

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

Drug Utilization Review Board
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HP Enterprise Services / Forbes Field
Capital Room
Topeka, KS

DUR Board Members Present

Tim Heston, DO
Roger Unruh, D.O.
Kevin Waite, Pharm.D.
John Kollhoff, Pharm.D.
Jim Backes, Pharm.D.

DUR Board Members Absent

Russell Scheffer, MD
Judy McDaniel Dowd, PA-C
Michael Burke, MD, PhD

DHCF Staff Present

F.E. Bustillo, III, MD
Kelley Melton, Pharm.D.
Carol Arace, Administrative Specialist

HP Enterprise Services Staff Present

Karen Kluczykowski, RPh
Nancy Perry, R.N.

HID Staff Present

Nicole Ellermeier, Pharm.D.

MCO Staff Present

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

Representatives

Mary Shefchyk, NovoNordisk
Sam Smothers, MedImmune
Andrew Thompson, Celgene
Marla Wiedenmann,
NovoNordisk
Ted Sheedy, GSK
Dave Sproat, BMS
Edie Dodson, Genzyme
Joe Summers, UCB
Dana Koehn, Baxter
Jeff Knappen, Allergan
Biran Patel, NovoNordisk
Mary Jo DeFlorio, J&J
Evan Rushing, Alkermes
Patrick Moty, Supernus
Molly Skelsey, Astra Zeneca
Lance Webb, Genzyme
Scott Maurice, B-I
Susan Zalenski, J&J
Brent Hildebrand, Gilead
Mary Deane, Regeron
Teresa Blair, Amgen
Jim Baumann, Pfizer
Eric Gardner, Vertex
Toni Pegues, Genentech
Mike Hauger, Genentech
Brian Rose, Merck
Ray Lancaster, Gilead
Mike Krug, Sunovion
Heather Jones, GSK
Risa Reuscher, Amgen
Joe Schuch, Pfizer
Rob Hansen, Pfizer
Mark Weisz, Otsuka
Deb Bock, AbbVie

		Bill Branch, Vivus Diane Hanna, Celgene
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Kevin Waite called the meeting to order at 10:08am.	
A. Announcements	Dr. Ellermeier advised where individuals should park. Dr. Melton introduced Dr. Backes as the newest DUR board member.	
II. Old Business A. Review and Approval of April 9, 2014 DUR Meeting Minutes		Dr. Unruh made motion to accept the minutes as presented. Dr. Heston seconded the motion. The minutes were approved unanimously.
III. New Business A. Revised Prior Authorization (PA) Criteria 1. Incivek® (telaprevir) i. Revised PA Criteria ii. *Public Comment iii. Board Discussion	Background 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 ensure appropriate use.	Dr. Heston made motion to accept the revised PA Criteria Dr. Kollhoff seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR INITIAL PRIOR AUTHORIZATION 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"> • Patient must have a diagnosis of chronic hepatitis C • Patient must have genotype 1 hepatitis C • Patient must have stage 3 or 4 liver fibrosis • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Incivek must be used in combination with peginterferon alfa and ribavirin • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Incivek • 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) • Dose must not exceed 6 tablets per day • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months <p>LENGTH OF INITIAL APPROVAL 12 weeks</p> <p>Ribavirin and Peginterferon alfa are approved when using triple therapy with Incivek if Incivek criteria are met</p> <p>DISCONTINUATION CRITERIA</p> <ul style="list-style-type: none"> • Provider must submit HCV RNA level after treatment week 4 within 7 days to prevent discontinuation of therapy • Therapy will be discontinued if the HCV RNA level is above 1,000 IU/mL after treatment week 4 <p>Public Comment No Public Comment</p> <p>Board Discussion Language for illicit substance use or alcohol abuse was discussed and changes made per that conversation.</p>	
<p>2. Victrelis® (boceprevir)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <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 ensure appropriate use.</p>	<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 INITIAL PRIOR AUTHORIZATION 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"> • Patient must have a diagnosis of chronic hepatitis C • Patient must have genotype 1 hepatitis C • Patient must have stage 3 or 4 liver fibrosis • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Victrelis must be used in combination with peginterferon alfa and ribavirin • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Victrelis • 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) • Dose must not exceed 12 capsules per day • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months <p>LENGTH OF INITIAL APPROVAL 44 weeks</p> <p>Ribavirin and Peginterferon alfa are approved when using triple therapy with Victrelis if Victrelis criteria are met</p> <p>DISCONTINUATION CRITERIA</p> <ul style="list-style-type: none"> • Provider must submit HCV RNA level after treatment week 12 and 24 within 7 days to prevent discontinuation of therapy • 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 <p>Public Comment No Public Comment</p> <p>Board Discussion Updated the illicit substance use and alcohol abuse bullet point.</p>	
<p>3. Olysio® (simeprevir)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>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 ensure appropriate use.</p>	<p>Dr. Unruh made motion to accept the revised PA Criteria</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT: (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"> • Patient must have a diagnosis of chronic hepatitis C • Patient must have genotype 1 hepatitis C • If patient has subtype 1a they must have a negative test for NS3-Q80k polymorphism • Patient must have stage 3 or 4 liver fibrosis • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Olysio must be used in combination with Peginterferon alfa and ribavirin • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Olysio • 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) • Dose must not exceed 1 capsule per day • PATIENT MUST NOT have a history of ILLICIT SUBSTANCE use OR ALCOHOL ABUSE within THE PAST 6 MONTHS <p>LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT 12 weeks</p> <p>Ribavirin and peginterferon alfa are approved when using triple therapy with Olysio, if Olysio criteria are met.</p> <p>DISCONTINUATION CRITERIA FOR ONE DIRECT ACTING AGENT</p> <ul style="list-style-type: none"> • Provider must submit HCV RNA level after treatment week 4, within 7 days, to prevent discontinuation of therapy • Therapy will be discontinued if the HCV RNA level is greater than or equal to 25IU/mL after treatment week 4 <p>Public Comment No Public Comment.</p> <p>Board Discussion There was discussion around genotype 1a and illicit use.</p> <p>Dr. Ellermeier confirmed for Dr. Waite that Genotype1 is the only one that has a subtype 1a. Updated the illicit substance use and alcohol abuse bullet point.</p>	
<p>4. Sovaldi® (sofosbuvir)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>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 ensure appropriate use.</p>	<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>

