OHIO DEPARTMENT OF MEDICAID
Pharmacy & Therapeutics Committee
GoToMeeting

https://attendee.gotowebinar.com/register/1764029386883171083
January 12th, 2022
10:00 AM
MEETING MINUTES

Committee Members Present:
Scott Baran, RPh
Suzanne Eastman, RPh, MS Vice Chair
Stephen Hersey, MD
Karen Jacobs, DO Chair
Melissa Jefferis, MD
Sherri Sievers, APRN

Ohio Medicaid Staff Present:
Michelle Barger, PharmD
Andrew Chenevey, PharmD
Yana Doughty, PharmD
Brian Gallow, PharmD
Meghan Nestleroth, PharmD

Contract Staff/Change Healthcare Staff Present:
Jeffrey Barkin, MD
Kaitlyn Bernard, PharmD
Jill RK Griffith, BS, PharmD
Steve Liles, PharmD
Gail Master, RPh

Also present were approximately 72 observers, most representing pharmaceutical manufacturers.

I. Opening Comments

Scott Baran welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience then explained the blended in-person and virtual arrangements for the meeting.

II. Call to Order

Dr. Jacobs called the meeting to order at 10:03 AM EST.

III. Introductions

The Committee members, ODM pharmacy staff, and Change Healthcare staff introduced themselves. Quorum was established.

IV. Approval of the October 6, 2021 Meeting Minutes

The minutes from the prior P&T meeting were reviewed and approved by the Committee.

V. Administrative Matters

The conflict-of-interest statement was reviewed. All members signed this statement for this year. During the annual bylaws review, discussion ensued regarding Article V (2)(e), interested party not submitting a signed conflict of interest (COI). A motion was made that if a signed COI is not submitted prior to the meeting, the interested party will be denied from speaking. ODM pharmacy will take this back for further review and bring back at the next meeting. The rest of the bylaws were approved as presented.

VI. Ohio Department of Medicaid Policy Update

The Ohio Department of Medicaid reported that as Medicaid's Next Generation of Managed Care project continues to work closer to the 7/1/2022 go live date, ODM remains committed to working with both our Single Pharmacy Benefit Manager and Pharmacy Pricing and Audit Consultant vendors to ensure a smooth transition for our members and transparency throughout the pharmacy program. ODM continues to ensure access to COVID-19 vaccines and boosters during the public health emergency and is working with the Ohio Department of Health (ODH) as oral COVID-19 medication treatments gain emergency use authorization (EUA).

In DUR updates, ODM has received some Letters of Interest for our vacant DUR Committee positions. Submissions are currently being reviewed and evaluated.
In related DUR news, two members of the DUR Board announced their resignations. The ODM Pharmacy team has worked with professional pharmacist organizations to identify and recommend two new candidates for these appointed positions. We are currently working through the appointment and contracting process with both candidates, and we hope to have finalized announcements soon.

Next, ODM is working on some new DUR interventions. In one intervention, ODM is reaching out to prescribers whose patients with asthma or COPD have demonstrated suboptimal adherence to their controller inhalers. The goal is to remind prescribers to discuss potential barriers to adherence with their patients, identify solutions, and stress the importance of adherence for improved health outcomes. Another intervention is aimed at members who are taking butalbital-containing

medications in high doses or for long-term use. The goal of this intervention is to encourage prescribers to reevaluate the dose and/or the duration of butalbital while weighing its risk/benefit ratio and to encourage tapering off butalbital if clinically indicated. Our latest intervention involves children who are taking multiple antipsychotics. The goal is to remind prescribers to conduct baseline screening and regular monitoring for associated metabolic disorders, and the importance of behavioral counseling.

In P&T Committee news, work continues to identify, recommend, and appoint two candidates to the vacant positions on our committee. The ODM Pharmacy team is working with several different professional organizations and will continue to provide updates as developments occur.

Lastly, two pharmacists have joined the ODM Pharmacy Team. Please join me in welcoming Andrew Chenevey and Meghan Nestleroth. We are excited about their addition and look forward to their clinical contributions and assistance with departmental initiatives.

