

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

January 14, 2015

77 S. High Street, Columbus, OH, Room 1960

Committee members present: Susan Baker, CNS; Suzanne Eastman, PharmD; Jennifer Hauler, DO; Mike Howcroft, RPh; Karen Jacobs, DO, Acting Chair; Margaret Scott, RPh

Xerox staff present: Stephanie Levine, PharmD, Clinical Manager

ODM staff present: Patti Nussle, RPh; Jill Griffith, PharmD

Approximately 30 stakeholders were present, most representing pharmaceutical manufacturers.

The meeting was called to order at 10:01 AM by Dr. Jacobs, acting chair.

- A. Conflict of Interest Statement. Committee members who were present signed the conflict of interest statement. P&T Committee members are required to sign the statement annually. A copy of the statement is attached.
- B. Interested Party Presentations
Brian Beesley, DO, primary care HIV specialist, requested that the Committee allow primary care HIV specialists to prescribe hepatitis C virus (HCV) Direct Acting Antivirals (DAA).
Pamela Kibbe, MS, CNP, requested that the committee add Harvoni as a preferred agent.
- C. Old Business: HCV Analysis
Dr. Levine presented information on ODM fee-for-service utilization of drugs for HCV treatment in 2014. The presentation is attached to these minutes.
- D. New Business: Drugs Under Review
 1. Central Nervous System: Multiple Sclerosis – Plegridy (peginterferon beta-1a), Biogen Idec.
A representative of Biogen Idec provided a clinical overview. Dr. Jacobs asked if any head to head comparison data is available. The representative responded that no data are available now, but the company is planning pharmacokinetic/pharmacodynamics studies vs. Rebif. Ms. Scott gave the ODM and Xerox recommendation that Plegridy be placed in non-preferred status, using the current PDL criteria, which is a trial of one month with a preferred agent.
The committee vote was unanimous.
 2. Infectious Disease Agents: Hepatitis C – Harvoni (ledipasvir/sofosbuvir) tablets, Gilead.
A representative of Gilead presented clinical information. Mr. Howcroft presented the ODM proposed criteria for DAAs, attached. Dr. Jacobs asked how ODM will monitor sobriety. Mr. Howcroft said the prescriber will need to monitor continued sobriety. Dr. Jacobs asked if there is a normal time after the failure of one therapy to start a different HCV therapy. The Gilead representative said that 12 weeks is needed to determine the sustained viral response (SVR), then the new treatment could start. The Gilead representative and Ms. Kibbe agreed that, logistically, six months after the first treatment is reasonable. The committee discussed the definition of decompensated cirrhosis, and whether hepatitis B vaccination must be completed before HCV treatment begins. ODM agreed to follow up on these questions for the next meeting.

The vote to use the proposed guidelines was unanimous, with the understanding that HCV DAAs will be discussed at the next meeting.

3. Respiratory Agents – Grastek (timothy grass pollen allergen extract) and Ragwitek (short ragweed pollen allergen extract) sublingual tablets, Merck.

A representative of Merck presented clinical information. Ms. Scott presented the ODM proposed criteria for sublingual allergen extracts, attached.

The committee vote to approve the criteria was unanimous.

The meeting was adjourned with a reminder that the next meeting is scheduled for Wednesday, April 8, 2015.

Notes from ODM after the meeting:

All recommendations will be implemented.



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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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Pharmacy and Therapeutics Committee
 January 14, 2015
 Stephanie Levine, PharmD

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3Q2014 vs 2Q2014 OHIO DEPARTMENT of MEDICAID FEE FOR SERVICE (ODM-FFS) HEPATITIS C VIRUS (HCV) DRUG SPEND

Drug	3Q2014			2Q2014		
	Number of Claims	Total Amount Paid to Pharmacies	% of Total Amount Paid to Pharmacies	Number of Claims	Total Amount Paid to Pharmacies	% of Total Amount Paid to Pharmacies
INCIVEK	0	\$0	0%	2	\$34,271	1%
OLYSIO	51	\$1,159,787	29%	19	\$449,677	13%
PEGASYS	21	\$74,174	2%	59	\$170,348	5%
PEGINTRON	5	\$17,454	0%	4	\$13,930	0%
RIBAVIRIN (all formulations)	63	\$19,203	0%	109	\$32,106	1%
SOVALDI	92	\$2,636,480	67%	91	\$2,726,275	79%
VICTRELIS	4	\$30,148	1%	1	\$7,665	0%
TOTALS	236	\$3,937,247	100%	285	\$3,434,271	100%

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YEAR TO DATE (October 2014) UNIQUE MEMBERS and TOTAL PRESCRIPTIONS PER HEPATITIS C VIRUS (HCV) DRUG

DRUG NAME	Unique Members YTD (Jan –Oct 2014)	Total RX (Jan – Oct 2014)
VICTRELIS	2	67
PEGINF	46	109
RIBAVIRIN	90	206
OLYSIO	34	80
SOVALDI	101	205
INCIVEK	2	5
Totals	126	612

