Drug Utilization Review Board Meeting
Minutes
May 21, 2014

The West Virginia Medicaid Drug Utilization Review (DUR) Board meeting was called to order with the following in attendance:

Members Present:
Ernest Miller, DO,
Pat Regan, PharmD
Chris Terpening, PharmD, PhD
Kc Lovin, PA-C
Lester Labus, MD., Chairman
C.K. Babcock, PharmD
Scott Brown, RPh, Vice Chair (via phone)
Mary Nemeth-Pyles, MSN, RN, CS
John Vanin, MD

Members Absent:
Myra Chiang, MD
Kerry Stitzinger, RPh

DHHR/BMS Staff Present:
Vicki Cunningham, RPh, Director of Pharmacy Services
Brian Thompson, MS, PharmD, DUR Coordinator
Gail Goodnights, Drug Rebate Program Director
Bill Hopkins, Pharmacy Operations Manager
Doug Sorvig, Administrative Assistant

Contract Staff:
Steve Small, M.S., RPh, Rational Drug Therapy Program
Eric Sears, RPh, Molina Medicaid Solutions
Larry Dent, PharmD, Xerox State Healthcare

I. **INTRODUCTIONS** - Dr. Lester Labus, Chairman, welcomed everyone to the Board meeting.

II. **APPROVAL OF THE February 19, 2014 MINUTES** - A motion was made, seconded and passed to accept the minutes of the February 19, 2014 DUR Board meeting.

III. **OLD BUSINESS**
   A. Dr. Labus announced the election of Kc Lovin as the new DUR Vice Chair.
   B. **Cost of Tampered-Proof Pseudoephedrine Products Data** - Dr. Labus gave an overview of the report provided by the Bureau.. A motion was made, seconded and passed to limit the covered pseudoephedrine products to the tamper-proof formulation.

IV. **NEW BUSINESS**

A. **Speakers:**

1 **Mark Verman-Johnson & Johnson- Invokana**

2 **Greg Morrow-Genzyme- Aubagio Criteria**

3 **Joe Martinez-Valeritas-V-Go Criteria**

B. **Updates from April 23, 2014 P&T Committee Meeting:**

1 Inhaled Antibiotic Category-Bethkis was made preferred

2 Platelet Aggregation Inhibitors-Effient was made preferred.

3 Hepatitis C Agents-Sovaldi status was tabled until the August 27, 2014, meeting.

C. **PDL Criteria Changes**

1 Multiple Sclerosis Agents-Draft criteria read and approved.

2 PPI Criteria Clarification/Max Dosing-Draft criteria read and approved.

3 Hypoglycemia. Incretin Mimetics/Enhancers Draft criteria read and approved Hypoglycemics, SGLT2- Draft criteria read and approved.
See Attachment A

D. **Kalydeco (**ivacaftor**) Prior Authorization Criteria:**

1 Diagnosis of cystic fibrosis with a G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549R, S549N, OR G551D mutation in the CFTR gene.

2 Greater than six (6) years of age.

3 No concurrent therapy with rifampin, phenobarbital, carbamazepine, phenytoin of St. John's Wort.

4 Dosage does not exceed 150mg twice daily
References: Kalydeco® (package insert) Vertex Pharmaceuticals Inc. Boston, MA March 2014
Draft criteria was read and approved.

E. **Xolair (**omalizumab**) Prior Authorization Criteria –Addition of criteria for Chronic Idiopathic Uricaria**

1 Diagnosis is Chronic Idiopathic Urticaria and not other allergic conditions or other forms of urticaria.

2 Patient is 12 years of age or older.

3 Prescribed by a board certified Allergist, Immunologist, or Dermatologist

4 Documented failure of, or contraindication to, maximum tolerable dosing* of scheduled H-1 antihistamine, leukotriene inhibitor, and immunosuppressive therapies

5 Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria.

6 *Intolerance or contraindication of maximum dosing of H-1 Antihistamine must be clearly documented and justified on the prior authorization request. Medication purchase history will be reviewed as part of the process for prior authorization review. As-needed or "burst" therapies will not be considered as adequate therapy attempts.

7 Prior Authorization requests will be initially granted for three (3) months. Further prior authorization will be granted for an additional 12 months after documented receipt of therapy success.

8 Therapy success will be reviewed based on clinically documented improvement from prior to initiating omalizumab, including at least one of the following:
   a Decrease in oral corticosteroid use
   b Reduction in exacerbation frequency
   c Reduction in exacerbation intensity
   d Improvement in clinical condition

9 Chronic Idiopathic Urticaria (CIU): Omalizumab 150 or 300 mg SC every 4 weeks. Dosing in CIU is not dependent on serum IgE level or body weight. (Package Insert)

References: Xolair® (package insert) Genentech Inc. South San Francisco, CA. March 2014

Draft criteria was read and approved.

