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

October 8, 2014
77 S. High Street, Columbus, OH, Room 1960

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

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 10:04 AM by Dr. Hunter, chair.

A. Interested Party Presentations. No interested parties requested a presentation. A letter from the Ohio AIDS Coalition in support of Triumeq was distributed to members prior to the meeting.
B. Old Business: Hepatitis C Virus (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. The committee asked about the prescription that was prescribed by a resident, how many HCV patients are in Ohio, and what follow-up will be done on patients completing treatment.
C. New Business: Drugs Under Review
   1. Blood Agents: Platelet Aggregation Inhibitors – Zontivity (vorapaxar sulfate), Merck
      A representative of Merck provided a clinical overview. Dr. Levine presented the recommendation from Xerox and ODM for non-preferred status, because Zontivity is add-on treatment. Clinical criteria were proposed requiring a history of myocardial infarction (MI) or peripheral arterial disease (PAD); no history of stroke, transient ischemic attack, or intracranial hemorrhage; for PAD, patient must be at high risk for limb ischemia or peripheral artery revascularization; for MI prevention, the patient must have concomitant use of statins and hypertension controlled. Zontivity should be used in combination with clopidogrel and/or aspirin.
      Dr. Hunter expressed concern that the drug has irreversible activity so an acute bleed may be difficult to treat. The Merck representative recommended stopping the drug and giving supportive therapy. There is no antidote or reversal agent, and the antiplatelet activity continues for up to 8 days so giving platelets is not an appropriate option.
      The committee voted unanimously to accept the recommendation for non-preferred status and clinical criteria.
   2. Endocrine Agents: Diabetes Adjunctive Therapy – Tanzeum (albiglutide), GSK.
      Dr. Levine presented the recommendation from Xerox and ODM for non-preferred status, because efficacy is not significantly different than other drugs in the class.
      The committee voted unanimously to accept the recommendation for non-preferred status.

3. Immunomodulator Agents for Systemic Inflammatory Disease – Otezla (apremilast), Celgene.
   A representative from Celgene presented a clinical overview. Dr. Levine presented the recommendation from Xerox and ODM for non-preferred status, because the preferred alternatives in the class are indicated for psoriatic arthritis and there is no evidence that Otezla is more effective than the alternatives.
   Dr. Eastman asked if Otezla is indicated for treatment-naïve patients. The representative responded that the drug is approved for patients with moderate to severe psoriatic arthritis who are candidates for systemic or phototherapy.
   The committee voted unanimously to accept the recommendation for non-preferred status.
4. Infectious Disease Agents: Antivirals-HIV – Triumeq (abacavir/dolutegravir/lamivudine), Viiv
   A representative from Viiv presented a clinical overview. Dr. Levine presented the recommendation from Xerox and ODM for preferred status.
   The committee voted unanimously to accept the recommendation for preferred status.

The meeting was adjourned with a reminder that the next meeting is scheduled for Wednesday, January 7, 2014 (date corrected from the reminder listed on the agenda).

Notes from ODM after the meeting:

All recommendations will be implemented.

Ohio | Department of Medicaid

John R. Kasich, Governor
John B. McCarthy, Director

Pharmacy and Therapeutics Committee
October 8, 2014
Stephanie Levine, PharmD
Xerox State Healthcare

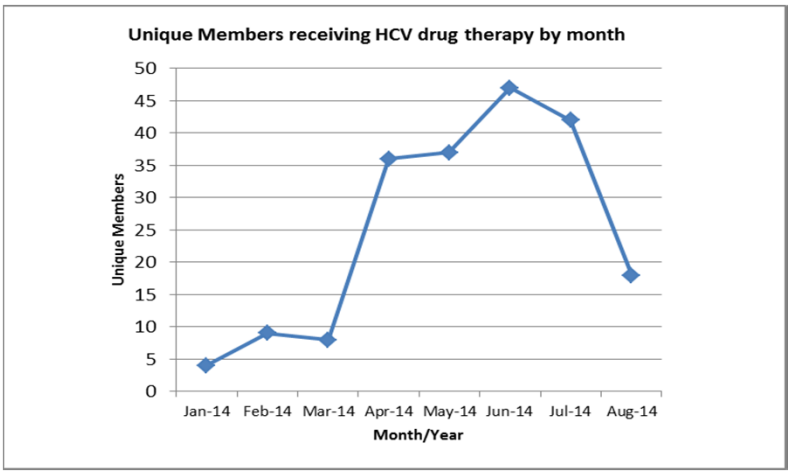
2Q2014 OHIO DEPARTMENT OF MEDICAID FEE FOR SERVICE HEPATITIS C VIRUS (HCV) DRUG SPEND