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HCV DRUG UTILIZATION OVER TIME

Unique Members receiving HCV drug therapy by month

Month/Year	Unique Members
Jan-14	4
Feb-14	9
Mar-14	8
Apr-14	36
May-14	37
Jun-14	47
Jul-14	42
Aug-14	30
Sep-14	24
Oct-14	22

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US PIPELINE & UPDATES, HCV DRUGS

FDA approval (or anticipated)	MFT	Drug	Comments
10.10.14	Gilead	sofosbuvir + ledipasvir	Update: Approved – Harvoni™ (10.10.2014)
Nov-14	BMS	daclatasvir + asunaprevir (response rate 90%)	Update: BMS revoked NDA in Oct 2014; however, they will seek US FDA approval for daclatasvir with simeprevir
12.19.2014	Abbvie	ABT-267, ABT-333 and ABT-450/ritonavir.	Update: Approved – Viekira PAK™ (12.19.2014)
2015 (breakthrough therapy FDA designation)	Merck	All oral combination: grazoprevir (NS3/4A protease inhibitor) /elbasvir (NS5A replication complex inhibitor)	Update: Merck is hastening development; plans to file NDA in the first half of 2015. Efficacy rate of 90% in G1 patients

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MARKET EVENTS -ENHANCED HCV DRUG COMPETITION

Major Pharmacy Benefit Managers’(PBM) Coverage:

- **Express Scripts:** Exclusive coverage of AbbVie’s Viekira™ for HCV Genotype 1 (for select plans, current patients grandfathered)
- **CVS Caremark:** Exclusive coverage of Gilead’s Sovaldi®/Harvoni™ (for select plans)
- **Prime Therapeutics:** Will prefer both Harvoni™ and Viekira™

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MARKET EVENTS -ENHANCED HCV DRUG COMPETITION

Major Plan Announcements

- **Anthem (Express Scripts largest customer) announces exclusive coverage of Gilead's Harvoni™**
- **Veterans Affairs announces \$596/pill price for Sovaldi® (no pricing announced for Viekira™ or Harvoni™)**

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CONCURRENT DISEASE STATES

- **Eight (8) post transplant members; one (1) awaiting transplant**
- **One (1) member taking Suboxone; one (1) member taking Vivitrol**
- **Four (4) members with HIV**
- **Two (2) members with HBV**
- **Sixteen (16) members on chronic Xifaxan and/or lactulose (advance liver disease)**
- **Two (2) members with hepatic carcinoma**
- **Four (4) members on ESA or WBC stimulating agent**
- **Two (2) members with possible history of breast cancer [taking exemestane (Aromasin) & letrozole (Femara)]**

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HCV DRUG REGIMENS UTILIZED

HCV REGIMEN	Jan 2014- July 2014		Jan 2014 - Oct 2014	
	# Unique Members	% of all regimens	# Unique Members	% of all regimens
RIBAVIRIN/SOVALDI	27	28%	37	29%
PEG-INF/RIBAVIRIN/SOVALDI	26	27%	29	23%
OLYSIO/SOVALDI	18	18%	33	26%
PEG-INF/RIBAVIRIN	11	11%	12	10%
PEG-INF/SOVALDI	1	1%	1	1%
RIBAVIRIN	8	8%	9	7%
PEG-INF/INCIVEK	1	1%		0%
PEG-INF	1	1%	2	2%
PEG-INF/RIBAVIRIN/INCIVEK	1	1%		0%
PEG-INF/RIBAVIRIN/VICTRELIS	3	3%	2	2%
RIBAVIRIN/OLYSIO/SOVALDI	1		1	1%
Totals	98	100%	126	100%

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PRESCRIBERS OF SOVALDI DRUG REGIMENS

SOVALDI PRESCRIBER SPECIALTY 1/1/2014 –10/31/2014

Prescriber Specialty	# Members Treated	%
GI	51	50.50%
GI/ID	1	0.99%
Hepatologist	30	29.70%
ID	18	17.82%
Internal Medicine (TPL claim)	1	0.99%
Grand Total	101	100%

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GENOTYPE PREVALENCE of SOVALDI RXs		
GENOTYPE PREVALENCE of SOVALDI RXs– 1/1/2014 –10/31/2014		
Genotype	# Members	%
1	66	65%
1	48	48%
1A	11	11%
1B	7	7%
2	16	16%
2	10	10%
2A/2C	1	1%
2B	5	5%
3	13	13%
3	11	11%
3A	2	2%
4	3	3%
4	3	3%
Unknown	3	3%
TPL claims	1	1%
Liver transplant	1	1%
Not documented	1	1%
Grand Total	101	100%

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CONCLUSION
<ul style="list-style-type: none"> Emerging HCV anti-viral marketplace has created an extremely dynamic clinical and financial landscape AASLD/IDSA guidelines have been updated twice in the last sixty days with new recommendations and regimens Follow-up on sustained viral response (SVR) is difficult given that almost 80% of members start HCV therapy in Medicaid FFS and then move to Managed Care before completing HCV therapy We anticipate greater growth in prescriptions and treated members in the next six –twelve months now that FDA has approved more agents
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**Hepatitis C Virus (HCV) Direct Acting Antiviral (DAA) PA Criteria
For Ohio Medicaid Fee-for-Service**

All HCV DAAs require clinical prior authorization. Only regimens recommended by the American Association for the Study of Liver Diseases (AASLD) will be approved. Patients must meet all criteria below.

