

**Drug Utilization Review Board
Meeting Minutes, Open Session
October 9, 2013**

<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 John Kollhoff, Pharm.D. Daniel Sutherland, RPh Roger Unruh, D.O. Kevin Waite, Pharm.D.</p> <p>DUR Board Members Absent Judy McDaniel Dowd, PA-C</p> <p>DHCF Staff Present Brandy Allen Katy Brown, Pharm.D. Kelley Melton, Pharm.D.</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 Russ Wilson, J&J Scott Goldfarb, GSK Dave Sproat, BMS Teresa Blair, Amgen Susan Zalenski, J&J Lisa Borland, Vertex Matthew Stafford, Merck Don Larsen, Forrest Julie McDavitt, BI Scott Maurice, BI Marc Salit, Baxter Marla Wiedenmann, NNI Sara Nollette, Novartis Eric Gardner, Vertex Jim Baumann, Pfizer Wesley Kosko Phil King, Pfizer Risa Reuscher, Amgen Scott Edelhauser, Alcon Jim Fowler, Astra-Zeneca Mike Hauger, Gentech Lee Ding, Gentech Berend Koops, Merck Terry McCurren, Otsuka</p>
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Kevin Waite called the meeting to order at 10:07am.	
A. Announcements	<p>Dr. Waite advised that if anyone is going to talk, a conflict of interest disclosure would need to be filled out and comments would be limited to 5 minutes per topic. Dr. Ellermeier advised where individuals should park.</p> <p>Dr. Melton introduced Katy Brown, the new pharmacist with DHCF. She filled Shelly Liby's position at the agency.</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>II. Old Business</p> <p>A. Review and Approval of July 10, 2013 DUR Meeting Minutes</p>		<p>Dr. Kollhoff made motion to accept the minutes as presented.</p> <p>Dr. Unruh seconded the motion.</p> <p>The minutes were approved unanimously.</p>
<p>III. New Business</p> <p>A. New Preferred Drug List (PDL) Classes</p> <p>1. Hepatitis C Protease Inhibitors</p> <p>i. Non-Preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>In September 2013, the PDL Committee approved the addition of “Hepatitis C Protease Inhibitors” to the PDL. Prior authorization criteria to allow patients access to non-preferred agents are being proposed.</p> <div data-bbox="527 573 1619 708" style="border: 1px solid black; padding: 5px;"> <p>Please check the appropriate box and provide the required information to receive the required non-preferred drug.</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> </div> <p>Public Comment</p> <p>Matt Stafford, Merck, mentioned that with the agents in this class, a patient should not start on one agent and then switch to another.</p> <p>Lisa Borland, Vertex, stated that she was available for questions regarding Incivek.</p> <p>Board Discussion</p> <p>Dr. Sutherland questioned the necessity of some of the PDL PA criteria, namely ‘intolerance to a preferred drug’ and ‘inadequate response to a preferred drug’.</p> <p>Dr. Waite agreed, stating that the patient would move on to a different treatment modality if a Protease Inhibitor was not successful.</p> <p>Dr. Ellermeier suggested that these criteria could be removed. Dr. Melton confirmed with the MCOs that this would be possible.</p> <p>Matt Stafford, Merck, suggested that one thing to consider might be that there are subtle differences between the drugs in this class, which should be accounted for somewhere in the criteria. Dr. Waite stated that this should be covered by the 3rd criteria (‘absence of appropriate formulation or indication of the drug’).</p>	<p>Dr. Kollhoff made motion to accept the amended non-preferred PA criteria.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>2. Urologics: Beta-3 Adrenergic Agonists</p> <p>i. Non-Preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>In September 2013, the PDL Committee approved the addition of “Urologics: Beta-3 Adrenergic Agonists” to the PDL. Prior authorization criteria to allow patients access to non-preferred agents are being proposed. The criteria are consistent with all other classes on the PDL</p> <div style="border: 1px solid black; padding: 5px;"> <p>Please check the appropriate box and provide the required information to receive the required 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><input type="checkbox"/> Patient has had an inadequate response to preferred drug. Name of preferred agent patient tried: _____</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> </div> <p>Public Comment</p> <p>None</p> <p>Board Discussion</p> <p>Dr. Melton mentioned that for both this class and the next, even though there is currently only one agent in the class, they were added to the PDL in anticipation of new agents to market.</p>	<p>Dr. Kollhoff made motion to accept the non-preferred PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>3. Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors</p> <p>i. Non-Preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>In September 2013, the PDL Committee approved the addition of “SGLT2 Inhibitors” to the PDL. Prior authorization criteria to allow patients access to non-preferred agents are being proposed. The criteria are consistent with all other classes on the PDL</p>	<p>Dr. Sutherland made motion to accept the non-preferred PA criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	<p>Please check the appropriate box and provide the required information to receive the required 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><input type="checkbox"/> Patient has had an inadequate response to preferred drug. Name of preferred agent patient tried: _____</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>Public Comment: None</p> <p>Board Discussion: None</p>	
<p>4. Oral Multiple Sclerosis Agents</p> <p>i. Non-Preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>In September 2013, the PDL Committee approved the addition of “Oral Multiple Sclerosis Agents” to the PDL. Prior authorization criteria to allow patients access to non-preferred agents are being proposed. The criteria are consistent with all other classes on the PDL.</p> <p>Please check the appropriate box and provide the required information to receive the required 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><input type="checkbox"/> Patient has had an inadequate response to preferred drug. Name of preferred agent patient tried: _____</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>Public Comment</p> <p>Sara Nollette, Novartis, offered to entertain any questions regarding Gilenya or the class.</p> <p>Board Discussion</p> <p>Dr. Waite asked if the DUR board had previously reviewed these drugs for PA criteria.</p> <p>Dr. Melton stated that these drugs had been reviewed, along with Ampyra, which was not included in the class because it’s labeled indications are slightly different. She also stated that the PDL Board really reviewed the mechanism of action of these drugs, and that although they were different, the PDL Committee approved them for PDL inclusion</p>	<p>Dr. Heston made motion to accept the amended non-preferred PA criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	regardless. She stated that this class may not even end up on the PDL because of these clinical concerns.	