Drug	Number of Claims	Total Amount Paid to Pharmacies	% of Total Amount Paid to Pharmacies
INCIVEK	2	$34,271	1%
MODERIBA	2	$501	0%
OLYSIO	19	$449,677	13%
PEGASYS	59	$170,348	5%
PEGINTRON	4	$13,930	0%
REBETOL	3	$1,251	0%
RIBASPHERE	54	$19,345	1%
RIBAVIRIN	50	$11,009	0%
SOVALDI	91	$2,726,275	79%
VICTRELIS	1	$7,665	0%
Totals	**285**	**$3,434,271**	**100%**

YEAR TO DATE UNIQUE MEMBERS & TOTAL PRESCRIPTIONS PER HCV DRUG

DRUG NAME	Unique Members YTD (Jan –Aug 2014)	Total RX
VICTRELIS	3	6
PEGINF	48	97
RIBAVIRIN	80	163
OLYSIO	27	50
SOVALDI	83	144
INCIVEK	2	5
Totals		**465**

HCV DRUG UTILIZATION OVER TIME



US PIPELINE, HCV DRUGS

FDA approval (anticipated)	Manufacturer	Drug	Comments
October 10, 2014	Gilead	Sovaldi + ledipasvir	All oral
November 2014	BMS	Dakinza + Sunvepra (asunaprevir) (response rate 90%)	All oral, not as effective as Dakinza + Sovaldi combination (response rate 100%) which was approved in the European Union
December 2014	Abbvie	ABT-267, ABT-333 and ABT-450/ritonavir.	All oral, Three in one pill
2016	Merck	All oral, combination of MK-5172, its NS3/4A protease inhibitor, and MK-8742, an NS5A	

ADHERENCE TO SOVALDI

- Three (3) members received only one fill (all three remained in FFS)
- Four (4) members filled Sovaldi fifteen (15) days after anticipated fill date
- Fourteen (14) members have completed Sovaldi therapy
- Twenty-eight (28) members received their first dose from FFS and have subsequently moved to an MCO

CONCURRENT DISEASE STATES

- Seven (7) post transplant members
- Five (5) members taking Suboxone concurrently
- One (1) member with HIV
- One (1) member with HBV
- Sixteen (16) members on chronic Xifaxan and/or lactulose (advance liver disease)
- One (1) member with hepatic carcinoma
- One (1) member with a history of breast cancer [taking exemestane (Aromasin)]

HCV DRUG REGIMENS UTILIZED

	Jan 2013- July 2014		Jan 2013 - Aug 2014	
HCV Regimen	# Unique Members	% of all regimens	# Unique Members	% of all regimens
Ribavirin/Sovaldi/ (all oral drug regimen)	27	28%	28	26%
PEG-INF/Ribavirin/Sovaldi/	26	27%	27	25%
Olysio/Sovaldi/ (all oral drug regimen)	18	18%	26	24%
PEG-INF/Ribavirin/	11	11%	13	12%
PEG-INF/Sovaldi/	1	1%	1	1%
Ribavirin/	8	8%	7	6%
PEG-INF/Ribavirin/Olysio/Sovaldi/±	1	1%	1	1%
PEG-INF/Incivek/	1	1%	1	1%
PEG-INF/	1	1%	1	1%
PEG-INF/Ribavirin/Incivek/	1	1%	1	1%
PEG-INF/Ribavirin/Victrelis/	3	3%	3	3%
Totals	98	100%	109	100%

MEMBERS on BEHAVIORAL HEALTH MEDICATIONs (BHM) and HCV

Total members on a BHM	49
Members on a BHM and all oral HCV regimen	23
Members not on a BHM and on an all oral HCV regimen due to history of behavioural health issues	5 (out of 8 requests)
Members on a BHM and on PEG-INF regimen	23
Members on a BHM and HCV regimen is unclear	3

PRESCRIBERS OF HCV DRUG REGIMENS

Specialty	# of Members Treated	# of Practitioners within Specialty
Gastroenterology	57	43
Hepatologist	22	10
Infectious Disease	20	5
Nurse Practitioner	3	3
Family Practice	2	2
Internal Medicine	2	1
Medical Resident	1	1
Psychiatrist	1	1
Bariatric medicine	1	1
Grand Total	**109**	**67**

CONCLUSION

- Market place is dynamic
- Drug therapy regimens are dynamic and may vary among specialists
- Follow-up with prescribers on sustained viral response (SVR) is ongoing
- Continued tailoring of clinical criteria