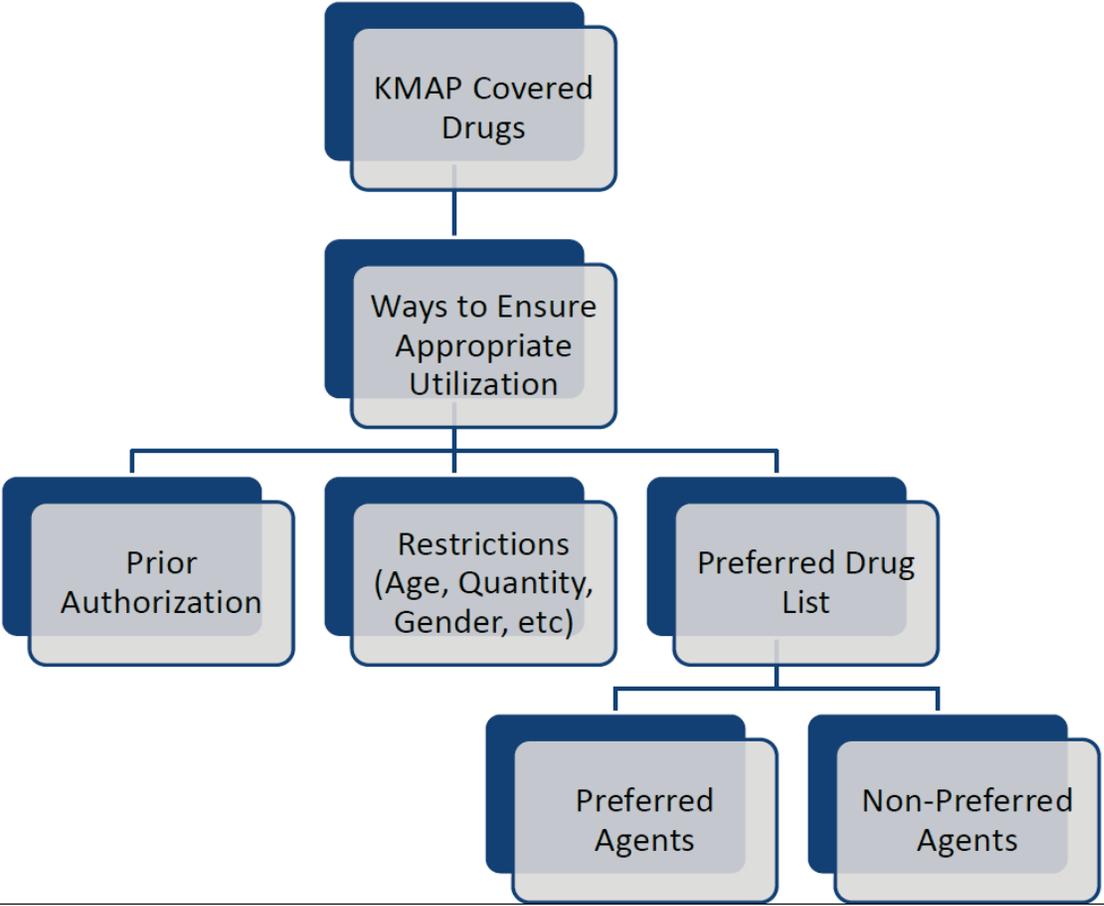


**Drug Utilization Review Board
Meeting Minutes, Open Session
January 8, 2014**

<p>Drug Utilization Review Board Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital Room Topeka, KS</p>	<p>DUR Board Members Present Judy McDaniel Dowd, PA-C Tim Heston, DO Russell Scheffer, MD Roger Unruh, D.O. Kevin Waite, Pharm.D.</p> <p>DUR Board Members Absent Michael Burke, MD, PhD John Kollhoff, Pharm.D. Daniel Sutherland, RPh</p> <p>DHCF Staff Present Kelley Melton, Pharm.D. Cynthia Stortz</p> <p>HP Enterprise Services Staff Present Karen Kluczykowski, RPh Nancy Perry, R.N.</p> <p>HID Staff Present Nicole Ellermeier, Pharm.D.</p> <p>MCO Staff Present Tom Kaye RPh, MBA, FASHP: Sunflower State Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh, BBA: Amerigroup Kansas</p>	<p>Representatives Susan Zalenski, J&J Sam Smothers, MedImmune Berend Koops, Merck Teresa Blair, Amgen Michele Puyear, Gilead Heather Jones, GSK Dave Sproat, BMS Patrick Jensen, Aegerion Risa Reuscher, Amgen Matthew Stafford, Merck Phil King, Pfizer Eric Gardner, Vertex Adriana Sanchez, Supernus Terry McCurren, Otsuka Julie McDavitt, Boehringer- Ingelheim Marla Wiedenmann, NovoNordisk Rudell Christian, Otsuka Dennis Jacobsen, Genzyme</p>
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Kevin Waite called the meeting to order at 10:05am announcing that we now have a quorum present and can begin the meeting.	
