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PHARMACY BENEFIT UPDATE

FALL/WINTER 2017 ISSUE



Preferred Drug List (PDL) News:

PDL Changes

This issue of the Pharmacy Benefit Updates contains changes to the Preferred Drug List for January 1, 2018 as well as updates on MaineCare pharmacy benefit changes.

Non-preferred					
Adcirca Tab	Aerospan	Asmanex	Besivance Susp		
Calcium Acetate	Ciprofloxacin HCL	Cleocin Cream	Colazal		
Tab					
Colchicine Tab	Depo- Testosterone Oil	Dipentum	Doxercalcif Cap		
Doxercalcif Inj	Eliphos	Flovent Diskus	Floxin		
Gentak	Gentamicin Sulfate	Harvoni	Kapvay		
Maxitrol Oint	Methylphenidate ER (00406 manufacturer/NDC)	Methylphenidate HCL Chew	Metrogel Vaginal Gel		
Neomycin/Poly HC	Paricalcitol Cap	Paricalcitol Inj	Pentasa		
Rowasa	Sovaldi	Starlix	Technivie		
Tobradex ST Drop	Tyvaso	Veletri	Vesicare		
Susp Viekira Pak	Viekira XR	Vigamox	Vosevi		
Preferred					
Amitiza	Aptensio XR	Aranesp	Armodafinil		
Atomoxetine (66993 manufacturer/NDC)	Bevespi Aerosphere	Clindesse	Colchicince Cap		
Dextroamphetamine ER	Granix	Humulin U- 500	Ilevro		

Linzess	Lotemax Susp	Nateglinide	Neo/Poly/Dexameth Oint
Neo/Poly/Dexameth Susp	Nuwiq Vial	Orenitram	Quetiapine XR
Saphris	Sulfacetamide/Prednisolone	Testosterone Cypionate	Tobradex Drop Susp
Vyvanse Chew	Xyntha	Zylet Susp	

The following Medications have additional PDL clarifications or criteria

Latuda will be non-preferred with established users grandfathered.

Mircera and Drisdol Caps is no longer available and will be removed from the PDL.

Fulyzaq is non-preferred and has undergone a name change to Mytesi. It has been updated on the PDL.

Vitamin D3 400 unit drops (NDC specific) will now be preferred.

Mavyret and Epclusa are preferred with a clinical PA.



National Average Drug Acquisition Cost (NADAC)

The federal Centers for Medicare and Medicaid Services (CMS) has directed state Medicaid agencies to adopt fee-for-service pharmacy payment policies designed to pay pharmacies for the actual acquisition cost of drugs plus a reasonable professional dispensing fee, based on the actual cost to the pharmacy of dispensing drugs to Medicaid members. Additional details can be found on the CMS fact sheet at the following link:

 $\underline{https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-01-21.html.}$

A copy of the CMS Covered Outpatient Drugs Final Rule (CMS-2345FC) published on February 2, 2016 can be found on the Federal Register at this link:

 $\underline{https://www.federalregister.gov/articles/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs}$

MaineCare will use a "lower-of" methodology utilizing the benchmark of the National Drug Average Acquisition Cost (NADAC) and Wholesale Acquisition Cost (WAC), in addition to the current methodology. The NADAC is based on CMS' monthly surveys of retail pharmacies to determine average acquisition costs for covered outpatient drugs. This additional federal pricing source will update each week when published by CMS.

Beginning September 1, 2017, Change Healthcare implemented the first of the monthly updated NADAC prices and incorporated these into the "lower of logic" when calculating the reimbursement, consistent with the pharmacy pricing reimbursement policy. Payment of covered outpatient drugs, including over-the-counter drugs, dispensed by an enrolled pharmacy will include the reimbursement for the Actual Acquisition Cost (AAC) of the drug plus a professional dispensing fee. AAC is defined as the lower of:

- a. The National Drug Average Acquisition Cost (NADAC)
- b. The Wholesale Acquisition Cost (WAC) + 0%
- c. The State Maximum Allowable Cost (SMAC)

- d. The Federal Upper Limit (FUL)
- e. AWP, Brand: 16%, and Generic and Specialty: 16.67%
- f. Submitted Ingredient Cost
- g. The provider's Usual and Customary (U&C) charges
- h. The Gross Amount Due (GAD)

Additionally, in September 2016 MaineCare invited all Medicaid enrolled pharmacies to participate in a pharmacy cost of dispensing survey in order to analyze the cost of dispensing prescription medications to MaineCare members.

