

**Drug Utilization Review Board
Meeting Minutes, Open Session
April 8, 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. Russell Scheffer, MD Judy McDaniel Dowd, PA-C Kevin Waite, PharmD.</p> <p>DUR Board Members Absent Jim Backes, PharmD.</p> <p>DHCF Staff Present Kelley Melton, Pharm.D. Liane Larson, Pharm.D. Carol Arace, Administrative Assistant</p> <p>HP Enterprise Services Staff Present Karen Kluczykowski, RPh Nancy Perry, R.N.</p> <p>HID Staff Present Ariane Casey, Pharm.D.</p> <p>MCO Staff Present Angie Zhou, Pharm.D.: Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p>Representatives Scott Donald, HID Jared Albright, Sunflower Jason Schwier, Amgen Jeff Knappen, Allergan Joel Meyer, Novartis Kari Suttee, Novartis Todd Cowan, Novartis Berend Koops, Merck Andrena Scholl, Merck Scott Maurice, Boehringer Ingelheim Bob Gustafson, Lundbeck David Tworek, Lundbeck Michele Puyear, Gilead Brent Hildebrand, Gilead Dave Sproat, Bristol-Myers Squibb Phil King, Pfizer Mary Jo DeFlorio, J&J Janie Huff, Takeda Eric Gardner, Vertex Lisa Borland, Vertex Chris Beal, Otsuka Patrick Harvey, Walgreens Anthony Hoover, Novo Nordisk Torey Batts, Teva</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Waite called the meeting to order at 10:04 am.	
A. Announcements	<ul style="list-style-type: none"> • Dr. Melton gave introduction of the new HID Pharmacist, Dr. Ariane Casey. • Dr. Melton announced Dr. Angie Zhou was attending on behalf of Jonalan Smith. 	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<ul style="list-style-type: none"> • Dr. Melton offered reminder as to where the meeting guests should park. • Dr. Melton reminded those that wanted to speak to fill out the disclosure form. 	
II. Old Business A. Review and Approval of January 14, 2015 DUR Meeting Minutes		Dr. Unruh made motion to accept the minutes as presented Ms. Dowd seconded the motion The minutes for January 14, 2015 are approved as written
II. Old Business B. Tabled Prior Authorization Criteria 1. Onfi® (Clobazam)	<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, but since that time, utilization has increased. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information. The DUR board tabled this topic at the January 2015 DUR meeting after a discussion regarding efficacy in off-labeled indications. The prior authorization criteria has remained the same. Clinical information regarding appropriate use is presented.</p> <p>CRITERIA for Lennox-Gastaut Syndrome (LGS) (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be 2 years of age or older • Patient must have a diagnosis of Lennox-Gastaut Syndrome • Patient is receiving Onfi as an adjunctive treatment to at least one other anti-epileptic medication • Must be prescribed by or in consultation with a neurologist <p>LENGTH OF APPROVAL: 12 months</p> <p>Public Comment David Tworek, Lundbeck; available to answer questions</p> <p>Board Discussion Discussed different indications and efficacy; greatest efficacy in LGS; data in other diagnoses is from 1970's per David Tworek.</p>	Dr. Unruh made motion to accept the PA Criteria. Dr. Kollhoff seconded the motion The criteria were approved unanimously
III. New Business A. Revised Prior Authorization (PA) Criteria 1. Sovaldi® (sofosbuvir) i. Revised PA Criteria	<p>Background Prior authorization criteria for Sovaldi was last revised in July 2014, and at that time, the guidelines have been updated to define those patients who should be treated first. The criteria is being revised to exclude specific staging of fibrosis and to include clarification of which patients are candidates for treatment with Sovaldi® (e.g., advanced liver disease,</p>	Ms. Dowd made motion to accept the revised PA Criteria Dr. Sheffer seconded the motion

TOPIC	DISCUSSION	DECISION AND/OR ACTION
