



Department of Medicaid

OHIO DEPARTMENT OF MEDICAID

Pharmacy & Therapeutics Committee

Ohio Department of Medicaid

50 W. Town Street, Room A535

Columbus, OH

January 16, 2019

10:00 AM

MINUTES

Committee Members Present:

Tracey Archibald, PharmD

Michelle Barger, PharmD

Scott Baran, RPh

Karen Jacobs, DO Chair

Stephen Hersey, MD

Melissa Jefferis, MD

Suzanne Eastman, RPh, MS

Susan Baker, CNP

Nathan Samsa, DO, PharmD

Committee Members Not Present:

Jennifer Gwilym, DO

Mary Ann Dzurec, PharmD

Contract Staff/Change Healthcare Staff Present:

Laureen Biczak, DO

Chad Bissell, PharmD

Jill RK Griffith, BS, PharmD

Benjamin Link, PharmD

Gail Master, RPh

Also present were approximately 44 observers, most representing pharmaceutical manufacturers.

I. Call to Order

Dr. Jacobs called the meeting to order at 10:03 a.m.

II. Introductions

Dr. Jacobs welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. The committee introduced themselves.

III. Administrative Matters

All members were invited to review and sign their annual conflict of interest statements.

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IV. Department of Medicaid Update

Dr. Archibald introduced a new pharmacist at the Ohio Department of Medicaid, Scott Baran, RPh. She announced that last week Governor Mike DeWine appointed a new Medicaid Director, Maureen Corcoran. Dr. Archibald introduced a new member of the P&T Committee, Nathan Samsa, DO, PharmD. She announced that the unified preferred drug list (PDL) has been delayed indefinitely. This did not impact planned changes to Medicated Assisted Therapy for Opioid Addiction (MAT) and Hepatitis C clinical criteria discussed at the previous meeting; these requirements are aligned with the Managed Care Plans (MCP) and Fee for Service (FFS). Specifically, for all MCPs and FFS, the Hepatitis C treatment fibrosis requirement will remain at F0 and there is open access to all forms of oral MAT. MAT utilization will be monitored retrospectively. Dr. Archibald also provided an update on the DUR Board/Committee work. The most recent DUR intervention is looking at diabetes medication adherence. Beginning February 1st, compounds exceeding \$100 will be reviewed for appropriateness and medical necessity. Long Term Care and Intermediate Care Facility members are excluded from this compound review. Additionally, all IV, TPN and sterile pharmacy claims are also excluded. Dr. Archibald also informed the committee of new Coordinated Service Program (CSP) rules that went into effect January 1st. These rules are the same for both MCPs and FFS. She announced that the cost of dispensing survey for 2018 was completed and resulted in no proposed changes for FFS professional dispensing fee. The report is available online.

V. Approval of the October 3rd, 2018 Meeting Minutes

The minutes from the prior P&T meeting were reviewed. Ms. Baker moved to approve the minutes, seconded by Dr. Jefferis. The minutes were approved.

VI. Drug Class Announcements

There were no drug class announcements

VII. Interested Party Presentations

Central nervous System (CNS) Agents: anticonvulsants: Epidiolex® (cannabidiol)

[Note: Dr. Patel presented during the Preferred Drug List Review]

Dr. Anup Patel discussed the indications for Epidiolex, the incidence of Lennox-Gastaut Syndrome and Dravet Syndrome in the US population and stated that this was the first medication approved for Dravet Syndrome. Dr. Patel answered questions from the Committee regarding treatment options, ongoing research, and access to Epidiolex therapy.

VIII. Preferred Drug List Review

a. Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors: Nivestym™ (filgrastim)

Dr. Link provided a clinical overview of this medication and Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown

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below:

Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors

LENGTH OF AUTHORIZATIONS: Dependent on diagnosis

ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:

Approval based upon diagnosis:

Diagnosis	Approval Length
Acute Myeloid Leukemia (AML)	14 days or duration of chemotherapy regimen
Malignancy at risk for febrile neutropenia or undergoing myeloablative chemotherapy prior to allogeneic or autologous bone marrow transplantation	14 days or duration of chemotherapy regimen
Myeloid Engraftment for bone marrow transplant (BMT)	1 month
Severe, chronic neutropenia with absolute neutrophil count (ANC) of less than 500/mm ³ and have symptoms associated with neutropenia (e.g. fever, infections, oropharyngeal ulcers).	1 month
Hematopoietic radiation injury syndrome	1 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 all medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
- Has the patient failed therapeutic trials of two weeks with preferred medications?

