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DUR DIGEST

The Bulletin of Medicaid Drug Utilization Review (DUR) in Ohio Fee-For-Service

Introduction to Change Healthcare

Change Healthcare is the pharmacy benefit administrator for the Ohio Department of Medicaid (ODM). Our role is to manage and coordinate the Ohio Medicaid Fee-for-Service (FFS) claims processing and prior authorization determination activity. Change Healthcare is also delegated to administer the Retrospective Drug Utilization Review (DUR) program for the Ohio Medicaid FFS population.

Ohio Pharmacy Board Rules for Opioids[1]

Adopted on August 31, 2017 and updated on December 29, 2017, and June 1, 2018, Ohio Rules limit the prescribing of opioids for acute pain. These rules are as follows:

- No more than a 7-day supply for adults
- No more than a 5-day supply for minors with consent of parent/guardian unless in exempt situations
    a. Medical emergency
    b. Associated with surgery
    c. Prescriber's judgement if believed consent would be a detriment to health or safety.
    d. Treatment in a hospital/emergency facility/ambulatory surgical facility/nursing home/pediatric respite program/residential care facility/freestanding rehabilitation facility.
    e. Prescription is a compound substance containing opioid issued at time of discharge from facility or other location described in (d).
- Prescribing greater than the day supply limits must be documented to be reasonable based on patient's specific reason in their record.
- Total morphine equivalent dose (MED) must not exceed an average of 30 MED per day.
- Must include first four alphanumeric characters of ICD-10 or full procedure code on all controlled substances.

These rules do not apply to chronic patients, cancer, palliative care, hospice, addiction, inpatient or veterinarians.

Compounds

Beginning February 1, 2019, compounds at or above $100 (excluding dispensing fee) will require a prior authorization. Patients residing in Long Term Care or Intermediate Care Facilities will be excluded. Intravenous, TPN, and sterile pharmacy claims will also be excluded. There are certain criteria for which the compound claim will be approved. These include:

- There is a current supply shortage of the commercial product;
- The patient has a medical need for a dosage form or strength that is not commercially available;
- The patient had a trial and intolerance or contraindication to the commercially available product;

- The commercially available product has been discontinued by the manufacturer for reasons other than lack of safety or effectiveness.

Other criteria include:

- Each of the active ingredients must be used for an indication that is FDA approved or compendia supported;
- The dosing guidelines must be within guidelines for each active ingredient;
- The compound must contain at least one prescription medication.

The compound will not be approved if:

- The request is for a compound identical to a commercially available product (unless response to drug shortage);
- If there are FDA approved therapies or other standard therapies for the medical condition being treated, and the patient has not tried and failed such therapies;
- The compound is used for a medical condition that is not covered by Ohio Medicaid, for example, cosmetic use, obesity and infertility.

Pharmacy Administered Injections [OAC 4729-5-40]

Beginning 09/07/2018, pharmacists will be reimbursed an administration fee of $19.35 (instead of the usual dispensing fee) for certain injectables administered in the pharmacy (excluding those participants residing in a Long Term or Intermediate Care Facility).

Dispensing Limits [OAC 5160-9-03]

The maximum day's supply per claim is 34 days for most drugs. Medications that are typically prescribed for long-term maintenance therapy are allowed up to a 102-day supply. The following is a list of the drug classes that allow a higher day's supply to be dispensed.

Drug Class	Examples
ENDOCRINE	
CONTRACEPTIVES	Norethindrone/ethinyl estradiol, Levonorgestrel/ethinyl estradiol
CORTICOSTEROIDS	Budesonide, Dexamethasone, Prednisone
ESTROGENS/PROGESTINS	Conjugated Estrogens, Estradiol, Medroxyprogesterone
HYPOGLYCEMICS, ORAL	Glyburide, Metformin, Pioglitazone, Acarbose
INSULINS	Insulin glargine, Insulin NPH, Insulin Regular, Insulin Lispro
OSTEOPOROSIS AGENTS, ORAL	Alendronate, Calcitrol, Raloxifene
THYROID AGENTS	Levothyroxine, L-thyroxine
CARDIOVASCULAR	
ANGINA/HTN/HF AGENTS	Amlodipine, Atenolol, Benazepril/HCTZ, Carvedilol, Digoxin, Diltiazem, Isosorbide MN, Lisinopril, Losartan, Metoprolol, Valsartan/HCTZ
ANTIARRHYTHMICS	Propafenone, Quinidine, Sotalol
ANTICOAGULANTS, ORAL	Warfarin
ANTIPLATELET INHIBITORS	Clopidogrel, Dipyridamole, Prasugrel
DIURETICS	Furosemide, HCTZ, Spironolactone
LIPOTROPICS	Atorvastatin, Fenofibrate, Niacin ER
COUGH, COLD & ALLERGY	
RX AND OTC	Cetirizine, Diphenhydramine, Fluticasone, Loratadine, Loratadine/PSE
RESPIRATORY	
ANTIASTHMATIC/COPD AGENTS	Albuterol, Formoterol, Ipratropium, Montelukast, Salmeterol/fluticasone, Tiotropium
CENTRAL NERVOUS SYSTEM	
ANTIDEPRESSANTS	Amitriptyline, Duloxetine, Sertraline
ANTICONVULSANTS	Carbamazepine, Gabapentin, Topiramate
ANTIPARKINSON AGENTS	Benztropine, Pramipexole, Ropinirole
ANTIPSYCHOTICS	Quetiapine, Risperidone, Ziprasidone
MISCELLANEOUS	
GASTROINTESTINAL AGENTS	Cimetidine, Ranitidine, Famotidine, Lansoprazole, Omeprazole
GENITOURINARY AGENTS	Darifenacin, Oxybutynin, Tamsulosin
IMMUNOSUPRRESSANTS	Cyclosporine, Mycophenolate
PANCREATIC ENZYMES	Pancrealipase
URICOSURIC AGENTS	Allopurinol, Probenecid
VITAMINS & MINERALS	Calcium+D, Daily MVI, Ferrous sulfate, Magnesium, Potassium, Prenatal