A. Announcements	<p>Nicole Ellermeier advised where individuals should park when attending this meeting.</p> <p>Kelley indicated Katy Brown, Pharmacist has resigned her position with KDHE in October, 2013 as her husband relocated to Iowa.</p> <p>Kelley introduced Dr. Russell Scheffer, a new DUR board member.</p>	
II. Old Business A. Review and Approval of	Dr. Waite then instructed members to review the minutes from the last meeting.	Dr. Unruh made motion to accept the minutes as

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>October 9, 2013 DUR Meeting Minutes</p>	<p>A roll was then taken and the minutes were approved.</p>	<p>presented.</p> <p>Ms. Dowd seconded the motion.</p> <p>The minutes were approved unanimously.</p>
<p>III. New Business DUR Overview</p>	<p>Dr. Melton presented an overview of drug coverage and the DUR process for KanCare.</p>  <pre> graph TD A[KMAP Covered Drugs] --> B[Ways to Ensure Appropriate Utilization] B --> C[Prior Authorization] B --> D["Restrictions (Age, Quantity, Gender, etc)"] B --> E[Preferred Drug List] E --> F[Preferred Agents] E --> G[Non-Preferred Agents] </pre>	
<p>A. Prior Authorization Criteria Revisions</p> <p>1. Aromatase Inhibitors (Arimidex® (anastrozole),</p>	<p>Background</p> <p>The aromatase inhibitors prior authorization criteria were initially approved in July 2009 to prevent off-label use for fertility. The National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium supports several off-label uses for the aromatase inhibitors,</p>	<p>Dr. Scheffer made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>Aromasin® (exemestane), Femara® (letrozole)</p> <p>i. Revised PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>including: endometrial cancer, uterine sarcomas, ovarian cancer for some agents, and breast cancer risk reduction for one agent. Due to the level of support in NCCN, the prior authorization criteria are being revised to include these indications.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR BREAST CANCER (ALL AGENTS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of breast cancer <p>CRITERIA FOR ENDOMETRIAL CANCER (ALL AGENTS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of endometrial carcinoma <p>CRITERIA FOR UTERINE SARCOMA (ALL AGENTS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of uterine sarcoma <p>CRITERIA FOR OVARIAN CANCER (ARIMIDEX & FEMARA ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of ovarian cancer <p>CRITERIA FOR BREAST CANCER RISK REDUCTION (AROMASIN ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be postmenopausal • Patient must have a life expectancy of ≥ 10 years • Patient must not have surgical risk reduction (mastectomy) • Patient must meet one of the following: <ul style="list-style-type: none"> ○ Patient must have a family history of or known genetic predisposition to breast cancer ○ Patient must have a lifetime risk of breast cancer $> 20\%$ based on models largely dependent on family history ○ Patient must be 35 years of age or older with an increased risk of breast cancer as determined by a modified Gail model (5-year breast cancer risk $\geq 1.7\%$) ○ Patient must have a history of lobular carcinoma in situ ○ Patient must have a history of thoracic radiation under 30 years of age <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment:</p> <p>Dr. Waite then asked if there was any public comment at this time. There were no public comments made at this time.</p> <p>Board Discussion</p> <p>Dr. Waite then opened the floor to board discussion. He then indicated he personally felt these were very appropriate, common uses of these drugs for the patients.</p> <p>Clarification was made that these were expansions beyond the package insert, no new limitations were added. It is expanding what would be approved with the initial care request. This is trying to cut out the appeal process for certain situations and thus removing</p>	<p>motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	obstacles for usage.	
