

**Drug Utilization Review Board
Meeting Minutes, Open Session
July 10, 2013**

Drug Utilization Review Board
Meeting Minutes, Open Session
HP Enterprise Services / Forbes Field
Capital Room
Topeka, KS

DUR Board Members Present

Judy McDaniel Dowd, PA-C
Tim Heston, DO
John Kollhoff, Pharm.D.
Roger Unruh, D.O.
Kevin Waite, Pharm.D.

DUR Board Members Absent

Daniel Sutherland, RPh

DHCF Staff Present

Brandy Allen
Kelley Melton, Pharm.D.

HP Enterprise Services Staff Present

Karen Kluczykowski, RPh
Nancy Perry, R.N.

HID Staff Present

Nicole Ellermeier, Pharm.D.

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

Representatives

Dan Larsen, Forest
Jim Baumann, Pfizer
Sam Smothers, MedImmune
Dave Sproat, Bristol-Meyer
Berend Koops, Merck
Jen Dabrowski, Allergan
Jared Lurk, Novartis
Phil King, Pfizer
Teresa Blair, Amgen
Risa Reuscher, Amgen
Matthew Stafford, Merck
Jerry Clewell, Abbuie
Eric Gardner, Vertex
Kathleen Karnik, Janssen
Rob Hansen, Pfizer
Natalie Johnson, Stormont Vail
Barbara Boner, Novartis
Russ Wilson, J&J
Deron Grothe, Teva
Janie Huff, Takeda
Kera Nathler, Merck
Grant Cale, Bristol-Myers Squibb
Patty Minear, Lilly
Brian Strickland, Gilead
Carrie Kimes, UHC
Michael, Massmann, Pfizer
Mary Shefchyk, Novo Nordisk
Mike Ketcher, Novo Nordisk
Susan Zalenski, J&J
Carmen Oliver, Biogen Idec
Jay Parsons, Pfizer
LeAnn Bell, KHI
Pat Hubbell
Keith Gulley, Allergan
Scott Maurice, Boehringer

		Ingelheim Scott Edelhauser, Alcon Carol Curtis, Astra-Zeneca Fred Davids, Stormont Vail Brad Willie, Novartis Jim Fowler, Astra Zeneca Mike Hauger, Genentech
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Kevin Waite called the meeting to order at 10:04am.	
A. Announcements	Dr. Waite advised that if anyone is going to talk, a conflict of interest disclosure would need to be filled out. Dr. Ellermeier advised where individuals should park.	
II. Old Business A. Review and Approval of April 10, 2013 DUR Meeting Minutes	Dr. Melton pointed out one change to the minutes, in that criteria had been added to the minutes, due to requests presented. They will be posted on website if and when the board approves the minutes.	Ms. Dowd made motion to accept. Dr. Heston made 2 nd . Minutes approved unanimously.
B. Tabled PA Criteria 1. Restasis® (cyclosporine ophthalmic emulsion) i. PA Criteria ii. *Public Comment iii. Board Discussion	Background Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. The DUR board tabled this topic at the April 2013 DUR meeting after a discussion regarding the concurrent use of other agents when beginning therapy with Restasis. The prior authorization criteria have been updated to allow patients to use other therapies for the first 3 months of Restasis therapy.	Dr. Heston made motion to approve PA criteria Dr. Kollhoff 2 nd motion Board passed.

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	<p>CRITERIA FOR INITIAL APPROVAL must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of keratoconjunctivitis sicca (dry eyes) • Patient must be 16 years of age or older • Must be prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist <p>LENGTH OF INITIAL APPROVAL 3 months</p> <p>CRITERIA FOR RENEWAL must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must not be using ophthalmic anti-inflammatory drugs <p>LENGTH OF RENEWAL APPROVAL 12 months</p> <p><u>Public Comment</u></p> <p>Jennifer Dabrowski, Allergan, retired comment unless there are questions.</p> <p>Dr. Melton advised that Jennifer had been working with Nicole, Lisa and herself that points out some key discussion points that has been provided to the board as well.</p> <p><u>Board Discussion</u></p> <p>No Board Discussion</p>	
<p>III. New Business</p> <p>A. KanCare PA Criteria and Limitation Overview</p> <p>1. Sunflower</p>	<p><u>Background</u>, Tom Kaye, Sunflower State Health Plan, went through a Power Point presentation of the DUR guidelines for Sunflower State Health Plan.</p>	
<p>A. New Preferred Drug List (PDL) Class</p> <p>1. Allergic Rhinitis Combination Products</p> <p>i. Non-Preferred PDL PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>In March 2013, the PDL Committee approved the addition of “Allergic Rhinitis Combination Products” 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. Kollhoff moved to approve the criteria.</p> <p>Ms. Dowd seconded.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<div data-bbox="531 139 1633 386" style="border: 1px solid black; padding: 5px;"> <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: _____ _____ <input type="checkbox"/> Patient has had an inadequate response to preferred drug. Name of preferred agent patient tried: _____ _____ <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: _____ _____ </div> <p data-bbox="531 418 768 448"><u>No Public Comment</u></p> <p data-bbox="531 480 774 509"><u>No Board Discussion</u></p>	
<p data-bbox="111 548 464 784">2. Anticholinergics for Maintenance Treatment of COPD i. Non-Preferred PDL PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p data-bbox="531 548 667 578"><u>Background</u></p> <p data-bbox="531 610 1619 740">In March 2013, the PDL Committee approved the addition of “Anticholinergics for Maintenance Treatment of COPD” 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 data-bbox="531 773 1633 1019" style="border: 1px solid black; padding: 5px;"> <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: _____ _____ <input type="checkbox"/> Patient has had an inadequate response to preferred drug. Name of preferred agent patient tried: _____ _____ <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: _____ _____ </div> <p data-bbox="531 1052 768 1081"><u>No Public Comment</u></p> <p data-bbox="531 1114 774 1143"><u>No Board Discussion</u></p>	<p data-bbox="1661 548 2018 610">Dr. Kollhoff moved to approve the criteria.</p> <p data-bbox="1661 643 1902 672">Ms. Dowd seconded.</p> <p data-bbox="1661 704 1881 766">The motion passed unanimously.</p>
<p data-bbox="90 1187 436 1390">B. Prior Authorization Criteria Revisions 1. Ilaris® (canakinumab) i. Revised PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p data-bbox="531 1187 667 1216"><u>Background</u></p> <p data-bbox="531 1248 1598 1346">In May 2013, the Food and Drug Administration (FDA) expanded the labeled indications for Ilaris to include the treatment of systemic juvenile idiopathic arthritis. Revised prior authorization criteria are being proposed to include this new indication.</p>	<p data-bbox="1661 1187 2007 1248">Ms. Dowd moved to approve the PA criteria.</p> <p data-bbox="1661 1281 1902 1310">Dr. Unruh seconded.</p> <p data-bbox="1661 1343 1881 1404">The motion passed unanimously.</p>