BLOOD AGENTS: HEMATOPOIETIC AGENTS-COLONY STIMULATING FACTORS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GRANIX® (tbo-filgrastim) NEUPOGEN® (filgrastim)	FULPHILA™ (pegfilgrastim-jmdb) LEUKINE® (sargramostim) NEULASTA® (pegfilgrastim) NIVESTYM™ (filgrastim) ZARXIO® (filgrastim-sndz)

- b. Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors: Jivi® (antihemophilic factor, recombinant, pegylated-aucl)

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Dr. Link provided a clinical overview of this medication and Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

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Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors

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 previously, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:

Approval based upon diagnosis and dosage appropriate to weight, patient pharmacokinetic factors, and presence of inhibitors.

PDL CRITERIA:

- Is there any reason the patient cannot use a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to all medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
- Has the patient had a demonstrated trial of one preferred medications?
- For extended half-life factors, prescribing physician attests that patient is not a suitable candidate for treatment with shorter-acting half-life product.
- If Rebinyn^o is requested, confirmation that it is not being used for routine prophylaxis

BLOOD AGENTS: FACTOR VII CONCENTRATE

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NOVOSEVEN (factor VIIa recombinant)	

BLOOD AGENTS: FACTOR VIII

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ADVATE* (factor VIII recombinant)	ADYNOVATE* (factor VIII recombinant) †
HEMOFIL M* (factor VIII human)	AFSTYLA* (factor VIII recombinant)
KOATE* (factor VIII human)	ELOCTATE* (factor VIII recombinant, fc fusion protein) †
KOGENATE FS* (factor VIII recombinant)	JIVI ^o (factor VIII recombinant, pegylated-aucI) †
MONOCLATE-P* (factor VIII human)	KOVALTRY* (factor VIII recombinant)
NOVOEIGHT* (factor VIII recombinant)	OBIZUR* (factor VIII recombinant, porcine sequence)
NUWIQ* (factor VIII recombinant)	
RECOMBINATE* (factor VIII recombinant)	
XYNTHA* (factor VIII recombinant)	

†Denotes long-half life factor

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c. Central Nervous System (CNS) Agents: Anti-Migraine Agents: Ajovy™ (fremanezumab-vfrm)

Maggie Murphy, PharmD, MS, presented clinical information on Ajovy™ on behalf of Teva. Following the presentation, Dr. Link added his clinical comments. A question was asked about the binding sites of this medication compared to other drugs in its class. A discussion ensued regarding appropriate number of trials of medications prior to use of these agents. Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

Central Nervous System (CNS) Agents: Anti-Migraine Agents

LENGTH OF AUTHORIZATIONS: 6 months

APPROVAL 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 all preferred medications
 - History of unacceptable/toxic side effects to at least two preferred medications
 - Has the patient failed a therapeutic trial of at least two weeks with at least two medications not requiring prior approval

CLINICAL CONSIDERATIONS FOR PROPHYLAXIS:

Prior Authorization will not be given for prophylaxis unless the patient has exhausted or has contraindications to at least three other “controller” migraine medications (i.e., beta-blockers, neuroleptics, tricyclic antidepressants, and/or serotonin-norepinephrine). Provider must also provide the number of headache days over the past month (average over the last 3 months is also acceptable).

Re-authorization of controller medications need to demonstrate significant reduction in number of migraine days per month.

ADDITIONAL INFORMATION

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

CNS AGENTS: ANTI-MIGRAINE AGENTS – CALCITONIN GENE-RELATED PEPTIDE RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	AIMOVIG™ (erenumab-aooe)† AJOVY™ (fremanezumab-vfrm) EMGALITY™ (galcanezumab)

†Initial Dose is limited to 70mg once monthly; may request dose increase if 70mg fails to provide adequate relief over two consecutive months.

* 675mg doses (quarterly administration) will not be authorized until patient has demonstrated efficacy of medication for at least 90 days

d. Central nervous System (CNS) Agents: anticonvulsants: Epidiolex® (cannabidiol)

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Following Dr. Patel’s presentation, Kelly A. Hollenack, PharmD, MBA, MS answered questions for Epidiolex® on behalf of Greenwich. Dr. Link added his clinical comments and Dr. Archibald recommended a Non-Preferred placement on the PDL. The Committee discussed the criteria appropriate for use of the medication. Votes were taken, and the committee approved the proposed category, shown below:

ADDITIONAL CRITERIA FOR CANNABINOID

LENGTH OF AUTHORIZATIONS: Initial Authorization 6 months
Subsequent Authorizations 1 year