Based on the survey results, MaineCare has determined that the new "Professional Dispensing Fee" for retail community pharmacies, institutional, or long-term care pharmacies, and non-FQHC 340B pharmacies and specialty pharmacies will be \$11.89. Therefore, the dispensing fee was adjusted from the current \$3.35 on September 1, 2017. This change will not affect Mail Order pharmacies; the dispensing fee will continue to be \$2.50 for MaineCare and \$1.00 for Rx Plus.



Maintenance Rules

Effective January 8, 2018, all drugs defined by Medispan as "maintenance" medication **must** be dispensed in a 90-day supply after an initial 30-day fill. If the member has previously been on the medication and received 30 days of the medications listed below, they will need to get a 90-day supply with the current refill. If you are trying to fill for less than 90 days, you will receive the following rejection message:

Maintenance Drug: 90-day supply required.

- There are exceptions to the maintenance requirement:
- Maintenance rule does not apply to brand name medications
- Members identified in member eligibility as long-term care recipients will be exempt from the requirements of the 90-day maintenance rule.
- Controlled substances considered maintenance medications will also not be considered and will be excluded from the 90-day rule.

The classes of medications that are affected are listed below:

ACE ALCOHOL DETERRENTS
ALS DRUGS ALZHEIMER
ANALGESICS ANDROGENS

ANGIOTENSIN RECEPTOR BLOCKERS **ANTIANGINALS ANTIARRHYTHMICS** ANTIASTHMATIC **ANTICOAGULANTS ANTICONVULSANTS ANTIDEPRESSANTS ANTIHYPERTENSIVES** ANTIEMETIC - 5-HT3 RECEPTOR ANTAGONISTS ANTIMALARIAL AGENTS ANTIMYCOBACTERIALS/ANTITUBERCULOSIS ANTI-PARKINSONIAN DRUGS **ANTIPSYCHOTICS ANTIRETROVIRALS ANTISPASMODICS** ANTITHYROID THERAPIES ARB'S AND DIURETICS ARTHRITIS - MISC.

BPH CALCIUM CHANNEL BLOCKERS

CARDIAC GLYCOSIDES CCB / LIPID CHOLESTEROL CONTRACEPTIVES

COX 2 INHIBITORS CYTO-MEGALOVIRUS AGENTS

DENTAL PRODUCTS DIABETIC DIURETICS ESTROGEN

ARTIFICIAL SALIVA/STIMULANTS

GI GLUCOCORTICOIDS – MINERALOCORTICOIDS

BETA BLOCKERS

GOUT HEPATITIS B ONLY
IMMUNOSUPPRESSANTS LITHIUM
LINCOSAMIDES/OXAZOLIDINONES/ LEPROSTATICS MINERALS

MONO-NITRATES MULTIPLE SCLEROSIS AGENTS MUSCLE RELAXANTS NEUROLOGICS - MISC.

NICARDIPINES NITRO – PATCHES, SUBLINGUAL/SPRAY

NSAIDS OPTHALMICS OSTEOPOROSIS PARKINSONS

PHOSPHATE BINDERS PLATELET AGGR. INHIBITORS
PROGESTINS PSYCHOTHERAPEUTIC COMBINATION

PURINE ANALOG RHEUMATOID ARTHRITIS
SEDATIVE/HYPNOTICS – BARBITURATE SOMATOSTATIC AGENTS

THYROID HORMONES TOPICAL - STEROID LOCAL ANESTHETICS

UROLOGICAL - MISC. VAGINAL – ESTROGENS

VASOPRESSINS VITAMINS

This list will be posted on: www.mainecarepdl.org



PA Statistics

For the third quarter of 2017, there were 31,001 unique PA requests, and 91% were approved. The average determination time was 2.04 hours. The top five most frequently requested drugs were:

Suboxone (3,158)

Oxycodone HCL (1,764)

Omeprazole (1,473)

Adderall (1,110)

Hydrocodone-Acetaminophen (1,104)



FDA Alerts

General Anesthetic and Sedation Drugs: Drug Safety Communication - New Warnings for Young Children and Pregnant Women

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm533195.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA approves Jardiance to reduce cardiovascular death in adults with type 2 diabetes http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm531517.htm?source=gov delivery&utm medium=email&utm source=govdelivery

FDA Releases Draft Guidance for Industry: "Considerations in Demonstrating Interchangeability with a Reference Product."-Drug Information Update http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/U CM537135.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA confirms elevated levels of belladonna in certain homeopathic teething products http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm538684.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Chlorhexidine Gluconate: Drug Safety Communication - Rare But Serious Allergic Reactions <a href="http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProduct-s/ucm539575.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA updates warnings for oral and injectable fluoroquinolone antibiotics due to disabling side effects https://www.fda.gov/Drugs/DrugSafety/ucm511530.htm?source=govdelivery&utm_medium=em ail&utm_source=govdelivery

Canagliflozin (Invokana, Invokamet) - Drug Safety Communication: Increased Risk of Leg and Foot Amputations

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm558605.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA identifies no harmful effects to date with brain retention of gadolinium-based contrast agents for MRIs; review to continue https://www.fda.gov/Drugs/DrugSafety/ucm559007.htm?source=govdelivery&utm_medium=em_ail&utm_source=govdelivery

FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women

https://www.fda.gov/DrugS/DrugSafety/ucm549679.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA alerts consumers of nationwide voluntary recall of EpiPen and EpiPen Jr https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm550170.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Information on Erythropoiesis-Stimulating Agents (ESA) Epoetin alfa (marketed as Procrit, Epogen), Darbepoetin alfa (marketed as Aranesp)

https://www.fda.gov/DrugS/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm109375.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA approves two hepatitis C drugs for pediatric patients

https://www.fda.gov/NewsFvents/Newsroom/PressAnnouncements/ucm55140

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm551407.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Brilinta (ticagrelor) 90 mg tablets, 8-count Physician Sample Bottles: Recall of Lot # JB5047 - Due to Report of Another Medicine in One Bottle

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm560786.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Mibela 24 Fe Chewable Tablets by Lupin Pharmaceuticals Inc.: Recall - Out of Sequence Tablets and Missing Expiry/Lot Information

 $\frac{https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm560908.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery$

Novopen Echo Insulin Delivery Device by Novo Nordisk: Recall - May Crack or Break If Exposed to Certain Chemicals

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm565955.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA requests removal of Opana ER for risks related to abuse

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

<u>Keytruda (pembrolizumab) in Patients with Multiple Myeloma: FDA Statement - Two Clinical</u> Trials on Hold

 $\frac{https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProduc}{ts/ucm574347.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery}$

FDA Drug Safety Communication: FDA recommends separating dosing of potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) from all other oral drugs

https://www.fda.gov/Drugs/DrugSafety/ucm572484.htm?source=govdelivery&utm_medium=em
ail&utm_source=govdelivery

Next Drug Utilization Review (DUR) Committee Meeting

Comments on the PDL or any PAs, either proposed or already in effect, may be made at these meetings or by e-mail, letter, or phone if more convenient.

For DUR questions, you may contact:

Jill Kingsbury, Director of Pharmacy, MaineCare Services Jill.Kingsbury@maine.gov

For PA/PDL questions, you may contact:

Michael Ouellette, R.Ph mouellette@changehealthcare.com

Jeffrey Barkin, MD jbarkin@changehealthcare.com

Date: March 13, 2018

Time: 5:30-8:30pm

Location: The Armory (Augusta, ME)

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