ii. *Public Comment iii. Board Discussion	<p>extrahepatic manifestations, and complications due to chronic hepatitis C).</p> <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 • 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, Sovaldi, Harvoni, Viekira Pak or other direct acting Hepatitis C agent) • 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 have one of the following: <ul style="list-style-type: none"> ○ Advanced fibrosis (as defined by a <u>Metavir</u> score of F3) ○ Compensated cirrhosis ○ Liver transplant ○ Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (eg, vasculitis) ○ Proteinuria ○ <u>Nephrotic syndrome</u> ○ <u>Membranoproliferative glomerulonephritis</u> <p>LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT 12 weeks</p> <p>Ribavirin and <u>peginterferon alfa</u> 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) 	<p>Dr. Heston abstained</p> <p>The criteria were approved</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 • 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, Harvoni, or Viekira Pak • Patient must have one of the following: <ul style="list-style-type: none"> ○ Advanced fibrosis (as defined by a <u>Metavir</u> score of F3) ○ Compensated cirrhosis ○ Liver transplant ○ Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (eg, vasculitis) ○ Proteinuria ○ <u>Nephrotic</u> syndrome ○ <u>Membranoproliferative</u> glomerulonephritis • 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> Michele Puyear, Gilead; comments regarding HIV and HCV co-infection shows rapid</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>progression and should be considered high priority to be treated.</p> <p>Board Discussion Questioned if drug should be taken out of prior/current therapy; since prior therapy with meds have not been studied, meds were still included.</p>	
<p>2. Olysio® (simeprevir)</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Prior authorization criteria for Olysio was last revised in July 2014, and at that time, the guidelines have been updated to define those patients who should be treated first. The criteria is being revised to exclude specific staging of fibrosis and to include clarification of which patients are candidates for treatment with Olysio® (e.g., advanced liver disease, extrahepatic manifestations, and complications due to chronic hepatitis C).</p>	<p>Dr. Sheffer 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 • 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, Sovaldi, Harvoni, Viekira Pak or other direct acting Hepatitis C agent) • 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 • Patient must have one of the following: <ul style="list-style-type: none"> ○ Advanced fibrosis (as defined by a <u>Metavir</u> score of F3) ○ Compensated cirrhosis ○ Liver transplant ○ Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (eg, vasculitis) ○ Proteinuria ○ <u>Nephrotic</u> syndrome ○ <u>Membranoproliferative</u> glomerulonephritis <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 	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 • 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, Harvoni or Viekira Pak • 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 cytoglobulinemia with end-organ manifestations (<u>eg, vasculitis</u>) ○ Proteinuria ○ <u>Nephrotic syndrome</u> ○ <u>Membranoproliferative glomerulonephritis</u> • 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></p> <p><u>Board Discussion</u></p>	
<p>3. Weight Loss Drugs (Saxenda® [liraglutide])</p> <ol style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>The prior authorization criteria for weight loss agents was last revised in January 2015, and since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Saxenda.</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</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/topiramate 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 • For <u>liraglutide</u>, patient must not be taking another GLP-1 receptor agonist • For <u>liraglutide</u>, patient must not be taking insulin concurrently <p>LENGTH OF APPROVAL FOR PHENTERMINE 21 days ONLY</p> <p>LENGTH OF APPROVAL FOR LIRAGLUTIDE 16 weeks</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 NALTREXONE/BUPROPION: (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>	<p>unanimously</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<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 PHENTERMINE/TOPIRAMATE 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/topiramate ER and maintains the 3% weight loss The patient has lost a total of 5% of pretreatment weight within 6 months of initiating phentermine/topiramate ER and maintains the 5% weight loss <p>LENGTH OF RENEWAL APPROVAL FOR PHENTERMINE/TOPIRAMATE ER 3 months</p> <p>RENEWAL CRITERIA FOR <u>LIRAGLUTIDE</u>: (must meet all of the following)</p> <ul style="list-style-type: none"> The patient has lost a total of 4% of pretreatment weight within 16 weeks of initiating therapy with <u>liraglutide</u> and maintains the 4% weight loss <p>LENGTH OF RENEWAL APPROVAL FOR <u>LIRAGLUTIDE</u> 16 weeks</p> <p><u>Public Comment</u> Anthony Hoover, Novo Nordisk; available for questions</p> <p><u>Board Discussion</u></p>	