- Patient has a diagnosis of Lennox-Gastaut syndrome or Dravet syndrome
- Patient has trialed and failed (inadequate seizure control or intolerance) 3 prior anticonvulsant therapies for one month each (**Note:** not required to be met for a diagnosis of Dravet Syndrome)
- Prescriber has obtained serum transaminases (ALT and AST) and total bilirubin levels prior to starting therapy
- Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)

ANTICONVULSANTS: CANNABINOID

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EPIDIOLEX® (cannabidiol)†	

*Excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

e. Central Nervous System (CNS) Agents: Anti-Migraine Agents: Emgality™(galcanezumab)

Dr. Link provided a clinical overview of this medication and Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

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Central Nervous System (CNS) Agents: Anti-Migraine Agents

LENGTH OF AUTHORIZATIONS: 6 months

APPROVAL 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 all preferred medications
 - History of unacceptable/toxic side effects to at least two preferred medications
 - Has the patient failed a therapeutic trial of at least two weeks with at least two medications not requiring prior approval

CLINICAL CONSIDERATIONS FOR PROPHYLAXIS:

Prior Authorization will not be given for prophylaxis unless the patient has exhausted or has contraindications to at least three other “controller” migraine medications (i.e., beta-blockers, neuroleptics, tricyclic antidepressants, and/or serotonin-norepinephrine). Provider must also provide the number of headache days over the past month (average over the last 3 months is also acceptable).

Re-authorization of controller medications need to demonstrate significant reduction in number of migraine days per month.

ADDITIONAL INFORMATION

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

CNS AGENTS: ANTI-MIGRAINE AGENTS – CALCITONIN GENE-RELATED PEPTIDE RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
	AIMOVIG™ (erenumab-aooe)† AJOVY™ (fremanezumab-vfrm)* EMGALITY™ (galcanezumab)

†Initial Dose is limited to 70mg once monthly; may request dose increase if 70mg fails to provide adequate relief over two consecutive months.

* 675mg doses (quarterly administration) will not be authorized until patient has demonstrated efficacy of medication for at least 90 days

f. Central nervous System (CNS) Agents: Antipsychotic, Second generation: Perseris™ (risperidone)

Indivior gave their requested time to present back to the committee. Dr. Link provided a clinical overview of this medication. Dr. Archibald recommended the drug be placed on a preferred status on the PDL. Votes were taken, and the committee approved the proposed category, shown below:



Central Nervous System (CNS) Agents: Atypical Antipsychotics

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 do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

PSYCHIATRIST EXEMPTION:

Physicians who are registered with Ohio Medicaid as having a specialty in psychiatry 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 by a psychiatrist. The exemption will be processed by the claims system when the pharmacy has submitted the prescriber on the claim using the individual identifier for the psychiatrist.

LENGTH OF AUTHORIZATIONS: 1 year

STEP THERAPY: all agents listed

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

ANTIPSYCHOTICS, SECOND GENERATION, LONG-ACTING INJECTABLES*

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ABILIFY MAINTENA* (aripiprazole)	
ARISTADA™ (aripiprazole lauroxil)	
ARISTADA™ Initio (aripiprazole lauroxil)	
INVEGA SUSTENNA* (paliperidone)	
INVEGA TRINZA* (paliperidone)	
PERSERIS™ (risperidone)	
RISPERDAL CONSTA* (risperidone)	
ZYPREXA RELPREVV* (olanzapine)	

* 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.

g. Central Nervous System (CNS) Agents: Neuropathic Pain: Ztlido™ (lidocaine)

Dr. Link provided a clinical overview of this medication. A discussion ensued around potential for secondary exposure to the patch as well as the clinical criteria for coverage. It was confirmed that inadequate adhesion with the generic lidocaine patches currently preferred would satisfy the criteria of

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therapeutic failure. Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

Central Nervous System (CNS) Agents: Neuropathic Pain

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 there has been a therapeutic failure to no less than a one-month trial of at least two medications not requiring prior authorization

CNS AGENTS: NEUROPATHIC PAIN

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMITRIPTYLINE (generic of Elavil [®])	GRALISE [®] (gabapentin)
CARBAMAZEPINE (generic of Tegretol [®])	HORIZANT [®] (gabapentin enacarbil)
CLOMIPRAMINE (generic of Anafranil [®])	LYRICA [®] CR (pregabalin)
DESIPRAMINE (generic of Norpramin [®])	ZTLIDO™ topical delivery system (lidocaine)
DOXEPIN (generic of Sinequan [®])	
DULOXETINE (generic of Cymbalta [®])	
GABAPENTIN (generic of Neurontin [®])	
IMIPRAMINE (generic of Tofranil [®])	
LIDOCAINE patch (generic of Lidoderm [®])	
LYRICA [®] (pregabalin)	
NORTRIPTYLINE (generic of Pamelor [®])	
OXCARBAZEPINE (generic of Trileptal [®])	

h. Immunomodulator Agents for Systemic Inflammatory Disease: Ilumya™ (tildrakizumab-asmn)