Step 1: Patient Readiness Evaluated

- Patient must be 18 years or older.
- Female patient must have a negative pregnancy test within the last 30 days and must not be lactating.
- Patient must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy.
- If patient is a recovering substance abuser/alcoholic and in a prescribed medication assisted therapy program, must continue counseling during HCV treatment and maintain sobriety.
- Patient's psychiatric status has been stable for 6 months documented in medical record. If patient has mental health conditions that are not currently being treated, then a mental health professional must be consulted to assess for patient readiness before HCV treatment can begin.
- Vaccinate against Hepatitis A and Hepatitis B.
- Patient must not have severe renal impairment (eGFR < 30 mL/min/1.73m²) or end stage renal disease requiring hemodialysis.
- Patient must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information for each agent.
- Patient must agree in writing to being adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers may use the form below or a similar form that covers all four points. Patient signature is required. This statement and patient signature must be included as part of the prior authorization request.

Hepatitis C Patient Readiness:

_____ (print name) agrees to the following:

1. I have not abused alcohol, injectable drugs, or other controlled substances for at least 6 months prior to starting Hepatitis C treatment, and I will not use these substances while being treated for Hepatitis C. If I am involved in a support group or counseling for addiction, I will continue therapy to encourage successful abstinence.
2. I have been reasonably adherent with all my current medications for all conditions and will take my Hepatitis C treatment daily as prescribed.
3. I have a history of showing up for scheduled appointments and labs, and will continue to show up for all appointments and lab tests while taking Hepatitis C treatment.
4. If I have mental health conditions, I have been and will continue to adhere to my prescribed mental health medications and/or psychotherapy.

Patient signature: _____ **Date:** _____

Step 2: Clinical Assessment of Disease

- Confirmation of chronic hepatitis C (CHC):
 - Hepatitis C Virus (HCV) antibody test reactive
 - Provide HCV RNA load measured within 90 days prior to starting DAA therapy
 - Specify the Genotype
- Document progression of disease:
 - Document the degree of liver fibrosis:
 - Metavir score (scale of 1-4) must be F3 (bridging fibrosis) or F4 (cirrhosis); or
 - Ishak score (scale of 1-6) is F4-F5 (bridging cirrhosis) or F6 (cirrhosis)
 - If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score. Patients with decompensated cirrhosis will be approved for therapy only after consultation with a physician in a liver transplant center.
 - Document any HCV-related extra hepatic manifestations: e.g., lymphoma, symptomatic cryoglobulinemia, membranoproliferative glomerulonephritis
- Indicate any relevant co-infection, e.g., HIV or Hepatitis B
- Document that patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions
- Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (patient will not be approved if any other HCV treatments have been used in the last 6 months)

Step 3: Direct Acting Antivirals (DAA) conditions for coverage

- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist
- Initial approval: 8 week period
- HCV RNA testing is required every 4 weeks; treatment beyond the initial 8 weeks of therapy require confirmation of lowered viral load; refills will NOT be granted unless a greater than or equal to a 2 log reduction in the HCV RNA or the HCV RNA is less than 25 IU/mL
- HIV/HCV-coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications
- No lost or stolen medication will be replaced
- Only regimens listed as recommended or alternative in the current AASLD guidance (<http://hcvguidelines.org>) will be approved. Regimens listed as not recommended will not be approved.

**Sublingual Allergen Extract PA Criteria
For Ohio Medicaid Fee-for-Service**

Sublingual allergen extracts will be approved for patients who meet all of the following criteria:

- Patient age is consistent with product labeling
- Patient has tested positive for allergy to the appropriate allergen
- Patient is not being treated with daily asthma medication (i.e., if patient has asthma, it is mild/intermittent and does not require controller medications)
- Patient would receive allergy shots in the absence of sublingual therapy
- Symptoms were present for 120 or more days during the previous allergy season
- Claims history of 90 or more days of at least two different classes of allergy symptom treatment during the previous allergy season. Allergy symptom treatments include:
 - Oral antihistamines (first or second generation)
 - Nasal antihistamines
 - Nasal corticosteroids
 - Ophthalmic antihistamines or mast cell stabilizers
 - Montelukast

Product	Allergen	Age	Duration of therapy
Grastek®	Timothy grass or cross-reactive grass pollens	5 – 65	Initiate treatment at least 12 weeks before expected onset of each grass pollen season and continue throughout pollen season. Grass pollen is high in spring through early summer.
Ragwitek®	Short ragweed pollen	18 – 65	Initiate treatment at least 12 weeks before expected onset of each ragweed pollen season and continue throughout pollen season. Ragweed pollen is high in summer to early fall.