OHIO DEPARTMENT OF MEDICAID

Pharmacy & Therapeutics Committee
Ohio Department of Medicaid
50 W. Town Street, Room C621-A and C621-B
Columbus, OH
July 11, 2018
10:00 AM
MINUTES

Committee Members Present:
Tracey Archibald, PharmD
Michelle Barger, PharmD
Karen Jacobs, DO Chair
Mary Ann Dzurec, PharmD
Stephen Hersey, MD
Melissa Jefferis, MD
Suzanne Eastman, RPh, MS

Committee Members Not Present:
Sandra Hrometz, Rph PhD,
Jennifer Gwilyn, DO
Susan Baker, CNP

Contract Staff/Change Healthcare Staff Present:
Jacqueline Hedlund, MD
Jill RK Griffith, BS, PharmD
Ben Link, PharmD
Gail Master, RPh

Also present were approximately 50 observers, most representing pharmaceutical manufacturers.

I. Call to Order

Karen Jacobs called the meeting to order at 10:02 a.m.

II. Introductions

Dr. Jacobs welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. All parties seated at the table introduced themselves and gave a brief statement about their professional credentials and affiliations.

Ohio Department of Medicaid

III. Administrative Matters

Dr. Archibald announced that the committee members need to sign the updated conflict of interest form and signatures were collected.

IV. Department of Medicaid Update

Dr. Archibald indicated that Dr. Hauler has stepped down from the P&T Committee. The Department is currently working on finding a replacement. Dr. Archibald indicated that there are open positions on both the DUR Board and DUR Committee. Request for Letters of Interest for the DUR Committee are posted on The Ohio Department of Administrative Services (DAS) website through July 31, 2018. Dr. Archibald discussed ways interested parties stay informed on updates to the pharmacy program and mentioned specifically the DUR Digest posted on the pharmacy website, as well as the ability to sign up to receive email notifications regarding prior authorization criteria changes. Dr. Archibald announced that therapeutic categories for the phased in single preferred drug list initiative for January 1, 2019 are still under consideration. Interested parties should periodically check the pharmacy website for updates related to this topic. Dr. Archibald indicated a vendor has been selected to conduct the state's Cost of Dispensing Survey. The surveys will be distributed to pharmacies this summer. Dr. Archibald announced that effective July 1, 2018, Fee for Service, along with all of the Managed Care Plans placed a payment limit of a maximum of 30 Morphine Equivalent Dose per prescription on short-acting opioids for new start patients (no opioids in the previous 90 days).

V. Approval of the April 11, 2018 Meeting Minutes

The minutes from the prior P&T meeting were approved.

VI. Drug Class Announcements

Dr. Link announced that the manufacturer of Technivie®, Viekira™ and Viekira XR™ have voluntarily removed their drug from the market and so these products are no longer reflected on the Preferred Drug List (PDL).

VII. Interested Party Presentations

Kelly Maynard, representing Little Hercules Foundation

Discussed Duchenne Muscular Dystrophy (DMD) and access to medication treatments.

VIII. Preferred Drug List Review

a) Central Nervous System (CNS) Agents: Parkinson's Agents: Gocovri™ (amantadine)

Dr. Hedlund provided a clinical overview of this medication. Votes were taken and the committee approved the proposed category, shown below:

Ohio Department of Medicaid

Central Nervous System (CNS) Agents: Parkinson's Agents

LENGTH OF AUTHORIZATIONS: 1 year

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 both of the following are true:

1. If there has been a therapeutic failure to no less than a one-month trial of at least one medication not requiring prior approval
2. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
3. Neupro® may be approved if the patient is unable to swallow.

PARKINSON'S AGENTS – DOPAMINERGIC AGENTS, ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMANTADINE	GOCOVRI™ (amantadine er)

b) Endocrine Agents: Diabetes-Oral Hypoglycemics: Segluromet™ (ertugliflozin and metformin)

Dr. Hedlund provided a clinical overview of this medication. Votes were taken and the committee approved the proposed category, shown below:

Ohio
Department of Medicaid

Endocrine Agents: Diabetes – Oral Hypoglycemics

LENGTH OF AUTHORIZATIONS: 1 year

STEP THERAPY: All oral hypoglycemics

1. For a drug requiring step therapy, there must have been inadequate clinical response to metformin products (either single-ingredient or in a sulfonylurea/ metformin or TZD/metformin combination), including a trial of no less than three months of at least one preferred metformin product
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including metformin and a trial of no less than three months of at least one preferred or step therapy product

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication within the same class 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

DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR COMBINATIONS

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	SYNJARDY® (empagliflozin and metformin) SYNJARDY® XR (empagliflozin and metformin)	GLYXAMBI® (empagliflozin/ linagliptin) INVOKAMET® (canagliflozin/ metformin) INVOKAMET® XR (canagliflozin/ metformin) SEGLUROMET™ (ertugliflozin/metformin) XIGDUO XR® (dapagliflozin/ metformin)

