

**Ohio Department of Medicaid (ODM)
Pharmacy & Therapeutics Committee
Quarterly Meeting
October 14, 2015
10:00 am**

MINUTES

Committee Members Present:

Susan Baker, CNP
Suzanne Eastman, PharmD
Jennifer Hauler, DO
Cheryl Huffman, MD
Karen Jacobs, DO
Melissa Jefferis, MD
Margaret Scott, RPh

Committee Members Not Present:

Sandra Hrometz PhD, RPh

Contract Staff/GHS Staff Present:

Laureen Biczak, DO
Chad Bissell, PharmD
Jill RK Griffith, BS, PharmD
Steve Liles, PharmD

Also present were approximately 28 observers, most representing pharmaceutical manufacturers.

I. Call to Order

Karen Jacobs, DO, called the meeting to order at 10:07 am.

II. Introductions

Ms. Margaret Scott, ODM Pharmacist, welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. She introduced Goold Health Systems (GHS), the ODM fee-for-service Preferred Drug List (PDL) and Supplemental Rebate (SR) vendor. She recognized Dr. Griffith, PharmD, former ODM DUR Director, as the GHS Ohio Account Manager. GHS will be lending P&T and PDL support, as well as implementing a generic drug maximum allowable cost list on October 15th, 2015 and a point of sale (POS) system in 2016. All parties seated at the table introduced themselves and gave a brief statement about their professional credentials and affiliations. Ms. Scott reminded guests to sign in and that industry presenters are limited to five minutes.

III. Administrative Matters

Ms. Scott reviewed the P&T Committee member Conflict of Interest form that must be signed annually. P&T Committee By-Laws were introduced. Ms. Scott outlined the P&T Committee: purpose, duties and process; membership appointment, term, officers, responsibilities, removal and resignation process; meeting frequency and procedure; quorum, public participation guidelines, disclosure of interest; and finally, amendment of the By-Laws. Clarifications were recommended by the Committee.

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Ms. Scott stated that the PDL is completely updated once per year; quarterly updates are implemented throughout the year. The P&T Committee works in an advisory capacity and that ODM is responsible for final decisions related to the PDL. She stated that ODM takes into account recommendations from the P&T Committee and the clinical contractor before making a final decision. The By-Laws will be adopted, elections held, and the Conflict of Interest forms signed during the January 2016 meeting.

IV. Department of Medicaid Update

Ms. Scott updated the Committee on the Governor's Cabinet Opiate Action Team. The group completed work on acute pain prescribing guidelines. The guidelines are being circulated for stakeholder review and consensus.

V. Approval of June 10, 2015 Meeting Minutes

Dr. Jacobs asked for additions or corrections to the June 10, 2015 meeting. There were no additions or corrections. The minutes stand approved.

VI. Introduction to Goold Health System and Meeting Format

Dr. Bissell introduced GHS as a company with 40 years of Medicaid experience and also a subsidiary of Emdeon, with offices throughout the United States. The Ohio GHS team is under construction. A pharmacist and physician will be at P&T meetings to present clinical information and review reports. The entire PDL will be reviewed once a year. New drugs will be reviewed quarterly. New drug and therapeutic class review documents will be provided to committee members in advance of the meetings. Dr. Biczak provided additional information about the development and content of the GHS clinical documents. Dr. Bissell would like to use Robert's Rules during the meetings with a motion, second and vote for each drug reviewed.

VII. Drug Class Announcements

Ms. Scott stated that both Advicor and Simcor are coming off the market.

VIII. Interested Party Presentations

There were no interested party presentations.

IX. Preferred Drug List Proposal

Pharmaceutical manufacturers were given the opportunity to present clinical information on their products and respond to questions from committee members.

A. Corlanor

GHS recommended that Corlanor be made non-preferred in the Cardiovascular Agents: Angina, Hypertension & Heart Failure category. Additionally, GHS recommended clinical criteria be met for prior authorization. Clinical discussion ensued. Votes were taken. The approved category and criteria are below.

HYPERPOLARIZATION-ACTIVATED CYCLE NUCLEOTIDE-GATED CHANNEL INHIBITOR CLINICAL PRIOR AUTHORIZATION CRITERIA:

Ivabradine (Corlanor®) may be approved if all of the following are met:

1. Diagnosis of stable, symptomatic heart failure, and
2. Left ventricular ejection fraction less than or equal to 35%, and
3. Resting heart rate 70 bpm or higher, and
4. Patient in sinus rhythm, and

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- Heart failure symptoms persisting with maximally tolerated doses of beta blockers, or patient has a contraindication to beta blocker therapy.