<p>B. Prior Authorization Criteria Revisions</p> <p>1. Buprenorphine for Opioid Dependence (Suboxone® & Zubsolv® (buprenorphine/naloxone), & Subutex® (buprenorphine))</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>In July 2013, the U.S. Food and Drug Administration (FDA) approved Zubsolv for the maintenance treatment of opioid dependence. Revised prior authorization criteria are being proposed to include this new agent.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR BUPRENORPHINE/NALOXONE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of opioid dependence • Patient must be actively involved in addiction treatment • Prescriber must have a current XDEA number • Prescriber must practice in Kansas or a border city and be an enrolled provider with plan • Daily dose of buprenorphine must not exceed 24mg for Suboxone and Subutex or 17.1mg for Zubsolv <p>CRITERIA FOR BUPRENORPHINE Must meet all of the criteria for buprenorphine/naloxone and one of the following:</p> <ul style="list-style-type: none"> • Patient must be pregnant • Patient must have a documented medical allergy to naloxone <p>RENEWAL CRITERIA Must meet all initial criteria and the following:</p> <ul style="list-style-type: none"> • Patient has not received any other narcotic agents since last prior authorization approval <p>LENGTH OF APPROVAL 3 months</p> </div> <p>Public Comment: None</p> <p>Board Discussion</p> <p>Dr. Kollhoff asked what qualified as a border city. Dr. Melton stated that this is a city within 50 miles. This is defined in regulation, as scripts are required to be dispensed by an in-state pharmacy or a border city pharmacy. The exceptions however, include limited distribution drugs, Third Party Liability claims, and foster child cases.</p> <p>Dr. Unruh asked if you must be pregnant to use the drugs, and Dr. Ellermeier clarified that this only applies to Subutex. She stated that this is done to prevent patients from not using the Naloxone component.</p> <p>Dr. Sutherland asked about the criteria that the patient has not received any other narcotic agents. He questioned how this could be reviewed if the patient received scripts out of state. Dr. Melton stated that this check is done using MCO prescription claims, and that a</p>	<p>Dr. Kollhoff made motion to accept the PA criteria.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	check of K-TRACS is not built in to that process.	
<p>2. Xyrem® (sodium oxybate)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Xyrem is a central nervous system depressant indicated for the treatment of cataplexy in narcolepsy and excessive daytime sleepiness in narcolepsy. In July 2009, the DUR Board approved prior authorization criteria for Xyrem requiring the Pharmacy Program Manager review all prior authorizations. Revised prior authorization criteria are being proposed to ensure appropriate utilization based upon the FDA-approved indications.</p> <p>CRITERIA FOR XYREM Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have one of the following diagnoses: <ul style="list-style-type: none"> ○ Cataplexy in narcolepsy ○ Excessive daytime sleepiness in narcolepsy • Patient must be enrolled in the Xyrem Success Program • Prescriber must be enrolled in the Xyrem Success Program • Patient must not be taking a sedative hypnotic agent concurrently • Patient must not have an existing diagnosis of succinic semialdehyde dehydrogenase deficiency • Patient must be 18 years of age or older <p>RENEWAL CRITERIA FOR XYREM Must meet the following:</p> <ul style="list-style-type: none"> • Patient must not be taking a sedative hypnotic agent concurrently <p>LENGTH OF APPROVAL 3 months</p> <p>Public Comment: None</p> <p>Board Discussion</p> <p>Dr. Waite asked how many claims there have been for this drug. Dr. Melton stated that under fee-for-service, she believed they'd had two patients approved for it. Dr. Ellemeier added that there had been utilization from January to July 2013 for the MCOs under the pharmacy benefit.</p> <p>Dr. Heston asked if this had criteria in the past. Dr. Melton stated that in the past, it required program manager review. So, if the specialty pharmacy tried to submit a claim, it would deny, and the state pharmacy manager would review each claim individually.</p> <p>Dr. Heston stated that he had a concern regarding the 3 month duration, and stated that if a patient needs this medication, they need it for an extended time period. Dr. Waite stated</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>

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	<p>that this 3 month approval duration may be part of the REMS.</p> <p>Dr. Ellermeier stated that in the package insert, it states that consultation with the provider should be done every 3 months. Dr. Heston stated that this is true, but that the PA re-approval may be an unnecessary burden. Dr. Ellermeier asked if more appropriate renewal criteria would just look for sedative-hypnotic use.</p> <p>Dr. Kollhoff asked if the claims data can be used to see if the patient has had follow-up with the prescriber to initiate an auto-approval beyond the 3 month period. Lisa Todd stated that she didn't know if each MCO had this capability, but stated that if this were possible, physicians would have to bill very promptly to avoid some of the issues associated with a billing lag in medical claims. Tom Kaye added that there could also be issues with how physician visits are coded when billed.</p> <p>Dr. Kollhoff asked how much the drug cost, and Dr. Melton stated that she did not know. Dr. Ellermeier added that the concern around this drug is more about abuse of the drug.</p> <p>Dr. Waite asked Dr. Heston if he was comfortable with the PA criteria as amended, which looks for sedative hypnotic use. Dr. Heston stated that this is probably appropriate, and Dr. Ellermeier offered that a longer approval time period could be included.</p> <p>Dr. Waite stated that he would prefer to leave the approval length at 3 months, since this is more in line with the package insert.</p>	