Dr. Biczak provided a clinical overview of this medication. Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

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Immunomodulator Agents for Systemic Inflammatory Disease

LENGTH OF AUTHORIZATIONS: Dependent on indication

INDICATIONS:

	Adalimumab	Etanercept	Abatacept	Anakinra	Apremilast	Baricitinib	Brodalumab	Certolizumab	Golimumab	Guselkumab	Ixekizumab	Sarilumab	Secukinumab	Tildrakizumab -asmn	Tocilizumab	Tofacitinib
Rheumatoid Arthritis	✓	✓	✓	✓		✓		✓	✓			✓			✓	✓
Juvenile Idiopathic Arthritis	✓	✓	✓												✓	
Psoriatic Arthritis	✓	✓	✓		✓			✓	✓		✓		✓			✓
Ankylosing Spondylitis	✓	✓						✓	✓				✓			
Crohn's Disease	✓							✓								
Ulcerative Colitis	✓								✓							✓
Plaque Psoriasis	✓	✓			✓		✓	✓		✓	✓		✓	✓		
Uveitis	✓															
Cryopyrin-Associated Periodic Syndrome				✓												
Cytokine Release Syndrome															✓	
Giant Cell Arteritis															✓	
Hidradenitis Suppurativa	✓															

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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
 - Plaque Psoriasis
 - Psoriatic Arthritis
 - Polyarticular Juvenile Idiopathic Arthritis
 - Crohn's Disease
 - Ankylosing Spondylitis
 - Psoriasis
 - Uveitis
 - Cryopyrin-Associated Periodic Syndrome
 - Giant Cell Arteritis
 - Hidradenitis Suppurativa
- Diagnosis of Moderate to Severe Ulcerative Colitis (UC) (Humira, Simponi, and Xeljanz 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 immunosuppressants.
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 is an initial clinical response to Humira after 8 weeks of therapy, but no improvement in the progression of ulcerative colitis symptoms after 6 months, Simponi or Xeljanz 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
Xeljanz – 60 pills 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
- Step therapy: secukinumab (Cosentyx[®]) may be approved for labeled indications after a trial of adalimumab (Humira[®])

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ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	COSENTYX™ (secukinumab)	ACTEMRA® syringe (tocilizumab) ILUMYA™ (tildrakizumab-asmn) KEVZARA® (sarilumab) KINERET® syringe (anakinra) SILIQ™ (brodalumab) TALTZ™ (ixekizumab injection) TREMFYA™ (guselkumab)

- i. Infectious Disease Agents: Antivirals-HIV: Delstrigo™ (doravirine, lamivudine and tenofovir disoproxil)**
Steven B. Smith, Pharm D, MBA presented Delstrigo™ on behalf of Merck Sharpe & Dohme. Following his presentation, Dr. Biczak provided her clinical comments. Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

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Infectious Disease Agents: Antivirals – HIV

LENGTH OF AUTHORIZATIONS: 1 year

GRANDFATHERING:

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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 (AI) (Descovy[®])
- Raltegravir (Isentress[®]) plus tenofovir alafenamide/emtricitabine (AI) (Descovy[®])
- Bictegravir/emtricitabine/tenofovir (Biktarvy[®])†

†Recommended Initial Regimen based upon March 27, 2018 NIH News Release

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[®])

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? If applicable, the request must address the inability to use the individual components.

HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS AND COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SYMFI & SYMFI LO™ (efavirenz/lamivudine/tenofovir)	DELSTRIGO™ (doravirine, lamivudine, and tenofovir disoproxil)

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j. Infectious Disease Agents: Antivirals-HIV: Pifeltro™ (doravirine)

Steven B. Smith, Pharm D, MBA presented Pifeltro™ on behalf of Merck Sharpe & Dohme. Following his presentation, Dr. Biczak provided her clinical comments. Dr. Archibald recommended a Non-Preferred place on the PDL. 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[®])
- Bictegravir/emtricitabine/tenofovir (Biktarvy[®])†

†Recommended Initial Regimen based upon March 27, 2018 NIH News Release

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[®])

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? If applicable, the request must address the inability to use the individual components.

