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

October 9, 2013
30 E. Broad Street, Columbus, OH, Lobby Hearing Room

Committee members present: Suzanne Eastman, PharmD; Jennifer Hauler, DO; Michael Howcroft, RPh; Karen Jacobs, DO; Margaret Scott, RPh; Michael Wascovich, RPh.

Xerox staff present: Stephanie Levine, RPh, Clinical Manager

ODM staff present: Jill Griffith, PharmD, DUR Director

Approximately 55 stakeholders were present, most representing pharmaceutical manufacturers.

The meeting was called to order at 10:00 AM by Mr. Wascovich, acting chair.

1) Interested party presentations – no requests were received on topics relevant to the agenda.
2) Old Business
   a) Review of Medicaid claims: Do patients using Veramyst require fewer ophthalmic antihistamines than patient using other nasal steroids?
      Ms. Scott presented claims data from Ohio Medicaid and another state's Medicaid program to show that patients using Veramyst are not more likely to require other medications to control seasonal allergy symptoms. Mr. Wascovich commented that parity among products was demonstrated.
      A copy of the data is attached.
   b) Preferred Drug List
      i) CNS Agents, Multiple Sclerosis oral agents
         1. Aubagio (teriflunomide) – Genzyme/Sanofi
         2. Gilenya (fingolimod) – Novartis
         3. Tecfidera (dimethyl fumarate) – Biogen Idec

         Representatives of each manufacturer presented clinical information about their products.
         Dr. Levine gave the recommendation from Xerox and the state for preferred status for Tecfidera and non-preferred status for Aubagio and Gilenya.
         Dr. Jacobs asked if the recommendation is based on the monitoring required with Gilenya. Ms. Scott said that was a consideration, along with information received from practicing neurologists. Mr. Wascovich noted that Tecfidera is dosed twice daily, while Gilenya is dosed once daily and has been marketed longer so has more data. Dr. Jacobs suggested both Tecfidera and Gilenya should be preferred. Mr. Wascovich would prefer to choose one product; he has consulted with physicians at the Cleveland Clinic Mellen Center and they did not express a preference. Dr. Eastman commented that therapy is patient-dependent and based on the disease state so she would prefer more options. Mr. Wascovich asked for a vote on both Gilenya and Tecfidera being put into preferred status, since the committee will re-evaluate these products in June.

The vote was four to one in favor of both Tecfidera and Gilenya being preferred, with Ms. Scott dissenting.

ii) Immunomodulator Agents for Systemic Inflammatory Disease, new indication for ulcerative colitis
   1. Humira (adalimumab) – Abbvie
   2. Simponi (golimumab) – Janssen
   3. Proposed clinical criteria

   Representatives of each manufacturer presented clinical information about their product specific to the indication for ulcerative colitis.
   Ms. Scott presented the proposed clinical criteria, attached.
   The vote was unanimous to adopt the proposed criteria.

3) New Business
   a) Infections Disease Agents, Antivirals for HIV: Tivicay (dolutegravir sodium) – Viiv Healthcare
      A representative of Viiv presented clinical information about the drug.
      Dr. Levine gave the recommendation from Xerox and the state for preferred status for Tivicay.
      The committee vote was unanimous to add Tivicay to preferred status.
   b) Gastrointestinal Agents, Anti-Emetics: Diclegis (doxylamine succinate and pyridoxine hydrochloride) – Duchesnay
      A representative of Duchesnay presented information about the drug.
      Dr. Levine gave the recommendation from Xerox and the state for non-preferred status for Diclegis.
      Ms. Scott presented the proposed clinical criteria, attached to the minutes.
      The committee vote was unanimous to implement the proposed criteria.
   c) CNS Agents, Medication Assisted Therapy: Zubsolv (buprenorphine and naloxone) – Orexo
      A representative of Orexo presented information about the drug.
      Dr. Levine gave the recommendation from Xerox and the state for non-preferred status for Zubsolv.
      Dr. Jacobs noted the increased bioavailability of Zubsolv that requires less buprenorphine than Suboxone. She also asked whether the improved taste of Zubsolv may result in increased diversion. Dr. Hauler asked if there has been discontinuation of the competitor product based on mouth feel or taste. Dr. Eastman asked what criteria would be used to approve a non-preferred product. Dr. Jacobs suggested adverse events due to the formulation of Suboxone, and volunteered to check with addiction specialists to determine an appropriate length of trial for the preferred product.
      The committee vote was unanimous to place Zubsolv in non-preferred status, with criteria to be determined after Dr. Jacobs consults with colleagues.

The meeting was adjourned at 11:49 AM with a reminder that the next meeting is scheduled for Wednesday, January 8, 2014.

Notes from ODM after the meeting:

The committee recommendations to add Gilenya, Tecfidera, and Tivicay to preferred status and Diclegis and Zubsolv to non-preferred status were accepted. The approved criteria for immunomodulators for ulcerative colitis and anti-emetics will be implemented.