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	<p>CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT: (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"> • Patient must have a diagnosis of chronic hepatitis C (CHC) • Patient must have genotype 1, 2, 3, or 4 hepatitis C • Patient must have stage 3 or 4 liver fibrosis • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Sovaldi must be used in combination with ribavirin • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi • 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) • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Dose must not exceed 1 capsule per day <p>LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT 12 weeks</p> <p>Ribavirin and peginterferon alfa are approved when using triple therapy with Sovaldi, if Sovaldi criteria are met.</p> <p>RENEWAL CRITERIA FOR ONE DIRECT ACTING AGENT: (must meet one of the following)</p> <ul style="list-style-type: none"> • Patient is infected with genotype 3 CHC (an additional 12 weeks of therapy of therapy will be approved for a max of 24 weeks) • 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) • 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) 	

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	<p>CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF TWO DIRECT ACTING AGENTS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C (CHC) genotype 1 • Patient must have stage 3 or 4 liver fibrosis • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Dose must not exceed 1 capsule per day • Patient must not be on previous or concurrent therapy with Victrelis Incivek • Patient must not be on previous or concurrent therapy with Olysio unless the patient is interferon ineligible defined as one or more of the following: <ul style="list-style-type: none"> ○ Documented intolerance to IFN ○ Autoimmune hepatitis or other autoimmune disorder ○ Documented hypersensitivity to PEG or any of its components ○ Decompensated hepatic disease ○ Major uncontrolled depressive illness ○ A baseline neutrophil count below 1500 a baseline platelet count below 90,000 or baseline hemoglobin below 10 g/dL ○ A history of preexisting cardiac disease <p>LENGTH OF INITIAL APPROVAL 4 weeks</p> <p>RENEWAL CRITERIA FOR TWO DIRECT ACTING AGENTS: (must the following)</p> <ul style="list-style-type: none"> • Prescriber must document adherence by patient of greater than or equal to 90% for both agents <p>LENGTH OF RENEWAL APPROVALS 4 weeks for a total of 12 weeks of treatment</p> <p><u>Public Comment</u> Public comment from Mr. Greg Lancaster centered around Liver staging, IFN ineligible criteria, and length of 2 agents criteria. Mr. Lancaster also questioned the continuity in care with the length of time needed for the initial approval.</p> <p><u>Board Discussion</u> Dr. Ellermeier stated the length of approval is appropriate for determining patients are being adherent. The MCOs discussed their adherence outreach. Weekly outreach by MCOs about adherence. Updated the illicit substance use and alcohol abuse bullet point.</p>	
5. Buprenorphine Agents (Bunavail® (buprenorphine/naloxone)	<p><u>Background</u> Prior authorization criteria for Buprenorphine agents for opioid dependence were last revised in October 2013. Since the last revision, a new agent has been approved. Prior</p>	Dr. Kollhoff made motion to accept the revised PA Criteria