Ohio Department of Medicaid

c) Endocrine Agents: Diabetes-Oral Hypoglycemics: Steglujan™ (ertugliflozin and sitagliptin)

Dr. Hedlund provided a clinical overview of this medication. Votes were taken and the committee approved the proposed category, shown below:

Endocrine Agents: Diabetes – Oral Hypoglycemics

LENGTH OF AUTHORIZATIONS: 1 year

STEP THERAPY: All oral hypoglycemics

1. For a drug requiring step therapy, there must have been inadequate clinical response to metformin products (either single-ingredient or in a sulfonylurea/ metformin or TZD/metformin combination), including a trial of no less than three months of at least one preferred metformin product
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including metformin and a trial of no less than three months of at least one preferred or step therapy product

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication within the same class 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

DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR AND DPP-4 COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
No less than three months of at least one preferred DPP-4 and SGLT product	QTERN® (dapaglifozin/saxagliptin) STEGLUJAN™ (ertugliflozin/sitagliptin)

50 W. Town Street, Suite 400
Columbus, Ohio 43215
Pharmacy.medicaid.ohio.gov

Ohio
Department of Medicaid

d) Infectious Disease Agents: Antibiotics - Cephalosporins: Daxbia™ (cephalexin)

Dr. Hedlund provided a clinical overview of this medication. Votes were taken and the committee approved the proposed category, shown below:

Infectious Disease Agents: Antibiotics – Cephalosporins

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills

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. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
   - Note diagnosis and any culture and sensitivity reports
3. If there have been therapeutic failures to no less than a three-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

CEPHALOSPORINS, FIRST GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CEFADROXIL capsules, suspension (generic of Duricef®) CEPHALEXIN 250mg, 500 mg capsules, suspension (generic of Keflex®)	CEPHALEXIN 750mg (generic of Keflex®) DAXBIA™ (cephalexin)

Ohio
Department of Medicaid

e) Infectious Disease Agents: Antivirals-HIV: Biktarvy®
(bictegravir, emtricitabine and tenofovir alafenamide fumarate)

Dr. Link provided a clinical overview of this medication. Votes were taken and the committee approved the proposed category, shown below:

Infectious Disease Agents: Antivirals – HIV

LENGTH OF AUTHORIZATIONS: 1 year

GRANDFATHERING:
Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

NIH RECOMMENDED REGIMENS – TREATMENT NAIVE PATIENTS

Integrase Strand Transfer Inhibitor-Based Regimens:
ODM Preferred:

- Dolutegravir (Tivicay®) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada®)
- Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine (AI) (Genvoya®)
- Raltegravir (Isentress®) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada®)
- Dolutegravir (Tivicay®) plus tenofovir alafenamide/emtricitabine (AII) (Descovy®)
- Raltegravir (Isentress®) plus tenofovir alafenamide/emtricitabine (AII) (Descovy®)

ODM Non-Preferred/PA Required

- Dolutegravir/abacavir/lamivudine (only for patients who are HLA-B*5701 negative) (AI) (Triumeq®)
- Elvitegravir/cobicistat/tenofovir disoproxil fumarate/emtricitabine (AI) (Stribild®)

Protease Inhibitor-Based Regimens:
ODM Preferred:

- Darunavir (Prezista®) plus ritonavir (Norvir®) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada®)
- Darunavir (Prezista®) plus ritonavir (Norvir®) plus tenofovir alafenamide/emtricitabine (AII) (Descovy®)

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

1. Allergy to medications not requiring prior approval
2. Contraindication to recommended regimens not requiring prior approval
3. History of unacceptable/toxic side effects to medications not requiring prior approval
4. Has the patient had a therapeutic trial of at least one month with at least one medication not requiring prior approval?

HIV INTEGRASE INHIBITOR & NUCLEOSIDE ANALOG COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BIKTARVY® (bictegravir/emtricitabine/tenofovir)	

Ohio Department of Medicaid

f) Infectious Disease Agents: Antivirals - HIV: Symfi Lo™ (efavirenz, lamivudine and tenofovir disoproxil fumarate)

Dr. Link provided a clinical overview of this medication. Votes were taken and the committee approved the proposed category, shown below:

Infectious Disease Agents: Antivirals – HIV

LENGTH OF AUTHORIZATIONS: 1 year

GRANDFATHERING:
Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

NIH RECOMMENDED REGIMENS – TREATMENT NAIVE PATIENTS

Integrase Strand Transfer Inhibitor-Based Regimens:
ODM Preferred:

- Dolutegravir (Tivicay®) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada®)
- Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine (AI) (Genvoya®)
- Raltegravir (Isentress®) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada®)
- Dolutegravir (Tivicay®) plus tenofovir alafenamide/emtricitabine (AII) (Descovy®)
- Raltegravir (Isentress®) plus tenofovir alafenamide/emtricitabine (AII) (Descovy®)

