

Ohio Department of Medicaid (ODM) P&T Committee Meeting Minutes

April 9, 2014

30 E. Broad Street, Columbus, OH, Room 2925

Committee members present: Susan Baker, CNS; Suzanne Eastman, PharmD; Jennifer Hauler, DO; Cheryl Huffman, MD; Robert Hunter, DO, Chair; Karen Jacobs, DO; Melissa Jefferis, MD; Margaret Scott, RPh.

Xerox staff present: Stephanie Levine, PharmD, Clinical Manager

ODM staff present: Jill Griffith, PharmD, DUR Director

Approximately 50 stakeholders were present, most representing pharmaceutical manufacturers.

The meeting was called to order at 10:00 AM by Dr. Hunter, chair.

A. Conflict of Interest Policy

Dr. Hunter reviewed the Conflict of Interest policy and asked all members to sign and return to Ms. Scott.

B. Interested Party Presentations

1. Epilepsy Foundation of Greater Cincinnati and Columbus

- a) Doug Simmons on behalf of Kathy Schrag, Executive Director
- b) Emily Klatte, MD
- c) Scott Badzik

2. Pam Kibbe, RN, MS, CNP, Hepatology Nurse Practitioner

C. Old Business: Preferred Drug List (PDL) proposed changes to be discussed at June P&T meeting

Ms. Scott presented information regarding lowering the maximum allowed dose of buprenorphine to 16mg per day in most circumstances, see attached presentation. The proposal will be discussed at the next meeting. Committee members expressed general support but asked ODM to provide more information at the next meeting about the prescribers of doses above 16mg per day.

D. New Business: Drugs Under Review

1. Infectious Disease Agents, Hepatitis C

- a) Sovaldi™ (sofosbuvir tablets), Gilead Sciences, Inc. A representative of Gilead provided a clinical overview. Ms. Scott presented ODM's proposed prior authorization criteria (attached). The criteria were approved unanimously by the committee.
- b) Olysio™ (simepravir capsule), Janssen Therapeutics. A representative of Janssen presented a clinical overview. Ms. Scott recommended prior authorization criteria including the following:
 - Genotype 1 virus
 - If genotype 1a, must not have the Q80k genetic polymorphism
 - Ensure drug to drug interactions are managed

- Use response-guided length of therapy outlined in the FDA-approved product labeling
 - If the patient is ineligible for interferon, may approve in combination with Sovaldi
- The criteria were approved unanimously by the committee.
2. Genitourinary Agents, Electrolyte Depletor Agents: Velphoro[®] (sucroferric oxyhydroxide chewable tablets), Fresenius Medical Care. A representative from Fresenius presented a clinical overview of the drug.
Ms. Scott presented ODM's recommendation for non-preferred (third tier) status. Ms. Eastman noted the lower pill burden of this product as compared with other electrolyte depletor agents and recommended preferred brand (second tier) status. The committee voted 7 to 2 against third-tier placement, with Dr. Huffman and Ms. Scott in the minority.
 3. Endocrine Agents, Diabetes Oral Hypoglycemics: Farxiga[™] (dapagliflozin tablets), Astra Zeneca Pharmaceuticals. A representative from Astra Zeneca presented a clinical overview of the drug.
Ms. Scott presented ODM's recommendation for non-preferred (third tier) status. The committee vote was unanimous for non-preferred status.
 4. CNS Agents, Antidepressants: Fetzima[™] (levomilnacipran ER capsules), Forest Pharmaceuticals. A representative from Forest presented a clinical overview of the drug. Dr. Jacobs asked several questions about the clinical trials. She noted that the clinical theory for targeting norepinephrine reuptake is for patients showing low energy and cognitive deficits. Dr. Hauler asked Dr. Jacobs about clinical differences between Fetzima and other drugs. Dr. Jacobs said she has not used this drug extensively, and until she sees more evidence of how it is being used in clinical practice, would agree with the third tier status. She also mentioned she will share with the committee any new information that comes to light. The committee vote for third tier placement was unanimous.
 5. CNS Agents, Anticonvulsants: Fycompa[™] (perampanel tablets CIII), Eisai Inc. A representative of Eisai gave a clinical overview of the drug.
Ms. Scott presented ODM's recommendation for non-preferred status. The committee vote was unanimous for non-preferred.