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<p>Buccal film))</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>authorization criteria revisions are being proposed to include Bunavail.</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p>CRITERIA FOR BUPRENORPHINE/NALOXONE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of opioid dependence • Patient must be actively involved in addiction treatment • Prescriber must have a current XDEA number • Prescriber must practice in Kansas or a border city and be an enrolled provider with plan • Daily dose of buprenorphine must not exceed 24mg for Suboxone and Subutex, 17.1mg for Zubsolv, or 12.6mg for Bunavail <p>CRITERIA FOR BUPRENORPHINE Must meet all of the criteria for buprenorphine/naloxone and one of the following:</p> <ul style="list-style-type: none"> • Patient must be pregnant • Patient must have a documented medical allergy to naloxone <p>RENEWAL CRITERIA Must meet all initial criteria and the following:</p> <ul style="list-style-type: none"> • Patient has not received any other narcotic agents since last prior authorization approval • Prescriber has reviewed the patient's K-TRACS profile and confirmed the patient is not receiving any narcotic agents in addition to their buprenorphine agent (information regarding the K-TRACS program may be found on The Kansas Board of Pharmacy web site) • If patient has received opioids the prescriber must validate the reason for use and include information regarding the patient treatment plan <p>LENGTH OF APPROVAL 3 months</p> </div> <p>Public Comment None</p> <p>Board Discussion Discussion around the medical necessity and reason for use of a short-term opioid, and requiring the documentation of those narcotic medications. Especially in a 24 hour turn around. Dr. Heston had concerns with the criteria causing excessive amount paperwork that physicians must go through to care for their patients in a timely manner.</p>	<p>Dr. Backes seconded the motion.</p> <p>The criteria were approved; Dr. Heston opposed.</p>
<p>6. Kalydeco® (ivacaftor)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background Kalydeco is a treatment for cystic fibrosis indicated for patients age 6 years and older. Prior authorization criteria were initially approved in April 2012; since that time, the indication has been expanded to include additional genetic mutations. Prior authorization criteria are being revised to include all FDA-approved indications.</p>	<p>Dr. Unruh made motion to accept the revised PA Criteria</p> <p>Dr. Kollhoff seconded the motion.</p>

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	<p>CRITERIA FOR Kalydeco: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be at least 6 years old. • Patient must have a diagnosis of cystic fibrosis. • Patient must have one of the following the G551D mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R • Patient must not be homozygous for the <i>F508del</i> mutation in the CFTR gene. <p>LENGTH OF APPROVAL: 6 months</p> <p>Public Comment None.</p> <p>Board Discussion None</p>	<p>The criteria were approved unanimously</p>
<p>7. Xolair® (omalizumab)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Xolair is an anti-IgE antibody indicated for moderate to severe persistent asthma in patients with a positive skin test to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids, and chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite antihistamine treatment. Prior authorization criteria were initially approved in July 2005 and are being revised to include all FDA-approved indications and align more closely with the guidelines for the diagnosis and management of asthma.</p>	<p>Dr. Unruh made motion to accept the revised PA Criteria</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously</p>

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	<p>CRITERIA FOR ALLERGIC ASTHMA Must meet all of the following:</p> <ul style="list-style-type: none"> • Must be prescribed by or in consultation with a pulmonologist, allergist, or immunologist • Patient must have a diagnosis of moderate to severe persistent asthma diagnosis for at least 1 year (diagnosis must be based upon NHLBI criteria – see attached table) • Patient must have a positive skin test or in vitro reactivity to a perennial aeroallergen • Patient must be 12 years of age or older • Patient must be taking and be compliant with a high-dose inhaled corticosteroid and a long-acting beta₂-agonist • Patient must have symptoms that are not well controlled while compliant with asthma controller medication (based upon NHLBI criteria – see attached table) • Dosing must be based upon attached table <p>RENEWAL CRITERIA FOR ASTHMA Must meet all of the following:</p> <ul style="list-style-type: none"> • Documentation of monthly injections. If patient has missed 2 or more injections the renewal request will be denied based upon non-compliance • Patient must have documented improvement in lung function test: FEV1 of at least 12% or PEF of at least 20% • Patient must have a documented decrease in the number of asthma exacerbations and symptomatic improvement per physician assessment <p>CRITERIA FOR CHRONIC IDIOPATHIC URTICARIA Must meet all of the following:</p> <ul style="list-style-type: none"> • Must be prescribed by or in consultation with an allergist, or immunologist • Patient must have a diagnosis of chronic idiopathic urticaria • Patient must be 12 years of age or older • Patient must be symptomatic despite H1 antihistamine treatment • Dosing must not exceed 300mg every 4 weeks <p>LENGTH OF APPROVAL 6 months</p> <p>Public Comment None</p> <p>Board Discussion Dr. Waite stated that there is considerable improvement in the way the criteria this has been re-structured.</p>	
<p>8. Promacta® (eltrombopag)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Promacta is a thrombopoietin receptor antagonist indicated for the treatment of thrombocytopenia in patients with chronic ITP and patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Prior authorization criteria were last revised in July 2013, and are being revised to include all FDA-approved indications.</p>	<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>