<p>C. New Prior Authorization Criteria</p> <p>1. Xgeva® (denosumab)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Xgeva has the same active ingredient as Prolia®, which has approved prior authorization criteria. Xgeva is being proposed for prior authorization criteria to remain consistent among denosumab products. Xgeva is approved for the prevention of skeletal-related events in patients with bone metastases from solid tumors, and the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Prior authorization criteria are being proposed based upon FDA-approved indications.</p>	<p>Dr. Sutherland 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>CRITERIA FOR BONE METASTASES FROM SOLID TUMORS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have bone metastases from a solid tumor • Patient must be 18 years of age or older • Patient must not be receiving Prolia concurrently <p>CRITERIA FOR GIANT CELL TUMOR OF BONE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have giant cell tumor of bone • Patient must be 13 years of age or older • Patients aged 13-17 years of age must meet the following: <ul style="list-style-type: none"> ○ Patient must have reached skeletal maturity, defined by at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus) ○ Patient must have reached a body weight of ≥ 45 kg • Patient must not be receiving Prolia concurrently <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p> <p>Risa Reuscher, Amgen, provided an update regarding the new indication that was incorporated into the Xgeva PA Criteria. In July of 2013, it was approved for Giant Cell Tumor of the Bone, and Dr. Reuscher stated that the dosing is somewhat different than typical Xgeva dosing. She also stated that the J code for Prolia and Xgeva is the same, and that they agree with the PA criteria as proposed.</p> <p>Board Discussion: None</p>	
<p>2. Ravicti® (glycerol phenylbutyrate)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Ravicti is indicated for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and/or amino acid supplementation alone. 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. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	<p>CRITERIA FOR RAVICTI Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a urea cycle disorder • Patient has failed management with dietary protein restriction and/or amino acid supplementation alone • Patient must be 2 years of age or older • Patient must be on a protein restrictive diet • Patient must not have a known hypersensitivity to phenylbutyrate • Dose must not exceed 19 grams per day <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment: None</p> <p>Board Discussion</p> <p>Dr. Kollhoff asked if there was a timeframe for failed management. Dr. Ellermeier stated that there was not, just that the dietary protein restriction and/or amino acid supplementation was a requirement in the package insert.</p> <p>Dr. Waite asked Dr. Unruh if this was a pediatric disorder. Dr. Unruh stated that in his 40 years of practice, he had not seen this.</p> <p>Dr. Ellermeier stated that there had not been claims for this drug yet.</p>	
<p>3. Buphenyl® (sodium phenylbutyrate)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Buphenyl is indicated as adjunctive therapy in the chronic management of patients with UCDs. Buphenyl must be combined with dietary protein restriction and, in some cases, essential amino acid supplementation. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR BUPHENYL Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a urea cycle disorder • Must not be used for management of acute hyperammonemia • Patient must weigh ≥20 kg • Patient must be on a protein restrictive diet • Dose must not exceed 20 grams per day <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment: None</p>	<p>Dr. Unruh made motion to accept the PA criteria.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	Board Discussion: None	
<p>4. Diclegis® (doxylamine succinate/pyridoxine hydrochloride)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Diclegis is a fixed dose combination drug product of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog. It is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div data-bbox="527 412 1621 782" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR DICLEGIS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must be pregnant • Patient must have nausea and vomiting of pregnancy (i.e., morning sickness) • Patient must not have responded to conservative management for nausea and vomiting of pregnancy • Patient must not be taking a monoamine oxidase inhibitor (MAOI) concurrently • Patient must not have a known hypersensitivity to doxylamine succinate, other ethanalamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation • Patient must be 18 years of age or older • Dose must not exceed 4 tablets per day <p>LENGTH OF APPROVAL 3 months</p> </div> <p>Public Comment: None</p> <p>Board Discussion</p> <p>Dr. Kollhoff asked for utilization on the drug, and Dr. Melton stated the data showed 5 paid claims for 5 beneficiaries. Dr. Kollhoff then asked what the cost of these claims was, and Dr. Melton stated that this was a little over \$1,100 total.</p> <p>Dr. Sutherland asked how ‘not responsive to conservative management’ was being defined. Dr. Ellermeier stated that this referred to lifestyle changes such as eating smaller meals or eating at a different time of day, and did not include other pharmaceutical interventions such as using ondansetron first.</p> <p>Dr. Kollhoff asked if there was any way for a patient to get the individual medications through the PDL. Dr. Melton stated that she wasn’t sure if both were covered drugs. Tom Kaye added that the inability to do step therapy made this solution not possible.</p>	<p>Dr. Kollhoff made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>5. Ospemifene® (ospemifene)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p>	<p>Background</p> <p>Ospemifene is an estrogen agonist/antagonist indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause. Prior</p>	<p>Dr. Sutherland made motion to accept the PA criteria.</p>