The meeting was adjourned with a reminder that the next meeting is scheduled for Wednesday, June 11, 2014. The June meeting is an all-day meeting to review the entire PDL.

Notes from ODM after the meeting:

The committee recommendations for prior authorization criteria for Sovaldi and Olysio will be implemented. The committee's recommendation for non-preferred status for Farxiga, Fetzima, and Fycompa will be implemented. The committee's recommendation for preferred brand (second tier) status for Velphoro is under review.



Department of Medicaid

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Pharmacy and Therapeutics Committee Conflict of Interest Policy

Purpose: To require members of the Department of Medicaid Pharmacy and Therapeutics Committee to abide by this policy so that scientific and economic data serves as the primary basis in rendering objective decisions about drugs being considered for coverage by Ohio Medicaid.

Definition: A potential “conflict of interest” may exist when a committee member has a relationship with a manufacturer of the medication or class of medications being considered that could inappropriately influence his/her judgment, or the judgment of other members. This may include a relationship with a manufacturer of a drug which competes with the drug under consideration. A relationship with a manufacturer may include any of the following:

- Acceptance of honoraria
- Participation in speaker’s bureau
- Acceptance of support for travel for professional or education activities
- Acceptance of research support
- Relationship valued at \$500 or more with one company
- Consultant arrangement

Policy Statements

1. A member shall not participate in the discussion of an issue that is before the committee unless he/she has first disclosed any potentially relevant conflict of interest.
2. The committee will determine if a specific activity or relationship represents a potential conflict of interest and whether the member disclosing a potentially relevant conflict should continue to participate in the discussion.

Procedure: Committee members must sign this agreement once each year.

Signature _____ Date _____

Printed Name _____



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Buprenorphine Dosing: Evidence Shows 16 mg/day is Enough

P&T Committee April 9, 2014
Margaret Scott, RPh, and Mike Howcroft, RPh



Department of Medicaid

FDA-Approved Label

- Buprenorphine/Naloxone is indicated for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.
- Dosing: Administered sublingually as a single daily dose.
 - ✓ SUBOXONE sublingual film is indicated for maintenance treatment. The recommended target dosage of SUBOXONE sublingual film is 16 mg/4 mg buprenorphine/naloxone/day as a single daily dose.
 - ✓ One ZUBSOLV 5.7/1.4 mg sublingual tablet provides equivalent buprenorphine exposure to one SUBOXONE 8/2 mg sublingual tablet. ZUBSOLV sublingual tablet is indicated for maintenance treatment. The recommended target dosage of ZUBSOLV sublingual tablet is 11.4 mg/2.8 mg buprenorphine/naloxone/day (two 5.7/1.4 mg tablets) as a single daily dose

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FDA-Approved Label: Pharmacology

- Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor.
- Buprenorphine has a mean elimination half-life from plasma ranging from 24 to 42 hours and naloxone has a mean elimination half-life from plasma ranging from 2 to 12 hours.
- Comparisons of buprenorphine to full opioid agonists such as methadone and hydromorphone suggest that sublingual buprenorphine produces typical opioid agonist effects which are limited by a ceiling effect.

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Published Evidence

- NEJM, DBPC study evaluating efficacy of buprenorphine in 326 heroin addicts
 - ✓ Early termination of study because of the **effectiveness of buprenorphine 16 mg** versus placebo
- Published report, December 2012 by R. Mattick concluded:
 - ✓ Buprenorphine is an effective medication in the maintenance treatment of heroin dependence, **retaining individuals in treatment at any dose above 2 mg** and suppressing illicit opioid use at doses 16 mg or greater based on placebo-controlled trials
- Saturation of the mu-opioid receptors, Neuropsychopharmacology 2003, M. Greenwald
 - ✓ **16 mg produces an 85% to 92% saturation**
 - ✓ 32 mg produces a 95% to 98% saturation

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Medical Board: Maximum 16 mg/day

- Draft State Medical Board Ohio Administrative Code Rule 4731-11-12, “Office Based Opioid Treatment”

Paragraph (B)(10)

The physician shall not prescribe, personally furnish, or administer greater than 16 mg/day of buprenorphine per day to a patient, except in one of the following situations:

- a) The dosage greater than 16 mg was established before the effective date of this rule; or
- b) The physician has consulted with a board certified addictionologist or addiction psychiatrist, who has recommended the dosage greater than 16 mg

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Medical Board: Maximum 16 mg/day

- Medical board filing: “A panel of five independent experts in addiction medicine was subsequently convened to provide input as to the best current practices in treating opiate addiction...All panel members agreed a prescription above 16 milligrams of specifically approved buprenorphine products per day was not commonly necessary and with a dosage of more that sixteen milligrams per day the patient is more inclined to sell the drug.”