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	<p>CRITERIA FOR CHRONIC IMMUNE, IDIOPATHIC THROMBOCYTOPENIA (ITP) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic immune, idiopathic thrombocytopenia • Patient must have had an inadequate response to one of the following <ul style="list-style-type: none"> ○ Corticosteroids ○ Immunoglobulins ○ Splenectomy • Patient must be 18 years of age or older • Must be prescribed by or consultation with a hematologist or oncologist <p>CRITERIA FOR THROMBOCYTOPENIA IN HEPATITIS C Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C with thrombocytopenia • Patient must be on interferon-based therapy • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist <p>LENGTH OF APPROVAL 6 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>9. Growth Hormones</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>The prior authorization criteria for human growth hormones were last revised in September 2007. Prior authorization criteria are being revised to improve consistency in approval and denial determinations based on the FDA-approved indications.</p>	<p>Dr. Unruh made motion to accept the revised PA Criteria</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Prior Authorization for Initiation of Growth Hormone in Children</p> <p>CRITERIA FOR PEDIATRIC GROWTH HORMONE DEFICIENCY: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology. • Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls). • Diagnosis must be presented upon request. • Height velocity must be <25th percentile for age <ul style="list-style-type: none"> ○ Requires at least 6 months of growth data ○ Growth curve must be submitted ○ EXCEPTION: neonatal hypopituitarism/hypoglycemia • Normal thyroid function tests (TSH 0.4-4.0 mIU/L) • Failure to respond to 2 growth hormone secretagogues with peak <10ng/mL <ul style="list-style-type: none"> ○ MRI required for neonatal growth hormone deficiency AND those with peak <5ng/mL ○ EXCEPTION: neonatal hypopituitarism/hypoglycemia where either GH peak <10ng/mL during documented hypoglycemia is indication of GH deficiency OR documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septo-optic dysplasia, or other midline defects) • Request should be for any of the following: <ul style="list-style-type: none"> ○ Tev-Tropin[®], Omnitrope[®], Humatrope[®], Norditropin[®], Nutropin[®], Saizen[®], Genotropin[®] <p>CRITERIA FOR PANHYPOPITUITARISM: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology. • Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls). • Diagnosis must be presented upon request. • Patient must have documented deficiencies of AT LEAST one pituitary hormone; TSH, ACTH, LH/FSH, ADH. <ul style="list-style-type: none"> ○ Deficiencies in thyroid and Cortisol must be treated before performance of the GH stimulation test. • Height velocity <25th percentile for age: <ul style="list-style-type: none"> ○ Requires at least 6 months of growth data ○ Growth curve must be submitted ○ EXCEPTION: neonatal hypopituitarism/hypoglycemia • Degree of GH deficiency must be documented by response to 2 GH secretagogues: <ul style="list-style-type: none"> ○ Patient must be on stable doses of other replacement hormones before performing stimulation tests. ○ Normal thyroid levels documented before testing (TSH 0.4-4.0 mIU/L). ○ <5ng/mL = severe and <10ng/mL = deficiency ○ EXCEPTION: – neonatal hypopituitarism/hypoglycemia where either GH peak <10ng/ml during documented hypoglycemia is indication of GH deficiency or documented structural abnormalities of the 	

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	<p>CRITERIA FOR CHRONIC RENAL INSUFFICIENCY: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology. • Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls). • Diagnosis must be presented upon request. • Patient must have a confirmed diagnosis of CRI by a Pediatric Nephrologist. • Height velocity <25th percentile for age: <ul style="list-style-type: none"> ○ Requires at least 6 months of growth data ○ Growth curve must be submitted • Request must be for one of the following: <ul style="list-style-type: none"> ○ <u>Nutropin[®]</u> <p>CRITERIA FOR TURNER OR NOONAN SYNDROME: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology. • Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls). • Diagnosis must be presented upon request. • Patient must have a confirmed diagnosis of Turner or Noonan syndrome by karyotype. • Patient must have normal thyroid function tests (TSH 0.4-4.0 <u>mIU/L</u>). • Height velocity <25th percentile for age or height <5th percentile: <ul style="list-style-type: none"> ○ Requires at least 6 months of growth data ○ Growth curve must be submitted • Request must be for one of the following: <ul style="list-style-type: none"> ○ Turner Syndrome <ul style="list-style-type: none"> ▪ <u>Omnitrope[®], Humatrope[®], Norditropin[®], Nutropin[®], Genotropin[®]</u> ○ Noonan Syndrome <ul style="list-style-type: none"> ▪ <u>Norditropin[®]</u> 	