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<p>iii. Board Discussion</p>	<p>authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR OSPHENA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have dyspareunia • Patient must be 18 years of age or older • Patient must be female • Patient must be menopausal or postmenopausal • Patient must be taking a progestin concurrently or no longer have a uterus • Patient must not have any of the following contraindications <ul style="list-style-type: none"> ○ Undiagnosed abnormal genital bleeding ○ Known or suspected estrogen-dependent neoplasia ○ Active or history of DVT or pulmonary embolism ○ Active or history of arterial thromboembolic disease (e.g., stroke or myocardial infarction) ○ Known or suspected pregnancy • Dose must not exceed 1 tablet per day <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment: None</p> <p>Board Discussion: None</p>	<p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>6. Prialt® (ziconotide intrathecal infusion)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Prialt is an intrathecal infusion N-type calcium channel antagonist indicated for the management of severe chronic pain in patients for whom Intrathecal therapy is warranted, and who are intolerant or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or Intrathecal morphine. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Kollhoff made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>

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	<p>CRITERIA FOR PRIALT Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of severe chronic pain • Patient must be 18 years of age or older • Patient must be intolerant or refractory to at least one of the following treatments for chronic pain: <ul style="list-style-type: none"> ○ Systemic analgesics ○ Adjunctive therapies ○ Intrathecal morphine • The dose must not exceed 19.2 mcg/day • Patient must not have any of the following contraindications <ul style="list-style-type: none"> ○ Pre-existing history of psychosis ○ A contraindication to the use of Intrathecal analgesia including: <ul style="list-style-type: none"> ▪ The presence of infection at the microinfusion injection site ▪ Uncontrolled bleeding diathesis ▪ Spinal canal obstruction that impairs circulation of cerebrospinal fluid ○ Concomitant treatment or medical condition that would render Intrathecal administration hazardous ○ A known hypersensitivity to ziconotide or any of its formulation components • Prescriber must be experienced in the technique of intrathecal administration and who is familiar with the drug and device labeling <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment: None</p> <p>Board Discussion</p> <p>Dr. Waite asked about the lack of provider restrictions in the PA criteria. Dr. Sutherland asked if this was by a pump mechanism or direct injection. Dr. Melton stated that this was administered via a pump.</p> <p>Dr. Kollhoff asked if there was utilization, and Dr. Melton stated that there was none, but that the data was only for pharmacy claims.</p> <p>Dr. Waite reiterated his concern that any prescriber could write for an intrathecal drug. Dr. Melton asked the MCOs if they had some provider types that this could be limited to, or if there was a possibility to limit this to the medical side only.</p> <p>Dr. Brown added that the package insert states that the drug should only be prescribed by a ‘prescriber experienced in the technique of intrathecal administration and who is familiar with the drug and device labeling’. Dr. Melton stated that adding this statement may give the MCOs the latitude to review prescribers up front.</p>	

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	<p>Dr. Melton stated that the drug does have a specialty pharmacy distribution network, which would make claims for Prialt fall under the pharmacy benefit.</p> <p>Dr. Waite stated that he would like to add the criteria regarding prescriber administration experience to the criteria. Dr. Melton also offered to return the topic to the board in the future if it would be helpful. Dr. Waite stated that he was comfortable approving the criteria now, but that he would be curious to see more data in the future.</p>	
<p>7. Benlysta® (belimumab)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Benlysta is a B-lymphocyte stimulator-specific inhibitor indicated for the treatment of adults with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div data-bbox="527 581 1619 1109" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR BENLYSTA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of systemic lupus erythematosus (SLE) • Patient must have a positive anti-nuclear antibody (ANA) or anti-DNA antibody test • Patient must be taking at least one of the following SLE standard treatments <ul style="list-style-type: none"> ○ Corticosteroids ○ Antimalarials ○ NSAIDs ○ Immunosuppressives • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a rheumatologist • Patient must not be receiving other biologic therapies, including B-cell targeted therapies concurrently • Patient must not be receiving intravenous cyclophosphamide concurrently • Patient must not be currently treated for a chronic infection • Patient must not have had an anaphylactic response to a previous dose of belimumab <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment</p> <p>Scott Goldfarb with Glaxo Smith Kline stated that the criteria was consistent with the package insert, however he also pointed out that the SELENA SLEDAI scale is primarily utilized in clinical trials as an objective measure for disease activity. He reported that this scale is not used in routine clinical practice, and that it does have some limitations in clinical practice, namely that classic Lupus symptoms such as arthralgias and fatigue are not picked up by the tool. He also stated that the tool was all-or-none and did not pick up gradations in lupus severity.</p>	<p>Dr. Unruh made motion to accept the amended PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Dr. Sutherland asked Mr. Goldfarb if the scoring system had any applicability in guiding treatment. Mr. Goldfarb stated that the tool is used more in a clinical trial setting typically to operationally define what active disease is.