VII. Presentations by Drug Manufacturers

a. Lybalvi – Alkermes

VIII. Presentations by Interested Parties

a. Steven Katz, MD, representing Ohio Health. Qulipta

IX. Unified Preferred Drug List (Unified PDL) Proposals

a. **Cardiovascular Agents: Angina, Hypertension and Heart Failure. Kerendia (finerenone tablet), Bayer Healthcare Pharmaceuticals Inc.**

Dr. Barkin provided a clinical overview of Kerendia. ODM recommended Kerendia as "Non-Preferred, PA required". The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Acebutolol	Aliskiren
Amlodipine	Candesartan
Amlodipine Valsartan	Candesartan/Hydrochlorothiazide
Amlodipine/Benazepril	Carospir
Amlodipine/Olmesartan	Carvedilol ER
Amlodipine/Valsartan/Hydrochlorothiazide	Corlanor
Atenolol	Edarbi
Atenolol/Chlorthalidone	Diltiazem 24HR ER Tabs
Benazepril	Edarbyclor
Benazepril/Hydrochlorothiazide	Enalapril Sol

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Betaxolol
Bisoprolol
Bisoprolol/Hydrochlorothiazide
Bystolic BvG
Captopril
Captopril/Hydrochlorothiazide
Cartia XT
Carvedilol
Clonidine
Diltiazem
Diltiazem 12HR ER Cap
Diltiazem 24HR ER Cap
Doxazosin
Dutoprol
Enalapril
Enalapril/Hydrochlorothiazide
Entresto PA
Epaned BvG
Eplerenone
Felodipine ER
Fosinopril
Fosinopril/Hydrochlorothiazide
Guanfacine
Hemangeol AR
Hydralazine
Irbesartan
Irbesartan/Hydrochlorothiazide
Labetalol
Lisinopril
Lisinopril/Hydrochlorothiazide
Losartan
Losartan/Hydrochlorothiazide
Olmesartan
Olmesartan/Amlodipine/ Hydrochlorothiazide
Olmesartan/Hydrochlorothiazide
Methyldopa
Methyldopa/Hydrochlorothiazide
Metoprolol Succinate ER
Metoprolol Tartrate
Hydralazine/Hydrochlorothiazide
Innopran XL
Isradipine
Kapspargo
Katerzia
Kerendia
Nebivolol
Nimodipine
Nisoldipine
Nymalize
Qbrelis
Sotylize
Tekturna/HCT
Telmisartan
Telmisartan/Hydrochlorothiazide
Verapamil 200, 300mg ER 24HR
Verquvo

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Metoprolol/Hydrochlorothiazide
Minoxidil
Moexipril
Nadolol
Nadolol/Bendroflumethiazide
Nicardipine
Nifedipine
Perindopril
Pindolol
Prazosin
Propranolol
Propranolol/Hydrochlorothiazide
Quinapril
Quinapril/Hydrochlorothiazide
Ramipril
Ranolazine
Sotalol
Spironolactone
Spironolactone/Hydrochlorothiazide
Telmisartan/Amlodipine
Terazosin
Timolol
Trandolapril
Trandolapril/Verapamil
Valsartan
Valsartan/HCTZ
Verapamil
Verapamil SR

Legend

AR (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
BvG (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

PRIOR AUTHORIZATION CRITERIA:

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

- ☐ Allergy to all medications not requiring prior approval

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

KERENDIA CRITERIA:

1. Patient must meet all the following criteria:
   - A diagnosis of Chronic Kidney Disease due to Type 2 Diabetes
   - Be on maximum tolerated dose of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker
   - Allergy, intolerance, or inadequate response to an SGLT2 Inhibitor

b. **Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute. Trudhesa, (dihydroergotamine mesylate aerosol), Impel NeuroPharma, Inc.**

Dr. Barkin provided a clinical overview of Trudhesa. ODM recommended Trudhesa as "Non-Preferred, PA required". The committee voted and recommended the proposed category and clinical criteria for Nurtec ODT as shown below:

PREFERRED	NON-PREFERRED
Naratriptan	Almotriptan
Nurtec ODT QL ST	Dihydroergotamine
Rizatriptan	Eletriptan
Sumatriptan	Ergomar
	Frovatriptan
	Migergot
	Onzetra Xsail
	Reyvow
	Sumatriptan/Naproxen
	Tosymra
	Trudhesa
	Ubrelvy
	Zolmitriptan

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ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 180 Days

PRIOR AUTHORIZATION CRITERIA:

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

- o Allergy to preferred medications
- o Contraindication to all preferred medications
- o History of unacceptable/toxic side effects to at least two preferred medications

STEP THERAPY APPROVAL CRITERIA:

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of at least 14 days with at least two medications not requiring prior approval
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of at least 14 days with at least one medication requiring step therapy

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per 34 days is restricted based on the manufacturer's package insert.