<p>2. Stelara® (ustekinumab)</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 Stelara were initially approved in January 2010 and revised in January 2011 and April 2012. Since the last update to the criteria, a new indication has been approved for psoriatic arthritis. Revised prior authorization criteria are being proposed to include this new indication.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PLAQUE PSORIASIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of plaque psoriasis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • Patient must be a candidate for systemic therapy or phototherapy <p>CRITERIA FOR PSORIATIC ARTHRITIS (PSA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of psoriatic arthritis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>LENGTH OF APPROVAL 6 months</p> </div> <p>Public Comment</p> <p>No public comment was made at this time.</p> <p>Board Discussion</p> <p>Dr. Waite then opened the floor for board discussion. Not hearing any, he then entertained a motion for approval.</p>	<p>Ms. Dowd made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>3. Cimzia® (certolizumab pegol)</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 Cimzia were initially approved in July 2008 and revised in November 2008 and April 2012. Since the last update to the criteria, two new indications were approved for psoriatic arthritis and ankylosing spondylitis. Revised prior authorization criteria are being proposed to include the new 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 CROHN'S DISEASE (CD): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Crohn's disease • Must be prescribed by a gastroenterologist • Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has used a conventional Crohn's disease therapy (see attached table) OR there is documentation of inadequate response, contraindication, allergy, or intolerable side effects to a conventional Crohn's disease therapy (see attached table) <p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of rheumatoid arthritis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR PSORIATIC ARTHRITIS (PSA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of psoriatic arthritis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>CRITERIA FOR ANKYLOSING SPONDYLITIS (AS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of ankylosing spondylitis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days <p>LENGTH OF APPROVAL 6 months</p> <p>Public Comment</p> <p>No public comments were made at this time.</p> <p>Board Discussion</p> <p>Dr. Waite then opened the floor for board discussion. Hearing none, he then entertained a motion to approve the criteria.</p>	
<p>4. Actemra® (tocilizumab)</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 Actemra were initially approved in April 2010 and revised in April 2012 and 2013. Since the last update to the criteria, a new subcutaneous formulation has been approved for rheumatoid arthritis. Revised prior authorization criteria are being</p>	<p>Dr. Unruh made motion to accept the PA criteria.</p> <p>Dr. Scheffer seconded the</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>proposed to include the new formulation.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA) (SUBQ & IV FORMULATIONS): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of rheumatoid arthritis • Must be prescribed by a rheumatologist • Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one Disease-Modifying Anti-Rheumatic Drug (DMARD) (see attached table) • Prior to initiation of therapy patient must have an absolute neutrophil count (ANC) $\geq 2,000$ cells/mm³ • Prior to initiation of therapy patient must have a platelet count $\geq 100,000$ cells/mm³ • Prior to initiation of therapy patient must have normal liver function tests (LFTs) (ALT or AST) <ul style="list-style-type: none"> ○ 1.5 times the upper limit of normal (ULN) is considered abnormal for tocilizumab therapy initiation <p>RENEWAL CRITERIA FOR RA: (must meet initial criteria in addition to all of the following)</p> <ul style="list-style-type: none"> • Documentation of ANC, platelets and LFTs every 4-8 weeks • Documentation of lipid parameters 4-8 weeks after initiation of therapy and then every 24 weeks <p>CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA) (IV FORMULATIONS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of juvenile idiopathic arthritis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 2 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • Prior to initiation of therapy patient must have an ANC $\geq 2,000$ cells/mm³ • Prior to initiation of therapy patient must have a platelet count $\geq 100,000$ cells/mm³ • Prior to initiation of therapy patient must have normal LFTs (ALT or AST) <ul style="list-style-type: none"> ○ 1.5 times the upper limit of normal (ULN) is considered abnormal for tocilizumab therapy initiation <p>RENEWAL CRITERIA FOR JIA: (must meet initial criteria in addition to all of the following)</p> <ul style="list-style-type: none"> • Documentation of ANC, platelets and LFTs beginning with the second infusion, then every 2-4 weeks • Documentation of lipid parameters 4-8 weeks after initiation of therapy and then every 24 weeks <p>LENGTH OF APPROVAL 6 months</p> </div> <p><u>Public Comment</u></p> <p>No public comments were made at this time.</p> <p><u>Board Discussion</u></p> <p>Dr. Waite then opened the floor for board discussion.</p> <p>Dr. Heston then asked if the Juvenile Arthritis is not indicated because it wasn't studied as far as we know? He indicated he was concerned about a negative study. Dr. Waite indicated</p>	<p>motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION								