</p> <p>Dr. Melton asked Mr. Goldfarb what is done in instances when other payers want a SELENA SLEDAI score for PA administration. For example, do prescribers walk through the tool and assign a score, even though they would not typically have done this as part of routine treatment. Mr. Goldfarb stated that most payers are not requiring use of the SELENA SLEDAI score, but that if a payer did, a physician would have to work through the tool somehow.</p> <p><u>Board Discussion</u></p> <p>Dr. Waite asked Dr. Heston for his thoughts on the SELENA SLEDAI scale. Dr. Heston stated that a lot of the metrics in the tool were not directly related to lupus, but that he did not necessarily see it being an issue with PA approval.</p> <p>Dr. Melton also mentioned that because of the low SELENA SLEDAI score in the criteria, the patients should qualify relatively easily. However, this may also means that the tool presents an undue burden to providers.</p> <p>Dr. Waite agreed that nearly any significant symptom would put a patient into the range of the necessary score, and that the SELENA SLEDAI score criteria should be removed. The board agreed.</p>	
<p>8. Soliris® (eculizumab)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Soliris is a complement inhibitor indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria to reduce hemolysis, and the treatment of patients with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy. Prior authorization criteria are being proposed to ensure appropriate use based on 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 PAROXYSMAL NOCTURNAL HEMOGLOBINURIA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of paroxysmal nocturnal hemoglobinuria • Patient must be 18 years of age or older • Patient must not have an unresolved serious <i>Neisseria meningitidis</i> infection • Patient must be vaccinated against <i>Neisseria meningitidis</i> at least 2 weeks prior to initiation of therapy with Soliris unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection <p>CRITERIA FOR ATYPICAL HEMOLYTIC UREMIC SYNDROME Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of atypical hemolytic uremic syndrome (aHUS) • The diagnosis of aHUS is supported by the absence of Shiga toxin-producing <i>E. coli</i> infection • Patient must be 2 months of age or older • Patient must not have an unresolved serious <i>Neisseria meningitidis</i> infection • Patient must be vaccinated against <i>Neisseria meningitidis</i> at least 2 weeks prior to initiation of therapy with Soliris unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection <p>LENGTH OF APPROVAL 3 months</p> <p>Public Comment: None</p> <p>Board Discussion</p> <p>Dr. Waite asked if the criteria for vaccination is something the MCOs would build in on their end or if it served as a reminder to the provider. Lisa Todd and Jennifer Murff stated that the provider is asked if vaccination has been completed as part of PA approval.</p>	
<p>9. Bivigam® (immune globulin intravenous (human))</p> <ol style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background</p> <p>Bivigam is an immune globulin indicated for the treatment of primary humoral immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Heston made motion to accept the PA criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME <u>Must</u> meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/m<u>mm</u>L • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> <p>Public Comment: None</p> <p>Board Discussion</p> <p>Dr. Sutherland asked if the evidence in the compendia was persuasive that off-label use is appropriate. Dr. Ellermeier stated that the compendia were reviewed for those indications that have the highest level of evidence. She stated that other compendia indications could be approved, but only through an appeals process. Dr. Sutherland questioned liability in the cases where a provider is using a drug off-label with the approval of the state.</p> <p>Tom Kaye stated that Sunflower will follow DUR criteria, and look to compendia in appealed cases, and will approve those cases that have supporting evidence. Dr. Melton stated that</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>this is why Dr. Ellermeier reviewed indications for levels of evidence.</p> <p>Dr. Sutherland stated that typically the board sticks to labeled indications, and asked what process the MCOs follow for off-label uses. Dr. Melton explained that the PAs are approved based on the criteria developed by the DUR Board, but for those cases where providers would like to use a drug off-label, the provider can appeal to have the MCO review the PA denials.</p> <p>Dr. Ellermeier stated that there is precedence for this in the Lidoderm. Dr. Melton also mentioned that off label uses of Botox will get approved, such as limb spasticity in cerebral palsy.</p>	
<p>10. Carimune® NF (immune globulin intravenous (human))</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background</p> <p>Carimune NF is an immune globulin indicated for the maintenance treatment of patients with primary immunodeficiencies, and the treatment of acute or chronic immune thrombocytopenic purpura. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Sutherland 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 PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR IMMUNE THROMBOCYTOPENIC PURPURA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have immune thrombocytopenic purpura • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR IMMUNE THROMBOCYTOPENIC PURPURA 6 months</p> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME <u>Must</u> meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mL • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> <p>Public Comment: None</p> <p><u>Board Discussion</u></p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Dr. Sutherland asked where the criteria for off-label uses was derived from. Dr. Ellermeier stated that this was pulled from compendia recommendations. DrugDex and Clinical Pharmacology were used for this purpose.	