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	<p>CRITERIA FOR CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of CAPS, including: <ul style="list-style-type: none"> ○ Familial Cold Autoinflammatory Syndrome (FCAS) ○ Muckle-Wells Syndrome (MWS) • Patient must be 4 years of age or older • Patient must have an evaluation for latent tuberculosis (TB) with a TB skin test prior to initial prior authorization approval • Patient must not be taking another IL-1 blocking agent or biologic agent (see attached table) within the past 30 days • Quantity limit of one vial (180mg) every 8 weeks <p>CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of active, systemic juvenile idiopathic arthritis • Must be prescribed by or in consultation with a rheumatologist or dermatologist • Patient must have an evaluation for latent TB with a 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 <p>LENGTH OF APPROVAL 1 year 6 months</p> <p><u>Public Comment</u></p> <p>Jared Lurk, Novartis, reiterated what Dr. Ellermeier stated about Ilaris, and stated that he agrees with the prior authorization criteria. He also stated that the indication was approved after an accelerated review, and that it is the only treatment FDA-approved for the treatment of JIA that is available as a once-monthly subcutaneous injection.</p> <p><u>No Board Discussion</u></p>	
<p>2. Promacta® (eltrombopag)</p> <ol style="list-style-type: none"> i. Revised PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>In November 2012, the FDA expanded the labeled indications for Promacta® to include treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Revised prior authorization criteria are being proposed to include this new indication.</p>	<p>Dr. Heston moved to approve the revised Promacta® criteria.</p> <p>Dr. Unruh seconded.</p> <p>The motion passed unanimously.</p>

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	<p>CRITERIA FOR CHRONIC IMMUNE, IDIOPATHIC THROMBOCYTOPENIA (ITP) <u>Must</u> meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic immune, idiopathic thrombocytopenia • Patient must have had an inadequate response to one of the following <ul style="list-style-type: none"> ○ Corticosteroids ○ Immunoglobulins ○ Splenectomy • Patient must be 18 years of age or older • Must be prescribed by or consultation with a hematologist or oncologist • Patient must be enrolled in PROMACTA CARES • Must be prescribed by a provider enrolled in PROMACTA CARES <p>CRITERIA FOR THROMBOCYTOPENIA IN HEPATITIS C <u>Must</u> meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C with thrombocytopenia • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist <p>LENGTH OF APPROVAL 6 months</p> <p><u>No Public Comment</u></p> <p><u>No Board Discussion</u></p>	
<p>3. Simponi® (golimumab)</p> <p>i. Revised PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>In May 2013, the FDA expanded the labeled indications for Simponi to include the treatment of adults with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine. Revised prior authorization criteria are being proposed to include this new indication.</p>	<p>Ms. Dowd move to approve the revised Simponi® criteria.</p> <p>Dr. Heston seconded.</p> <p>The motion passed unanimously.</p>

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	<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 moderate to severe, active rheumatoid arthritis • Must be given in combination with methotrexate, unless patient has a contraindication to methotrexate • Must be prescribed by or in consultation with a rheumatologist • Patient must have an evaluation for latent tuberculosis (TB) with a 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 active psoriatic arthritis • Must be prescribed by or in consultation with a rheumatologist or dermatologist • Patient must have an evaluation for latent TB with a 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 active Ankylosing spondylitis • Must be prescribed by or in consultation with a rheumatologist • Patient must have an evaluation for latent TB with a 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 	

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	<p>CRITERIA FOR ULCERATIVE COLITIS (UC) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of moderate to severe, active ulcerative colitis • Patient must meet one of the following <ul style="list-style-type: none"> ○ Patient has had an inadequate response to or failed to tolerate one of the following <ul style="list-style-type: none"> ▪ oral aminosalicylates ▪ oral corticosteroids ▪ azathioprine ▪ 6-mercaptopurine ○ Patient has an inability to taper corticosteroids without a return of the symptoms of UC (i.e., patient is corticosteroid dependent) • Patient must have an evaluation for latent TB with a 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>Kathleen Karnik, Janssen Pharmaceuticals, stated that she agrees with the PA criteria and was available for any questions.</p> <p>No Board Discussion</p>	
<p>4. Tuberculosis Agents (aminosalicylate sodium, aminosalicylic acid (Paser Granules®), bedaquiline (Sirturo®), capreomycin (Capstat®), cycloserine (Seromycin®), ethambutol (Myambutol®), ethionamide (Trecator®), isoniazid (Niazid®, Nydravid®), isoniazid/pyridoxine (Niazid-B6®), pyrazinamide, rifabutin (Mycobutin®), rifampin (Rifadin®, Rimactane®), rifampin/isoniazid (Isonarif®,</p>	<p>Background</p> <p>Agents used to treat tuberculosis have required a prior authorization since 1997 to ensure that patients being treated for tuberculosis are being treated by the health department. In 2012 a new agent for the treatment of tuberculosis, Sirturo, was approved. The prior authorization criteria for tuberculosis agents are being revised to condense all agents into one criteria set and include the new agent, Sirturo.</p> <p>CRITERIA FOR TUBERCULOSIS AGENTS Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must not have a diagnosis of <i>Mycobacterium tuberculosis</i> • All prescriptions written for indications other than <i>Mycobacterium tuberculosis</i> will be authorized for the length of time requested by the prescriber <p>NOTE: Medications for the treatment of TB can be obtained from the Department of Health and Environment</p>	<p>Dr. Unruh moved to approve the criteria.</p> <p>Ms. Dowd seconded.</p> <p>The motion passed unanimously.</p>