Nurtec ODT quantity limit is 8 per 30 days

c. **Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis. Qulipta (atogepant tablet), AbbVie Inc.**

Dr. Barkin provided a clinical overview of Qulipta. Discussion ensued about the requirement of a headache diary and intolerance to an injectable drug. ODM recommended Qulipta as "Non-Preferred, PA required". The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Aimovig QL ST	Emgality
Ajovy ST	Nurtec ODT
Cardiovascular Agents: Beta-Blockers	Qulipta
CNS Agents: Anticonvulsants	
CNS Agents: Serotonin-Norepinephrine Reuptake Inhibitors	
CNS Agents: Tricyclic Antidepressants	

Legend

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QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: Initial Authorization 180 days
Subsequent Authorizations 365 days

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PRIOR AUTHORIZATION CRITERIA:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval?Acceptable reasons include:
  - Allergy to preferred medications
  - Contraindication to three preferred medications
  - History of unacceptable/toxic side effects/intolerance to at least three preferred medications

STEP THERAPY REQUIRED PREFERRED MEDICATION:

- For a drug requiring step therapy, there must have been inadequate clinical response to a trial of at least 30 days each to at least three controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors).

NON-PREFERRED MEDICATION:

- For a non-preferred medication drug there must have been inadequate clinical response to a trial of at least 30 days each to at least three controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors) AND an inadequate clinical response or intolerance to a trial of at least 30 days of one step therapy required preferred medication.

ADDITIONAL CRITERIA FOR MIGRAINE PROPHYLAXIS:

1. Patient must have one of the following diagnoses:
   a. **Episodic** migraine with the following frequencies of migraine:
      I. 4-15 headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attackon average.
   b. **Chronic** migraine with the following frequencies of migraine:
      I. 15 or more headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attackon average
2. Prior Authorization may be approved if the patient has failed a trial of at least 30 days eachto at least three controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors).
3. Initial authorization will be limited to 180 days. Re-authorization for 365 days will be allowed based upon evidence of improved headache control (such as a headache diary or attestation of ongoing efficacy from provider).

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per 30 days is restricted based on the manufacturer's package insert.

*Aimovig Initial Dose is limited to 70mg once per 30 days; may request dose increase if 70mg failsto provide adequate relief over 60 consecutive days.
* Ajovy 675mg doses (quarterly administration) will not be authorized until patient hasdemonstrated efficacy of medication for at least 90 days.

d. **Central Nervous System (CNS) Agents: Atypical Antipsychotics. Invega Hafyera ER (paliperidone palmitate injection), Janssen Pharmaceuticals, Inc and Lybalvi (olanzapine-samidorphan L-malate tablet), Alkermes, Inc.**

Dr. Barkin provided clinical overviews for both Invega Hafyera ER and Lybalvi. ODM recommended Invega Hafyera ER as "Preferred, Clinical PA required", then recommended Lybalvi as "Non-Preferred, PA required". Both drugs require additional clinical criteria that must be met before coverage. The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Abilify Maintena	Abilify Mycite
Aripiprazole	Aripiprazole Sol
Aristada	Asenapine
Aristada Initio	Caplyta
Clozapine	Clozapine ODT Rapdis
Fanapt ST	Fluoxetine/Olanzapine
Geodon	Lybalvi
Invega BvG	Nuplazid
Invega Hafyera ER PA	Olanzapine ODT
Invega Sustenna	Paliperidone
Invega Trinza	Rexulti
Latuda ST	Secuado
Olanzapine	Versacloz
Perseris	Vraylar
Quetiapine	Zyprexa Relprevv
Quetiapine ER	
Risperdal	
Risperdal Consta	
Risperidone	
Saphris BvG ST	
Ziprasidone	

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ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

GRANDFATHERING:
Patients who have a claim for a non-preferred drug, or drug requiring step therapy, 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 donot have claims history (e.g., new to Medicaid), will be approved for PA after prescriber contact.

PSYCHIATRIST EXEMPTION:
Providers (as identified below) are exempt from prior authorization of any non-preferred second-generation antipsychotic, or step therapy of any preferred brand, in the standard tablet/capsule dosage forms. Other dosage forms may still require prior authorization. The exemption will be processed by the claims system when the pharmacy has submitted the prescriber on the claim using the individual national provider identifier (NPI) for the provider.