<p>11. Flebogamma® (immune globulin intravenous (human))</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Flebogamma is an immune globulin indicated for the treatment of primary immune deficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mL • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> <p>Public Comment: None</p> <p>Board Discussion: None</p>	<p>Dr. Sutherland 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>12. Octagam® (immune globulin intravenous (human))</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Octagam is an immune globulin indicated for the treatment of primary humoral immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mcl • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> </div> <p>Public Comment: None</p> <p>Board Discussion: None</p>	<p>Dr. Unruh made motion to accept the PA criteria.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>13. Privigen® (immune globulin intravenous (human))</p> <p>i. PA Criteria</p>	<p>Background</p> <p>Privigen is an immune globulin indicated for the treatment of primary humoral immunodeficiency, and chronic immune thrombocytopenic purpura. Prior authorization</p>	<p>Dr. Sutherland made motion to accept the PA criteria.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
ii. *Public Comment iii. Board Discussion	<p>criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>CRITERIA FOR IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have chronic idiopathic thrombocytopenic purpura • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR IDIOPATHIC THROMBOCYTOPENIC PURPURA 6 months</p> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mcl • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> </div> <p>Public Comment: None</p>	<p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Board Discussion: None	
<p>14. Gammaplex® (immune globulin intravenous (human))</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Gammaplex is an immune globulin indicated for the treatment of primary humoral immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mcl • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> </div> <p>Public Comment: None</p> <p>Board Discussion: None</p>	<p>Dr. Kollhoff made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>15. Gammagard® S/D (immune globulin intravenous</p>	<p>Background</p> <p>Gammagard S/D is an immune globulin indicated for the treatment of primary</p>	<p>Dr. Kollhoff made motion to</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>(human))</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>immunodeficiency, prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia, prevention and/or control of bleeding in Chronic Idiopathic Thrombocytopenia Purpura, and prevention of coronary artery aneurysms associated with Kawasaki syndrome. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> </div> <p>CRITERIA FOR B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have B-cell chronic lymphocytic leukemia • Must be prescribed for prophylaxis of bacterial infections • Patient must have recurrent bacterial infections associated with CLL or hypogammaglobulinemia • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR B-CELL CLL 6 months</p> <p>CRITERIA FOR IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have chronic idiopathic thrombocytopenic purpura • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <div style="border: 1px solid black; padding: 5px;"> <p>LENGTH OF APPROVAL FOR IDIOPATHIC THROMBOCYTOPENIC PURPURA 6 months</p> </div>	<p>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 KAWASAKI SYNDROME Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Kawasaki syndrome • Patient must be receiving aspirin therapy concurrently • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR KAWASAKI SYNDROME 6 months</p> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME <u>Must</u> meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mL • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> <p><u>Public Comment:</u></p> <p>Mark Salit, Baxter, stated that from an efficacy point of view, IVIG products appear to function similarly, and many prescribers consider there to be class indications. He then went on to explain that not every IVIG product is appropriate for every patient. He stated that the products are also not interchangeable with each other, and that patients can experience adverse events when switching IVIG products. Dr. Salit also stated that waiting for appeals is not clinically appropriate as some conditions, such as Stevens-Johnson syndrome need immediate treatment.</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Dr. Sutherland asked Dr. Salit for his commentary on the off-label use of his company's product. Dr. Salit stated that the 6 month approval duration is likely too short for B-Cell CLL, but that for chronic ITP the duration is probably fine. Dr. Salit stated that a weeklong PA for Guillain-Barre syndrome could be problematic. He stated that the HIV criteria is appropriate.</p> <p>Dr. Salit also mentioned concerns about the appropriateness of having products available for indications for which their dosing is impractical.</p> <p>Board Discussion:</p> <p>To address some of Dr. Salit's concerns, Dr. Melton stated that approval durations may simply necessitate that a PA be renewed for continued therapy. She also stated that while a given indication of an IVIG product may not be used in practice, the state's prerogative is to have as many appropriate indications of a given drug available as possible.</p> <p>Dr. Waite added that in the case of a Stevens-Johnson patient, a PA could be reviewed post-drug administration, given the emergent nature of the situation.</p>	
