH OF APPROVAL FOR VIEKIRA PAK: 4 weeks</p> <p>Public Comment Edalisa Martin, Manufacturer representative, announced that she is available for questions.</p> <p>Board Discussion None</p>	<p>motion.</p> <p>The criteria were approved unanimously.</p>
2. Lemtrada™ (alemtuzumab) i. PA Criteria ii. *Public Comment iii. Board Discussion	<p>Background</p> <p>Lemtrada is a monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.</p>	<p>Dr. Heston 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>CRITERIA for Lemtrada: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple sclerosis • Patient must have a relapsing form of multiple sclerosis • Patient must be 17 years of age or older • Must be prescribed by or in consultation with a neurologist • Patient must have had an inadequate response to two or more drugs indicated for the treatment of multiple sclerosis (example of drugs: an interferon, <u>natalizumab</u>, <u>mitoxantrone</u>, or <u>glatiramer</u>) • Patient must not have human immunodeficiency virus (HIV) • Patient must have the following lab tests completed prior to initial approval: <ul style="list-style-type: none"> ○ Complete blood count ○ Serum creatinine level ○ Urinalysis with urine cell counts ○ Thyroid function <p>Prior authorizations will be approved for 1 year</p> <p><u>Public Comment</u> Jason Enders, manufacturer representative, offered information on method of treatment and risk of using prior to failure of two other treatment options.</p> <p>Marie St.Clark, Physician Therapist working with MS patients, spoke about personal experience with patience using this product and encouraged use earlier than failure with two other products.</p> <p><u>Board Discussion</u> Physician can use appeal process for use earlier than two failed products.</p>	
<p>3. Trulicity™ (dulaglutide)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Trulicity is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents in this class.</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
	<p>CRITERIA for dulaglutide: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be at least 18 years old. • Patient must have a diagnosis of Type 2 Diabetes. <ul style="list-style-type: none"> ◦ Diagnosis of Type 2 Diabetes must be documented by HbA1c > 6.5% • Patient must have HbA1c between 6.5% - 9.0% • Patient must have history of another diabetic agent in the previous 30 days (see table for examples of drug classes). • Patient must not have history or family history of medullary thyroid carcinoma in the past 2 years. • Patient must not have history of multiple endocrine neoplasia syndrome type 2 in the past 2 years. <p>RENEWAL CRITERIA: (must meet one of the following)</p> <ul style="list-style-type: none"> • Documented improvement of HbA1c from pretreatment levels • Achievement or maintenance of therapeutic goals (HbA1c ≤ 6.5%) <p>LENGTH OF APPROVAL: 6 months</p> <p>Public Comment <u>None</u></p> <p>Board Discussion Discussed patient requirement of history of use of another product within 30 days; not first line monotherapy; A1c decrease threshold.</p>	
<p>4. Hetlioz® (tasimelteon)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Hetlioz is a melatonin receptor antagonist indicated for the treatment of non-24-hour sleep-wake disorder (non-24). Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved indication.</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p>CRITERIA FOR HETLIOZ Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of non-24-hour sleep-wake disorder • Patient must be 18 years of age or older • Dose must not exceed 20mg/day <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment <u>None</u></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><u>Board Discussion</u> <u>None</u></p>	
<p>5. Idiopathic Pulmonary Fibrosis Treatments (Esbriet® [pirfenidone] & Ofev® [nintedanib])</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p><u>Background</u> Esbriet is a pyridone and Ofev is a kinase inhibitor; both are indicated for the treatment of idiopathic pulmonary fibrosis. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <div data-bbox="527 440 1633 703" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR IDIOPATHIC PULMONARY FIBROSIS (IPF): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of idiopathic pulmonary fibrosis • Must be prescribed by or in consultation with a pulmonologist • Patient must be 18 years of age or older • Patient must have baseline liver function tests prior to initiating treatment per package insert <p>LENGTH OF APPROVAL 12 months</p> </div> <p><u>Public Comment</u> Two manufacturer representatives offered availability for questions</p> <p><u>Board Discussion</u> Discussion about liver function test and requirement of baseline LFT to encourage and remind physician of importance of monitoring not for decision making criteria for PA. Change made to require that product be prescribed by or in consultation with a pulmonologist.</p>	<p>Dr. Unruh made motion to accept the PA Criteria</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria were approved unanimously with changes.</p>
<p>6. Banzel® (rufinamide)</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p><u>Background</u> Banzel is an anti-epileptic drug indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age and older. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p>	<p>Dr. Heston 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>CRITERIA for Lennox-Gastaut Syndrome (LGS) (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be 4 years of age or older • Patient must have a diagnosis of Lennox-Gastaut Syndrome • Patient is receiving Banzel as an adjunctive treatment to at least one other anti-epileptic medication • Must be prescribed by or in consultation with a neurologist • Patient must not have Familial Short QT syndrome <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment <u>None</u></p> <p>Board Discussion Board confirmed that there are agents approved for younger patients.</p>	
<p>7. Sabril® (vigabatrin)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Sabril is an anti-epileptic drug indicated for adjunctive treatment of refractory complex partial seizures and infantile spasms. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p>CRITERIA for Refractory Complex Partial Seizures (CPS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have vision assessment completed at baseline and every 3 months while on medication, or documentation of vision assessment exemption (e.g. patient is blind) • Must be prescribed by or in consultation with a neurologist • Patient must have a diagnosis of refractory complex partial seizures • Patient must be 10 years of age or older • Patient has responded inadequately to alternative treatments • Patient is receiving Sabril as an adjunctive therapy to at least one other anti-epileptic medication <p>CRITERIA for Infantile Spasms: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have vision assessment completed at baseline and every 3 months while on medication, or documentation of vision assessment exemption (e.g. patient is blind) • Must be prescribed by or in consultation with a neurologist • Patient must have a diagnosis of infantile spasms • Patient must be 1 month to 2 years of age <p>LENGTH OF APPROVAL: 6 months</p> <p>Public Comment <u>None.</u></p> <p>Board Discussion</p>	<p>Dr. Kollhoff made motion to accept the PA Criteria</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously with change.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Discussion about the age gap. Change from visual assessment to vision assessment.	
<p>8. Onfi® (clobazam)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Onfi is an anti-epileptic drug indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older. In April 2012, the DUR board approved diagnosis restrictions for Onfi, but since that time, utilization has increased. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p>Public Comment <u>None</u></p> <p>Board Discussion MCO's are seeing higher utilization of this product. Current patients will likely be grandfathered to avoid disruption of therapy. There is an appeal process for patients outside of the criteria. Board discussed option to table in effort to allow additional time to examine off-label use.</p>	<p>Dr. Kollhoff made motion to table the PA Criteria</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria was tabled.</p>
IV. Open Public Comment	<p>Public Comment There were no additional public comments offered during this meeting.</p> <p>Announcement was made by Dr. Melton that criteria can be sent to attendees via email in advance of the meeting. Attendees should request criteria and should refrain from taking flash photography of presentation screen during the meeting to alleviate disruptions to board and other attendees.</p> <p>Board Discussion</p>	
V. Adjourn	<p>The meeting was adjourned at 11:15am.</p> <p>The next meeting will be on April 8, 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. Kollhoff made motion to adjourn the meeting.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion was approved unanimously.</p>