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<p>Rifamate®), rifampin/isoniazid/pyrazinamide (Rifater®), rifapentine (Priftin®))</p> <p>i. Revised PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>No Public Comment</p> <p>Board Discussion</p> <p>Ms. Dowd asked why patients were required to go through the Health Department. Dr. Melton stated that the Health Department has a program set up wherein they pay for TB medications. She also stated that the pharmacy program consulted with the part of KDHE that manages this program to ensure that they were adding the new drugs. She also explained that a patient can go to their local health department and confirm their tuberculosis diagnosis. The state Health Department mails those medications to the local Health Department, which also allows TB drug shortages to be better managed.</p>	
<p>C. New Prior Authorization Criteria</p> <p>1. Marinol® (dronabinol)</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background</p> <p>In May 2009, the DUR board approved override criteria for patients taking doses above 20mg per day of Marinol. The criteria are being revised to require prior authorization on all Marinol prescriptions, regardless of dose. Prior authorization criteria are being proposed based upon appropriate diagnoses and prescriber specialty.</p> <div data-bbox="527 769 1629 1159" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION: (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"> ○ Intractable nausea associated with cancer chemotherapy ○ Anorexia associated with weight loss in patients with AIDS • Must be prescribed by or in consultation with an oncologist or HIV specialist • Doses ≤ 20mg/day have been trialed and found to be ineffective for nausea control • Dose must not exceed 30mg/day <p>CRITERIA FOR RENEWAL: (must meet one of the following)</p> <ul style="list-style-type: none"> • Patients with a diagnosis of AIDS wasting must have continued wasting based on reductions of BMI • Patients with nausea associated with cancer chemotherapy must have continued nausea associated with cancer chemotherapy <p>LENGTH OF APPROVAL 6 months</p> </div> <p>No Public Comment</p> <p>Board Discussion</p> <p>Dr. Heston stated that he'd like to see this be available for use in elderly care. While he has never personally had a case that Remeron and Megace could not take care of, it may be something to consider for this population.</p> <p>Dr. Ellermeier stated that the MCOs can speak more specifically to their plans, but that in</p>	<p>Dr. Heston moved to approve the revised dronabinol criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>

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	<p>general for indications not supported by the package insert, an appeals process is available to the prescriber. For unlabeled indications, the prescriber could submit documentation from the compendia or studies that support a drug's use, which the state would then review on a case-by-case basis.</p> <p>Dr. Melton also mentioned that if a patient is elderly and has Medicare Part D, this PA would not be required if Medicare has paid primary.</p>	
<p>2. Xeljanz® (tofacitinib)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Background</p> <p>Xeljanz is a new biologic agent used for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. Prior authorization criteria are being proposed to remain consistent among all biologic agents and to ensure appropriate use based on FDA-approved labeling information.</p> <div style="border: 1px solid black; padding: 5px;"> <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 moderate to severe, active rheumatoid arthritis • Patient must have had an inadequate response or intolerance to methotrexate • Must be prescribed by or in consultation with a rheumatologist • Patient must have an evaluation for latent tuberculosis (TB) with a TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken a biologic agent (see attached table) in the past 30 days • Patient must have had the following labs checked prior to initial prior authorization <ul style="list-style-type: none"> ○ lymphocyte count ○ absolute neutrophil count (ANC) ○ hemoglobin <p>RENEWAL CRITERIA FOR RA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have the following labs checked every 3 months <ul style="list-style-type: none"> ○ lymphocyte count ○ ANC ○ hemoglobin <p>LENGTH OF INITIAL AND RENEWAL APPROVAL 6 months</p> </div> <p>Public Comment</p> <p>Phil King, Pfizer, stated that they have no concerns with the criteria, but that Xeljanz is not a</p>	<p>Ms. Dowd moved to approve the Xeljanz® criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>