FFS: Physicians who are registered with Ohio Medicaid as having a specialty in psychiatry
MCOs: Physicians with a specialty in psychiatry, nurse practitioners certified in psychiatric mental health, or clinical nurse specialists certified in psychiatric mental health, who are credentialed via the Medicaid managed care plan.

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

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

STEP THERAPY:
1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least one preferred product
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred or step therapy products.

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ADDITIONAL CRITERIA FOR INVEGA HAFYERA ER:

1. Treatment with 4 months of Invega Sustenna or 3 months of Invega Trinza before starting Invega Hafyera.

ADDITIONAL CRITERIA FOR LYBALVI:

2. Patient must not be using opioids.
3. Patient must not be undergoing acute opioid withdrawal.

ADDITIONAL CRITERIA FOR AGENTS FOR PARKINSON' S DISEASE PSYCHOSIS (NUPLAZID):

Pimavanserin (Nuplazid) may be approved if all the following are met:

1. Patient is diagnosed with Parkinson's disease and has psychotic symptoms (hallucinations and/or delusions) that started after Parkinson's diagnosis
2. These psychotic symptoms are severe and frequent enough to warrant treatmentwith an antipsychotic AND are not related to dementia or delirium
3. The patient's other medications for Parkinson's Disease have been reduce or adjusted and psychotic symptoms remain OR patient is unable to tolerate adjustment of these other medications
4. There has been inadequate clinical response to a trial of no less than 30 days ofeither quetiapine or clozapine OR these therapies cannot be utilized
5. An exemption to the criteria will be granted for prescribing doctors with a neurology specialty to a patient with a history of an anti-Parkinson's agent.

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a preferred medication?Acceptable reasons include:

- ☐ Allergy to preferred medications
- ☐ Contraindication to or drug interaction with preferred medications
- ☐ History of unacceptable/toxic side effects to preferred medications
- ☐ For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form.
- ☐ The requested medication's corresponding generic (if covered by the state) has beenattempted and failed or is contraindicated.
- ☐ Lurasidone (pregnancy category B) may be approved if a patient is pregnant
- ☐ Abilify Mycite will be restricted to prescribing by a psychiatrist following an aripiprazoleserum blood level draw indicating need for further investigation of adherence.

ANTIPSYCHOTICS, SECOND GENERATION and SSRI COMBINATION

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	A trial of no less than 30 days eachof at least two preferred second-generation oral antipsychotics or step therapy products	FLUOXETINE/OLANZAPINE (generic of Symbyax®)

+ Long-Acting Injectable Antipsychotics may be billed by the pharmacy if they are not dispensed directly to the patient. If not administered by the pharmacist, the drug must be released only to the administering provider or administering provider's staff, following all regulations for a Prescription Pick-Up Station as described by the Ohio Board of Pharmacy.+

e. **Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents. Azstarys (serdexmethylphenidate-dexmethylphenidate capsule), Corium, Inc**

Dr. Barkin provided a clinical overview of Azstarys. ODM recommended Azstarys as "Non-Preferred, PA required". The committee voted and recommended the proposed category as shown below:

PREFERRED	NON-PREFERRED
Amphetamine/Dextroamphetamine ER	Adhansia XR
Amphetamine/Dextroamphetamine IR	Adzenys ER
Atomoxetine Cap	Adzenys XR ODT
Clonidine ER	Amphetamine Tab
Concerta	Azstarys
Dexmethylphenidate Tab	Cotempla XR ODT
Dexmethylphenidate ER (generic of Focalin XR)	Daytrana
Dextroamphetamine ER Cap	Dyanavel XR
Dextroamphetamine Sol [AR]	Evekeo ODT
Dextroamphetamine Tab	Jornay PM
Focalin XR	Methamphetamine
Guanfacine ER	Methylphenidate Chewable Tab
Methylphenidate ER Cap (generic of Metadate CD, Ritalin LA)	Methylphenidate ER (generic of Aptensio XR, Relexxii)
Methylphenidate ER Tab (generic of Concerta, Methylin ER, Ritalin SR)	Mydayis
Methylphenidate Sol [AR]	Vyvanse Chewable Tab
Methylphenidate Tab	Zenzedi

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Qelbree ST
Quillichew ER
Quillivant XR
Ritalin LA
Vyvanse Cap

Legend

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ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

Short Acting products considered separately from Long-Acting products

PRIOR AUTHORIZATION CRITERIA:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - ☐ Allergy to at least two medications not requiring prior approval
   - ☐ Contraindication to all medications not requiring prior approval
   - ☐ History of unacceptable/toxic side effects to at least two medications not requiring prior approval
   - ☐ ~~Preferred long-acting non-solid dosage forms may be approved for a patient over age 12 if the patient is unable to swallow pills~~
   - ☐ Has the patient failed a therapeutic trial of at least 14 days with at least two medications not requiring prior approval?