	<p>there was no study that he was aware of.</p> <p>Dr. Waite then entertained a motion to approve this as written.</p>									
<p>5. Pulmonary Arterial Hypertension Agents (Opsumit® (macitentan))</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 the pulmonary arterial hypertension agents were approved in April 2013. Since the approval, a new agent has been approved by the FDA, Opsumit. Revised prior authorization criteria are being proposed to include the new agent.</p> <table border="1" data-bbox="520 402 1631 906"> <tr> <td data-bbox="520 402 751 427">MANUAL GUIDELINES</td> <td data-bbox="751 402 1631 906"> <p>The following drug(s) require prior authorization:</p> <p>Ambrisentan Tablets (Letairis®)</p> <p>Bosentan Tablets (Tracleer®)</p> <p>Epoprostenol Injection (Flolan®, Veletri®)</p> <p>Iloprost Inhalation Solution (Ventavis®)</p> <p>Macitentan (Opsumit®)</p> <p>Sildenafil Tablets, Oral Suspension, and Injection (Revatio®)</p> <p>Treprostinil Inhalation Solution (Tyvaso®)</p> <p>Treprostinil Injection (Remodulin®) </p> <p>Tadalafil Tablets (Adcirca®)</p> </td> </tr> <tr> <td colspan="2" data-bbox="520 751 1631 776">CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)</td> </tr> <tr> <td colspan="2" data-bbox="520 808 1631 865"> <ul style="list-style-type: none"> • Patient must have a diagnosis of pulmonary arterial hypertension (PAH) • Must be prescribed by or in consultation with a pulmonologist, cardiologist, or specialized treatment center </td> </tr> <tr> <td colspan="2" data-bbox="520 881 1631 906">LENGTH OF APPROVAL 12 months</td> </tr> </table> <p>Public Comment</p> <p>No public comments were made at this time.</p> <p>Board Discussion</p> <p>Dr. Waite then opened the floor to board discussion. Being none, he then entertained a motion to approve the criteria.</p>	MANUAL GUIDELINES	<p>The following drug(s) require prior authorization:</p> <p>Ambrisentan Tablets (Letairis®)</p> <p>Bosentan Tablets (Tracleer®)</p> <p>Epoprostenol Injection (Flolan®, Veletri®)</p> <p>Iloprost Inhalation Solution (Ventavis®)</p> <p>Macitentan (Opsumit®)</p> <p>Sildenafil Tablets, Oral Suspension, and Injection (Revatio®)</p> <p>Treprostinil Inhalation Solution (Tyvaso®)</p> <p>Treprostinil Injection (Remodulin®) </p> <p>Tadalafil Tablets (Adcirca®)</p>	CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)		<ul style="list-style-type: none"> • Patient must have a diagnosis of pulmonary arterial hypertension (PAH) • Must be prescribed by or in consultation with a pulmonologist, cardiologist, or specialized treatment center 		LENGTH OF APPROVAL 12 months		<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>
MANUAL GUIDELINES	<p>The following drug(s) require prior authorization:</p> <p>Ambrisentan Tablets (Letairis®)</p> <p>Bosentan Tablets (Tracleer®)</p> <p>Epoprostenol Injection (Flolan®, Veletri®)</p> <p>Iloprost Inhalation Solution (Ventavis®)</p> <p>Macitentan (Opsumit®)</p> <p>Sildenafil Tablets, Oral Suspension, and Injection (Revatio®)</p> <p>Treprostinil Inhalation Solution (Tyvaso®)</p> <p>Treprostinil Injection (Remodulin®) </p> <p>Tadalafil Tablets (Adcirca®)</p>									
CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)										
<ul style="list-style-type: none"> • Patient must have a diagnosis of pulmonary arterial hypertension (PAH) • Must be prescribed by or in consultation with a pulmonologist, cardiologist, or specialized treatment center 										
LENGTH OF APPROVAL 12 months										
<p>6. Long-Acting Opioids (Zohydro ER® (hydrocodone extended-release))</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Dose optimization limits and override criteria were initially approved for the long-acting opioids in April 2010. Since the last update to the criteria, a new agent has been approved. Revised prior authorization criteria are being proposed to include the new agent, Zohydro ER.</p>	<p>Dr. Scheffer 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 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. <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><u>Public Comment</u></p> <p>No public comments were made at this time.</p> <p><u>Board Discussion</u></p> <p>Ms. Dowd clarified that under the bullet under “Renewal Criteria” they must meet “all of the following” to which Nicole answered “yes”. They can meet “1”, “2” or all of “3”.</p> <p>Dr. Scheffer asked for clarification of “3a”. Nicole then indicated that they patient should be on only one long acting agent at a time and then potentially a short action for a breakthrough. Dr. Scheffer indicated he was not sure that it read that way. A discussion of board members followed regarding clarifying this to reduce misinterpretation. The board then asked for MCO input. A discussion followed with clarification on the process that would have to be followed regarding covering a high dose of this medication. The criteria was amended to change the phrase of 3a to read: “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”.</p> <p>This was agreed upon as it was made clear the board did not want this issue to be a road block, but rather they see it as a hurdle to go over. Clarification was made regarding anything above the 4-a-day limitation is what would require the preauthorization.</p>	
<p>B. New Prior Authorization Criteria</p> <ol style="list-style-type: none"> 1. Olysio® (simeprevir) <ol style="list-style-type: none"> i. PA Criteria 	<p><u>Background</u></p> <p>Olysio is a newly approved hepatitis C virus protease inhibitor indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Other hepatitis C virus protease inhibitors include Victrelis and Incivek; both of these agents</p>	<p>Ms. Dowd made motion to accept the PA criteria.</p> <p>Dr. Scheffer seconded the</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