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	<p>biologic agent, but a Janus Kinase Inhibitor, which means it targets an intracellular signaling pathway.</p> <p><u>Board Discussion</u></p> <p>Ms. Dowd asked if the length of the initial and renewal approvals was consistent with other mediations used to treat Rheumatoid Arthritis. Dr. Melton stated that it was.</p>	
<p>3. Rilutek® (riluzole)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Rilutek is indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS). Rilutek has been used off-label for various other diagnoses, but there is no information to support the off-label use of this medication in the compendia. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div data-bbox="527 626 1547 894" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of amyotrophic lateral sclerosis • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a neurologist <p>LENGTH OF APPROVAL 6 months</p> </div> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>Ms. Dowd asked if it was FDA-approved only for ALS, and Dr. Waite stated that is its only approved indication, but that there is off-label use seen in neurologic conditions.</p>	<p>Dr. Kollhoff moved to approve the Rilutek® criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>4. Xifaxan® (rifaximin)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Xifaxan is a rifamycin antibacterial indicated for the treatment of travelers' diarrhea in patients 12 years of age and older caused by noninvasive strains of <i>Escherichia coli</i> and to reduce the risk of overt hepatic encephalopathy recurrence in patients 18 years of age and older. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Heston moved to approve the Xifaxan® criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR HEPATIC ENCEPHALOPATHY: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of hepatic failure • Patient has had a previous episode of hepatic encephalopathy • Patient must be ≥18 years of age <p>LENGTH OF APPROVAL 12 months</p> <p>CRITERIA FOR TRAVELERS' DIARRHEA: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient must be ≥12 years of age • Patient must have a positive culture and susceptibility for noninvasive strain(s) of <i>Escherichia coli</i> • Patient does not have diarrhea complicated by fever or blood in the stool • Patient does not have diarrhea due to pathogens other than <i>E. coli</i> <p>LENGTH OF APPROVAL 30 days</p> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p>	
<p>5. Aubagio® (teriflunomide)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Aubagio was approved in late 2012 for the treatment of patients with relapsing forms of multiple sclerosis. In October 2012, the DUR board approved prior authorization criteria for multiple sclerosis agents. Prior authorization criteria are being proposed to remain consistent with other multiple sclerosis treatments and to ensure appropriate use based on FDA-approved labeling information.</p> <p>CRITERIA FOR MULTIPLE SCLEROSIS (MS) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple sclerosis • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a neurologist • Patient must not take leflunomide concurrently • Female patients must use contraception concurrently with Aubagio and must have a negative pregnancy test within 30 days prior to initiation of therapy • Patient must be evaluated for latent tuberculosis (TB) with a TB skin test prior to initial prior authorization approval • Dose should not exceed 1 tablet per day <p>LENGTH OF APPROVAL 1 year</p> <p><u>No Public Comment</u></p>	<p>Ms. Dowd moved to approve the Aubagio® criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><u>Board Discussion</u></p> <p>Ms. Dowd asked if a negative pregnancy test was required within a certain timeframe on any other medications. Dr. Ellermeier stated that this was required for other medications. Dr. Waite stated that it begs the question if there needs to be language included about the concurrency of the test. Dr. Ellermeier stated that language could be included that specifies the timeframe within which a patient must have had a negative pregnancy test.</p>	
<p>6. Tecfidera® (dimethyl fumarate)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Tecfidera was approved in 2013 for the treatment of patients with relapsing forms of multiple sclerosis. In October 2012, the DUR board approved prior authorization criteria for multiple sclerosis agents. Prior authorization criteria are being proposed to remain consistent with other multiple sclerosis treatments and ensure appropriate use based on FDA-approved labeling information.</p> <div data-bbox="527 670 1388 979" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR MULTIPLE SCLEROSIS (MS) Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of multiple sclerosis • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a neurologist • Dose should not exceed 2 capsules per day <p>LENGTH OF APPROVAL 1 year</p> </div> <p><u>No Public Comment</u></p> <p><u>No Board Discussion</u></p>	<p>Dr. Heston moved to approve the Tecfidera® criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>7. H.P. Acthar Gel® (repository corticotropin)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>H.P. Acthar Gel is indicated for use in infantile spasms, multiple sclerosis, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, and edematous state. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information and current evidence in the literature.</p>	<p>Dr. Unruh moved to approve the H.P. Acthar Gel® criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR INFANTILE SPASMS: (must meet all of the following)</p> <ul style="list-style-type: none"> ▪ Patient has a diagnosis of infantile spasms ▪ Prescribed by or in consultation with a neurologist ▪ Patient is ≤ 2 years of age <p>CRITERIA FOR MULTIPLE SCLEROSIS: (must meet all of the following)</p> <ul style="list-style-type: none"> ▪ Patient has a diagnosis of multiple sclerosis ▪ Prescribed by or in consultation with a neurologist <p>CRITERIA FOR RHEUMATIC DISORDERS: (must meet all of the following)</p> <ul style="list-style-type: none"> ▪ Patient has one of the following diagnoses: <ul style="list-style-type: none"> ○ psoriatic arthritis ○ rheumatoid arthritis ○ juvenile rheumatoid arthritis ○ ankylosing spondylitis ▪ Prescribed by or in consultation with a rheumatologist <p>CRITERIA FOR COLLAGEN DISEASES: (must meet all of the following)</p> <ul style="list-style-type: none"> ▪ Patient has one of the following diagnoses: <ul style="list-style-type: none"> ○ systemic lupus erythematosus ○ systemic dermatomyositis (polymyositis) ▪ Prescribed by or in consultation with a rheumatologist <p>CRITERIA FOR DERMATOLOGIC DISORDERS: (must meet all of the following)</p> <ul style="list-style-type: none"> ▪ Patient has one of the following diagnoses: <ul style="list-style-type: none"> ○ erythma multiforme ○ Stevens-Johnson syndrome ▪ Prescribed by or in consultation with a dermatologist <p>CRITERIA FOR ALLERGIC STATES: (must meet all of the following)</p> <ul style="list-style-type: none"> ▪ Patient has a diagnosis of serum sickness ▪ Prescribed by or in consultation with an allergist or immunologist 	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR OPHTHALMIC DISEASES: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has one of the following diagnoses: <ul style="list-style-type: none"> o keratosis o iritis o iridocyclitis o diffuse posterior uveitis and choroiditis o optic neuritis o chorioretinitis o anterior segment inflammation • Prescribed by or in consultation with an optometrist or ophthalmologist <p>CRITERIA FOR RESPIRATORY DISEASES: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has a diagnosis of sarcoidosis • Prescribed by or in consultation with a pulmonologist <p>CRITERIA FOR EDEMATOUS STATE: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has proteinuria in the nephritic syndrome without uremia of the idiopathic type or that due to lupus erythematosus • Prescribed by or in consultation with a rheumatologist or nephrologist <p>LENGTH OF APPROVAL 12 months</p> <p><u>No Public Comment</u></p> <p><u>No Board Discussion</u></p>	
<p>8. Incivek® (telaprevir)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Incivek is a hepatitis C virus NS3/4A protease inhibitor indicated, in combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Kollhoff moved to approve the amended Incivek criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR INITIAL PRIOR AUTHORIZATION Must meet all of the following:</p> <p><i>*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of 12 weeks of Incivek therapy total)*</i></p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C • Patient must have genotype 1 hepatitis C • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Incivek must be used in combination with peginterferon alfa and ribavirin • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Incivek • Patient must not have been on previous hepatitis C protease inhibitor therapy (i.e. previous trial with Victrelis or Incivek) • Dose must not exceed 6 tablets per day <p>LENGTH OF INITIAL APPROVAL 12 weeks</p> <p>Ribavirin and Peginterferon alfa are approved when using triple therapy with Incivek if Incivek criteria are met</p> <p>DISCONTINUATION CRITERIA</p> <ul style="list-style-type: none"> • Provider must submit HCV RNA level after treatment week 4 within 7 days to prevent discontinuation of therapy • Therapy will be discontinued if the HCV RNA level is above 1,000 IU/mL after treatment week 4 <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>Dr. Waite mentioned that the '30 days' pregnancy language should be added to this criteria as well.</p> <p>Dr. Melton mentioned that one of the issues that has come up when reviewing the Incivek and Victrelis criteria with the companies that own them is the idea of some kind of grace period to make sure patients are not going without therapy, or just approving one initial PA so that patients are not required to complete renewal PAs. Dr. Melton suggested that the board and MCOs look in to the feasibility of building in a 2-3 week grace period while the PA is in being reviewed to ensure that a patient does not get the initial 4 weeks of therapy, and then has an interruption in therapy while their renewal PA is being reviewed.</p> <p>Eric Gardner, Vertex, stated that there have been quite a few health plans that have allowed</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>the initial approval to be 5 weeks to allow the HCV-RNA test to come back to the doctor, which is another consideration to avoid stoppage in therapy. He also mentioned that this is true especially because the drug is required to go through specialty pharmacy.</p> <p>Ms. Todd stated that if, for some reason the PA cannot be approved, a 72-hour supply is approved. Dr. Melton stated that the consideration she'd like to see incorporated is for the 'worst case' scenario whereby the patient's therapy would not be interrupted even if they ran into issues getting prior authorization.</p> <p>Dr. Kollhoff asked Mr. Gardner how Incivek was provided. Gardner stated that it was provided as a 4-week therapy dosepack, but that specialty pharmacies can break this down to a weekly dose.</p> <p>Dr. Melton stated that with the HCV agents, you will frequently see patients discontinue therapy due to side effects, which brings into question the necessity of renewal criteria.</p> <p>Dr. Kollhoff asked if there was any way to have the PA renewal be contingent on the lab draw. Dr. Melton stated that some other states will authorize the drug from the beginning, and then the providers are required to submit lab values, but the drug is not waiting for PA while this is in process. If the plan is not seeing continued lab draws by the prescriber, they could end date the PA.</p> <p>Dr. Waite asked the MCO representatives if they were comfortable approving the PA for 12 weeks up front and then checking a lab value at 5 weeks. Dr. Melton stated that the follow-up criteria could be called 'discontinuation criteria' since the MCO would end-date the PA if they did not receive follow-up lab information from the prescriber.</p> <p>The criteria was amended to include the discussed changes.</p> <p>The board later returned to the Incivek criteria to add a statement regarding the automatic approval of ribavirin and pegylated interferon when used as triple therapy. A motion to approve this amendment was made by Ms. Dowd and seconded by Dr. Heston. The motion passed unanimously.</p> <p>The board later returned to the Incivek criteria again to add an infectious disease specialist as a prescriber. A motion to approve this amendment was made by Ms. Dowd and seconded by Dr. Unruh. The motion passed unanimously.</p>	
