

**Drug Utilization Review Board
Meeting Minutes, Open Session
October 8, 2014**

<p>Drug Utilization Review Board Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital Room Topeka, KS</p>	<p>DUR Board Members Present Tim Heston, DO Roger Unruh, D.O. John Kollhoff, PharmD. Jim Backes, PharmD. Russell Scheffer, MD</p> <p>DUR Board Members Absent Judy McDaniel Dowd, PA-C Kevin Waite, PharmD.</p> <p>DHCF Staff Present Kelley Melton, PharmD. Liane Larson, PharmD Carol Arace, Administrative Assistant</p> <p>HP Enterprise Services Staff Present Karen Kluczykowski, RPh Nancy Perry, R.N.</p> <p>HID Staff Present Nicole Ellermeier, PharmD.</p> <p>MCO Staff Present Jonalan Smith, Pharm.D., FASCP: Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p>Representatives Deb Bock, Abbvie B. Effertz, Grifols John Esslinger MD, United Health Care Rob Hansen, Pfizer Berend Koops, Merck Mike Krug, Sunovion Kate Kulesher, Novartis Scott Maurice, Boehringer- Ingelheim Julie McDavitt, Boehringer- Ingelheim Deepak Singh, Novartis Oncology Kathy Skoglund, Novartis Oncology Sam Smothers, Medimmune/Astra Zeneca Dave Sproat, Bristol Myers Squibb Amber Thieman, Sunflower Marla Wiedenmann, Novo Nordisk</p>
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Kollhoff called the meeting to order at 10:07am.	
A. Announcements	Dr. Melton offered a reminder as to where meeting guests should park. Dr. Melton reminded attendees that public comments are limited to 5 minutes per person per topic. Dr. Melton introduced Liane Larson, PharmD as a new KDHE-DHCF staff member	
II. Old Business A. Review and Approval of July 9, 2014 DUR Meeting Minutes		Dr. Unruh made motion to accept the minutes as presented. Dr. Heston seconded the

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		<p>motion.</p> <p>The minutes were approved. Dr. Scheffer abstained, because he was not present at previous meeting.</p>
<p>II. New Business</p> <p>A. New Preferred Drug List Classes</p> <p>1. Fixed Dose Combination Products for Hyperlipidemia</p> <p>i. Non-preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>At the September 2014 PDL meeting, the committee approved the addition of the Fixed Dose Combination Products to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.</p> <div style="border: 1px solid black; padding: 5px;"> <p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> Patient has a medical intolerance to preferred drug. Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p>_____</p> <p><input type="checkbox"/> Patient has had an inadequate response to preferred drug. Name of preferred agent patient tried: _____</p> <p>_____</p> <p><input type="checkbox"/> An appropriate formulation or indication is not available as a preferred drug. Please specify which formulation or indication is needed and information supporting the need: _____</p> <p>_____</p> </div> <p>Public Comment</p> <p>None</p> <p>Board Discussion</p> <p>Dr. Ellermeir clarified for Dr. Scheffer the ‘appropriate formulation’ (ie: liquid versus pill).</p>	<p>Dr. Scheffer made motion to accept the revised PA Criteria</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>2. Anti-Infective/Steroid Otic Combination Products</p> <p>i. Non-preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>At the September 2014 PDL meeting, the committee approved the addition of the Anti-Infective/Steroid Combination Products to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.</p> <div style="border: 1px solid black; padding: 5px;"> <p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> Patient has a medical intolerance to preferred drug. Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p>_____</p> <p><input type="checkbox"/> Patient has had an inadequate response to preferred drug. Name of preferred agent patient tried: _____</p> <p>_____</p> <p><input type="checkbox"/> An appropriate formulation or indication is not available as a preferred drug. Please specify which formulation or indication is needed and information supporting the need: _____</p> <p>_____</p> </div> <p>Public Comment</p>	<p>Dr. Heston made motion to accept the revised PA Criteria</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	<p>None</p> <p><u>Board Discussion</u></p> <p>None</p>	
<p>3. Oral Immune Disease Modifying Agents</p> <p>i. Non-preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>At the September 2014 PDL meeting, the committee approved the addition of the Oral Immune Disease Modifying Agents to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.</p> <div style="border: 1px solid black; padding: 5px;"> <p>Please check the appropriate box and provide the required information to receive the requested non-preferred drug.</p> <p><input type="checkbox"/> Patient has a medical intolerance to preferred drug. Please provide the name of the preferred drug and clinical symptoms of intolerance experienced by the patient: _____</p> <p>_____</p> <p><input type="checkbox"/> Patient has had an inadequate response to preferred drug. Name of preferred agent patient tried: _____</p> <p>_____</p> <p><input type="checkbox"/> An appropriate formulation or indication is not available as a preferred drug. Please specify which formulation or indication is needed and information supporting the need: _____</p> <p>_____</p> </div> <p><u>Public Comment</u></p> <p>None</p> <p><u>Board Discussion</u></p> <p>None</p>	<p>Dr. Unruh made motion to accept the revised PA Criteria</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>B. Revised Prior Authorization (PA) Criteria</p> <p>1. Testosterone Agents (Vogelxo® (testosterone gel))</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Prior authorization criteria for testosterone agents were last revised in July 2014. Since that time, a new agent has been approved—Vogelxo testosterone gel. Prior authorization criteria are being revised to include this new agent as well as testosterone powder for compounding.