ii. *Public Comment iii. Board Discussion	<p>require prior authorization. Prior authorization criteria are being proposed to ensure use based upon FDA-approved indications.</p> <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 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 • 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 previous or concurrent hepatitis C protease inhibitor therapy (i.e. previous trial with Victrelis, Incivek, or Olysio) • Dose must not exceed 1 capsule per day <p>LENGTH OF INITIAL APPROVAL 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</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><u>Public Comment</u></p> <p>Adam Sprecker, Clinical Pharmacist with Janssen medical team indicated he was available to answer any questions they may have on this new product. Dr. Waite thanked Mr. Sprecker and asked him to complete a Conflict of Interest form.</p> <p><u>Board Discussion</u></p> <p>Dr. Waite then opened the floor for a board discussion. A comment was made regarding the robust number of Hepatitis C agents that have come on the market, and questioning if there are any limitations regarding duplicity of therapy? Multiple agents being used for treatment would certainly inadvertently increase the overall cost. After a discussion, changing the reading to “must not have been on previous or concurrent”.</p> <p>If there are changes from normal usage, a special request may be requested and considered. A motion was entertained to approve with the changes as requested.</p>	<p>motion.</p> <p>The criteria were approved unanimously.</p>
2. Sovaldi® (sofosbuvir) i. PA Criteria	<p><u>Background</u></p> <p>Sovaldi is a newly approved hepatitis C virus nucleotide analog NS5B polymerase inhibitor</p>	<p>Dr. Scheffer made motion to</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
ii. *Public Comment iii. Board Discussion	<p>indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Prior authorization criteria are being proposed to ensure use based upon FDA-approved indications.</p> <p><u>CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)</u></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 • Dose must not exceed 1 capsule per day <p>LENGTH OF INITIAL APPROVAL 12 weeks</p> <p>Ribavirin and peginterferon alfa are approved when using triple therapy with Sovaldi, if Sovaldi criteria are met.</p> <p><u>RENEWAL CRITERIA: (must meet one of the following)</u></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><u>Public Comment</u></p> <p>Michelle Puyear with Gilead Sciences and Medical Affairs stated if there were any questions she is available to answer them.</p> <p><u>Board Discussion</u></p> <p>A question was posed regarding clarification of the sixth bullet regarding the female patients and the negative pregnancy tests. This was clarified as the fact we would look for a negative pregnancy test up front, but monthly testing would be up to the provider.</p> <p>A motion was entertained to approve the criteria.</p>	<p>accept the PA criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>
3. Otrexup® (methotrexate) i. PA Criteria ii. *Public Comment iii. Board Discussion	<p><u>Background</u></p> <p>Otrexup is a new subcutaneous formulation of methotrexate indicated for patients with rheumatoid arthritis, juvenile idiopathic arthritis, and psoriasis. Due to the cost and specific indications for the new methotrexate formulation, prior authorization criteria are being</p>	<p>Dr. Scheffer made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>proposed to ensure use based upon FDA-approved indications.</p> <p>CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of rheumatoid arthritis • Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one first line therapy (example: full dose non-steroidal anti-inflammatory agents) • Must be prescribed by or in consultation with a rheumatologist • Dose must be between 10mg and 25mg per week <p>CRITERIA FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of polyarticular juvenile idiopathic arthritis • Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one first line therapy (example: full dose non-steroidal anti-inflammatory agents) • Must be prescribed by or in consultation with a rheumatologist • Dose must be between 10mg and 25mg per week <p>CRITERIA FOR PSORIASIS: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of psoriasis • Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one other therapy (example: full dose non-steroidal anti-inflammatory agents) • Must be prescribed by or in consultation with a dermatologist • Dose must be between 10mg and 25mg per week <p>LENGTH OF APPROVAL 6 months</p> <p><u>Public Comment</u></p> <p>There was no public comment at this time.</p> <p><u>Board Discussion</u></p> <p>Dr. Waite asked if the criteria should be added on the second bullet point. Motion entertained with one change for approval.</p>	<p>The criteria were approved unanimously.</p>
<p>4. Breo Ellipta® (fluticasone furoate/vilanterol)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Breo Ellipta is a new inhaled corticosteroid and long-acting beta-adrenergic agonist combination indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</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>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR BREO 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 <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p> <p>No public comment at this time.</p> <p>Board Discussion</p> <p>Clarification of the age of 18 being because it wasn't studied at younger ages was done.</p>	