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Most Patients Prescribed \leq 16mg

- Current PDL guideline:
Maximum dose of buprenorphine is 24 mg/day (16 mg is the target, no patient should receive more than 32 mg/day)
- Medicaid Claims for Suboxone, Calendar Year 2013:
 - ✓ Unique individuals = 3070
 - ✓ Unique Prescribers = 447
 - ✓ Total Claims for Suboxone = 10,803
- **\leq 16mg/day: 8196 = 76% of all claims, 2469 individuals**
- **$>$ 16 mg/day: 2607 = 24% of all claims, 925 individuals**

Note: Individuals do not equal 3070 as one individual may have received an Rx for $>$ 16mg and $<$ 16mg and thus counted more than once.

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Consensus for 16mg

- FDA-approved product labeling
- Clinical studies
- Pharmacology: the mu-opioid receptors saturated 85% - 92%
- State medical board draft rule
- Medicaid claims data show \leq 16 mg/day is the dose that is filled at the pharmacy 76% of the time

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PROPOSED OHIO MEDICAID SOVALDI PA CRITERIA

LENGTH OF INITIAL APPROVAL 12 weeks – 24 weeks (genotype 3 and post liver transplant)

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Dose not to exceed Sovaldi 400 mg once a day
- Patient readiness assessed
- Discussion of deferred therapy (more effective / less toxic treatments)
- Vaccinate against Hepatitis A and Hepatitis B
- Maintenance of sobriety (alcohol/controlled drugs/IV drug use)
- Tests to confirm a diagnosis of chronic hepatitis C (CHC) and laboratory monitoring
 - Hepatitis C Virus (HCV) antibody test reactive
 - HCV RNA detected
 - Specify the Genotype
 - Patient must not have severe renal impairment (GFR < 30 ml/min/1.73m²) or end stage renal disease requiring hemodialysis
 - Include report of evaluation for advanced fibrosis using liver biopsy, imaging (ultrasound, computed tomography scan), or non-invasive markers:
 - Generally treat: Liver biopsy: Fibrosis score F3 (pre-cirrhosis or bridging fibrosis) or Fibrosis score F4 (cirrhosis)
 - Is there relevant coinfection: hepatitis B surface antigen, and HIV antibody
 - Generally treat: patients with co-morbidity that accelerate the rate of hepatic fibrosis or immune compromise (HIV)
 - Any evidence of HCV-related extra-hepatic manifestations:
 - Generally treat patients with: lymphoma, symptomatic cryoglobulinemia, membranoproliferative glomerulonephritis

Recommended initial regimen and treatment duration for Sovaldi combination therapy in HCV mono-infected and HCV/HIV-1 co-infected patients:

Genotype	Treatment	Duration
1 or 4	Sovaldi 400 mg + IFN + RBV	12 weeks
1 -Interferon ineligible, interferon non-responder, advanced liver disease, low WBC, low platelets, post liver transplant	Sovaldi 400 mg + Olysio 150 mg With or without RBV or Sovaldi 400 mg + RBV	12 weeks 24 weeks
2	Sovaldi 400 mg + RBV	12 weeks 24 weeks in post liver transplant
3	Sovaldi 400 mg + RBV	24 weeks
3 (cirrhotic, previous non-responder)	Sovaldi 400 mg + IFN + ribavirin	12 weeks
4 - Interferon ineligible, interferon non-responder, advanced liver disease, low WBC, low platelets, post liver transplant	Sovaldi 400 mg + RBV	24 weeks
Hepatocellular carcinoma in patients waiting for liver transplantation	Sovaldi 400 mg + RBV	Up to 48 weeks or until the time of liver transplantation whichever comes first
5 or 6	Sovaldi 400 mg + IFN + RBV	12 weeks

HCV = hepatitis C virus; INF = pegylated interferon; RBV = ribavirin