</p>	<p>Dr. Scheffer 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 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> Discussion around how compounds are covered – NDC's are currently covered individually with discussion to move to methodology where they would be covered as a class.</p> <p>No data is currently available as to how often powder is used/covered.</p> <p>Confirmed that this criteria requires lab results to approve the initial PA.</p>	
<p>2. Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors (Jardiance® (empagliflozin))</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u> Prior authorization criteria for the SGLT2 Inhibitors were approved in April 2014. Since that time, a new agent has been approved—Jardiance. Prior authorization criteria are being revised to include this new agent.</p>	<p>Dr. Heston made motion to accept the revised PA Criteria</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	<p>CRITERIA FOR SGLT2 INHIBITORS 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 60 mL/min/1.73m² for dapagliflozin OR above 45 mL/min/1.73m² for canagliflozin or empagliflozin • Patient MUST NOT have any of the following contraindications: <ul style="list-style-type: none"> ○ Active bladder cancer ○ End-stage renal disease ○ Currently on dialysis <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment Julie McDavitt, manufacturer’s representative, offered to be available for questions.</p> <p>Board Discussion Dr. Heston and Dr. Backes initiated discussion as to why alternative medication therapy isn’t required. Dr. Melton confirmed that due to State Statute from 20+ years ago, Step Therapy can’t be introduced unless indicated by package insert. PA criteria is only way to manage use of this product.</p>	
<p>3. Enzyme Replacement Therapy (Cerdelga® (eliglustat))</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Prior authorization criteria for enzyme replacement therapy were initially approved in July 2014. Since that time, a new agent has been approved—Cerdelga. Prior authorization criteria are being revised to include this new agent.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <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. Scheffer made motion to accept the revised PA Criteria</p> <p>Dr. Backes seconded the motion.</p> <p>The criteria were approved unanimously</p>
<p>4. Promacta® (eltrombopag)</p>	<p>Background</p>	<p>Dr. Backes made motion to</p>

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i. Revised PA Criteria ii. *Public Comment iii. Board Discussion	<p>Prior authorization criteria for Promacta was initially approved in July 2009 and last revised in July 2014. Since that time, the FDA-approved indications have been expanded to include severe aplastic anemia in patients who have had an inadequate response to immunosuppressive therapy. Prior authorization criteria are being revised to include this new indication.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR APLASTIC ANEMIA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of severe aplastic anemia • Patient must have had an inadequate response to immunosuppressive therapy • Patient must be 18 years of age or older • Must be prescribed by or consultation with a hematologist or oncologist <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> </div> <p>Public Comment None</p> <p>Board Discussion Board discussion on trials and FDA approval.</p>	<p>accept the revised PA Criteria</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously</p>
5. Decubitus & Wound Care Products i. Revised PA Criteria ii. *Public Comment iii. Board Discussion	<p>Background Prior authorization criteria for decubitus and wound care products were initially approved in December 1994 and have been revised several times. Prior authorization criteria are being revised to include expanded approval for patients with severe partial thickness burns.</p>	<p>Dr. Backes made motion to accept the revised PA Criteria</p> <p>Dr. Scheffer seconded the motion.</p>

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	<p>CRITERIA FOR PRIOR AUTHORIZATION Must meet ONE of the following:</p> <ul style="list-style-type: none"> • Treatment of varicose, stasis, or decubitus ulcers stage II or higher <ul style="list-style-type: none"> ○ Must provide site of ulcer and approximate size • Treatment of dehiscent wounds <ul style="list-style-type: none"> ○ Must provide site of wound and approximate size • Treatment of severe partial or full thickness burns <ul style="list-style-type: none"> ○ Must provide site of burn and approximate size <p>RENEWAL CRITERIA Must meet all of the following</p> <ul style="list-style-type: none"> • Prescriber must provide an update on the size and stage of wound • Improvement in size and/or stage is required for renewal <p>LENGTH OF APPROVAL 3 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	<p>The criteria were approved unanimously</p>