<p>5. Brisdelle® (paroxetine)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Brisdelle is a selective serotonin reuptake inhibitor indicated for the treatment of vasomotor symptoms of menopause. Brisdelle is a low dose formulation of paroxetine and is not indicated for the treatment of any psychiatric condition. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR BRISDELLE: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be currently in menopause • Patient must currently have moderate to severe vasomotor symptoms (e.g. hot flashes and/or night sweats) associated with menopause <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p> <p>No public comment was made at this time.</p> <p>Board Discussion</p> <p>7.5mg once daily is the dosage. Motion was entertained for approval of criteria.</p>	<p>Dr. Scheffer made motion to accept the PA criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>6. Mirvaso® (brimonidine)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Mirvaso is a topical alpha adrenergic agonist indicated for the topical treatment of persistent facial erythema of rosacea. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Ms. Dowd 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 MIRVASO: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a dermatologist • Patient must have persistent (nontransient) erythema of rosacea <p>LENGTH OF APPROVAL 6 months</p> <p><u>Public Comment</u></p> <p>No public comment was made at this time.</p> <p><u>Board Discussion</u></p> <p>Dr. Waite asked for Ms. Dowd’s input on this. She stated they have been giving samples of this and have started to use it, but it takes a little while to see some noticeable improvement but it sounds like it could be promising.</p> <p>How necessary is bullet 2? It was discussed that a month’s supply is about \$300 and that a PA is necessary for consistency within the drug class.</p>	
<p>7. Trokendi XR® (topiramate extended-release)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Trokendi XR is a new, extended-release formulation of topiramate. Trokendi XR is indicated for the treatment of partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut Syndrome. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Unruh made motion to accept the PA criteria.</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>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 6 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 ○ Patient must be 6 years of age and using Trokendi XR as adjunctive therapy • Must be prescribed by or in consultation with a neurologist <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p> <p>No public comment was made at this time.</p> <p>Board Discussion</p> <p>This would be an agent that would not be added to the PDL as it can be used as a single agent in some cases.</p> <p>Dr. Waite clarified bullet 2 having to do with the dosage and being used as a mono agent rather than adjunctive therapy.</p>	
<p>8. Juxtapid® (lomitapide)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Juxtapid is a microsomal triglyceride transfer protein inhibitor indicated for patients with homozygous familial hypercholesterolemia. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of homozygous familial hypercholesterolemia based on the presence of one of the following: <ul style="list-style-type: none"> ○ Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus ○ An untreated LDL-cholesterol concentration >500mg/dL (13mmol/L) ○ Treated LDL-cholesterol ≥300mg/dL (7.76mmol/L) AND one of the following: <ul style="list-style-type: none"> ▪ Cutaneous or tendonous xanthoma before 10 years of age ▪ Untreated LDL cholesterol levels consistent with heterozygous FH in both parents (>190mg/dL) <p>LENGTH OF APPROVAL 12 months</p>	<p>Dr. Unruh made motion to accept the PA criteria.</p> <p>Dr. Scheffer seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Public Comment</p> <p>Patrick Jensen, MSL for Aegerion presented clinical findings regarding homozygous familial hypercholesterolemia (HOFH) treatment.</p> <p>Board Discussion</p> <p>Dr. Waite indicated he felt that based off what was read to them, the criteria pretty much catches all of them given the “one of the following”, rather than “all of the following” wording.</p> <p>Mr. Kaye stated he was concerned about the lack of substantiating criteria. He stated given the cost of the agent, he felt more efforts to validate the correct patient would be good stewardship of the funds.</p> <p>Dr. Melton indicated there was no utilization of this right now and given that this is targeting specifically the right patient and given the provider and pharmacy education required, we really don’t have anything else we can do with this.</p> <p>Mr. Jensen stated that the prescriber also has to attest that the patient prescribed this medication has HOFH, as well as a patient registry as a way to help monitor these patients.</p>	
<p>9. Kynamro® (mipomersen sodium)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Kynamro is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis indicated for patients with homozygous familial hypercholesterolemia. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div data-bbox="520 1057 1623 1360" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of homozygous familial hypercholesterolemia based on the presence of one of the following: <ul style="list-style-type: none"> ○ Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus ○ An untreated LDL-cholesterol concentration >500mg/dL (13mmol/L) ○ Treated LDL-cholesterol ≥300mg/dL (7.76mmol/L) AND one of the following: <ul style="list-style-type: none"> ▪ Cutaneous or tendonous xanthoma before 10 years of age ▪ Untreated LDL cholesterol levels consistent with heterozygous FH in both parents (>190mg/dL) <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment</p> <p>Dr. Dennis Jacobsen, Genzyme Company, Medical Affairs Division respectfully requested the</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