HYPERPOLARIZATION-ACTIVATED CYCLE NUCLEOTIDE-GATED CHANNEL INBITOR

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	CORLANOR® (ivabradine)

B. Entresto

GHS recommended that Entresto be made non-preferred in the Cardiovascular Agents: Angina, Hypertension & Heart Failure category. Additionally, GHS recommended clinical criteria be met for prior authorization. Clinical discussion ensued. Votes were taken. The approved category and criteria are below.

ARB/ NEPRILYSIN INHIBITOR COMBINATION CLINICAL PRIOR AUTHORIZATION

CRITERIA:

Valsartan/sacubitril (Entresto™) may be approved if all of the following are met:

- Diagnosis of chronic heart failure (NYHA Class II-IV), and
- Age greater than or equal to 18 years, and
- Left ventricular ejection fraction less than or equal to 35%, and
- No history of angioedema or unacceptable side effects with ACE inhibitor or ARB, and
- If patient has diabetes, not concomitantly taking aliskiren, and
- Not concomitantly taking an ACE inhibitor or other ARB, and
- Patient does not have severe hepatic impairment (Child-Pugh C).

ANGIOTENSIN II RECEPTOR ANTAGONIST/ NEPRILYSIN INHIBITOR/ COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
	ENTRESTO™ (valsartan/sacubitril)

C. Glatopa

GHS recommended that Glatopa be made non-preferred in the CNS Agents, MS Disease Modifying Agents, Injectable category. Clinical discussion ensued. Votes were taken and the approved category follows below.

CNS AGENTS: MULTIPLE SCLEROSIS DISEASE MODIFYING AGENTS, INJECTABLE *

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AVONEX® (interferon beta-1a)	COPAXONE® (glatiramer) 40MG
BETASERON® (interferon beta-1b)	EXTAVIA® (interferon beta-1b)
COPAXONE® (glatiramer) 20MG	GLATOPA™ (glatiramer)
REBIF® (interferon beta-1a)	PLEGRIDY® (peginterferon beta-1a)

*Patients on current regimens will be grandfathered.

D. Cosentyx

GHS recommended that Cosentyx be made non-preferred in the Immunomodulator Agents for Systemic Inflammatory Disease category. Clinical discussion ensued. Votes were taken and the approved category follows below.

ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
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	ACTEMRA [®] syringe (tocilizumab) COSENTYX [™] (secukinumab) KINERET [®] syringe (anakinra)
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E. Cresemba

GHS recommended that Cresemba be made non-preferred in the Infectious Disease Agents: Antifungals for Onchomycosis and Systemic Infections category. Clinical discussion ensued. Votes were taken and the approved category follows below.

INFECTIOUS DISEASE AGENTS: AGENTS FOR SYSTEMIC INFECTIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
FLUCONAZOLE (generic of Diflucan [®]) FLUCONAZOLE suspension (generic of Diflucan [®]) KETOCONAZOLE (generic of Nizoral [®])	CRESEMBA [®] (isavuconazonium) ITRACONAZOLE capsules (generic of Sporanox [®]) NOXAFIL [®] (posaconazole) SPORANOX [®] 100mg/10ml oral solution (itraconazole)

F. Stiolto

GHS recommended that Stiolto be made non-preferred in the Respiratory Agents, Beta-Adrenergic Combinations category. Clinical discussion ensued. Votes were taken and the approved category follows below.

RESPIRATORY AGENTS: BETA-ADRENERGIC COMBINATIONS

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED
ADVAIR DISKUS [®] (salmeterol/fluticasone) ADVAIR HFA (salmeterol/fluticasone) DULERA [®] (formoterol/mometasone) SYMBICORT [®] (formoterol/budesonide)	ANORO ELLIPTA (umeclidinium/vilanterol) BREO ELLIPTA (fluticasone/vilanterol) STIOLTO [™] (tiotropium/olodaterol)

X. Other Business

No other business was discussed.

XI. Next Meeting Dates

The next P&T Committee meeting will be held on Wednesday, January 13, 2016 at 10am, location to be announced.

XII. Adjournment

Dr. Jacobs adjourned the meeting at 11:37am.

ODM Actions: Following the meeting, ODM accepted all recommendations of the P&T Committee and will implement the recommendations by January 1, 2016.