<p>16. Gammagard® Liquid (immune globulin infusion (human))</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background</p> <p>Gammagard liquid is an immune globulin indicated as replacement therapy for primary humoral immunodeficiency, and as maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Sutherland 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 PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR MULTIFOCAL MOTOR NEUROPATHY Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have multifocal motor neuropathy • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR MULTIFOCAL MOTOR NEUROPATHY 6 months</p> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME <u>Must</u> meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mcl • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> <p><u>Public Comment</u></p> <p>Mark Salit, Baxter, stated that Multifocal Motor Neuropathy approval duration is too short. He also suggested that the Guillain-Barre and pediatric HIV indications should be added to</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>this product as well.</p> <p>Board Discussion</p> <p>Dr. Ellermeier clarified that the board wanted to add the Guillain-Barre & pediatric HIV indications.</p>	
<p>17. Gammaked® (immune globulin injection (human))</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Gammaked is an immune globulin indicated for the treatment of primary humoral immunodeficiency, idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have idiopathic thrombocytopenic purpura • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR ITP 6 months</p> <p>CRITERIA FOR CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have chronic inflammatory demyelinating polyneuropathy • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR CIDP 6 months</p>	<p>Dr. Kollhoff made motion to accept the PA criteria.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mL • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> <p>Public Comment: None</p> <p>Board Discussion: None</p>	
<p>18. Gamunex®-C (immune globulin injection (human))</p> <ol style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background</p> <p>Gamunex-C is an immune globulin indicated for the treatment of primary humoral immunodeficiency, idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Heston made motion to accept the PA criteria.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have idiopathic thrombocytopenic purpura • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR ITP 6 months</p> <p>CRITERIA FOR CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have chronic inflammatory demyelinating polyneuropathy • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR CIDP 6 months</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME <u>Must</u> meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS <u>Must</u> meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/<u>mcl</u>. • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> <p>Public Comment: None</p> <p>Board Discussion: None</p>	
<p>19. Hizentra® (immune globulin subcutaneous (human))</p> <ol style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background</p> <p>Hizentra is an immune globulin indicated for the treatment of primary immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Kollhoff made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR PRIMARY IMMUNODEFICIENCY DISEASE Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have primary immunodeficiency disease • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR PRIMARY IMMUNODEFICIENCY 6 months</p> <p>CRITERIA FOR GUILLAIN-BARRÉ SYNDROME Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have Guillain-Barré syndrome • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR GUILLAIN-BARRÉ SYNDROME 1 week</p> <p>CRITERIA FOR HIV PATIENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have symptomatic HIV • Patient must be 17 years of age or younger • Patient must have a CD4 lymphocyte count less than 200 cells/mcl • Patient must not have had a previous anaphylactic or severe systemic reaction to the administration of human immune globulin • Patient must not have IgA deficiency with antibodies to IgA and a history of hypersensitivity <p>LENGTH OF APPROVAL FOR HIV PATIENTS 6 months</p> <p><u>Public Comment</u></p> <p>Mark Salit, Baxter, stated that the off-label indications are not typically seen with this drug due to dosing concerns.</p> <p><u>Board Discussion:</u> None</p>	
<p>20. Vivaglobin® (immune globulin subcutaneous (human))</p> <ol style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Vivaglobin is an immune globulin indicated for the treatment of primary humoral immunodeficiency.</p> <p><u>Public Comment</u></p>	<p>Dr. Sutherland a made motion to remove Vivaglobin from PA criteria.</p> <p>Dr. Unruh seconded the motion.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Mark Salit, Baxter, stated that this product was removed from the market in 2012.</p> <p>Board Discussion</p> <p>Dr. Waite stated that he had also reviewed this and saw that it was no longer available.</p>	<p>The motion was approved unanimously.</p>
<p>21. Mekinist® (trametinib)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Mekinist is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Prior authorization criteria are being proposed to ensure appropriate use based on the specific genetic mutations approved by the FDA.</p> <div data-bbox="527 500 1438 734" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR MEKINIST Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of unresectable or metastatic melanoma • Patient must have a mutation of BRAF V600E or V600K • Patient must not have received previous treatment with a BRAF-inhibitor <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment</p> <p>Scott Goldfarb, Glaxo Smith Kline, stated that Mekinist is a new drug and that the criteria listed in consistent with the indication. Dr. Waite asked what drugs are BRAF Inhibitors. Mr. Goldfarb stated that Tafinlar and Zelboraf are the other current BRAF Inhibitors.</p> <p>Board Discussion: None</p>	<p>Dr. Sutherland made motion to accept the PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The criteria were approved unanimously.</p>