ODM Non-Preferred/PA Required

- Dolutegravir/abacavir/lamivudine (only for patients who are HLA-B*5701 negative) (AI) (Triumeq®)
- Elvitegravir/cobicistat/tenofovir disoproxil fumarate/emtricitabine (AI) (Stribild®)

Protease Inhibitor-Based Regimens:
ODM Preferred:

- Darunavir (Prezista®) plus ritonavir (Norvir®) plus tenofovir disoproxil fumarate/emtricitabine (AI) (Truvada®)
- Darunavir (Prezista®) plus ritonavir (Norvir®) plus tenofovir alafenamide/emtricitabine (AII) (Descovy®)

OTHER APPROVAL CRITERIA:

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

1. Allergy to medications not requiring prior approval
2. Contraindication to recommended regimens not requiring prior approval
3. History of unacceptable/toxic side effects to medications not requiring prior approval
4. Has the patient had a therapeutic trial of at least one month with at least one medication not requiring prior approval?

HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS AND COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SYMFI LO™ (efavirenz/lamivudine/tenofovir)	

Ohio
Department of Medicaid

g) Ophthalmic Agents: Glaucoma Agents: Rhopressa® (netarsudil)

Dr. Link provided a clinical overview of this medication. Votes were taken and the committee approved the proposed category, shown below:

Ophthalmic Agents: Glaucoma Agents

LENGTH OF AUTHORIZATIONS: 1 year

STEP THERAPY: ACROSS ALL AGENTS

1. For a product requiring step therapy, there must have been inadequate clinical response to preferred alternatives for glaucoma, including a trial of no less than one month of at least one preferred product
2. For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives for glaucoma, including a trial of no less than one month each of at least two preferred or step therapy products

OTHER APPROVAL 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
- Contraindications to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

GLAUCOMA AGENTS – RHO KINASE INHIBITORS

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
RHOPRESSA® (netarsudil)		

h) Respiratory Agents: COPD Anticholinergics (LAMA): Lonhala ™ Magnair ™ (glycopyrrolate)

Natalie Venon PhD, MBA, RRT, presented clinical information on Lonhala ™ Magnair ™ on behalf of Sunovion. Following her presentation, Dr. Link added his clinical comments. Votes were taken and the committee approved the proposed category, shown below:

Ohio Department of Medicaid

Respiratory Agents: Chronic Obstructive Pulmonary Disease

LENGTH OF AUTHORIZATIONS: 1 year for inhaled therapy
Daliresp evaluated with each refill

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? 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 two-week trial of at least one medication not requiring prior approval.

ADDITIONAL CRITERIA FOR ROFLUMILAST (DALIRESP®):
Patient must be adherent to concurrent therapy with long-acting beta agonist

RESPIRATORY AGENTS: COPD ANTICHOLINERGICS (LAMA)

NO PA REQUIRED " PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATROVENT HFA® (ipratropium) IPRATROPIUM nebulizer solution IPRATROPIUM/ALBUTEROL nebulizer solution (generic of Duoneb®) SPIRIVA® Handihaler® (tiotropium)†	COMBIVENT Respimat® (ipratropium/albuterol) INCRUSE ELLIPTA® (umeclidinium)† LONHALA™ MAGNAIR™ (glycopyrrolate) SEEBRI™ NEOHALER® (glycopyrrolate)† SPIRIVA® Respimat® (tiotropium) TUDORZA® (aclidinium bromide)†

†Denotes breath actuated inhaler

i) Respiratory Agents: Nasal Preparations- Glucocorticoids: Xhance ® (fluticasone propionate)

Dr. Link provided a clinical overview of this medication. Votes were taken and the committee approved the proposed category, shown below:

Respiratory Agents: Nasal Preparations

LENGTH OF AUTHORIZATIONS: 1 year

For a non-preferred drug, 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 or step therapy products

OTHER APPROVAL 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

RESPIRATORY AGENTS: NASAL PREPARATIONS - GLUCOCORTICOIDS

NO PA REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
FLUNISOLIDE FLONASE OTC® (fluticasone) FLUTICASONE (generic of Flonase®)	BECONASE®AQ (beclomethasone) BUDESONIDE (generic of Rhinocort Aqua®) DYMISTA® (fluticasone/azelastine) MOMETASONE (generic of Nasonex®) OMNARIS® (ciclesonide) QNASL® (beclomethasone) VERAMYST™ (fluticasone furoate) XHANCE™ (fluticasone) ZETONNA® (ciclesonide)

VIII. Other Business

No other business

IX. Next Meeting Date

The next meeting date is October 3, 2018 at 9:00 A.M. at Ohio Department of Medicaid, 50 W Town St. Dr. Jacobs reminded the audience that they need to submit their interest to present in advance of the meeting and should check the pharmacy website for details. The committee requested that only new information be presented by drug manufacturers. The Committee members inquired about the status of the Bylaw review. Dr. Archibald indicated that the Bylaws remain under review.

IX. Adjournment

Dr. Jacobs adjourned the meeting at 11:11 A.M.