F. **Thalomid** (thalidomide) **Prior Authorization Criteria -**shall be authorized for 12 months when:

1 The member has a diagnosis of multiple myeloma that is newly diagnosed and is receiving concurrent dexamethasone **OR**

2 The member has a diagnosis of severe erythema nodosum leprosum (ENL) with cutaneous manifestations

3 Provided that all of the following criteria have been met:
   a The member is age twelve (12) or older
   b The member is not pregnant
   c The prescriber is registered and the member is enrolled in the THALOMID REMS™ program
   d The member will be monitored for signs and symptoms of venous thromboembolism (VTE)
   e The member will not use Thalomid® as monotherapy in the presence of moderate to severe neuritis.
   f *Authorization for continued use shall be reviewed at least every 12 months to confirm that the member has experienced an objective response to therapy*.

References: Thalomid® (package insert). Celgene; Summit, NJ February 2013

G. **ExJade (**deferasirox**) Prior Authorization Criteria:**

1 **Transfusional iron overload:** Initial authorization for is for 3 months and may be authorized for continuation for up to 6 months
   a **For initiation of Therapy:**
      i Patient must be >2 years of age on the date of request for ExJade.
      ii Documentation of iron overload related to anemia found in patient's medical conditions, progress notes, and/or discharge notes.

iii Documentation in medical records of a recent history of frequent blood transfusions that has resulted in chronic iron overload.
iv Serum ferritin must be consistently >1000 mcg/L. (Lab results submitted should be dated within the past month.)
v Starting dose must not exceed 20mg/kg/day. Calculate dose to the nearest whole tablet (125 mg, 250 mg, or 500 mg) for the oral suspension.

b **For continuation of Therapy:**
i Serum ferritin must have been measured within 30 days of continuation of therapy request (copy lab results must be submitted).
ii Ferritin levels must be >500mcg/L.
iii Dose must not exceed 40mg/kg/day. Calculate dose to the nearest whole tablet (125 mg, 250 mg, or 500 mg) for the oral suspension.

2 **Non-transfusional iron overload:** Initial authorization for is for 6 months and may be authorized for continuation for another 6 months

a **For initiation of Therapy:**
i Patient must be >10 years of age on the date of request for ExJade
ii Documentation of iron overload related to anemia found in patient's medical conditions, progress notes, and/or discharge notes.
iii Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of initiation (copy of lab results must be submitted).
iv Serum ferritin levels must be >300mcg/L.
v Liver iron concentration (LIC) must be >5 mg Fe/g dried weight (dw)
vi Dose must not exceed: 10mg/kg/day (if LIC is <15 mg Fe/g dw), or 20mg/kg/day (if LIC is > 15 mg Fe/g dw)

b **For continuation of Therapy:**
i Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of continuation of therapy request (copy lab results must be submitted).
ii Serum ferritin levels must be >300mcg/L.
iii Liver iron concentration (LIC) must be >3 mg Fe/g dw.
iv Dose must not exceed: 10mg/kg/day (if LIC is 3 – 7 mg FE/g dw)or 20mg/kg/day (if LIC is >7 mg FE/g dw).

References: ExJade® (package insert). Novartis Pharmaceuticals Corporation; East Hanover, New Jersey October 2013

H. **Ferriprox (**deferiprone**) Prior Authorization Criteria:** Indicated for the treatment of transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate

1 **Criteria for use**
a Documented diagnosis of transfusional iron overload due to thalassemia syndromes
b In order to start therapy, absolute neutrophil count (ANC) must be greater than $1.5x10^9$/L or 1500/mm^3

c Patient has failed or has had an inadequate response to Desferal (deferoxamine) AND Exjade (deferasirox) as defined by serum ferritin >2,500mcg/L before treatment with Ferriprox OR patient has been intolerant to or experienced clinically significant adverse effects to Desferal (deferoxamine) or Exjade (deferasirox), such as evidence of cardiac iron overload or iron-induced cardiac dysfunction
d Ferriprox will not be authorized if there is a previous history of agranulocytosis
e Patient must not be pregnant
f Dose must not exceed 33 mg/kg 3 times daily

2 **Initial authorization** will be for 3 months and may be continued per manual review with the following criteria being considered:
a Experienced a ≥ 20% decline in serum ferritin within one year of starting therapy
b If serum ferritin falls and remains below 500mcg/L, the drug should be discontinued temporarily

References:

a Ferriprox (package insert). Rockville, MD: ApoPharma USA, Inc.; October 2011
b Deferiprone (Ferriprox); for iron overload. The Medical Letter 2012; 54:1384
c Olivieri N et al. Long Term Safety and Effectiveness of Iron-Chelation Therapy with Deferiprone for Thalassemia Major. N Engl J Med 1998; 339:417-423.
d Hoffbrand AV et al. Role of deferiprone in chelation therapy for transfusional iron overload. Blood 2003; 102:17-24.