<p>9. Victrelis® (boceprevir) i. PA Criteria</p>	<p><u>Background</u></p>	<p>Dr. Kollhoff moved to approve</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
ii. *Public Comment iii. Board Discussion	<p>Victrelis is a hepatitis C virus NS3/4A protease inhibitor indicated, in combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C. 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 INITIAL PRIOR AUTHORIZATION Must meet all of the following:</p> <p><i>*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of 44 weeks of Victrelis therapy total)*</i></p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C • Patient must have genotype 1 hepatitis C • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Victrelis must be used in combination with peginterferon alfa and ribavirin • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Victrelis • Patient must not have been on previous hepatitis C protease inhibitor therapy (i.e. previous trial with Victrelis or Incivek) • Dose must not exceed 12 capsules per day <p>LENGTH OF INITIAL APPROVAL 44 weeks</p> <p>Ribavirin and Peginterferon alfa are approved when using triple therapy with Victrelis if Victrelis criteria are met</p> <p>DISCONTINUATION CRITERIA</p> <ul style="list-style-type: none"> • Provider must submit HCV RNA level after treatment week 12 and 24 within 7 days to prevent discontinuation of therapy • Therapy will be discontinued if the HCV RNA level is above 100 IU/mL after treatment week 12 or if the HCV RNA level is detectable after treatment week 24 </div> <p>Public Comment</p> <p>Matt Stafford, Merck, asked that consideration be given to make this criteria consistent with the requirements outlined for Incivek. Stafford noted that the board had a copy of a PA criteria guide. He stated that indications and contraindications were captured well, but the length of initial approval should be reviewed to potentially allow for up to 44 weeks of therapy based on the patient profile. In terms of discontinuation steps, Stafford stated that the futility rules should be considered based on lab values at weeks 12 and 24. Stafford also stated that the pregnancy language should be made consistent with that of the previously</p>	<p>the amended Victrelis criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>reviewed criteria.</p> <p>Dr. Melton asked Mr. Stafford what rates are seen for patients completing the entire course of therapy that they are eligible for. Stafford stated that those patient who have an SVR response rate at the initial test, as many as 85-90% of patients will go on to have success. He also said that depending on initial response rates and the patient type (prior, null, partial responder or relapser), it varies anywhere from 40-71%.</p> <p>Stafford stated that what they see in other states is typically an initial approval, and then prescribers typically discontinue therapy for those patients without an SVR or with side effects.</p> <p><u>Board Discussion</u></p> <p>Dr. Ellermeier offered to update the ‘negative pregnancy test with 30 days’ criteria. Changes were also made to the criteria to clarify the meaning of a ‘treatment naïve’ patient.</p> <p>Dr. Melton stated that maybe the criteria may not even need to be reflective of the various patient types to allow for prescriber discretion and avoid the potential for complications.</p> <p>Matt Stafford, Merck, stated that many payers allow for the approval of Victrelis in conjunction with the pegylated interferon and ribavirin, such that all 3 are approved for the duration of therapy at the onset.</p> <p>Dr. Melton suggested that the criteria be condensed similar to Incivek, such that discontinuation criteria could be built in at weeks 13 and 25.</p> <p>Dr. Kollhoff suggested that it would be most effective to have pegylated interferon and ribavirin PAs approved in conjunction with Victrelis. Dr. Heston added that a Victrelis approval should automatically approve ribavirin and pegylated interferon.</p> <p>Dr. Melton asked if it would be possible to have a PA form for Incivek and Victrelis that could include what interferon and ribavirin products the prescriber would like to use, which would then automatically be approved by virtue of being used with Incivek and Victrelis. Tom Kaye, Sunflower State Health Plan, stated that he believed the best approach to be an up-front approval for all agents, with the pharmacy dispensing each drug as necessary.</p> <p>Dr. Ellermeier stated that for the interferons that are used in triple therapy, a criteria piece could be added that states they will be approved if Incivek or Victrelis are approved.</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Ms. Dowd stated that she was interested in seeing criteria from other states, and Stafford provided an example of Nebraska’s criteria.</p> <p>Dr. Kollhoff mentioned that there could still be complications with separate PA forms and separate approvals. Dr. Melton agreed that the PAs would all have to be done up front.</p> <p>Mr. Kaye mentioned that having a hepatologist or gastroenterologist prescribe the drug is key, as they are familiar with the regimens. Dr. Melton added that there are few enough of these prescribers that the MCOs could send out information that explains how the Prior Authorization for these agents would work.</p> <p>Dr. Kollhoff asked if a notation could be put on the interferon form that directs them to the Incivek or Victrelis criteria if it is being used for HCV triple therapy.</p> <p>The discussed changes to the criteria were made (pregnancy testing, length of initial approval, removal of renewal criteria, request for triple therapy being automatically completed, and discontinuation criteria).</p> <p>The board later returned to the Victrelis criteria to add an infectious disease specialist as a prescriber. A motion to approve this amendment was made by Ms. Dowd and seconded by Dr. Kollhoff. The motion passed unanimously.</p>	
<p>10. Pegasys® (peginterferon alfa-2a)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Pegasys is an antiviral indicated for the treatment of chronic hepatitis C. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Kollhoff moved to approve the Pegasys® criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR CHRONIC HEPATITIS B Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis B • Patient must have been serum HBsAg positive for at least 6 months • Patient must have evidence of HBV replication defined as one of the following <ul style="list-style-type: none"> ○ HBeAg positive patients – HBV DNA level >20,000 IU/mL ○ HBeAg negative patients – HBV DNA level ≥2,000 IU/mL • Patient must have evidence of active liver disease demonstrated by one of the following <ul style="list-style-type: none"> ○ persistent elevation in serum ALT (≥2 times upper limits of normal) ○ moderate to severe hepatitis or fibrosis on biopsy ○ evidence of icteric ALT flare ups • Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist • Patient must be 18 years of age or older • Patient must not have decompensated liver disease • Patient has not previously completed a full course of therapy with interferon or peginterferon <p>LENGTH OF APPROVAL FOR CHRONIC HEPATITIS B 48 weeks</p> <p>CRITERIA FOR INITIAL APPROVAL FOR CHRONIC HEPATITIS C (DOES NOT APPLY TO PATIENTS USING TRIPLE THERAPY)</p> <p>Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C • Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist • Patient must be 5 years of age or older • Patient has a detectable hepatitis C viral level (HCV RNA) in the serum • Patient is positive for HCV antibodies • Patient must not have decompensated liver disease • Must be taken in combination with ribavirin unless patient has a contraindication or intolerance to ribavirin therapy • Patient has not been previously treated with interferon alfa <p>RENEWAL CRITERIA FOR CHRONIC HEPATITIS C Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have an undetectable HCV-RNA at week 24 <p>LENGTH OF APPROVAL FOR CHRONIC HEPATITIS C 24 weeks (up to 48 weeks of total therapy)</p> <p>WHEN USED WITH TRIPLE THERAPY PATIENT MUST MEET CRITERIA FOR PROTEASE INHIBITOR FOR APPROVAL OF PEGASYS</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>The criteria was amended to include a statement regarding use in triple therapy.</p> <p>Dr. Kollhoff asked the MCOs if a check could be built in to ask for use in triple therapy as the first question of the criteria.</p>	
<p>11. PegIntron® (peginterferon alfa-2b)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>PegIntron is indicated as monotherapy, dual therapy, or triple therapy for the treatment of chronic hepatitis C. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Ms. Dowd moved to approve the PegIntron® criteria.</p> <p>Dr. Heston seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>RENEWAL CRITERIA FOR TREATMENT NAÏVE PATIENT ON PEGINTRON/RIBAVIRIN Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have an undetectable HCV-RNA at week 24 • Patients with genotype 1 may be approved for up to 48 weeks of therapy • Patients with genotypes 2 and 3 may be approved for up to 24 weeks of therapy <p>LENGTH OF APPROVAL FOR TREATMENT NAÏVE PATIENT ON PEGINTRON/RIBAVIRIN 12 weeks (up to a total of 48 weeks of therapy)</p> <p>RENEWAL CRITERIA FOR RETREATMENT WITH PEGINTRON/RIBAVIRIN Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have an undetectable HCV-RNA at weeks 12 and 24 <p>LENGTH OF APPROVAL FOR RETREATMENT WITH PEGINTRON/RIBAVIRIN 12 weeks (up to a total of 48 weeks of therapy)</p> <p>RENEWAL CRITERIA FOR PEDIATRIC PATIENT ON PEGINTRON/RIBAVIRIN Must meet all of the following:</p> <ul style="list-style-type: none"> • Patients with genotype 1 may be approved for up to 48 weeks of therapy • Patients with genotypes 2 and 3 may be approved for up to 24 weeks of therapy <p>LENGTH OF APPROVAL FOR PEDIATRIC PATIENT ON PEGINTRON/RIBAVIRIN 12 weeks (up to a total of 48 weeks of therapy)</p> <p>RENEWAL CRITERIA FOR PEGINTRON MONOTHERAPY Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have an undetectable HCV-RNA at week 24 <p>LENGTH OF APPROVAL FOR PEGINTRON MONOTHERAPY 12 weeks (up to a total of 52 weeks of therapy)</p> <p>IF PATIENT IS USING PEGINTRON FOR TRIPLE THERAPY PROTEASE INHIBITOR CRITERIA MUST BE APPROVED</p> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>The criteria was amended to include a statement regarding use in triple therapy.</p> <p>Ms. Dowd asked if the treatment naïve language in this criteria could be eliminated to clean the criteria up. Dr. Ellermeier explained that, while triple therapy criteria could be removed, criteria for other patient types should probably remain to guide the length of therapy.</p> <p>Dr. Waite noted that infectious disease prescribers are allowed to prescribe these agents,</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>which is a specialty that was left off of the Incivek and Victrelis criteria. Dr. Ellermeier stated that most Hepatitis C patients see gastroenterologists, but it may be wise to include infectious disease prescribers.</p>	