<p>4. Kalydeco® (ivacaftor)</p> <ol style="list-style-type: none"> Revised PA Criteria *Public Comment Board Discussion 	<p><u>Background</u> Prior authorization criteria for Kalydeco was last revised in July 2014, and since that time, a new gene mutation has been approved. Kalydeco is now approved for use in patients with a gene mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene R117H. The prior authorization criteria is being revised to include this new gene mutation.</p> <p>CRITERIA FOR Kalydeco: (must meet all of the following)</p> <ul style="list-style-type: none"> Patient must be at least 2 years old. Patient must have a diagnosis of cystic fibrosis. Patient must have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H Patient must not be homozygous for the <i>F508del</i> mutation in the CFTR gene. <p>LENGTH OF APPROVAL: 12 months</p> <p><u>Public Comment</u> Lisa Borland, Vortex; available for questions.</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>Board Discussion</p> <p>Questions arose about duration of PA; Lisa Borland provided information that a patient support program was offered from the manufacturer; changes to the duration of approval was changed to 12 months, rather than 6 months.</p>	
<p>5. Supprelin LA® (histrelin)</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 Supprelin LA was approved in October 2011. It is approved for the treatment of central precocious puberty (CPP) in children. Revised prior authorization criteria are being proposed to include other commonly used hormone evaluations for the diagnosis of CPP.</p> <p>CRITERIA for central precocious puberty: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be below age 11 for females and age 12 for males. • Patient must have onset of secondary sexual characteristics before 8 years of age in females and 9 years of age in males. • Diagnosis of central precocious puberty must be confirmed with the following: <ul style="list-style-type: none"> ▪ Hormone Evaluation: After GnRH or leuprolide administration, a LH (luteinizing hormone) level of > 5 U/L, OR ▪ Basal (no stimulation test) serum LH > 5 U/L, OR ▪ Basal (no stimulation test) LH > 0.3 U/L using ultra-sensitive assays (chemiluminescence immunoassay) ○ Bone age advanced one year beyond the chronological age. <p>Note: The recommended dose of Supprelin LA is one implant every 12 months. The implant should be removed after 12 months of therapy; at the time an implant is removed, another implant may be inserted to continue therapy.</p> <p>Prior Authorization will be approved for 1 (one) implant.</p> <p>Public Comment</p> <p>Board Discussion</p>	<p>Dr. Unruh 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> <p>1. Granix® (tbo-filgrastim)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Granix is a recently approved colony stimulating agent. 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. Kollhoff seconded the motion</p> <p>The criteria were approved unanimously</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR GRANIX: (must meet one of the following)</p> <ol style="list-style-type: none"> 1. Patient must have a non-myeloid malignancy 2. Patient must have concurrent or prior myelosuppressive chemotherapy <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment Torey Batts, Teva; provided pharmacology summary; recombinant through E. Coli; 3 trials: 1 for efficacy, 2 for safety; ADR Summary</p> <p>Board Discussion Discussion about difference from available filgrastim; Per Torey Batts: Neupogen vs. Granix: Same amino acid both in E. Coli may be different strain</p>	