Criteria for prior approval of Zubsolv are under review.

Ohio | Department of Medicaid

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

Do Patients Using Veramyst® Require Fewer Ophthalmic Antihistamines Than Patients Using Other Nasal Steroids?

Pharmacy & Therapeutics Committee

October 9, 2013

Ohio Medicaid Nasal Steroids 7/2012-6/2013 Unique Patients

Nasal Steroid Drug Name	Nasal Steroid Utilizers		Nasal Steroid + Ophthalmic Antihistamine		Nasal Steroid + Oral Antihistamine		Nasal Steroid + Ophthalmic Antihistamine + Oral Antihistamine	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
FLUNISOLIDE	54	0.31%	2	3.70%	21	38.89%	2	3.70%
FLUTICASONE PROPIONATE	***16,445***	***95.76%***	***1,126***	***6.85%***	***7,800***	***47.43%***	***793***	***4.82%***
VERAMYST	***41***	***0.24%***	***5***	***12.20%***	***22***	***53.66%***	***1***	***2.44%***
NASACORT AQ	271	1.58%	21	7.75%	148	55.00%	17	6.27%
NASONEX	317	1.85%	43	13.56%	159	50.16%	28	8.83%
RHINOCORT AQUA	23	0.13%	3	13.04%	13	56.52%	1	4.35%

"State X" Nasal Steroids 7/2011-6/2012 Unique Patients

Nasal Steroid Drug Name	Nasal Steroid Utilizers		Nasal Steroid + Ophthalmic Antihistamine		Nasal Steroid + Oral Antihistamine		Nasal Steroid + Ophthalmic Antihistamine + Oral Antihistamine	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
FLUNISOLIDE	235	0.67%	5	2.13%	116	49.36%	3	1.28%
FLUTICASONE PROPIONATE	***3,452***	***9.85%***	***21***	***0.61%***	***1,158***	***33.55%***	***12***	***0.35%***
VERAMYST	***6,597***	***18.82%***	***271***	***4.11%***	***3,024***	***45.84%***	***180***	***2.73%***
NASACORT AQ	99	0.28%	2	2.02%	35	35.35%	1	1.01%
NASONEX	24,633	70.28%	575	2.33%	10,907	44.28%	367	1.49%
RHINOCORT AQUA	6	0.02%	0	0%	1	16.67%	0	0%

"State X" Nasal Steroids Market Share Shift

	Veramyst Preferred		Veramyst Non-Preferred	
	7/2011 - 6/2012		7/2012 - 6/2013	
Nasal Steroid Drug Name	**Rx Total**	**Market Share**	**Rx Total**	**Market Share**
NASONEX	36,929	68.0%	43,071	76.4%
VERAMYST	***11,098***	***20.4%***	***505***	***0.9%***
FLONASE (Brand & Generic)	***5,736***	***10.6%***	***12,217***	***21.7%***
FLUNISOLIDE (Nasarel & Nasalide)	378	0.7%	217	0.4%
CICLESONIDE (Omnaris & Alvesco	0	0.0%	160	0.3%
NASACORT AQ (Brand & Generic)	128	0.2%	141	0.3%
BECLOMETHASONE (Qnasl & Beconase AQ)	33	0.1%	62	0.1%
RHINOCORT AQ	6	0.0%	13	0.0%
Total	**54,308**	**100.0%**	**56,386**	**100.0%**

DRAFT

Gastrointestinal Agents: Ulcerative Colitis Agents

LENGTH OF AUTHORIZATIONS: 5-Amino Salicylic Acid (ASA) Agents: 6 months
Tumor Necrosis Factor (TNF) Inhibitors:
Initial treatment 8 weeks
Re-approval 1 year

STEP THERAPY: Oral agents only

1) For a preferred brand oral agent, there must have been inadequate clinical response to preferred generic oral alternatives, including a trial of no less than one month of at least one preferred generic
2) For a non-preferred oral agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than one month each of at least two preferred generics or brands

CLINICAL PRIOR AUTHORIZATION: ***TNF Inhibitors***
Humira may be approved if there is an inadequate clinical response to at least three months of therapy with both 5-ASA and immunosuppresants.
Patients with primary nonresponse to one TNF inhibitor can be assumed to be nonresponders to the class. Initial approval for Humira will be for 8 weeks. If clinical response is not seen in 8 weeks, further therapy with TNF inhibitors will not be approved. If there has been a therapeutic failure to Humira after 6 months, Simponi may be approved.