<p>12. Infergen® (interferon alfacon-1) i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background</p> <p>Infergen is indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease. 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 INITIAL APPROVAL FOR CHRONIC HEPATITIS C Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of chronic hepatitis C • Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist • Patient must be 18 years of age or older • Patient has a detectable hepatitis C viral level (HCV RNA) in the serum • Patient is positive for HCV antibodies • Patient must not have decompensated liver disease <p>RENEWAL CRITERIA FOR CHRONIC HEPATITIS C Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have an undetectable HCV-RNA at week 24 and one of the following <ul style="list-style-type: none"> ○ Patient is on monotherapy with Infergen and tolerated previous interferon therapy and did not respond or relapsed following its discontinuation <ul style="list-style-type: none"> ▪ May be approved for up to 48 weeks of total therapy ○ Patient is on combination treatment with Infergen and ribavirin <ul style="list-style-type: none"> ▪ May be approved for up to 48 weeks of total therapy <p>LENGTH OF APPROVAL FOR CHRONIC HEPATITIS C 24 weeks (up to 48 weeks of total therapy)</p> </div> <p><u>No Public Comment</u></p> <p><u>No Board Discussion</u></p>	<p>Ms. Dowd moved to approve the Infergen® criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>
<p>13. Intron® A (interferon alfa-2b) i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p>Background</p> <p>Intron A is indicated in hairy cell leukemia, malignant melanoma, follicular lymphoma, condylomata acuminata, AIDS-related Kaposi's sarcoma, chronic hepatitis C, and chronic hepatitis B. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Heston moved to approve the Intron® A criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR HAIRY CELL LEUKEMIA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of hairy cell leukemia • Must be prescribed by or in consultation with an oncologist • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL FOR HAIRY CELL LEUKEMIA 1 year</p> <p>CRITERIA FOR MALIGNANT MELANOMA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of malignant melanoma • Must be prescribed by or in consultation with an oncologist • Patient must be 18 years of age or older • Patient must have had surgery within 56 days of treatment with Intron A <p>LENGTH OF APPROVAL FOR MALIGNANT MELANOMA 1 year</p> <p>CRITERIA FOR FOLLICULAR LYMPHOMA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of follicular lymphoma • Must be prescribed by or in consultation with an oncologist • Patient must be 18 years of age or older • Must be used in combination with anthracycline-containing chemotherapy <p>LENGTH OF APPROVAL FOR FOLLICULAR LYMPHOMA 1 year</p> <p>CRITERIA FOR CONDYLOMATA ACUMINATA Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of condylomata acuminata • Must be prescribed by or in consultation with a dermatologist or infectious disease specialist • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL FOR COBDYLOMATA ACUMINATA 1 year</p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR AIDS-RELATED KAPOSI'S SARCOMA Must meet all of the following:</p> <ul style="list-style-type: none"> ▪ Patient must have a diagnosis of AIDS-related Kaposi's sarcoma ▪ Must be prescribed by or in consultation with an oncologist or infectious disease specialist ▪ Patient must be 18 years of age or older <p>LENGTH OF APPROVAL FOR AIDS-RELATED KAPOSI'S SARCOMA 1 year</p> <p>CRITERIA FOR CHRONIC HEPATITIS B Must meet all of the following:</p> <ul style="list-style-type: none"> ▪ Patient must have a diagnosis of chronic hepatitis B ▪ Patient must have been serum HBsAg positive for at least 6 months ▪ Patient must have evidence of HBV replication defined as one of the following <ul style="list-style-type: none"> ○ HBeAg positive patients – HBV DNA level >20,000 IU/mL ○ HBeAg negative patients – HBV DNA level ≥2,000 IU/mL ▪ Patient must have evidence of active liver disease demonstrated by one of the following <ul style="list-style-type: none"> ○ persistent elevation in serum ALT (≥2 times upper limits of normal) ○ moderate to severe hepatitis or fibrosis on biopsy ○ evidence of icteric ALT flare ups ▪ Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist ▪ Patient must be 1 year of age or older ▪ Patient must not have decompensated liver disease ▪ Patient has not previously completed a full course of therapy with interferon or peginterferon <p>LENGTH OF APPROVAL FOR CHRONIC HEPATITIS B 24 weeks (patients <18 years of age) 16 weeks (patients ≥18 years of age)</p> <p><u>No Public Comment</u></p> <p><u>No Board Discussion</u></p>	
<p>14. Sylatron® (peginterferon alfa-2b)</p> <ul style="list-style-type: none"> i. PA Criteria ii. *Public Comment iii. Board Discussion 	<p><u>Background</u></p> <p>Sylatron is indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p>	<p>Dr. Unruh moved to approve the Sylatron® criteria.</p> <p>Ms. Dowd seconded.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>CRITERIA FOR INITIAL APPROVAL Must meet all of the following:</p> <ul style="list-style-type: none"> • Patient must have a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy • Must be prescribed by or in consultation with an oncologist • Patient must be 18 years of age or older <p>LENGTH OF APPROVAL 1 year</p> <p><u>No Public Comment</u></p> <p><u>No Board Discussion</u></p>	
<p>15. Topical & Buccal Testosterone Agents (Androderm® Transdermal, AndroGel®, Axiron® Topical Solution, Fortesta® Gel, Striant® Buccal, and Testim® Gel)</p> <p>i. PA Criteria ii. *Public Comment iii. Board Discussion</p>	<p><u>Background</u></p> <p>The topical and buccal testosterone agents are indicated for androgen replacement therapy in males with primary hypogonadism and hypogonadotropic hypogonadism. Due to the risk of off-label utilization, prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <p>r. E</p> <p>CRITERIA FOR PRIOR AUTHORIZATION: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has one of the following diagnoses: <ul style="list-style-type: none"> ○ Primary hypogonadism (congenital or acquired) <ul style="list-style-type: none"> ▪ Primary hypogonadism (testicular failure) due to conditions such as (but not limited to) cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals ○ Hypogonadotropic hypogonadism (congenital or acquired) <ul style="list-style-type: none"> ▪ Hypogonadotropic hypogonadism due to (but not limited to) idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation • Patient must be a male • Patient must have serum testosterone < 300 ng/dL <p>PATIENT MUST MEET INITIAL CRITERIA FOR RENEWALS</p> <p>LENGTH OF APPROVAL 12 months</p> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>Dr. Waite asked Dr. Unruh is consideration needed to be made for pediatric prescribing. Dr. Unruh stated that pediatric endocrinologists may be prescribing this drug. Dr. Kollhoff stated that, in his experience, these are medications being prescribed by primary care doctors. Dr.</p>	<p>Dr. Heston moved to approve the amended criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Ellemeier stated that there is a language such that this can be prescribed by or in consultation with an endocrinologist. Dr. Heston questioned if the endocrinologist requirement was necessary.</p> <p>Tom Kaye stated that they see prescribing by primary care physicians, and Dr. Melton stated that some of the indications appear to be treated by primary care physicians. The endocrinologist requirement was removed from the criteria.</p>	
<p>16. Delatestryl® (testosterone enanthate injection)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Delatestryl is indicated for androgen replacement therapy in males with primary hypogonadism and hypogonadotropic hypogonadism, to stimulate puberty in males with clearly delayed puberty, and for females with advancing inoperable metastatic breast cancer. Due to the risk of off-label utilization, prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div data-bbox="527 670 1633 1263" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR MALES: (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"> ○ Primary hypogonadism (congenital or acquired) <ul style="list-style-type: none"> ▪ Primary hypogonadism (testicular failure) due to conditions such as (but not limited to) cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals ○ Hypogonadotropic hypogonadism (congenital or acquired) <ul style="list-style-type: none"> ▪ Hypogonadotropic hypogonadism due to (but not limited to) idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation ○ Delayed puberty • Patient must be a male • Patient must have serum testosterone < 300 ng/dL <p>CRITERIA FOR FEMALES: (must meet all of the following)</p> <ul style="list-style-type: none"> • Patient has a diagnosis of metastatic breast cancer • Patient must be a female • Must be prescribed by or in consultation with an oncologist or endocrinologist <p>PATIENT MUST MEET INITIAL CRITERIA FOR RENEWALS</p> <p>LENGTH OF APPROVAL 12 months</p> </div> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>Dr. Melton mentioned that the endocrinologist requirement was also on this criteria. Dr.</p>	<p>Dr. Kollhoff moved to approve the amended criteria.</p> <p>Ms. Dowd seconded the motion.</p> <p>The motion passed unanimously.</p>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Waite stated that he didn't know if this would be any different from the topical agents.</p> <p>Dr. Ellermeier suggested that the oncologist requirement could also be removed, but Ms. Dowd and Dr. Heston stated that it should remain in the criteria.</p>	
<p>17. Testopel® Pellets (testosterone)</p> <p>i. PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p><u>Background</u></p> <p>Testopel is indicated for androgen replacement therapy in males with primary hypogonadism and hypogonadotropic hypogonadism, and to stimulate puberty in males with clearly delayed puberty. Due to the risk of off-label utilization, prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.</p> <div data-bbox="527 529 1627 1008" style="border: 1px solid black; padding: 5px;"> <p>CRITERIA FOR PRIOR AUTHORIZATION: (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"> ○ Primary hypogonadism (congenital or acquired) <ul style="list-style-type: none"> ▪ Primary hypogonadism (testicular failure) due to conditions such as (but not limited to) cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals ○ Hypogonadotropic hypogonadism (congenital or acquired) <ul style="list-style-type: none"> ▪ Hypogonadotropic hypogonadism due to (but not limited to) idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation ○ Delayed puberty • Must be prescribed by or in consultation with an endocrinologist • Patient must be a male • Patient must have serum testosterone < 300 ng/dL <p>PATIENT MUST MEET INITIAL CRITERIA FOR RENEWALS</p> <p>LENGTH OF APPROVAL 12 months</p> </div> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>Tom Kaye, Sunflower, stated that they have not seen much use of this, but that it will occasionally be seen. Dr. Melton asked if this product was only available via specialty channels. Mr. Kaye reported that it is a buy-and-bill product.</p> <p>Dr. Heston asked if this medication was used in females, and Dr. Ellermeier reported that it was not.</p>	<p>Ms. Dowd moved to approve the criteria.</p> <p>Dr. Heston seconded.</p> <p>The motion passed unanimously.</p>
<p>D. Miscellaneous Items</p> <p>1. Smoking Cessation</p>	<p><u>Background</u></p>	