Department of Medicaid

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

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 information regarding the safety, efficacy, and effectiveness of prescribed drugs within a class or classes of prescribed drugs 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 or company selling or distributing the medication or class of medications being considered that could inappropriately influence the member’s judgment, or the judgment of other members. This may include a relationship with a manufacturer or company that competes with the drug under consideration. A relationship with a manufacturer or company may include, but is not limited to, any of the following:

- Holding a shareholder interest;
- Having a consultant arrangement;
- Acceptance of honoraria;
- Participation in speaker’s bureau;
- Acceptance of support for travel for professional or education activities;
- Acceptance of research support; or
- Relationship valued at \$500 or more with one company.

Policy Statements

A Committee member shall:

- Avoid any action that might give rise to the appearance of impropriety;
- Abstain from all formal or informal issues if you have a relationship with a manufacturer or company that has a product under consideration or a competing product is being considered;
- Withdraw completely from questions where a potential conflict of interest may exist;
- Seek advice and assistance from the Ohio Ethics Commission if necessary to determine whether a potential conflict of interest exists.

Adapted from “Helpful Ethics Guidance for State and Local Board and Commission Members,” http://ethics.ohio.gov/education/factsheets/board_and_commission_member_dos_and_donts.pdf

Procedure: Committee members must sign this agreement annually.

Signature: _____ Date: _____

Printed Name: _____

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Ohio Pharmacy & Therapeutics Committee By-Laws

Article I - PURPOSE

Section I – Duties

The Pharmacy and Therapeutics Committee (Committee) has been established pursuant to Ohio Revised Code §5164.7510 to shall assist the Ohio Department of Medicaid (ODM) and its Medicaid Director with developing and maintaining a Preferred Drug List (PDL) for the Medicaid program.

Section II - Process

The Committee shall review and recommend to the Medicaid Director drugs that should be included on the PDL. The Committee's recommendations shall be made based on the evaluation of competent evidence regarding the relative safety, efficacy, and effectiveness of prescribed drugs within a class or classes of prescribed drugs. A vote by a majority of a quorum is necessary to make recommendations to the Director. In the case of a tie, the Chairperson shall decide the outcome.

Article II - MEMBERSHIP

Section I - Appointment

- 1) The Committee shall consist of ten members and the members shall be appointed by the Medicaid Director. The Director shall seek recommendations for membership from relevant professional organizations. A candidate for membership recommended by a professional organization shall have professional experience working with Medicaid recipients. Committee members shall possess recognized knowledge and expertise in one or more of the following:
 - a. The clinically appropriate prescribing of covered outpatient drugs;
 - b. The clinically appropriate dispensing and monitoring of covered outpatient drugs;
 - c. Drug use review, evaluation and intervention; or
 - d. Medical quality assurance.
- 2) The ten members shall include: three pharmacists licensed under Chapter 4729 of the Revised Code; two doctors of medicine and two doctors of osteopathy who hold certificates to practice issued under Chapter 4731 of the Revised Code, and one of whom is a family practice physician; a registered nurse licensed under Chapter 4723 of the Revised Code; a pharmacologist who has a doctoral degree; and a psychiatrist who holds a certificate to practice issued under Chapter 4731 of the Revised Code.

Section II - Term

Each Committee member shall be appointed to a two-year term after which each member will come up for review and new members may be considered. Members may be appointed to an unlimited number of terms.

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Section III - Officers

There shall be a Chairperson and a Vice-Chairperson who shall be nominated and elected by a majority of the Committee. Other officers as deemed necessary and appropriate by the Committee may be nominated and elected by a majority vote. The Vice-Chairperson will take the place of the Chairperson upon his or her absence or request.

Section IV - Responsibilities

Committee members shall:

- 1) Review and recommend to the Medicaid Director the drugs that should be included on the PDL. Their recommendations shall be made based on the evaluation of competent, peer reviewed medical literature, professional guidelines and evidence regarding the relative safety, efficacy, and effectiveness of prescribed drugs within a class or classes of prescribed drugs.
- 2) Apply their knowledge of current clinical practice during discussions and the making of recommendations.
- 3) Attend and participate in all Committee meetings, unless they are excused for good cause shown or otherwise excused by the Chairperson. In the event the Chairperson is unable to attend, the Chairperson shall provide advance written notice for the absence to the ODM clinical vendor, who shall note the reasons for the absence in the meeting minutes.

Section V – Removal and Resignation

A Committee member may resign or may be removed at any time by the Medicaid Director, with or without cause.

Article III - MEETINGS

Section I - Frequency

The Committee will meet four times a year and at special meetings as determined by the Committee. One or more of the following topics may be discussed at the meetings:

- New brand drug or generic drugs on the market.
- Changes to be made to the PDL based on any local or national issues (including contract issues).
- Feedback from drug manufacturers and the public through a Public Comment session.