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	<p>CRITERIA FOR PRADER-WILLI SYNDROME: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology. • Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls). • Diagnosis must be presented upon request. • Patient must have a confirmed diagnosis of PWS by a Geneticist. • Patient must have normal thyroid function tests (TSH 0.4-4.0 <u>mIU/L</u>). • DEXA scan for body composition • Absence of obstructive sleep apnea by sleep study or treated obstructive sleep apnea • Height velocity <25th percentile for age or height <5th percentile: <ul style="list-style-type: none"> ○ Requires at least 6 months of growth data ○ Growth curve must be submitted • Request must be for one of the following: <ul style="list-style-type: none"> ○ <u>Omnitrope</u>[®], <u>Genotropin</u>[®] <p>Length of Approval: 6 months</p> <p>Prior Authorization for Renewal of Growth Hormone in Children</p> <p>A. Renewal of GH in children:</p> <ol style="list-style-type: none"> 1. History and physical notes, and growth curve from pediatric endocrinologist dated within 6months of request 2. Documented catch-up growth unless at target height percentile <p>B. Rationale for discontinuing GH therapy</p> <ol style="list-style-type: none"> 1. Growth velocity <2cm/year while on GH therapy 2. Noncompliance with GH therapy plan <ol style="list-style-type: none"> a. Compliance is defined as greater than or equal to 85% adherence to regimen (no more than one missed dose per week on average) b. Prescriber must attest to patient adherence, and prescription claims data may be used to verify adherence 3. Recommendations of treating pediatric nephrologist or endocrinologist due to changes in underlying conditions 4. Failure to show change in body composition, lipid profile, or growth rate in PWS <p>Length of Renewal: 6 months</p> <p>Prior Authorization for Growth Hormone in Adults</p> <p>A. Must be prescribed by or in consultation with an endocrinologist</p> <p>B. Patient must have one of the following:</p> <ol style="list-style-type: none"> a. diagnosis of pituitary insufficiency confirmed by growth hormone stimulation test (<5ng/mL serum concentration) and below normal IGF-1/IGFBP3 (see table for normal ranges) b. diagnosis of <u>panhypopituitarism</u> including those with surgical or radiological eradication of pituitary confirmed by MRI or CT scan 	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Prior Authorization for Growth Hormone in Adults</p> <ul style="list-style-type: none"> A. Must be prescribed by or in consultation with an endocrinologist B. Patient must have one of the following: <ul style="list-style-type: none"> a. diagnosis of pituitary insufficiency confirmed by growth hormone stimulation test (<5ng/mL serum concentration) and below normal IGF-1/IGFBP3 (see table for normal ranges) b. diagnosis of <u>panhypopituitarism</u> including those with surgical or radiological eradication of pituitary confirmed by MRI or CT scan C. If non-preferred Growth Hormone medication is being requested, then the Growth Hormone PDL form must also be completed and submitted for processing. Clinical Reviewers will follow established PDL guidelines. (Please note that for non-preferred drug requests the documentation must meet established clinical and PDL criteria to be approved. For requests for preferred drug then only the established clinical criteria must be met.) D. Request must be for one of the following: <ul style="list-style-type: none"> a. <u>Omnitrope[®], Humatrope[®], Norditropin[®], Nutropin[®], Saizen[®], Genotropin[®]</u> <p>Length of Approval: 1 year</p> <p>Public Comment None</p> <p>Board Discussion Dr. Waite stated that the criteria are re-organized. Dr. Ellermeier explained the criteria had been -re-organized and <u>more specific requirements were values-added to reduce the variance in approvals and denials based on close up the possible open to</u> interpretation issues.</p>	
<p>10. Testosterone Agents (Natesto[®] (testosterone nasal gel))</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Prior authorization criteria for testosterone agents were approved in July 2013. Since that time a new agent has been approved—Natesto nasal gel. Prior authorization criteria are being revised to include this new agent.</p>	<p>Dr. Kollhoff made motion to accept the revised PA Criteria</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR PRIOR AUTHORIZATION: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has one of the following diagnoses: <ul style="list-style-type: none"> ○ Primary hypogonadism (congenital or acquired) <ul style="list-style-type: none"> ▪ Primary hypogonadism (testicular failure) due to conditions such as (but not limited to) cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals ○ Hypogonadotropic hypogonadism (congenital or acquired) <ul style="list-style-type: none"> ▪ Hypogonadotropic hypogonadism due to (but not limited to) idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation • Patient must be a male • Patient must have serum testosterone < 300 ng/dL <p>PATIENT MUST MEET INITIAL CRITERIA FOR RENEWALS</p> <p>LENGTH OF APPROVAL 12 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>11. Long-Acting Opioids i. Revised PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p><u>Background</u> Override criteria for the long-acting opioids were last revised in January 2014 to include a new agent. Override criteria are being revised to include a requirement that prescribers review the patient's K-TRACS profile.</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>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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: <ol 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> <p>Public Comment None.</p> <p>Board Discussion Board discussion on the criteria requiring a ‘single KMAP enrolled prescriber’ and the review of the K-TRACS patient profile by the provider. Dr. Melton explained that the criteria are not required for ever long-acting opioid, only those claims that exceed the set limits. Meaning, the requirement is for the provider to review the K-TRACS patient profile for patients utilizing above average doses of long-acting opioids. what is driving this criteria, is the monthly limit. This PA does not kick in until the medication limit is exceeded.</p>	