STEP THERAPY:

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least two preferred products.

Note: Patients on non-preferred therapies are not required to obtain prior authorization for the use of their product until after June 30th, 2022. Providers may obtain prior authorization before June 30th,2022.

AR - Dextroamphetamine Solution: a PA is required for patients over 12 years old
AR - Methylphenidate Solution: a PA is required for patients over 12 years old

f. **Central Nervous System (CNS) Agents: Skeletal Muscle Relaxants, Non-Benzodiazepine. Ozobax (baclofen solution), Metacel Pharmaceuticals, LLC**

Dr. Barkin provided a clinical overview of Ozobax. ODM recommended Ozobax as "Non-Preferred, PA required". The committee voted and recommended the proposed category as shown below:

PREFERRED	NON-PREFERRED
Baclofen	Carisoprodol
Chlorzoxazone 250mg, 500mg	Chlorzoxazone 375mg, 750mg
Cyclobenzaprine 5, 10mg	Cyclobenzaprine 7.5mg
Dantrolene	Cyclobenzaprine ER
Methocarbamol	Metaxalone
Tizanidine Tab	Orphenadrine
	Ozobax
	Tizanidine Cap

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QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

PRIOR AUTHORIZATION CRITERIA:

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. Has there has been a 30-day trial with an agent not requiring prior approval?

Clinical criteria must be met for Soma/Carisoprodol products– approvable only if no other muscle relaxant oragent to treat fibromyalgia, or any musculoskeletal condition, would serve the clinical needs of the patient.

g. **Dermatological: Topical Acne Products. Winlevi (clascoterone cream), Sun Pharmaceutical Industries, Inc.**

Dr. Barkin provided a clinical overview of Winlevi. ODM recommended Winlevi as "Non-Preferred, PA required". The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Adapalene Gel 0.1% AR	Adapalene Cream, Sol 0.1% AR
Azelex Cream	Adapalene Gel 0.3% AR

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Benzoyl Peroxide	Adapalene/Benzoyl Peroxide AR
Clindamycin Gel	Aklief AR
Clindamycin Lot	Altreno AR
Clindamycin Sol	Amzeeq
Clindamycin/Benzoyl Peroxide	Arazlo AR
Erythromycin	Azelaic Acid Gel
Erythromycin/Benzoyl Peroxide	Benzoyl Peroxide Foam
Neuac	Clindacin Kit
Sodium Sulfacetamide	Clindamycin Foam
Sodium Sulfacetamide/Sulfur Cream	Clindamycin Swabs
Sodium Sulfacetamide/Sulfur Wash Susp	Clindamycin/Tretinoin AR
Tretinoin AR	Dapsone Gel
	Finacea Foam
	Onexton Gel
	Ovace Plus
	Plixda AR
	Sodium Sulfacetamide/Sulfur Gel
	Sodium Sulfaetamide Pads
	Tazarotene Cream 0.1% AR
	Tazarotene Foam 0.1% AR
	Winlevi

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LENGTH OF AUTHORIZATIONS: 365 Days

PRIOR AUTHORIZATION CRITERIA:

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☐ Allergy to all medications not requiring prior approval

☐ Contraindication to or drug-to-drug interaction with medications not requiring prior approval

☐ History of unacceptable/toxic side effects to medications not requiring prior approval

☐ Inadequate response to no less than a 30-day trial of at least at least three (3) medications not requiring prior approval

CLINICAL CRITERIA:

AR- All topical retinoids require prior authorization for patients age 24 years and older:

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- Patient diagnosis psoriasis – may approve tazarotene (Tazorac)
- Patient diagnosis acne vulgaris – may approve retinoid if the patient has a history of at least 30 days of therapy with alternative therapy (benzoyl peroxide, sodium sulfacetamide or antibiotic) in the previous 90 days
- Patient diagnosis skin cancer – may approve retinoid