I. **VGo Prior Authorization Criteria:** V-Go shall initially be approved for 3 months provided the following criteria have been met:

1 V-Go shall initially be approved for 3 months provided the following criteria have been met:
a For adults age 21 years and older requiring insulin
b Patient is a type-II Diabetic
c Must be accompanied by a prescription for U100 fast-acting insulin (e.g. insulin lispro or aspart)
d Patient must discontinue all other insulin products once V-Go has been started
e Total Daily Dose (TDD) of insulin (basal and/or mealtime) supplied by V-Go will be between 20 units to 76 units per day
f Failure to attain goal HgBA1C (as determined by the healthcare practitioner) after 6 months of current therapy, **or** the existence of a safety concern such as nocturnal hypoglycemia, needle or pen administration (i.e. poor eyesight or blindness, manual dexterity issues, cognition issues not including dementia)

2 Re-authorizations will be for 6 months and will require documentation that HgBA1C levels have decreased by at least 1% or are maintained at ≤8%. HgBA1C levels submitted must be for the most recent thirty (30) day period.

References:

a V-Go™ (package insert) Valeritas Inc. September 2011
b American Diabetes Association. Standards of Medical Care in Diabetes 2014. *Diabetes Care*. 2014; 37(suppl 1):S14-S80. January 2014

J. **Sovaldi (**sofosbuvir**) Prior Authorization Criteria:**

Criteria for Approval

1 Sovaldi must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
2 Patient is sofosbuvir treatment naïve; **AND**
3 Patient must be eighteen (18) years of age or older; **AND**
4 Patient may not be pregnant, as verified by a negative pregnancy test. In addition, a written commitment from the prescriber, the patient, and if applicable, the patient's partner, that birth control will be used to prevent pregnancy during the treatment must be collected and submitted to WV Medicaid; **AND**
5 Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by an accepted laboratory screening test in each of the three (3) months immediately prior to therapy (results **must** be submitted with request); **AND**
6 Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**
7 Patient meets the diagnosis and disease severity criteria (≥F3 fibrosis indicating cirrhosis or bridging fibrosis) as outlined in Table 1; **AND**
8 Patient must agree to complete regimen (as outlined in Table 1) and the patient and the provider must sign a written commitment that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;
9 For HIV-1 co-infected patients, patients must have the following:
   a CD4 count greater than 500 cells/mm3, if patient is not taking antiretroviral therapy; **OR**
   b CD4 count greater than 200 cells/mm3, if patient is virologically suppressed (e.g., HIV RNA < 200 copies/mL)

Duration of Approval

Initial approval is for 6 weeks except for patients with hepatocellular carcinoma awaiting liver transplant, who will receive 12 weeks initial approval. All indications require submission of an HCV RNA level at treatment week 4 (TW4). Continued coverage depends on documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. Patients awaiting transplant must also submit HCV RNA levels at TW12, TW24 and TW36.

Based on HCV genotype **(see Table 1 – Covered Regimens)**

1 Genotypes 1, 2, and 4 (including HCV-HIV-1 co-infection) - 12 weeks, maximum
2 Genotype 3 (including HCV-HIV-1 co-infection) - 12 weeks, maximum
3 Hepatocellular carcinoma awaiting liver transplant - 48 weeks, maximum (or until transplant).

Table 1 – Covered Regimens		
Documented HCV Genotype / Fibrosis Stage		
Diagnosis	**Approved Treatment Regimen**	**Regimen Duration**
HCV genotype 1 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• HCV with or without compensated cirrhosis (incl. hepatocellular carcinoma [HCC]) • HCV/HIV-1 co-infection	*Triple Therapy* sofosbuvir + peginterferon alfa + ribavirin*	12 weeks
HCV genotype 2 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection	*Dual Therapy* sofosbuvir + ribavirin*	12 weeks
HCV genotype 3 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection	*Triple Therapy* sofosbuvir + peginterferon alfa +_ribavirin*	12 weeks
HCV genotype 4 / ≥ Stage F3 (cirrhosis or bridging fibrosis)		
• HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection	*Triple Therapy* sofosbuvir + peginterferon alfa + ribavirin*	12 weeks
HCV genotype 1, 2, 3, or 4		
• Hepatocellular carcinoma awaiting liver transplantation **AND** • Meets Milan criteria: • In single hepatocellular (HC) carcinomas, tumor < 5 cm in diameter, **OR** • In multiple HC carcinomas, no more than 3 tumor modules, each < 3 cm in diameter, **AND** • No extrahepatic manifestations of the cancer and no evidence of vascular invasion of the tumor.	*Dual Therapy* sofosbuvir + ribavirin*	48 weeks *or until the time of liver transplantation, whichever occurs first*