TOPIC	DISCUSSION	DECISION AND/OR ACTION																								
<p>Limitations</p> <p>i. Limitations</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion</p>	<p>Currently smoking cessation therapies are limited to 12-24 weeks based on the agent being used. Chantix® (varenicline) is limited to 24 weeks of therapy per year; Zyban (bupropion) and nicotine patches are limited to 12 weeks of therapy per year. Limitations need to be approved for other nicotine agents, including nicotine nasal spray, inhalers, lozenges, and gum.</p> <div data-bbox="527 342 1493 927" style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;">Smoking Cessation Product Limitations</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #4F81BD; color: white;">Product</th> <th style="background-color: #4F81BD; color: white;">Duration of Treatment</th> <th style="background-color: #4F81BD; color: white;">Quantity Limit (per day)</th> </tr> </thead> <tbody> <tr> <td>Chantix® (varenicline)</td> <td>24 weeks</td> <td>2 tablets</td> </tr> <tr> <td>Zyban® (bupropion)</td> <td>12 weeks</td> <td>2 tablets</td> </tr> <tr> <td>Nicotine Inhaler</td> <td>24 weeks</td> <td>16 cartridges</td> </tr> <tr> <td>Nicotine Patches</td> <td>12 weeks</td> <td>1 patch</td> </tr> <tr> <td>Nicotine Nasal Spray</td> <td>12 weeks</td> <td>80 sprays (4 mL)</td> </tr> <tr> <td>Nicotine Lozenges</td> <td>12 weeks</td> <td>20 lozenges</td> </tr> <tr> <td>Nicotine Gum</td> <td>12 weeks</td> <td>24 pieces</td> </tr> </tbody> </table> <p style="margin-top: 10px;">Patients will be limited to one round of treatment per 365 days of each:</p> <ul style="list-style-type: none"> Chantix Zyban Nicotine Products (inhaler, patches, nasal spray, lozenges, or gum) </div> <p><u>No Public Comment</u></p> <p><u>Board Discussion</u></p> <p>Dr. Kollhoff questioned how the limitations would work with respect to patients switching products. Dr. Ellermeier explained how each limitation would work.</p> <p>Dr. Kollhoff asked if the limitations would be on Wellbutrin as well. Dr. Melton clarified that it would not be because the state is not able to place limitations on mental health medications such as Wellbutrin.</p>	Product	Duration of Treatment	Quantity Limit (per day)	Chantix® (varenicline)	24 weeks	2 tablets	Zyban® (bupropion)	12 weeks	2 tablets	Nicotine Inhaler	24 weeks	16 cartridges	Nicotine Patches	12 weeks	1 patch	Nicotine Nasal Spray	12 weeks	80 sprays (4 mL)	Nicotine Lozenges	12 weeks	20 lozenges	Nicotine Gum	12 weeks	24 pieces	
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<p>2. Retrospective Drug Utilization Review Intervention Topic Selections</p> <p>i. Intervention Topics</p>	<p><u>Background</u></p> <p>Each year Health Information Designs, LLC performs 5 retrospective DUR interventions for the fee-for-service population. For the state fiscal year 2014, the DUR board needs to select</p>	<p>Dr. Unruh moved to select the chosen intervention topics.</p> <p>Dr. Heston seconded the topic.</p>																								