~~**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 30-day trial of at least at least one medication in the same class not requiring prior approval.~~

h. **Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) / Selected GI and Gastrointestinal Agents: Opioid-Induced Constipation – administration reorganization**

ODM proposed to administratively reorganize the Gastrointestinal Agent categories. Initially 4 categories were proposed, including one for Traveler's Diarrhea. During the meeting, this category was removed and the following 3 categories and clinical criteria were reviewed:

- **Gastrointestinal Agents: Hepatic Encephalopathy**

Xifaxan was proposed to move from a non-preferred drug to a preferred drug with step therapy. The committee voted and recommended the proposed category and clinical criteria as shown below:

Gastrointestinal Agents: Hepatic Encephalopathy	
PREFERRED	**NON-PREFERRED**
Lactulose	
Xifaxan [ST]	

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ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

PRIOR AUTHORIZATION CRITERIA:

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

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

STEP THERAPY: all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to a

preferred alternative

2. XIFAXAN requires a diagnosis of hepatic encephalopathy and may be approved for monotherapy or add on therapy if there has been a therapeutic failure (defined as a recurrent episode) while on lactulose

- **Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea**

  Xifaxan is not a new medication, but with the administrative reorganization, Xifaxan moved from a non-preferred drug to a preferred drug with step therapy. The committee voted and recommended the proposed category and clinical criteria as shown below:

Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea

PREFERRED	NON-PREFERRED
Diphenoxylate/atropine	Alosetron
Loperamide	Viberzi
Xifaxan[ST]	

Legend

AR (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
BvG (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

PRIOR AUTHORIZATION 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

STEP THERAPY: all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to a preferred alternative
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 14-days of at least one step therapy product

- **Gastrointestinal Agents: Unspecified GI. Aemcolo (rifamycin tablet), RedHill Biopharma Ltd**

  Dr. Barkin provided a clinical overview of Aemcolo. ODM recommended Aemcolo as "Non-Preferred, PA required" but with additional clinical criteria that needs to be met. The committee voted and recommended the proposed category and clinical as shown below:

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Gastrointestinal Agents: Unspecified GI	
PREFERRED	**NON-PREFERRED**
Amitiza BvG ST	Aemcolo
Bisacodyl	Gattex
Casanthranol/Docusate Sodium	Linzess 72mcg
Dicyclomine	Lubiprostone
Diphenoxylate/Atropine	Motegrity
Lactulose	Mytesi
Linzess ST 145, 290mcg	Relistor
Loperamide	Symproic
Movantik ST	Trulance
Polyethylene Glycol	Zorbitive
Psyllium Fiber	
Senna	
Xifaxan ST	

Legend

AR (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
BvG (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

PRIOR AUTHORIZATION CRITERIA:

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 14-day trial of at least two medications not requiring prior approval

STEP THERAPY: all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including no less than a 14-day trial of at least two medications not requiring prior approval
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including no less than 14-day trial of at least ~~two~~ three preferred products including one step therapy product

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ADDITIONAL INFORMATION:

1. Patient must be 18 years or older
2. ZORBTIVE and GATTEX require a diagnosis of short bowel syndrome (SBS) and evidence of specialize nutritional support
   a. GATTEX requires evidence of parenteral nutrition support at least three times per 7 days and appropriate colonoscopy and lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) 180 days prior to initiation
   b. Re-authorization of these therapies requires evidence of improved condition (i.e. as measured by total volume, total calories, or decreased frequency of specialized nutrition support)
3. MYTESI requires a diagnosis of non-infectious diarrhea and evidence of concurrent HIV antiviral therapy
   a. MYTESI will be limited to no more than 2 tablets per day
4. RELISTOR and SYMPROIC require a history of chronic pain requiring continuous opioid therapy for 84 days or longer. Electronic PA will approve with a history of 90 days of opioid therapy in the previous 90 days, in addition to trials of preferred products
5. AEMCOLO initial approval criteria for Travelers' Diarrhea (TD) (must meet all):
   a. Diagnosis of TD
   b. Inability to take, or failure of, any of the following:
      - Azithromycin (generic Zithromax)
      - Ciprofloxacin (generic Cipro)
      - Levofloxacin (generic Levaquin)
      - Ofloxacin (generic Floxin)
      - Xifaxan (rifaximin)
   c. Approval duration is 3 days

i. **Genitourinary Agents: Urinary Antispasmodics. Myrbetriq (mirabegron granule suspension), Astellas Pharma US, Inc.**

Dr. Barkin provided a clinical overview of Myrbetriq Granules. ODM recommended Myrbetriq Granules as "Non-Preferred, PA required" with an age restriction. The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Gelnique	Darifenacin
Myrbetriq Tab	Gemtesa
Oxybutynin	Myrbetriq Granules [AR]
Oxytrol For Women	Tolterodine
Solifenacin	Trospium
Toviaz	Vesicare LS [AR]

Legend

AR (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
BvG (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

PRIOR AUTHORIZATION CRITERIA:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
   - ☐ Allergy to all medications not requiring prior approval
   - ☐ Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval.