<p>6. Xolair® (omalizumab)</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Prior authorization criteria for Xolair was last revised in July 2014 to include the new FDA-approved indication for chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite antihistamine treatment. At that time the criteria for that indication was approved to require Xolair be prescribed by or in consultation with an allergist or immunologist. Prior authorization criteria are being revised to include “dermatologist” on the list of provider specialties that may prescribe Xolair for chronic idiopathic urticaria.</p>	<p>Dr. Backes made motion to accept the revised PA Criteria</p> <p>Dr. Scheffer 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, immunologist, or dermatologist • 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><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>7. Topical Acne Agents (Retin-A Micro® (tretinoin microspheres), Tretin-X® & Avita® (tretinoin))</p> <ol style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u> Prior authorization criteria for topical acne agents were initially approved in June 2011 and revised in July 2012. At that time, several agents were overlooked that should have been included in the criteria. Prior authorization criteria are being revised to add Retin-A Micro, Tretin-X, and Avita.</p>	<p>Dr. Scheffer 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 Acne Vulgaris (all agents): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Acne Vulgaris. • Patient must be 10 years of age or older (Atralin only) or 12 years of age or older (all other acne products). <p>CRITERIA for Plaque Psoriasis (Tazorac ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Plaque Psoriasis. • Patient must be 18 years of age or older. <p>CRITERIA for Rosacea (Finacea ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of inflammatory papules and pustules of mild to moderate rosacea. • Patient must be 18 years of age or older. <p>LENGTH OF APPROVAL 12 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>8. Synagis® (palivizumab)</p> <ul style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Prior authorization criteria for Synagis was last revised in October 2012 to follow the American Academy of Pediatrics (AAP) guidelines for the prophylaxis of RSV. In July 2014, the AAP released new guidelines, and prior authorization criteria are being revised to align more closely with the revised guidelines for RSV prophylaxis.</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; Dr. Heston opposed.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA for First RSV Season (Must meet all of the following)</p> <ul style="list-style-type: none"> • Treatment is being administered at the start or within the RSV season (based on geographical area) November 1 thru March 31 • Doses must not be administered more frequently than every 30 days • Maximum of 5 monthly doses • Patient is less than 12 months of age at the start of the RSV season • After initial dose and prior to each monthly refill, Synagis status form must be returned with date of last injection and current weight • Patient must meet one of the following: <ul style="list-style-type: none"> ○ Patient was born before 29 weeks of gestation ○ Patient has Chronic Lung Disease (CLD) AND was born before 32 weeks, 0 days gestation AND required >21% oxygen for at least 28 days after birth ○ Patient has a diagnosis of Cystic Fibrosis AND clinical evidence of CLD or nutritional compromise ○ Patient has moderate-to-severe pulmonary hypertension ○ Patient has <u>acyanotic</u> congenital heart disease (CHD) who have not had or completed surgical correction ○ Patient has <u>acyanotic</u> CHD and receives medication to control CHD regardless of surgical status ○ Patient has a neuromuscular condition that compromises the handling of respiratory tract secretions: infantile paralysis, cerebral degenerations, myoclonus, <u>spinocerebellar</u> disease, <u>Werdnig-Hoffman</u> disease, Spinal muscular atrophy and motor neuron disease. ○ Patient is undergoing a cardiac transplantation during the RSV season ○ Patient is profoundly immunocompromised during the RSV season <p>Discontinue monthly prophylaxis if a patient receiving prophylaxis experiences a breakthrough RSV hospitalization</p> <p>LENGTH OF APPROVAL: Up to 5 monthly doses</p>	

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	<p>CRITERIA for Second RSV Season (must meet all of the following)</p> <ul style="list-style-type: none"> • Treatment is being administered at the start or within the RSV season (based on geographical area) November 1 thru March 31 • Doses must not be administered more frequently than every 30 days • Maximum of 5 monthly doses • Patient is less than 24 months of age at the start of the RSV season • After initial dose and prior to each monthly refill, Synagis status form must be returned with date of last injection and current weight • Patient must meet one of the following: <ul style="list-style-type: none"> ○ Patient has CLD AND was born before 32 weeks, 0 days gestation AND required at least 28 days of oxygen after birth AND continues to require supplemental oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of the start of their second RSV season ○ Patient has a diagnosis of Cystic Fibrosis AND severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) ○ Patient has a diagnosis of Cystic Fibrosis and weight for length less than 10th percentile ○ Patient is undergoing a cardiac transplantation during the RSV season ○ Patient is profoundly immunocompromised during the RSV season <p>Discontinue monthly prophylaxis if a patient receiving prophylaxis experiences a breakthrough RSV hospitalization</p> <p>LENGTH OF APPROVAL: Up to 5 monthly doses</p> <p><u>Public Comment</u></p> <p>Sam Smothers, RN, MedImmune, provided comments in support of retaining the current 2012 guidelines. Testimony offered that some states have opted to wait a year to review impact of new guidelines.