The Committee also shall conduct, at least annually, a complete a review of the entire PDL.

Section II - Procedure

- 1) The tentative meeting agenda, draft PDL, any therapeutic class reviews and new drug monographs, and any other pertinent information will be made available electronically by the ODM clinical vendor to the Committee members no less than fourteen days in advance of the meeting.
- 2) For any meeting where the majority or all of the PDL is on the agenda, the meeting agenda, draft PDL and drug monographs/therapeutic class reviews, and any other pertinent information will be

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sent electronically by the clinical vendor to the Committee members no less than thirty days in advance of the meeting.

- 3) A detail committee agenda shall be posted on ODM's website not later than fourteen days prior to the date of a regularly scheduled meeting, and not later than seventy-two hours prior to the date of a special meeting called by the Committee. For meetings where a majority or all of the PDL is on the agenda, a draft PDL shall be posted on ODM's website.
- 4) During the Committee meetings, non-extracted PDL categories will be voted on by a consent agenda. Extracted categories will be reviewed and voted on individually. The Clinical vendor, Department representatives and Committee members are able to request extraction of any or all categories for any reason.
- 5) The Committee may establish one or more subcommittees to investigate and analyze issues consistent with the duties of the Committee under Ohio Revised Code §5164.7510. The subcommittee(s) may submit proposals to the Committee regarding the issues and the Committee may adopt, reject or modify the proposals.
- 6) The Committee shall post its recommendations on the website not later than seven days after the meeting at which the recommendation was approved.
- 7) The ODM clinical vendor shall take meeting minutes.
- 8) The Committee shall conduct its meeting according to parliamentary procedures outlined in *Robert's Rules of Order*.

Article IV - QUORUM

A quorum of five members of the Committee is required to conduct business. A majority will determine the Committee's election of officers, committee appointments, and recommendations.

No business can be transacted without a quorum except to adjourn the meeting. If a question is raised, debate is allowed but no vote can be taken.

Article V - PUBLIC PARTICIPATION

Drug manufacturers whose products are under review may be invited to make a presentation or submit written material to the Committee. Drug manufacturers should focus on the relative clinical merits of their drug versus comparable products, and not discuss price with the Committee. Presentations will be limited in time by the Chairperson.

An interested party not affiliated with a drug manufacturer may request, and shall be permitted, to make a presentation or submit written material to the Committee during a committee meeting. The presentation or other material shall be relevant to an issue under consideration by the Committee and any written material, including a transcript of testimony to be given on the day of the meeting, may be submitted to the Committee in advance of the meeting.

Guidelines:

- 1) Interested parties may request to provide information to the Committee by contacting the clinical vendor prior to a scheduled meeting, and submitting both a written explanation of the topic and a conflict of interest statement. The topic must be relevant to the agenda for the meeting. The conflict of interest statement must include the interested party's affiliation (employer, client, advocacy group, etc.), relationships with any pharmaceutical manufacturers, and any other relevant relationships.

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- 2) Presentation requests should be made by the Friday prior to the meeting. The clinical vendor will confirm presentations with the interested party by the Friday prior to the scheduled meeting.
 - a. Presentations will be limited to a maximum of five minutes, with the Committee chair having the option to extend or further limit the speaker's time depending on the situation.
 - b. The presenter should provide 12 hard copies of the presentation to the Committee.
- 3) Written information should be submitted in electronic form at least two business days prior to the scheduled meeting to give the Committee time to review the materials. Materials submitted after the deadline may not be considered by the Committee. Written information provided at the meeting will not be considered during the meeting.

Article VI - DISCLOSURE OF INTEREST

Members of the Committee will be required to submit, on an annual basis, a signed "Pharmacy and Therapeutics Committee Conflict of Interest Policy" form. Committee members have an ongoing duty to disclose to the Committee any conflicts or potential conflicts of interests.

If a member has an interest that may affect or be perceived to affect the member's independence of judgment, the member must recuse himself/herself from the voting process for the drug class concerned. This recusal includes but is not limited to refraining from deliberation or debate, making recommendations, volunteering advice and participating in the decision-making process in any way.

The Chairperson will review the criteria that members should use to determine whether to recuse themselves from the voting process at the beginning of each meeting and ask whether any members need to recuse themselves from consideration of a particular drug or class of drugs.

Article VII - AMENDMENT OF BY-LAWS

Amendments to the By-Laws may be decided by majority vote at any Committee meeting. Any proposed amendments must be submitted prior to the meeting and be included in the agenda of the meeting during which the vote will be taken.

Document History

Date	Action
10/1/2015	Draft