1. Patients under age 18 may be approved for tolterodine SR if there was inadequate clinical response to a trial of no less than 30 days of oxybutynin (IR or ER).
2. The requested non-preferred medication may be approved if there has been a therapeutic failure to a trial of no less than 30 days of at least two preferred medications with different active ingredients not requiring a prior authorization

AR – Vesicare LS: PA is not required for patients 2-5 years of age.
AR – Myrbetriq Sol: PA is not required for patients that are 3-5 years of age.

j. **Infectious Disease Agents: Antifungals. Brexafemme (ibrexafungerp tablet), SCYNEXIS, INC.**

Dr. Barkin provided a clinical overview of Brexafemme. ODM recommended Brexafemme as "Non-Preferred, PA required". The committee voted and recommended the proposed category as shown below:

Infectious Disease Agents: Antifungals ~~for Onychomycosis & Systemic Infections~~	
PREFERRED	**NON-PREFERRED**
Fluconazole	Brexafemme
Flucytosine	Cresemba
Griseofulvin	Itraconazole
Ketoconazole	Noxafil Susp
Terbinafine	Oravig
	Posaconazole
	Tolsura
	Voriconazole

LENGTH OF AUTHORIZATIONS: For the duration of the prescription (up to 180 days)

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PRIOR AUTHORIZATION CRITERIA:

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-to-drug interaction with medications not requiring priorapproval:
     - Drug interactions (inhibition of CYP450 system) Ketoconazole > Itraconazole > Voriconazole > Fluconazole
   - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the patient has a serious illness that causes them to be immunocompromised [i.e., AIDS, cancer, organ (solid or non-solid) transplant] then may approve the requested medication.
3. If there have been therapeutic failures to no less than a 7-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

1. If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital or other similar location, or if the patienthas just become Medicaid eligible and is already on a course of treatment with a medication requiring prior approval, then may approve the requested medication.
2. If the request is for a diagnosis other than fungal infection, please refer the case to a pharmacist. An off-label use may be approvable for a medication such as Nizoral for advanced prostate cancer or for Cushing's Syndrome when standard treatments have failed.

k. **Topical Agents: Immunomodulators. Opzelura (ruxolitinib phosphate cream), Incyte Corporation**

Dr. Barkin provided a clinical overview of Opzelura. ODM recommended Opzelura as "Non-Preferred, PA required". The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRD	NON-PREFERRED
Elidel AR BvG ST	Eucrisa
Protopic AR BvG ST	Opzelura
	Pimecrolimus
	Tacrolimus

Legend

AR (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
BvG (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

LENGTH OF AUTHORIZATIONS: 365 Days

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STEP THERAPY:

1. For a product requiring step therapy, there must have been an inadequate clinical response to no less than two 30-day trials of topical corticosteroids
2. For a non-preferred medication, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of the preferred medication.

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

CLINICAL INFORMATION

- ☐ Indicated for short-term and intermittent long-term treatment of atopic dermatitis if:
  - Alternative, conventional therapies (such as topical corticosteroids) are deemed inadvisable because of potential risks, or
  - There has been inadequate response or intolerance to alternative, conventional therapies (such as topical corticosteroids).
- ☐ Elidel and Protopic 0.03% are indicated in patients 2 years old or older. Protopic 0.1% is indicated in adults only.
- ☐ Opzelura is contraindicated for use in immunocompromised patients.