OTHER CRITERIA:
Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

1. Ulcerative Colitis Agents are available in oral (IR, ER), rectal (enema, suppository), and subcutaneous formulations. Patients with mild or moderate disease may be treated with either rectal or oral agents. ***Patients with moderate to severe disease may receive a TNF inhibitor after failing to respond to oral or rectal 5-ASA therapy and immunosuppressants.***
2. Efficacy among the different 5-ASA derivatives appears comparable.
3. The following quantity limits will apply for the injectable agents:
Humira – 7 pens/syringes during month one, then 2 pens/syringes per month
Simponi – 3 pens/syringes during month one, then 1 pen/syringe per month

DRAFT

ULCERATIVE COLITIS AGENTS – 5-ASA ORAL

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
BALSALAZIDE DISODIUM (generic of Colazal®) SULFASALAZINE (generic of Azulfidine®) SULFASALAZINE EC (generic of Azulfidine Entab®)	APRISO® (mesalamine) DELZICOL® (mesalamine) LIALDA® (mesalamine) PENTASA® (mesalamine)	ASACOL HD® (mesalamine) DIPENTUM® (olsalazine) GIAZO® (balsalazide disodium)

ULCERATIVE COLITIS AGENTS – 5-ASA RECTAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED
CANASA® suppositories (mesalamine) MESALAMINE enema (generic of Rowasa® and SFRowasa®)	MESALAMINE enema kit (generic for Rowasa® kit)

ULCERATIVE COLITIS AGENTS – TUMOR NECROSIS FACTOR INHIBITORS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
HUMIRA® pen, starter packs, syringe (adalimumab)	SIMPONI™ pen, syringe (golimumab)

DRAFT

Immunomodulator Agents for Systemic Inflammatory Disease

LENGTH OF AUTHORIZATIONS: ~~1 year~~ ***Dependent on Indication***

All products in this class require clinical prior authorization:

- No current infection; and
- Prior first-generation therapy appropriate for diagnosis; and
- Diagnosis of one of the following: ***1-year approval***:
  - Rheumatoid Arthritis
  - Psoriatic Arthritis
  - Polyarticular Juvenile Idiopathic Arthritis
  - Crohn's Disease
  - Ankylosing Spondylitis
  - Psoriasis
- ***Diagnosis of Moderate to Severe Ulcerative Colitis (UC) (Humira and Simponi only): initial approval 8 weeks, reapprovals 1 year***

  Humira may be approved if there is an inadequate clinical response to at least three months of therapy with both 5-ASA and immunosuppresants.
  Patients with primary nonresponse to one TNF inhibitor can be assumed to be nonresponders to the class. Initial approval for Humira will be for 8 weeks. If clinical response is not seen in 8 weeks, further therapy with TNF inhibitors will not be approved. If there has been a therapeutic failure to Humira after 6 months, Simponi may be approved.
  Quantity limits for UC diagnosis:
  Humira – 7 pens/syringes during month one, then 2 pens/syringes per month
  Simponi – 3 pens/syringes during month one, then 1 pen/syringe per month

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a three-month trial of at least one preferred medication

ANTI-INFLAMMATORY TUMOR NECROSIS FACTOR INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
CIMZIA® syringe (certolizumab pegol) ENBREL® kit, SureClik, syringe (etanercept) HUMIRA® pen, starter packs, syringe (adalimumab)	SIMPONI™ pen, syringe (golimumab) ORENCIA® syringe (abatacept)

DRAFT

ANTI-INFLAMMATORY INTERLEUKIN-1 RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	KINERET® syringe (anakinra)

JANUS KINASE INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	XELJANZ® tablet (tofacitinib citrate)

DRAFT

Gastrointestinal Agents: Anti-Emetics

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - Allergy to medications not requiring prior approval
   - Contraindication to or drug interaction with medications not requiring prior approval
   - History of unacceptable/toxic side effects to medications not requiring prior approval
2. ***The requested medication may be approved if there has been a therapeutic failure to no less than a seven-day trial on at least one medication not requiring prior approval.***

GASTROINTESTINAL AGENTS: ANTI-EMETIC AGENTS: 5-hydroxytryptamine 3 (5-HT3) receptor antagonists

NO PA REQUIRED "PREFERRED"	PA REQUIRED
EMEND® tablets, trifold (aprepitant) ONDANSETRON tablets, solution, ODT (generic of Zofran®)	ANZEMET® (dolasetron) GRANISETRON tablet, solution (generic of Kytril®) SANCUSO® patch (granisetron)

GASTROINTESTINAL AGENTS: ANTI-EMETIC AGENTS: non-5-HT3 receptor antagonists

NO PA REQUIRED "PREFERRED"	PA REQUIRED
DIMENHYDRINATE tablets DIPHENHYDRAMINE tablets, capsules, solution MECLIZINE tablets (generic of Antivert®) METOCLOPRAMIDE tablets (generic of Reglan®) PHOSPHORATED CARBOHYDRATE SOLUTION (generic of Emetrol®) PROCHLORPERAZINE tablets, suppositories (generic of Compazine®) PROMETHAZINE tablets, suppositories (generic of Phenergan®) TRANSDERM-SCOP® patch (scopolamine) TRIMETHOBENZAMIDE capsules (generic of Tigan®)	DICLEGIS® (doxylamine and pyridoxine)