TOPIC	DISCUSSION	DECISION AND/OR ACTION
ii. *Public Comment iii. Board Discussion	5 topics for intervention. <u>No Public Comment</u> <u>Board Discussion</u> Dr. Melton clarified that these topics still apply to fee for service, but that the MCOs will have to present information on their drug utilization programs to the DUR Board annually. The topics chosen were Adverse Atypical Antipsychotic Effect, Atazanavir Drug Interaction, and Polypharmacy.	The motion passed unanimously.
3. Selection of Board Chairperson	The DUR Board is required to annually select a board chairperson. Dr. Waite is willing to serve as board chair for the next year.	Ms. Dowd moved to name Dr. Waite board chairperson. Dr. Kollhoff seconded the motion. The motion passed unanimously.
IV. Open Public Comment	<u>Public Comment</u> Carol Curtis, Astra Zeneca, asked Dr. Melton a question regarding drugs or classes that have already gone through the KAR 129-5-1 process, namely if a drug has to go through this process again if changes are made at DUR. Dr. Melton clarified that this is not the case, and that once a drug has been added to this regulation, that DUR is free to amend the PA criteria as they see fit. As a follow up question, Ms. Curtis asked when changes to PDL or DUR PA criteria become effective so that providers know the criteria has changed. Dr. Melton clarified that PDL changes are made monthly, and that PA updates of this nature would only occur on the 1 st day of the month. For clinical PAs, the MCOs have to take PA criteria internally and set timelines for PA application. These will vary for each MCO, so there is not a date that could always be associated with PA changes. The MCOs however, will be responsible for communicating PA updates to provider. Ms. Curtis asked when the MCOs will begin posting PA criteria.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	<p>Dr. Melton stated that this is not yet something that has been asked of the MCOs, but this is a goal that is being worked towards.</p> <p>Dr. Melton also added that manufacturers can request a copy of proposed PA criteria once an agenda is posted for the DUR meeting, so that they are able to review the PA criteria in advance and provided meaningful feedback at the DUR meetings.</p> <p>Dr. Ellermeier was recognized for her hard work for DUR throughout KanCare.</p>	
V. Adjourn	<p>The meeting was adjourned at 12:24pm.</p> <p>The next meeting will be on Wednesday October 9, 2013. 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 moved to adjourn.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>The motion passed unanimously.</p>