<p>B. New Prior Authorization Criteria</p> <ol style="list-style-type: none"> 1. Xartemis XR® (oxycodone/acetaminophen) <ol style="list-style-type: none"> i. Override Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Xartemis XR is an extended-release formulation of oxycodone and acetaminophen indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate. A limit of an initial 7 day supply and 4 tablets per day without an override is being proposed along with criteria for override above 7 days or 4 tablets per day.</p>	<p>Dr. Kollhoff 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>CRITERIA for Xartemis: (must meet one of the following)</p> <ul style="list-style-type: none"> • Patient is being tapered off of medication. <ul style="list-style-type: none"> ○ Taper schedule must be included with PA request. Taper must be complete within 7 days. <p>OR</p> <ul style="list-style-type: none"> • Patient has a new cause of acute pain resulting in the necessity of additional <u>days</u> supply of Xartemis XR. <ul style="list-style-type: none"> ○ Documentation of new cause of acute pain must be included with PA request. <p>Prior Authorization will be approved for one fill (maximum of 7 <u>days</u> supply).</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> Dr. Ellermeier noted the placement in therapy for Xartemis is uncertain since it is indicated for a short term use. <u>The prior authorization would not be required for the first fill of this medication. It would only be required if the patient is taking the medication for longer than indicated. is criteria is for the second go around. Dr. Kollhoff will check on the initial rejection.</u></p>	
<p>2. Demerol® (meperidine)</p> <ul style="list-style-type: none"> i. Override Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u> Meperidine is indicated for the relief of moderate to severe pain. Meperidine should not be used for the treatment of chronic pain; it should only be used in the treatment of acute episodes of moderate to severe pain. Prolonged use may increase the risk of toxicity from the accumulation of the meperidine metabolite, normeperidine. A limit of 900mg per day for an initial 21 day supply is being proposed. Additional courses of therapy will require an override based on the proposed criteria</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 Meperidine: (must meet one of the following)</p> <ul style="list-style-type: none"> • Patient is being tapered off of medication. <ul style="list-style-type: none"> ○ Taper schedule must be included with PA request. Taper must be complete within 21 days. <p>OR</p> <ul style="list-style-type: none"> • Patient has a new cause of acute pain resulting in the necessity of additional <u>days</u> supply of meperidine. <ul style="list-style-type: none"> ○ Documentation of new cause of acute pain must be included with PA request. <p>Prior Authorization will be approved for one fill (maximum of 21 <u>days</u> supply).</p> <p><u>Public Comment</u></p> <p><u>None</u></p> <p><u>Board Discussion</u></p> <p>Dr. Waite noted <u>this criteria is similar</u> to the previous criteria <u>reviewed for Xartemis</u>. He <u>also noted there is not a</u>, <u>and clarifying no</u> need to be on this agent long term. Dr. Melton and Dr. Ellermeier explained <u>the there is a long-term</u> safety <u>issue with the of-use meperidine</u>, and that this PA would not take effect until the <u>limit was 900mg was being</u> exceeded.</p>	
<p>3. Eylea® (aflibercept)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Eylea is an intravitreal injection indicated for the treatment of patients with neovascular (wet) age-related macular degeneration and macular edema following central retinal vein occlusion. Prior authorization criteria are being proposed to ensure appropriate use based upon FDA-approved labeling information and to remain consistent with other agents used for the approved indications.</p>	<p>Dr. Kollhoff 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
	<div data-bbox="527 139 1509 537" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR EYLEA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must be 18 years of age or older • Patient must have one of the following: <ul style="list-style-type: none"> ○ Neovascular (wet) age-related macular degeneration (AMD) ○ Macular edema following central retinal vein occlusion (RVO) • Patient must not have an active ocular or periocular infection <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment None.</p> <p>Board Discussion None.</p>	
<p>4. Tanzeum® (albiglutide)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Tanzeum 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 are being proposed to ensure appropriate use based upon FDA-approved labeling information and to remain consistent with other agents in this class.</p> <div data-bbox="527 948 1633 1398" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA for Tanzeum: (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:</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> </div> <p>Public Comment</p>	<p>Dr. Kollhoff 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>None.</p> <p>Board Discussion Included clarification of maintenance of therapeutic goals.</p>	
<p>5. Enzyme Replacement Therapy (Cerezyme® (imiglucerase), Eleyso® (taliglucerase alfa), & VPRIV® (velaglucerase alfa))</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background Cerezyme, Eleyso, and VPRIV are 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 indications.</p> <div data-bbox="527 467 1455 695" style="border: 1px solid black; padding: 10px;"> <p>CRITERIA FOR ENZYME REPLACEMENT THERAPY Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Type 1 Gaucher disease <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment None.</p> <p>Board Discussion None.</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>