<p>2. Glyxambi® (empagliflozin/linagliptan)</p> <ol style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Glyxambi is a recently approved sodium-glucose co-transporter 2 (SGLT2) inhibitor combination indicated for the treatment of patients with type 2 diabetes mellitus (T2DM). 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>CRITERIA FOR SGLT2 INHIBITOR COMBINATIONS (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of type II diabetes • Patient MUST NOT have a diagnosis of type I diabetes • Patient must be 18 years of age or older • Patient must have an eGFR above 45 mL/min/1.73m² • Patient MUST NOT have any of the following contraindications: <ul style="list-style-type: none"> ○ End-stage renal disease ○ Currently on dialysis <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment Scott Maurice, Bolehringer Ingelheim; available for questions</p> <p>Board Discussion</p>	<p>Ms. Dowd made motion to accept the PA Criteria</p> <p>Dr. Sheffer seconded the motion</p> <p>The criteria were approved unanimously</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>3. Cosentyx® (secukinumab)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Cosentyx is an immunomodulator indicated for the treatment of moderate to severe plaque psoriasis. 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>CRITERIA FOR MODERATE TO SEVERE 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 • Patient must be 18 years or older • Patient must be a candidate for systemic therapy or phototherapy • Must be prescribed by or in consultation with a Dermatologist or Rheumatologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent in the past 30 days <p>LENGTH OF APPROVAL: 6 MONTHS</p> <p>Public Comment Todd Cowan, Novartis; No BBW for serious infection. 50% reduction in PASI in 3 weeks vs. Enbrel at 6 weeks; 55% - 90% PASI dependent on trial; full human IL-17A; does have loading/induction dose</p> <p>Board Discussion Questioned if TB test was required; Per Todd Cowan, it is still a recommended although not in the indication.</p>	<p>Dr. Heston made motion to accept the PA Criteria</p> <p>Ms. Dowd seconded the motion</p> <p>The criteria were approved unanimously</p>
<p>4. Lupaneta Pack® (leuprolide depot; norethindrone tablets)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Lupaneta Pack is a gonadotropin-releasing hormone analog/progestin combination medication indicated for the management of painful symptoms of endometriosis. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved indication.</p>	<p>Dr. Sheffer 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 Lupaneta Pack (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be female • Patient must have a diagnosis of endometriosis • Patient must be 18 years of age or older • Patient must not be pregnant • Patient must not be postmenopausal <p>RENEWAL CRITERIA for Lupaneta Pack (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be female • Patient must have a diagnosis of endometriosis • Patient must be 18 years of age or older • Patient must not be pregnant • Patient must not be postmenopausal • Bone mineral density must be assessed prior to renewal <p>LENGTH OF APPROVAL: 6 months at a time for a lifetime total of 12 months</p> <p><u>Public Comment</u></p> <p><u>Board Discussion</u></p>	
<p>5. Blincyto® (blinatumomab)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Blincyto is an antineoplastic monoclonal antibody indicated for the treatment of acute lymphoblastic leukemia (ALL). Prior authorization criteria is being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR BLINATUMOMAB: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of one of the following: <ul style="list-style-type: none"> ○ Relapsed Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL) ○ Refractory B-cell precursor ALL • Must be prescribed by or in consultation with an oncologist <p>LENGTH OF APPROVAL: 5 cycles (each cycle consists of 4 weeks continuous intravenous infusion followed by a 2-week treatment-free interval)</p> <p><u>Public Comment</u></p> <p><u>Board Discussion</u></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
	Discussion regarding number of cycles and duration of stopping therapy due to ADR's. MCO's must have a plan to have open dates but will monitor claims/# cycles so that if 5 cycles are required, will not have to receive multiple PA's to get full duration.	