	<p>committee consult a local expert, Dr. Patrick J Moriarty, MD, who is an expert in Lipid Disorders at the University of Kansas Medical Center and is willing to review this criteria if the committee would like him to. Dr. Jacobsen stated this criteria is not consistent with other criteria for HOFH. He went on to state there was a wide range of response with this disease having to do with the functioning of the LDL receptor.</p> <p>Dr. Waite and Dr. Melton pointed out that these were their package insert directions, and asked what more he would like to see done with these? Dr. Jacobs indicated that clarification of the “or, or, or” rather than the “and, and, and”.</p> <p>Dr. Melton indicated she was not sure how they could go less stringent when they were following the package insert directions. Dr. Waite indicated that since we don’t have anyone that is on this right now, if we approved this today and then had someone that would be a potential candidate for this that would meet these criteria, If we go ahead and approve this today, they’ll get approved and can move on to therapy from there. If Dr. Moriarty would like to discuss the criteria with you, Dr. Melton indicated she would be open to that as well.</p> <p>Dr. Melton clarified that every patient in his clinical trial met one of the criteria, to which Dr. Jacobs indicated that there were a couple of other criteria that were clinical and not laboratory-based that were used as well.</p> <p><u>Board Discussion</u></p> <p>Criteria is identical to those of the previous agent. Dr. Unruh asked what the cost of this agent is and Dr. Ellermeier stated that in her notes it states potentially around \$4000/week. Given that fact, Dr. Melton indicated she was okay with the fact the criteria may be more stringent than might be ideal. Dr. Waite indicated there is an appeals process that can be used and entertained a motion to approve the criteria as written.</p>	
<p>10. Neumega® (oprelvekin)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Neumega is indicated for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Scheffer 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 NEUMEGA: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a non-myeloid malignancy (non-myeloid malignancies include all types of carcinoma, all types of sarcoma, melanoma, lymphomas, lymphocytic leukemias (ALL and CLL), and multiple myeloma) • Patient must be receiving myelosuppressive chemotherapy • Patient must be at high risk of thrombocytopenia (e.g. patients who have experienced severe thrombocytopenia following a previous chemotherapy cycle) <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p> <p>No public comment at this time.</p> <p>Board Discussion</p> <p>All the criteria listed is package insert criteria. There were no questions or comments from the board and Dr. Waite entertained a motion to approve.</p>	
<p>11. Neulasta®(pegfilgrastim)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Neulasta is indicated to decrease the incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR NEULASTA: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a non-myeloid malignancy (non-myeloid malignancies include all types of carcinoma, all types of sarcoma, melanoma, lymphomas, lymphocytic leukemias (ALL and CLL), and multiple myeloma) • Patient must have received myelosuppressive chemotherapy <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p> <p>Risa Reuscher, Pharm Medical Liaison with Amgen stated they agreed with the boards criteria as presented and stated she would like to make herself available if there are any questions regarding Neulasta.</p> <p>Board Discussion</p> <p>On the last bullet, it should read, “must HAVE received myelosuppressive chemotherapy”.</p>	<p>Ms. Dowd made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>12. Nplate® (romiplostim)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Nplate is indicated for the treatment of patients with chronic immune thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-</p>	<p>Dr. Unruh made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>approved labeling information.</p> <div data-bbox="527 172 1512 492" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR NPLATE: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic immune thrombocytopenia (ITP) • Patient must have had an insufficient response to one of the following: <ul style="list-style-type: none"> ○ Corticosteroids ○ Immunoglobulins ○ Splenectomy • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL 12 months</p> </div> <p><u>Public Comment</u></p> <p>Risa Reuscher, Pharm Medical Liaison with Amgen stated they agreed with the boards criteria as presented and stated she would like to make herself available if there are any questions regarding Nplate.</p> <p><u>Board Discussion</u></p> <p>There was no board discussion at this time and Dr. Waite entertained a motion to approve the criteria as written.</p>	<p>motion.</p> <p>The criteria were approved unanimously.</p>
