



**Drug Utilization Review Board
Meeting Agenda, Open Session
July 10, 2013, 10:00 a.m.-2:00 p.m.**

Meeting Location

HP Enterprise Services, Capital Room
6700 SW Topeka Blvd, Bldg 283 J, Topeka, KS 66619

Board Members

Tim Heston, DO
John Kollhoff, PharmD
Judy McDaniel Dowd, PA-C
Daniel Sutherland, RPh
Kevin Waite, PharmD
Roger Unruh, DO

KDHE-DHCF Staff

Kelley Melton, PharmD

HP Enterprise Services/HID Staff

Nicole Ellermeier, PharmD
Nancy Perry, RN
Karen Kluczykowski, RPh

MCO Staff

Thomas Kaye, RPh, **Sunflower State Health Plan**
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of April 10, 2013 Meeting Minutes

B. Tabled Prior Authorization Criteria

1. Restasis® (cyclosporine ophthalmic emulsion)

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

III. NEW BUSINESS

A. KanCare Prior Authorization Criteria and Limitation Overview

1. Sunflower

B. New Preferred Drug List (PDL) Class

1. Allergic Rhinitis Combination Products

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.

- i. Non-Preferred PDL Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. Anticholinergics for Maintenance Treatment of COPD

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.

- i. Non-Preferred PDL Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

C. Prior Authorization Criteria Revisions

1. Ilaris® (canakinumab)

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.

- i. Revised Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. Promacta® (eltrombopag)

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.

- i. Revised Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

3. Simponi® (golimumab)

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.

- i. Revised Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

4. **Tuberculosis Agents (aminosalicylate sodium, aminosalicylic acid (Paser Granules®), bedaquiline (Sirturo®), capreomycin (Capstat®), cycloserine (Seromycin®), ethambutol (Myambutol®), ethionamide (Trecator®), isoniazid (Niazid®, Nydrazid®), isoniazid/pyridoxine (Niazid-B6®), pyrazinamide, rifabutin (Mycobutin®), rifampin (Rifadin®, Rimactane®), rifampin/isoniazid (Isonarif®, Rifamate®), rifampin/isoniazid/pyrazinamide (Rifater®), rifapentine (Priftin®))**

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.

- i. Revised Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

D. New Prior Authorization Criteria

1. **Marinol® (dronabinol)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. **Xeljanz® (tofacitinib)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

3. **Rilutek® (riluzole)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

4. **Aubagio® (teriflunomide)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

5. Tecfidera® (dimethyl fumarate)

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

6. H.P. Acthar Gel® (repository corticotropin)

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

7. Incivek® (telaprevir)

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

8. Victrelis® (boceprevir)

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

9. Pegasys® (peginterferon alfa-2a)

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

10. PegIntron® (peginterferon alfa-2b)

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

11. **Infergen® (interferon alfacon-1)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

12. **Intron® A (interferon alfa-2b)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

13. **Sylatron® (peginterferon alfa-2b)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

14. **Xifaxan® (rifaximin)**

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 *Escherichia coli* 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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

15. **Topical & Buccal Testosterone Agents (Androderm® Transdermal, AndroGel®, Axiron® Topical Solution, Fortesta® Gel, Striant® Buccal, and Testim® Gel)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

16. **Delatestryl® (testosterone enanthate injection)**

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

17. Testopel® Pellets (testosterone)

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.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

E. Miscellaneous Items

1. Smoking Cessation Limitations

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.

- i. Limitations
- ii. *Public Comment
- iii. Board Discussion

2. Retrospective Drug Utilization Review Intervention Topic Selections

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 5 topics for intervention.

- i. Intervention Topics
- ii. *Public Comment
- iii. Board Discussion

IV. OPEN PUBLIC COMMENT

V. ADJOURN

**Lunch will be provided for the DUR board members.
The next DUR board meeting is scheduled for October 9, 2013.**

*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

****THIS AGENDA IS SUBJECT TO CHANGE****