<p>22. Tafinlar® (dabrafenib)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Tafinlar is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E. Prior authorization criteria are being proposed to ensure appropriate use based on the specific genetic mutations approved by the FDA.</p> <div data-bbox="527 1166 1417 1393" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR TAFINLAR Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of unresectable or metastatic melanoma • Patient must have a mutation of BRAF V600E • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL 12 months</p> </div> <p>Public Comment</p>	<p>Dr. Sutherland 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>Scott Goldfarb, Glaxo Smith Kline, stated that the PA Criteria were consistent with the drug's label.</p> <p>Board Discussion: None</p>	
<p>23. Herceptin® (trastumab)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p>Background</p> <p>Herceptin is a Human Epidermal Growth Factor Receptor 2 (HER2) antagonist indicated for the treatment of HER2 overexpressing breast cancer, and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Prior authorization criteria are being proposed to ensure appropriate use based on the specific genetic marker approved by the FDA.</p>	<p>Dr. Kollhoff made motion to accept the PA criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The criteria were approved unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR METASTATIC GASTRIC CANCER Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma • Patient must have not received prior treatment for metastatic disease • Patient must be receiving trastuzumab in combination with cisplatin and capecitabine or 5-fluorouracil • Patient must be 18 years of age or older <p>CRITERIA FOR ADJUVANT BREAST CANCER Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of HER2 overexpressing breast cancer • Patient must have one of the following: <ul style="list-style-type: none"> ○ Node-positive disease ○ Node-negative disease and one of the following <ul style="list-style-type: none"> ▪ ER/PR-negative ▪ Tumor size >2cm ▪ Age <35 years of age ▪ Histological and/or nuclear Grade 2 or 3 • Patient must be receiving one of the following regimens: <ul style="list-style-type: none"> ○ Trastuzumab in combination with doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel ○ Trastuzumab in combination with docetaxel and carboplatin ○ Trastuzumab as a single agent following multi-modality anthracycline based therapy • Patient must be 18 years of age or older <p>CRITERIA FOR METASTATIC BREAST CANCER Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of HER2 overexpressing metastatic breast cancer • Must be used in combination with paclitaxel in patients who have not received prior treatment for metastatic disease • May be used as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL 12 months</p> <p>Public Comment</p> <p>Lee Deng, Genentech, stated that he was available to take any questions.</p> <p>Board Discussion: None</p>	
<p>D. Miscellaneous Items 1. KMAP SFY 2013 FFS Program</p>	<p>Background Dr. Ellermeier, Health Information Designs, LLC presented the KMAP SFY 2013 FFS Program</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION																
Assessment i. Program Assessment ii. *Public Comment iii. Board Discussion	Assessment. Public Comment: None Board Discussion: None																	
2. RDUR Intervention Topic Selection i. Intervention Topics ii. *Public Comment iii. Board Discussion	<p>Background Each year Health Information Designs, LLC performs 5 retrospective DUR interventions for the fee-for-service population. For state fiscal year 2014, the DUR board needs to select the remaining 2 topics for intervention. In July 2013, they selected 3 topics: Adverse Atypical Antipsychotic Effect, Atazanavir Drug Interaction, and Polypsychopharmacy. There were seven topics for the DUR board to choose from:</p> <table border="1" data-bbox="527 513 1577 1003"> <thead> <tr> <th data-bbox="527 513 1276 613">Proposed Intervention Topic</th> <th data-bbox="1276 513 1577 613">Potential Targeted Beneficiaries</th> </tr> </thead> <tbody> <tr> <td data-bbox="527 613 1276 670">1. Appropriate Contraceptive Use with Efavirenz</td> <td data-bbox="1276 613 1577 670">19</td> </tr> <tr> <td data-bbox="527 670 1276 727">2. Cardiovascular Disease State Management</td> <td data-bbox="1276 670 1577 727">24</td> </tr> <tr> <td data-bbox="527 727 1276 784">3. Hyperlipidemia and Diabetes</td> <td data-bbox="1276 727 1577 784">16</td> </tr> <tr> <td data-bbox="527 784 1276 841">4. Nevirapine Black Box Warning</td> <td data-bbox="1276 784 1577 841">21</td> </tr> <tr> <td data-bbox="527 841 1276 898">5. Inappropriate HIV Drug Regimen</td> <td data-bbox="1276 841 1577 898">12</td> </tr> <tr> <td data-bbox="527 898 1276 954">6. Benzodiazepine Use in Patients with COPD</td> <td data-bbox="1276 898 1577 954">19</td> </tr> <tr> <td data-bbox="527 954 1276 1003">7. Clozapine Black Box Warning</td> <td data-bbox="1276 954 1577 1003">17</td> </tr> </tbody> </table> <p>Public Comment No Public Comments</p> <p>Board Discussion Dr. Waite mentioned that the Black Box Warning topics may be most appropriate as they represent serious clinical issues.</p>	Proposed Intervention Topic	Potential Targeted Beneficiaries	1. Appropriate Contraceptive Use with Efavirenz	19	2. Cardiovascular Disease State Management	24	3. Hyperlipidemia and Diabetes	16	4. Nevirapine Black Box Warning	21	5. Inappropriate HIV Drug Regimen	12	6. Benzodiazepine Use in Patients with COPD	19	7. Clozapine Black Box Warning	17	<p>Dr. Unruh made motion to accept Black Box Warning Topics for Intervention.</p> <p>Dr. Sutherland seconded the motion.</p> <p>The topics were approved unanimously.</p>
Proposed Intervention Topic	Potential Targeted Beneficiaries																	
1. Appropriate Contraceptive Use with Efavirenz	19																	
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7. Clozapine Black Box Warning	17																	
IV. Open Public Comment	Public Comment: None																	
V. Adjourn	<p>The meeting was adjourned at 12:00.</p> <p>The next meeting will be on Wednesday January 8, 2014. It will begin at 10:00 am at the HP</p>	<p>Dr. Unruh made motion to adjourn the meeting.</p> <p>Dr. Sutherland seconded the</p>																

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Enterprises Services Office. **LUNCH WILL BE PROVIDED FOR DUR BOARD MEMBERS	motion. The motion was approved unanimously.