<p>6. Demser® (metyrosine)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Demser is an agent used for the treatment of pheochromocytoma in patients 12 years of age and older. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p>CRITERIA for Demser (must meet all of the following):</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of pheochromocytoma • Patient must be 12 years of age or older • Dose must not exceed 4 grams per day <p>LENGTH OF APPROVAL: 6 months</p> <p>Public Comment</p> <p>Board Discussion</p>	<p>Dr. Kollhoff made motion to accept the PA Criteria</p> <p>Dr. Sheffer seconded the motion</p> <p>The criteria were approved unanimously</p>
<p>7. Ragwitek® (short ragweed pollen allergen extract)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Ragwitek is an agent indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis in patients aged 18 through 65 years of age. Diagnosis is confirmed by a positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for short ragweed pollen. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p>CRITERIA FOR RAGWITEK: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of short-ragweed pollen-induced allergic rhinitis • Patient must have a positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for short ragweed pollen (<i>Ambrosia artemisiifolia</i>) • Patient must be between the ages of 18 and 65 years old • The first dose must be given under the supervision of a physician and monitored for at least 30 minutes • Patient must be prescribed auto-injectable epinephrine • Treatment must begin at least 12 weeks prior to onset of ragweed pollen season • Patient must not have a diagnosis of severe, unstable or uncontrolled asthma • Patient must not have a history of eosinophilic esophagitis <p>LENGTH OF APPROVAL: 6 MONTHS</p> <p>Public Comment</p>	<p>Ms. Dowd made motion to accept the PA Criteria</p> <p>Dr. Heston seconded the motion</p> <p>The criteria were approved unanimously</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Andrena Scholl, Merk; commented on specialist step</p> <p>Board Discussion Acknowledged the difficulty of specialists in allergy and immunology to be seen when other MD's are experts (specifically those who test for allergies); step was removed</p>	
<p>8. Grastek® (Timothy grass pollen allergen extract)</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background Grastek is an agent indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis in patients aged 5 through 65 years of age. Diagnosis is confirmed by a positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p> <p>CRITERIA FOR GRASTEK: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of grass pollen-induced allergic rhinitis • Patient must have a positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens • Patient must be between the ages of 5 and 65 years old • The first dose must be given under the supervision of a physician and monitored for at least 30 minutes • Patient must be prescribed auto-injectable epinephrine • Treatment must begin at least 12 weeks prior to onset of each grass pollen season • Patient must not have a diagnosis of severe, unstable or uncontrolled asthma • Patient must not have a history of eosinophilic esophagitis <p>LENGTH OF APPROVAL: 6 MONTHS</p> <p>Public Comment Andrena Scholl, Merk; available for questions</p> <p>Board Discussion Specialist step was also removed</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</p>
<p>9. Oralair® (Sweet vernal, Orchard, Perennial rye, Timothy, and Kentucky blue grass mixed pollens allergens extract)</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background Oralair is an agent indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis in patients aged 10 through 65 years of age. Diagnosis is confirmed by a positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for any of the five grass species contained in the product. 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 ORALAIR: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of grass pollen-induced allergic rhinitis • Patient must have a positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for any of the five grass species contained in the product (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass) • Patient must be between the ages of 10 and 65 years old • The first dose must be given under the supervision of a physician and monitored for at least 30 minutes • Patient must be prescribed auto-injectable epinephrine • Treatment must begin at least 4 months prior to onset of each grass pollen season • Patient must not have a diagnosis of severe, unstable or uncontrolled asthma • Patient must not have a history of eosinophilic esophagitis <p>LENGTH OF APPROVAL: 9 MONTHS</p> <p><u>Public Comment</u></p> <p><u>Board Discussion</u> Specialist step was also removed</p>	
<p>C. Miscellaneous Items 1. Managed Care Organization Annual Reports</p>	<p>Amerigroup, United Healthcare, and Sunflower will present reports detailing utilization trends and provider education efforts for 2014.</p> <ul style="list-style-type: none"> i. Overall MCO Utilization Data – Kelley Melton, Pharm.D. ii. Amerigroup Individual Report – Lisa Todd, RPh iii. United Healthcare Individual Report – Jennifer Murff, RPh iv. Sunflower Individual Report – Angie Zhou, Pharm.D. v. *Public Comment vi. Board Discussion 	
<p>IV. Open Public Comment</p>	<p><u>Public Comment</u> There were no additional public comments offered during this meeting.</p> <p><u>Board Discussion</u> Dr. Melton announced that this would be Dr. Kevin Waite’s last DUR meeting. An email would be sent out to ask others if they would be interested in becoming chair.</p>	
<p>V. Adjourn</p>	<p>The meeting was adjourned at 12:11 pm.</p> <p>The next meeting will be on July 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>Dr. Heston seconded the motion.</p> <p>The motion was approved unanimously</p>