<p>6. Leukine® (sargramostim)</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background Leukine is a colony-stimulating factor; prior authorization criteria are being proposed to remain consistent with the other colony-stimulating factors based upon FDA-approved labeling information.</p> <div data-bbox="527 1092 1633 1446" style="border: 1px solid black; padding: 10px;"> <p>CRITERIA FOR LEUKINE: (must meet one of the following)</p> <ol style="list-style-type: none"> 1. Patient must have a diagnosis of acute myelogenous leukemia (AML) <ul style="list-style-type: none"> a. Patient must have received chemotherapy 2. Patient is having or has had a transplantation of autologous peripheral blood progenitor cells 3. Patient has a diagnosis of non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL), or Hodgkin's disease <ul style="list-style-type: none"> a. Patient is undergoing an autologous bone marrow transplant 4. Patient is undergoing an allogeneic bone marrow transplant 5. Patient has undergone an allogeneic or autologous bone marrow transplant and engraftment is delayed or has failed <p>LENGTH OF APPROVAL 12 months</p> </div>	<p>Dr. Backes made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were tabled unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Public Comment None.</p> <p>Board Discussion None.</p>	
<p>7. Neupogen® (filgrastim)</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background Neupogen is a colony-stimulating factor; prior authorization criteria are being proposed to remain consistent with the other colony-stimulating factors based upon FDA-approved labeling information.</p> <div data-bbox="527 505 1633 906" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR NEUPOGEN: (must meet one of the following)</p> <ol style="list-style-type: none"> 1. Patient must have a diagnosis of acute myelogenous leukemia (AML) <ol style="list-style-type: none"> a. Patient must have concurrent or prior chemotherapy 2. Patient is having or has had a transplantation of autologous peripheral blood progenitor cells 3. Patient has a diagnosis of non-Hodgkin’s lymphoma (NHL), acute lymphoblastic leukemia (ALL), or Hodgkin’s disease <ol style="list-style-type: none"> a. Patient is undergoing an autologous bone marrow transplant 4. Patient is undergoing an allogeneic bone marrow transplant 5. Patient has undergone an allogeneic or autologous bone marrow transplant and engraftment is delayed or has failed <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment Risa Reuscher asks to change Criteria 1 from ‘Must have received chemotherapy’ to ‘patient must be receiving chemotherapy’ or eliminating criteria 1 altogether. As currently written, criteria 1 suggests the patient must have been receiving chemotherapy previously and that is not necessary according to the package insert.</p> <p>Board Discussion Dr. Waite offers wording in regard to Ms. Reuscher’s request as noted in 1.a.</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. Entyvio® (vedolizumab)</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background Entyvio is an integrin receptor antagonist indicated for the treatment of ulcerative colitis and Crohn’s disease. Prior authorization criteria are being proposed to ensure appropriate utilization based upon FDA-approved labeling information.</p>	<p>Dr. Heston made motion to accept the PA criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 moderately to severely active ulcerative colitis • Patient must be 18 years of age or older • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Must be prescribed by or in consultation with a gastroenterologist • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient had one of the following: <ul style="list-style-type: none"> ○ An inadequate response with, lost response to, or was intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator ○ An inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids <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 moderately to severely active Crohn's disease • Patient must be 18 years of age or older • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Must be prescribed by or in consultation with a gastroenterologist • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient had one of the following: <ul style="list-style-type: none"> ○ An inadequate response with, lost response to, or was intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator ○ An inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids <p>LENGTH OF APPROVAL 6 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>9. Otezla® (apremilast)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Otezla is a PDE4 inhibitor indicated for the treatment of adult patients with active psoriatic arthritis. Prior authorization criteria are being proposed to ensure appropriate utilization based upon FDA-approved labeling information.</p>	<p>Dr. Backes 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																
	<div style="border: 1px solid black; padding: 5px;"> <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>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment Diane Hanna pointed out that this is a new agent and offer eds to answer any questions from the Board. may have. In answer to Dr. Backes' question concerning expanded indication, Ms. Hanna stated there is currently a review submitted for psoriasis in front of the FDA.</p> <p>Board Discussion None.</p>																	
<p>C. Miscellaneous Items Fee-for-Service Retrospective Drug Utilization Review Topic Selections i. Topic Presentation ii. Board Discussion</p>	<p>Background Each year, the DUR Board selects five (5) intervention topics for mailings. For SFY 2015, at least 2–3 topics will be chosen today and, if needed, the remaining topics will be selected at the October 2014 DUR meeting.</p> <p>The following table shows a summary of the proposed intervention topics and the number of potential beneficiaries that may be targeted by each intervention. The number of potential beneficiaries is based upon the most recent ICER. The actual number of targeted beneficiaries for each intervention will be based upon the ICER for the month the intervention is performed.</p> <table border="1" data-bbox="520 1117 1465 1482"> <thead> <tr> <th>Proposed Intervention Topic</th> <th>Potential Targeted Beneficiaries</th> </tr> </thead> <tbody> <tr> <td>Therapeutic Duplication of Atypical Antipsychotics</td> <td>74</td> </tr> <tr> <td>Risk of Fracture/Osteoporosis</td> <td>37</td> </tr> <tr> <td>Diabetic Patient Not on an ACEI or ARB</td> <td>47</td> </tr> <tr> <td>Appropriate Monitoring of Atypical Antipsychotics</td> <td>146</td> </tr> <tr> <td>Inappropriate Use of Dronabinol</td> <td>13</td> </tr> <tr> <td>Polypsychopharmacy</td> <td>43</td> </tr> <tr> <td>Therapeutic Duplication of Antidepressants</td> <td>63</td> </tr> </tbody> </table>	Proposed Intervention Topic	Potential Targeted Beneficiaries	Therapeutic Duplication of Atypical Antipsychotics	74	Risk of Fracture/Osteoporosis	37	Diabetic Patient Not on an ACEI or ARB	47	Appropriate Monitoring of Atypical Antipsychotics	146	Inappropriate Use of Dronabinol	13	Polypsychopharmacy	43	Therapeutic Duplication of Antidepressants	63	<p>Dr. Kollhoff made motion to implement Proposed Intervention Topics #1, #2, #4, #6 and #7.</p> <p>Dr. Heston seconded the motion.</p> <p>The topics were approved unanimously.</p>