</p> <p>Dr. Esslinger, United HealthCare, provided comments in support of adopting the new 2014 guidelines</p> <p><u>Board Discussion</u></p> <p>Dr. Ellermeier reviewed changes in detail. Dr. Melton estimates that adopting the new 2014 guidelines will reduce qualifying patients by 50% (and reduce cost respectively). Dr. Melton recited states who have and have not adopted the new guidelines, states who are undecided, and states who have adopted a modified version of the new guidelines. Primary pushback has been from manufacturer rather than from provider community; although provider feedback could be received after new guidelines are implemented.</p> <p>There was a change made to the dosage to clarify ‘monthly’ dose.</p> <p>Dr. Heston recommended deferring for one year or until the next DUR meeting if the board could not make a decision today.</p>	

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	Last season pharmacy utilization: 989 claims, 538 patients, \$3,117,950 cost. These results do not capture inpatient doses or doses administered in the provider offices that are not billed through the pharmacy.	
<p>C. New Prior Authorization Criteria</p> <p>1. Alpha-1 Proteinase Inhibitors (Aralast NP®, Glassia®, Prolastin® C & Zemaira® (Alpha1 proteinase inhibitor (human)))</p> <p>i. Prior Authorization Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Alpha-1 proteinase inhibitors are indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Prior authorization criteria are being proposed for these agents to ensure appropriate use based upon the FDA-approved indications.</p> <div data-bbox="527 440 1633 800" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA for all agents: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be 18 years of age or older • Patient must be a non-smoker or be receiving smoking cessation treatment • Patient must be diagnosed with severe Alpha1-PI deficiency and clinically have evident emphysema <ul style="list-style-type: none"> ○ ATT serum concentration <11 µmol/L (80mg/dL if measured by radial immunodiffusion or 50 mg/dl if measured by nephelometry) ○ FEV₁ between 30 and 65% or a rapid decline in FEV₁ >120 ml/yr ○ Phenotype must be PiZZ, PiZ (null), Pi (null)(null) • Must be prescribed by or in consultation with a pulmonologist • Maximum dose of 60mg/kg once a week <p>Length of Approval: 3 months</p> </div> <p>Public Comment</p> <p>Bernie Effertz, offered information concerning the lack of Alpha 1 causing some patients to develop early emphysema.</p> <p>Board Discussion</p> <p>Clarification of needing to get an appeal if a provider wanted to go beyond the dose limitations.</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>2. Zykadia® (ceritinib)</p> <p>i. Prior Authorization Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Zykadia is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indication.</p>	<p>Dr. Scheffer made motion to accept the 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 ZYKADIA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) • Patient must have disease progression while on or is intolerant to crizotinib • Dose must not exceed 5 capsules per day (750mg/day) <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment Deepak Singh, Novartis, - offered to be available for questions.</p> <p>Board Discussion None</p>	
<p>3. Afrezza® (insulin human inhalation)</p> <p>i. Prior Authorization Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background Afrezza is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indications.</p> <p>CRITERIA FOR AFREZZA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of diabetes (type I or II) • If patient has a diagnosis of diabetes type I, patient must be using concurrent long acting insulin • Patient must NOT have a diagnosis of chronic lung disease (example: asthma or chronic obstructive pulmonary disease) • FEV1 must be documented as within normal limits prior to initiation • Patient must NOT be an active smoker as documented by prescriber <p>RENEWAL CRITERIA FOR AFREZZA Must meet all of the following</p> <ul style="list-style-type: none"> • FEV1 must be documented as within normal limits prior to renewal <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment Dr. Esslinger inquired about compliance monitoring and who develops the criteria. Dr. Melton responded that MCO's, Kansas, and HID partner to develop criteria based on package insert parameters.</p> <p>Board Discussion Dr. Backes inquired about utilization. Dr. Melton confirmed no utilization at this time; however, due to limitations of requiring step therapy, PA criteria guidelines are the only way to control use of this product and control costs for this high-dollar product.</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>