FDA Drug Safety Communication Third Quarter 2018

November 20, 2018 The Food and Drug Administration (FDA) is warning that when the multiple sclerosis (MS) medicine Gilenya (fingolimod) is stopped, the disease can become much worse than before the medicine was started or while it was being taken. This MS worsening is rare but can result in permanent disability. As a result, the FDA has added a new warning about this risk to the prescribing information of the Gilenya drug label and patient Medication Guide.

November 29, 2018 The U.S. Food and Drug Administration (FDA) is warning that rare but serious cases of stroke and tears in the lining of arteries in the head and neck have occurred in patients with multiple sclerosis (MS) shortly after they received Lemtrada (alemtuzumab). These problems can lead to permanent disability and even death. As a result, the FDA has added a new warning about these risks to the prescribing information in the drug label and to the patient Medication Guide. The risk of stroke has been added to the existing *Boxed Warning.*

November 29, 2018 The U.S. Food and Drug Administration (FDA) is warning that signs and symptoms of a life-threatening side effect called differentiation syndrome are not being recognized in patients receiving the acute myeloid leukemia medicine Idhifa (enasidenib). The Idhifa prescribing information and patient Medication Guide already contain a warning about differentiation syndrome. However, there are cases of differentiation syndrome not being recognized and patients not receiving the necessary treatment. As a result, the FDA is alerting health care professionals and patients about the need for early recognition and aggressive management of differentiation syndrome to lessen the likelihood of serious illness and death.

December 20, 2018 A U.S. Food and Drug Administration (FDA) review found that fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. They can occur with fluoroquinolones for systemic use given by mouth or through an injection. Fluoroquinolones should not be used in patients at increased risk unless there are no other treatment options available. The FDA is requiring that a new warning about this risk be added to the prescribing information and patient Medication Guide for all fluoroquinolones.

References

1. For Prescribers- New Limits on Prescription Opioids for Acute Pain. State of Ohio Board of Pharmacy. 2017 December 5. Available from: https://www.pharmacy.ohio.gov/Documents/Pubs/Special/ControlledSubstances/For%20Pharmacists%20-%20New%20Limits%20on%20Prescription%20Opioids%20for%20Acute%20Pain.pdf Accessed 11/21/2018.

2. Food and Drug Administration. 2018 Drug Safety Communications. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm199082.htm Accessed 12/20/ 2018.

Ohio | Department of Medicaid

Preferred Drug List (PDL) Changes

P&T Meeting Date: October 3rd, 2018

PDL Changes Effective Date: January 1st, 2019

NEW PREFERRED DRUGS	
THERAPEUTIC CLASS	**PREFERRED STATUS**
Analgesic Agents: NSAIDs	FLECTOR® patch (diclofenac epolamine) VOLTAREN® gel (diclofenac sodium)
Analgesic Agents: Opioids	EMBEDA® (morphine sulfate/ naltrexone) †
Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors	NEUPOGEN® (filgrastim) †
Blood Formation, Coagulation, and Thrombosis Agents: Hematopoietic Agents	RETACRIT® (epoetin alfa-epbx) †
Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors	ALPROLIX® (factor IX recombinant) †
Cardiovascular Agents: Lipotropics	ROSUVASTATIN (generic of Crestor®)
Central Nervous System (CNS) Agents: Anticonvulsants	FYCOMPA® (perampanel) LYRICA® (pregabalin)
Central Nervous System (CNS) Agents: Antipsychotics	ARISTADA™ Initio (aripiprazole lauroxil)
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents	APTENSIO XR™ (methylphenidate) CONCERTA® (methylphenidate ER)
Central Nervous System (CNS) Agents: Fibromyalgia Agents	LYRICA® (pregabalin)
Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction	BUNAVAIL® buccal film (buprenorphine/naloxone) BUPRENORPHINE SL tablets (generic of Subutex®) BUPRENORPHINE/NALOXONE SL tablets
Central Nervous System (CNS) Agents: Neuropathic Pain	LIDOCAINE patch (generic of Lidoderm®) LYRICA® (pregabalin)
Endocrine Agents: Androgens	DEPO-TESTOSTERONE (testosterone cypionate) TESTOSTERONE CYPIONATE (generic of Depo-Testosterone) TESTOSTERONE ENANTHATE (generic of Delatestryl)
Gastrointestinal Agents: Anti-Emetics	DICLEGIS® (doxylamine and pyridoxine)
Gastrointestinal Agents: Proton Pump Inhibitors	DEXILANT® (dexlansoprazole) NEXIUM® packets (esomeprazole)
Gastrointestinal Agents: Ulcerative Colitis Agents	DELZICOL® (mesalamine) LIALDA® (mesalamine) PENTASA® (mesalamine)
Genitourinary Agents: Urinary Antispasmodics	TOVIAZ® (fesoterodine)
Infectious Disease Agents: Antibiotics - Inhaled	TOBRAMYCIN inhalation from labeler 00093†
Infectious Disease Agents: Antivirals- HIV	SYMFI™ (efavirenz/lamivudine/tenofovir)
Ophthalmic Agents: Antibiotic and Antibiotic-Steroid Combination Drops and Ointments	MOXEZA® (moxifloxacin)
Ophthalmic Agents: Antihistamines & Mast Cell Stabilizers	AZELASTINE (generic of Optivar®) LASTACAFT® (alcaftadine)
Ophthalmic Agents: NSAIDs	ILEVRO® (nepafenac) NEVANAC® (nepafenac)
Otic Agents: Antibacterial and Antibacterial/Steroid	CIPRO HC® suspension (ciprofloxacin with