Proposed Intervention Topic	Potential Targeted Beneficiaries																	
Therapeutic Duplication of Atypical Antipsychotics	74																	
Risk of Fracture/Osteoporosis	37																	
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Proposed Topic #1 Therapeutic duplication of atypical antipsychotics may cause increased side effects, drug interactions, and cost, as well as decreased adherence to therapy. Therapeutic use of more than one antipsychotic should be justified with strong evidence (e.g., the patient does not respond to monotherapy) before being implemented.</p> <p>Proposed Topic #2 Increased osteoporosis risk and decreased bone marrow density (BMD) have both been associated with long-term proton pump inhibitor (PPI) use; however, osteoporosis does not exclude a patient from PPI therapy. Osteoporotic patients should be discontinued from therapy if multiple hip fracture risks exist. One study showed PPI use is associated with a lower BMD in the hip and femoral neck, especially in elderly patients, but this association does not increase over time. Patients requiring PPI therapy with multiple risk factors for fracture should be monitored closely and given the lowest dose and shortest duration of PPI therapy possible.</p> <p>Proposed Topic #3 Hypertension is a common comorbid condition with diabetes mellitus. Proper blood pressure management is important in diabetic patients in order to preserve and protect kidney function. In individuals who have no contraindications, ACEIs and ARBs are appropriate for blood pressure reduction in hypertension and may also effectively reduce proteinuria and provide renal protection in diabetic nephropathy. These effects are also seen in normotensive patients. The use of either an ACEI or an ARB may also help slow the progression of diabetic kidney disease.</p> <p>Proposed Topic #4 The use of atypical antipsychotics has been associated with weight gain, diabetes (including diabetic ketoacidosis), and increased triglycerides and LDL cholesterol along with decreased HDL cholesterol. Because of these risks, it is recommended to monitor patients at baseline with routine follow-up monitoring. Baseline monitoring should include factors such as personal and family history of cardiovascular disease and diabetes, weight and height, waist circumference, blood pressure, and fasting blood glucose and lipid panels. Most follow-ups should occur after 3 months of antipsychotic therapy and then annually; however, at initiation of therapy or if therapy is changed, patients should be monitored at 4, 8, and 12 weeks. Patients whose glucose or lipids worsen should be switched to an antipsychotic with decreased potential to cause weight gain or diabetes. Patients who develop diabetes should be referred to a physician experienced in treating this population.</p> <p>Proposed Topic #5 Marinol® (dronabinol) is approved for the treatment of anorexia associated with weight loss in patients with AIDS, and nausea and vomiting associated with cancer chemotherapy. The off-label use in patients without an appropriate diagnosis may represent inappropriate utilization of this medication and an unnecessary cost to KMAP.</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Proposed Topic #6 The use of two or more psychotropic agents may represent unintended duplicative therapy. Complex drug regimens, using multiple agents from multiple drug classes, increase the risk for adverse drug effects, drug-drug interactions, and non-adherence. There are several factors that influence overall costs; one of the most significant factors for cost is non-adherence.</p> <p>Proposed Topic #7 Therapeutic duplication of antidepressant agents may cause increased side effects, drug interactions, and cost, as well as decreased adherence to therapy. Patients treated with antidepressants should be assessed at 4 – 8 weeks for therapeutic response before augmentation should occur. If the patient has no or partial response, therapy modification options include increasing the dose of the current antidepressant (if tolerated), changing to a different antidepressant, or considering psychotherapy in combination with the antidepressant. If the patient does not respond sufficiently to psychotherapy, a consideration to add medication to the therapy may be made. If trials of two medications from the same class fail, switching to a different antidepressant class should be considered.</p> <p>Public Comment None.</p> <p>Board Discussion General discussion over all topics with a motion to #1, #2, #4, #6, and #7 as topics of choice. Topics were approved.</p>	
IV. Open Public Comment	<p>Background</p> <p>Public Comment Jim Baumann discussed that PA limits approved by the DUR Board have increased.</p> <p>Board Discussion Dr. Waite commented that there was an effort to make decisions for public safety as well as cost containment purposes. He noted there are an increased number of drugs approved for rare disease states, which are costly to treat and the board tries to ensure appropriate use of these costly medications. The Board noted and thanked Mr. Baumann for the comment.</p>	
V. Adjourn	<p>The meeting was adjourned at 11:56am.</p> <p>The next meeting will be on October 8, 2014. 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</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
		unanimously.