*Weight based ribavirin

Quantity Limit: One 400 mg tablet per day (28 tablets/28 days)

ALL OTHER REGIMEN REQUESTS WILL BE CONSIDERED ON A CASE-BY-CASE BASIS

Diagnostic/Disease Severity Evidence (must be attached to request)

1. Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
   a. Cirrhotic features on imaging
   b. Ascites
   c. Esophageal varices
   d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)
2. Fibrosis level of F3 (indicating bridging fibrosis) must be substantiated via biopsy or other accepted method (e.g. FibroSure Assay)

Criteria for Denial

1. Patient is pregnant.
2. Patient has not abstained from the use of illicit drugs and/or alcohol for at least three (3) months prior to the start of treatment, as evidenced by an accepted laboratory screening test.
3. Patient is not sofosbuvir naïve.
4. Patient is receiving concomitant hepatitis protease inhibitor therapy (e.g. telaprevir (Incivek), boceprevir (Victrelis), simeprevir (Olysio)).
5. Patient has decompensated cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C]).
6. Patient has severe renal impairment (eGFR < 30 mL/min/1.73m2) or end stage renal disease (ESRD) requiring hemodialysis.
7. Patient is post-liver transplant (safety and efficacy have not been established).
8. Patient has HCV genotype 5 or 6.
9. Patient is taking a concomitant medication that has a significant clinical interaction with sofosbuvir:
   a. tipranavir/ritonavir
   b. rifampin, rifabutin, rifapentine
   c. carbamazepine, phenytoin, phenobarbital, oxcarbazepine
   d. St. John's wort
10. Patient refuses treatment with Interferon but does not meet definition of Interferon Ineligibility. Interferon Alfa Ineligible is defined as:
    a. Intolerance to interferon alfa – patient must have documented trial
    b. Autoimmune hepatitis and other autoimmune disorders
    c. Hypersensitivity to peginterferon alfa or any of its components
    d. Decompensated hepatic disease
    e. A baseline neutrophil count below 1,500/μL, a baseline platelet count below 90,000/μL or baseline hemoglobin below 10 g/dL

Additional Considerations

1 Sofosbuvir combination treatment with ribavirin or peginterferon alfa/ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.
2 Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor.
3 Coverage shall be for one course of therapy in a lifetime. Exceptions may be considered on a case-by-case basis.
4 Lost or stolen medication replacement request will not be authorized.

References

1 Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
2 FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
3 Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. *N Engl J Med*. 2013; 368:1878-87. doi: 10.1056/NEJMoa1214853. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214853. Accessed January 2, 2014.
4 Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. *N Engl J Med.* 2013;368:1867-77. doi: 10.1056/NEJMoa1214854. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214854. Accessed January 2, 2014.
5 American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed February 18, 2014.

Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis*. 2000;20(1). Retrieved from www.medscape.com. Accessed February 26, 2014.

V. **REPORTS**

A. **Xerox State Healthcare –** Larry Dent gave an overview that included:
1 Recent Retrospective DUR activities;
a Hypertension Management
b Hyperlipidemia
c 2014 PDL Update Newsletter
d GI Disorders educational Mailing, Lice Management Newsletter and Asthma Educational Mailing
2 Intervention Outcomes; Atypical Antipsychotic Prescribing
a Target Group = Individuals receiving drug therapy with atypical antipsychotics who had issues related to compliance, increased risk of adverse events, and/or multiple prescribers
b Letters Mailed to 406 prescribers
c There were 1,315 targeted patients

3 Intervention Impact - There was a decrease of 23.3% in the number of clinical issues identified in the target group when looked at six months after the educational letters were mailed

4 Drug Expenditures
   a Target Group Medication Expenses Decreased 13.33%
   b Estimated 6 month Savings = $169,735

See Attachment B

B. **Molina Fourth Quarter Report –First Quarter 2014 -** Eric Sears gave an overview of the Molina 2014 First Quarter Report. The presentation included a review of the DUR Quarterly Overall Summary Report.
See Attachment C

C. **Rational Drug Therapy Program -** Steve Small gave a slide presentation overview of the program activities for the first quarter. The presentation included February, March and April 2014 program summaries, edit overrides and prior authorizations.
See Attachment D

VI. **OTHER BUSINESS - OPEN TO THE FLOOR** – None discussed

VII. **NEXT MEETING AND ADJOURNMENT**

A. A motion was made, seconded and approved to adjourn the meeting.
B. The meeting concluded at 6:30p.m.
C. The next meeting will be Wednesday, September 17, 2014 from 4:00 PM-6:00 PM located at the WVDHHR.

Submitted by:

Brian M. Thompson, PharmD