<p>13. Gilotrif®(afatinib)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Gilotrif is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor deletions or mutations. Prior authorization criteria are being proposed to ensure appropriate utilization based on specific genetic markers.</p> <div data-bbox="527 1052 1629 1226" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR GILOTRIF: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of metastatic non-small cell lung cancer (NSCLC) • Tumors must have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations <p>LENGTH OF APPROVAL 12 months</p> </div> <p><u>Public Comment</u></p> <p>Julie McDavitt, Pharmacist with Boehringer-Ingelheim Pharmaceuticals requested, given the importance of this agent, that further steps be eradicated.</p> <p><u>Board Discussion</u></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>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Mr. Kaye asked about bullet three “patient must be 18 years old”, stating that if they fulfill the requirements of the first two bullets this should be removed as this could create a barrier to treatment. Dr. Melton indicated that could be done and Dr. Waite indicated he saw nothing to prevent this. If there are no complications with this drug, there should be no problems with the age limitations being removed. The board was okay with removing that restriction.</p>	
<p>14. Afinitor®(everolimus) i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background Afinitor is a kinase inhibitor indicated for the treatment of breast cancer, neuroendocrine tumors of pancreatic origin, renal cell carcinoma, renal angiomyolipoma and tuberous sclerosis complex, and subependymal giant cell astrocytoma. In addition to the FDA-approved indications, NCCN Drugs & Biologics Compendia supports the use of Afinitor for Waldenstrom’s macroglobulinemia and lung neuroendocrine tumors. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information and NCCN supported uses.</p>	<p>Dr. Scheffer 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 ADVANCED HORMONE RECEPTOR-POSITIVE, HER2-NEGATIVE BREAST CANCER (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be postmenopausal • Patient must have a diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer (HR+ BC) • Must be used in combination with exemestane, after failure of treatment with letrozole or anastrozole • Patient must not be taking Afinitor Disperz concurrently <p>CRITERIA FOR ADVANCED NEUROENDOCRINE TUMORS OF PANCREATIC ORIGIN (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced or metastatic disease • Patient must not be taking Afinitor Disperz concurrently <p>CRITERIA FOR ADVANCED RENAL CELL CARCINOMA (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of advanced renal cell carcinoma (RCC) • Patient must have failed treatment with sunitinib or sorafenib • Patient must not be taking Afinitor Disperz concurrently <p>CRITERIA FOR RENAL ANGIOMYOLIPOMA WITH TUBEROUS SCLEROSIS COMPLEX (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery • Patient must not be taking Afinitor Disperz concurrently <p>CRITERIA FOR SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) WITH TUBEROUS SCLEROSIS COMPLEX (TSC) (TABLETS & DISPERZ): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have tuberous sclerosis complex (TSC) with subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected • Patient must not be taking Afinitor tablets and Disperz concurrently <p>CRITERIA FOR WALDENSTROM'S MACROGLOBULINEMIA (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of Waldenstrom's Macroglobulinemia (lymphoplasmacytic lymphoma) • Patient must not be taking Afinitor Disperz concurrently <p>CRITERIA FOR LUNG NEUROENDOCRINE TUMORS (TABLETS ONLY): (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of lung neuroendocrine tumors • Patient must not be taking Afinitor Disperz concurrently <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p> <p>Susan Zulenski, Johnson & Johnson thanked the committee and Kelley for the way the industry relationships are run. She stated they appreciate the willingness to listen to suggestions and concerns.</p> <p>On the PDL slide, one of the bullets was ways to ensure proper appropriate utilization. One of the bullets under that said edits, quantity limits and age. MCOs are able to do those edits without permission. Do those edits have to stay within the package insert or can they be</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>more restrictive. Dr. Melton indicated they could not be more restrictive than what the insert requires by virtue of them being required to cover what is federally rebated, but there are some things that do not have FDA guidance or package insert guidance. Dr. Melton went on to state that no, they couldn't put an age limit on a drug that's approved for 18 and up and say we'll only pay this if you are 'xyz' age. Of course there are exceptions to this.</p> <p>Susan then asked if there were plans to put the 2013 minutes back on line, and Kelley indicated yes, she was just really far behind.</p> <p>Board Discussion</p> <p>One thing to note is that there are two types, tablets and Disperz and they each have different indications.</p> <p>Being no further board discussion Dr. Waite entertained a motion to approve the criteria.</p>	
IV. Open Public Comment	Dr. Waite then opened the meeting to further public comment. There being none, Dr. Waite moved for a motion to adjourn the meeting.	
V. Adjourn	<p>The meeting was adjourned at 11:45am.</p> <p>The next meeting will be on Wednesday April 9, 2014. It will begin at 10:00 am at the HP Enterprises Services Office.</p> <p>**LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS</p>	<p>Ms. Dowd made motion to adjourn the meeting.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion was approved unanimously.</p>

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