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<p>4. Anoro® Ellipta® (umeclidinium/vilanterol)</p> <p>i. Prior Authorization Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background Anoro Ellipta is a combination anticholinergic/long-acting beta2-adrenergic agonist indicated for long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indications.</p> <div data-bbox="527 347 1633 613" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR ANORO ELLIPTA: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic obstructive pulmonary disease (COPD) • Patient must be 18 years of age or older • Dose must not exceed one inhalation per day <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment None</p> <p>Board Discussion Discussion around the specific device name, confirmed it is Ellipta.</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>5. Qudexy® XR (topiramate)</p> <p>i. Prior Authorization Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background Qudexy XR is a topiramate extended-release capsule indicated for the treatment of partial onset or primary generalized tonic-clonic seizures and seizures associated with Lennox-Gastaut syndrome. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indications.</p>	<p>Dr. Heston made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR LENNOX-GASTAUT SYNDROME (LGS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have seizures associated with a diagnosis of Lennox-Gastaut Syndrome • Must be using as adjunctive therapy • Patient must be 2 years of age or older • Must be prescribed by or in consultation with a neurologist <p>CRITERIA FOR PARTIAL ONSET OR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of partial onset or primary generalized tonic-clonic seizures • Must meet one of the following: <ul style="list-style-type: none"> ○ Patient must be 10 years of age or older ○ Patient must be 2 years of age or older and using Qudexy XR as adjunctive therapy • Must be prescribed by or in consultation with a neurologist <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment None</p> <p>Board Discussion Dr. Heston confirmed there are only two (2) indications for this product. Dr. Scheffer requested information regarding the requirement for a neurologist and access to neurologists in all parts of the state. Dr. Ellermeier clarified that a consultation or call with a neurologist would be appropriate; the prescriber does not have to be a neurologist.</p>	
<p>6. Zydelig® (idelalisib)</p> <ul style="list-style-type: none"> i. Prior Authorization Criteria ii. *Public Comment iii. Board Discussion 	<p>Background Zydelig is indicated for the treatment of relapsed chronic lymphocytic leukemia, relapsed follicular B-cell non-Hodgkin lymphoma, and relapsed small lymphocytic lymphoma. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.</p>	<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>CRITERIA FOR CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of relapsed CLL • Patient must be using in combination with rituximab <p>CRITERIA FOR FOLLICULAR B-CELL NON-HODGKIN LYMPHOMA (FL) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of relapsed FL • Patient must have received at least two prior systemic therapies for FL <p>CRITERIA FOR SMALL LYMPHOCYTIC LYMPHOMA (SLL) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of relapsed SLL • Patient must have received at least two prior systemic therapies for SLL <p>LENGTH OF APPROVAL 12 months</p> <p><u>Public Comment</u> None</p> <p><u>Board Discussion</u> None</p>	
<p>7. Ruconest® (C1 esterase inhibitor [recombinant])</p> <ol style="list-style-type: none"> i. Prior Authorization Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Ruconest is indicated for the treatment of acute attacks in adults and adolescent patients with primary hereditary angioedema (HAE). Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used to treat HAE.</p>	<p>Dr. Heston made motion to accept the PA criteria.</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p>CRITERIA for Hereditary Angioedema (HAE): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of HAE • Must be used for the treatment of an acute HAE attack • Must not be used for the treatment of a laryngeal HAE attack • Patient must be 13 years of age or older <p>LENGTH of APPROVAL: 6 months</p> </div> <p>Public Comment None</p> <p>Board Discussion Dr. Unruh asked how this is administered. Dr. Ellermeier confirmed it is self-administered IV. Dr. Backes asked about utilization. No utilization reported to date.</p>	
<p>D. Miscellaneous Items</p> <p>1. Fee-for-Service Annual Program Assessment</p> <p style="padding-left: 20px;">i. Presentation</p> <p style="padding-left: 20px;">ii. Board Discussion</p>	<p>Background</p> <p>The annual program assessment for the Medicaid fee-for-service population was presented to show drug trends over the past state fiscal year.</p> <p>Dr. Ellermeier presented highlights. Fee-for-service population only. Results do not include rebates or MCO data.</p> <p>Board Discussion</p> <p>Brief discussion on classes, claims and Title 19.</p>	
<p>IV. Open Public Comment</p>	<p>Public Comment</p> <p>There were no additional public comments offered during this meeting.</p> <p>Board Discussion</p> <p>None</p>	
<p>V. Adjourn</p>	<p>The meeting was adjourned at 11:54am.</p> <p>The next meeting will be on January 14, 2015. It will begin at 10:00am at the HP Enterprises Services Office.</p> <p>**LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS</p>	<p>Dr. Heston made motion to adjourn the meeting.</p> <p>Dr. Scheffer seconded the motion.</p> <p>The motion was approved unanimously.</p>