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HIV REVERSE TRANSCRIPTASE INHIBITORS, NON-NUCLEOSIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SUSTIVA® (efavirenz)	EDURANT® (rilpivirine) INTELENCE® (etravirine) NEVIRAPINE ER (generic of Viramune® XR) NEVIRAPINE IR (generic of Viramune®) PIFELTRO™ (doravirine) RESCRIPTOR® (delavirdine mesylate)

k. Respiratory Agents: Hereditary Angioedema: Takhzyro™ (lanadelumab-flyo)

David L. Griffin, BS, Pharm D presented clinical information on behalf of Shire. A question was raised as to the difference in pathways between this product and the preferred medications on the PDL. Following his presentation, Dr. Biczak provided her clinical comments. Dr. Jacobs mentioned that as more data comes out, the committee can revisit this drug. Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

Respiratory Agents: Hereditary Angioedema

LENGTH OF AUTHORIZATIONS: 12 months

All products in this class require clinical prior authorization:

- Diagnosis of hereditary angioedema
- History of recurrent angioedema (without urticaria) within the past 6 months
- History of recurrent episodes of abdominal pain and vomiting within the past 6 months
- History of laryngeal edema within the past 6 months
- Positive family history of angioedema

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 one episode of angioedema during use of a preferred medication

RESPIRATORY AGENTS: HEREDITARY ANGIOEDEMA

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CINRYZE® (C1 esterase inhibitor, plasma derived) HAEGARDA® (C1 esterase inhibitor, plasma derived)	BERINERT® (C1 esterase inhibitor, plasma derived) FIRAZYR® (icatibant acetate) KALBITOR® (ecallantide) RUCONEST® (C1 esterase inhibitor, recombinant) TAKHZYRO™ (lanadelumab-flyo)

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***l.* Topical Agents: Acne Preparations: Alverno™ (tretinoin)**

Dr. Biczak provided a clinical overview of this medication. Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

Topical Agents: Acne Preparations

LENGTH OF AUTHORIZATIONS: 1 year

CLINICAL CRITERIA:

All topical retinoids require prior authorization for patients over age 23:

- 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

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 one-month trial of at least one medication in the same class not requiring prior approval

RETINOID AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DIFFERIN® cream, gel, lotion (adapalene)	ADAPALENE cream, gel (generic of Differin®)
TAZORAC® cream, gel (tazarotene)	ALTRENO™ lotion (tretinoin)
TRETINOIN cream, gel (generic of Retin-A®)	ATRALIN® gel (tretinoin)
TRETINOIN micro gel (generic of Retin-A® micro)	ADAPALENE/BENZOYL PEROXIDE gel (generic of EPIDUO®)
	CLINDAMYCIN/TRETINOIN (generic of VELTIN®)
	FABIOR® foam (adapalene)
	PLIXDA™ pad (adapalene)
	ZIANA® gel (clindamycin/tretinoin)

***m.* Topical Agents: Acne Preparations: Plixda (adapalene)**

Dr. Biczak provided a clinical overview of this medication. Dr. Archibald recommended a Non-Preferred placement on the PDL. Votes were taken, and the committee approved the proposed category, shown below:

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Topical Agents: Acne Preparations

LENGTH OF AUTHORIZATIONS: 1 year

CLINICAL CRITERIA:

All topical retinoids require prior authorization for patients over age 23:

- 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

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 one-month trial of at least one medication in the same class not requiring prior approval

RETINOID AND COMBINATION PRODUCTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DIFFERIN [®] cream, gel, lotion (adapalene)	ADAPALENE cream, gel (generic of Differin [®])
TAZORAC [®] cream, gel (tazarotene)	ALTRENO [™] lotion (tretinoin)
TRETINOIN cream, gel (generic of Retin-A [®])	ATRALIN [®] gel (tretinoin)
TRETINOIN micro gel (generic of Retin-A [®] micro)	ADAPALENE/BENZOYL PEROXIDE gel (generic of EPIDUO [®])
	CLINDAMYCIN/TRETINOIN (generic of VELTIN [®])
	FABIOR [®] foam (adapalene)
	PLIXDA [™] pad (adapalene)
	ZIANA [®] gel (clindamycin/tretinoin)

IX. Other Business

There was no other business to discuss.

X. Next Meeting Date

The next meeting date is April 10, 2019 at 10:00 A.M. at Ohio Department of Medicaid, 50 W Town St.

XI. Adjournment

Dr. Jacobs adjourned the meeting at 11:35 A.M.

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