Combinations	hydrocortisone)
Respiratory Agents: Beta-Adrenergic Agonists - Inhaled, Short Acting	PROAIR RESPICLICK® (albuterol)
Respiratory Agents: Chronic Obstructive Pulmonary Disease	TUDORZA® (aclidinium)
Respiratory Agents: Hereditary Angioedema	HAEGARDA® (C1 esterase inhibitor) ᵀ
Respiratory Agents: Nasal Preparations	OLOPATADINE (generic of Patanase®)
Topical Agents: Immunomodulators	TACROLIMUS (generic of Protopic®)ᵀ

ᵀ PA required preferred

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	**NON-PREFERRED STATUS**
Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors	FULPHILA™ (pegfilgrastim-jmdb)
Blood Formation, Coagulation, and Thrombosis Agents: Hemopoietic Agents	PROCRIT® (epoetin alfa)
Cardiovascular Agents: Angina, Hypertension & Heart Failure	KAPSARGO™ (metoprolol succinate)
Cardiovascular Agents: Lipotropics	ZYPITAMAG™ (pitavastatin)
Central Nervous System (CNS) Agents: Anticonvulsants	SUBVENITE (lamotrigine)
Central Nervous System (CNS) Agents: Antidepressants	NEFAZODONE
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents	METHYLPHENIDATE ER (generic of Concerta®) Members on METHYLPHENIDATE ER (generic of Concerta®) will be grandfathered on therapy through June 30th, 2019
Central Nervous System (CNS) Agents: Parkinson's Agents	OSMOLEX ER™ (amantadine er)
Gastrointestinal Agents: Anti-Emetics	BONJESTA® (doxylamine and pyridoxine)
Immunomodulator Agents for Systemic Inflammatory Disease	OLUMIANT® (baricitinib)
Infectious Disease Agents: Antivirals- HIV	SYMTUZA™ (darunavir, cobicistat, emtricitabine, tenofovir alafenamide)

CHANGES IN CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
Analgesic Agents: NSAIDs	Change in criteria for transdermal and topical non-preferred products
Cardiovascular Agents: Angina, Hypertension & Heart Failure	Criteria for Entresto™ no longer includes requirements around angioedema or concomitant ACE/ARB use
Central Nervous System (CNS) Agents: Anti-Migraine	Prophylaxis requirements changed to 3 trials from all medications trialed
Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction	No PA required for preferred oral product
Central Nervous System (CNS) Agents: Neuropathic Pain	Removal of criteria around LIDOCAINE patch and LYRICA®
Endocrine Agents: Diabetes - Insulin	Definition of therapeutic failure added
Endocrine Agents: Diabetes - Non-Insulin	Definition of inadequate clinical response added
Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) / Selected GI	TRULANCE™ (plecanatide) requires step therapy through Amitiza® and Linzess™

Gastrointestinal Agents: Opioid-Induced Constipation	RELISTOR® and SYMPROIC® requires step therapy through Amitiza® and Movantik®
Immunomodulator Agents for Systemic Inflammatory Disease	Expanded indications for products in category

Infectious Disease Agents: Antivirals- Hepatitis C Agents	Allowance for continuation of therapy for members established on therapy under prior payer Removal of requirement that members be at F2 fibrosis for treatment to be approved Allowance for therapy to be approved if done in consultation with specialist; changes for authorization window
Respiratory Agents: Beta-Adrenergic Agonists - Inhaled, Long Acting	Removal of Step Therapy

For additional details, the Preferred Drug List (PDL) and clinical criteria can be found at:
http://pharmacy.medicaid.ohio.gov/drug-coverage