AR - pimecrolimus and tacrolimus: a PA is required for patients younger than 2 years old

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X. Other Business

An administrative reorganization of the Lipotropics PCSK9 criteria was reviewed by the committee. The committee voted and recommended the proposed clinical criteria as shown below:

LENGTH OF AUTHORIZATIONS: 365 Days all Lipotropics

Trial period	30 days of HMG-CoA Reductase Inhibitors, Niacin derivatives, ezetimibe (Zetia), 90 days for Fibrates, ~~84 days for PCSK9 inhibitors~~ and 84 days for ATP Citrate Lyase (ACL) Inhibitors
Number of non-PA agents	1 medication – The assumption is that the medication must be in the same class of medication required, if available, except for HMG-CoA reductase inhibitors – see specific criteria

PRIOR AUTHORIZATION 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-drug interaction with medications not requiring prior approval (pravastatin is the only HMG-CoA not metabolized by the cytochrome P450 liver enzyme system).
- History of unacceptable/toxic side effects to medications not requiring prior approval.

ADDITIONAL PRIOR AUTHORIZATION CRITERIA:

If there has been a 30-day trial with no less than two preferred HMG-CoA products, then a non-preferred HMG-CoA agent can be approved.

ADDITIONAL CRITERIA FOR COLESEVELEM (WELCHOL):

- Colesevelam may be approved as first-line therapy if there is a diagnosis of diabetes.
- Will be approved through systematic PA if there is a history of an oral hypoglycemic or insulin in the previous 120 days

ADDITIONAL CRITERIA FOR PCSK9 INHIBITORS

- For Repatha: Age ≥18 years with ASCVD or Age ≥10 years and Familial Hypercholesterolemia (FH) **OR** for Praluent: Age ≥18 years with ASCVD or FH **AND**
- Documented adherence to prescribed lipid lowering medications for previous 90 days

Baseline lab results are required, and approvals will ~~be limited to 84 days~~ be for 365 days ~~and then annually thereafter.~~ Subsequent approvals will require additional levels being done to assess changes.

- ~~Lipid profile required at day 56 for HeFH or ASCVD~~
- ~~Lipid profile required after 3rd dose for HoFH or ASCVD~~

Diagnosis of ~~Heterozygous~~ Familial Hypercholesterolemia (includes Heterozygous [HeFH] and

Homozygous [HoFH]) **AND** must meet ~~both~~ all:

1. ~~Total cholesterol > 290mg/dL or LDL-C > 190 mg/dL and one of the following:~~
   - ~~Presence of tendon xanthomas or 1st or 2nd degree relative with documented tendon xanthomas, MI at age ≤ 60 years or TC > 290mg/dL **OR**~~
   - ~~Confirmation of diagnosis by gene or receptor testing~~
2. Unable to reach goal LDL-C (LDL ≤ 100mg/dL for adults or LDL ≤ 110mg/dL for those < 18 years of age) with maximally tolerated dose of statin and ezetimibe (Zetia)
   - A trial of 2 or more high potency statins (atorvastatin or rosuvastatin)

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD) **AND** must meet both:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD or atherosclerotic origin

and

2. Unable to reach goal LDL-C (LDL ≤ 70mg/dL) with maximally tolerated dose of statin and ezetimibe (Zetia)
   - A trial of 2 or more high potency statins (atorvastatin or rosuvastatin)

~~Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH): must meet all:~~

~~1. Total cholesterol and LDL-C >600mg/dL and TG within reference range or confirmation of diagnosis by gene or receptor testing~~

~~2. Unable to reach goal LDL-C with maximally tolerated dose of statin plus ezetimibe (Zetia) 10 mg daily with at least 1 other concurrently administer lipid lowering agent~~

~~3. Age ≥13 years old~~

ADDITIONAL CRITERIA FOR ATP Citrate Lyase (ACL) Inhibitor:

All products in this class require clinical prior authorization:

- ☐ Age ≥18 years
- ☐ A trial and failure with one PCSK9 inhibitor
- ☐ Unable to reach goal LDL-C after a trial of 2 or more statins (one must be atorvastatin) at the maximally tolerated dose
  - Nexlizet (bempedoic acid and ezetimibe tablet) approval requires one of the previous statin trials to be in combination with ezetimibe (Zetia)
  - Documented adherence to prescribed lipid lowering medications for previous 90 days
  - Baseline lab results are required, and approvals will be limited to 84 days initially and then annually thereafter. Subsequent approvals will require additional levels being done to assess changes
  - Lipid profile required at 56 days for HeFH or ASCVD

XI. 2022 Meeting Dates

S. Baran announced the next meeting dates:
Wednesday April 6, 2022, Wednesday July 13, 2022, and September 28, 2022 which was previously planned to be on October 5, 2022.

XII. Adjournment

Dr. Jacobs adjourned the meeting at 1:37PM EST.