

PHARMACY BENEFIT UPDATE Fall 2010 Issue

Preferred Drug List (PDL) News

A. 2011 PDL CHANGES

Considering the several thousand drugs available on the MaineCare Preferred Drug List, there are very few changes being made this year. MaineCare is working hard to make more medications available and reduce the impact on providers and MaineCare members.

Preferred	Notes
Aggrenox	
Daytrana	<i>Additional long-term product option</i>
Dulera	<i>New preferred antiasthmatic combination product</i>
Kombiglyze	
Losartan	<i>New generic availability</i>
Losartan HCT	<i>New generic availability</i>
Norditropin	<i>Addition to GH preferred products, please review PDL for GHS criteria</i>
Renvela	<i>Diagnosis required</i>

Non-preferred	
Avodart	<i>Step 8, prior use of preferred agent prior to any approvals</i>
Boniva	<i>Please use other preferred agents</i>
Clearlax Powder	
Cozaar 25mg	<i>See supporting article for February 2011 change</i>
Cymbalta	<i>1. Fibromyalgia diagnosis- prior use and failure of preferred generics (amitriptyline or cyclobenzaprine) and gabapentin prior to approval. 2. Max daily dose 60mg and 1 capsule per day for all strengths. 3. Established users are grandfathered</i>
Enablex	<i>Use a preferred long acting antispasmodic</i>
Hyzaar	<i>See supporting article</i>
Jalyn	<i>Use of preferred (tamsulosin and finasteride) and (tamsulosin and non-preferred Avodart)</i>
Lovenox 300	<i>Use other strengths available to obtain desired dose.</i>
Omnitrope	<i>Step 5, prior use of preferred agents</i>
Oravig	
Renagel 800	<i>Renagel 400 still available as preferred</i>
Savella	<i>Fibromyalgia diagnosis and trial of a preferred generic (amitriptyline or cyclobenzaprine, and gabapentin) and Cymbalta prior to approval.</i>
Solaraze Gel	
Tracleer	<i>1. Prior trial of Letaris, WHO Group 1 diagnosis of PAH (Primary Pulmonary Hypertension) and NYHA functional class of 3. 2. For members with NYHA functional class of 4, Tracleer approval will be allowed with confirmation of diagnosis and functional class.</i>
Tribenzor	<i>Use preferred active ingredients which are available without PA.</i>
Vimovo	<i>Use a preferred NSAID and PPI separately.</i>
Zyclara	

B. AVANDIA

The U.S. Food and Drug Administration announced that it will significantly restrict the use of the diabetes drug Avandia (rosiglitazone) to patients with Type 2 diabetes who cannot control their diabetes on other medications. These new restrictions are in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with Avandia. FDA requires manufacturer to develop a risk evaluation and mitigation strategy. Accordingly, Avandia will be available to new patients only if they are unable to achieve glucose control on other medications and are unable to take Actos (pioglitazone), the only other drug in this class. Current users of Avandia who are benefiting from the drug will be able to continue using the medication. Doctors will have to attest to and document their patients' eligibility; patients will have to review statements describing the cardiovascular safety concerns associated with this drug and acknowledge they understand the risks.

C. COLCHICINE

The FDA has determined that older generic single-ingredient oral colchicines lack adequate safety data and cannot be marketed without appropriate FDA approval. According to the FDA, these products do not have approved New Drug Applications; therefore, the existing drug NDCs do not meet the definition of a covered outpatient drug and therefore are not eligible for inclusion in the Medicaid rebate program. Currently the only FDA approved colchicine available with safety data and dosing recommendations is Colcrys, which received FDA approval on 6/30/2009. Colcrys only has two indications; the acute treatment of gout and the chronic treatment of Familial Mediterranean Fever (FMF). Recommended doses of Colcrys (colchicine) for Familial Mediterranean Fever (FMF) and acute gout flares are different. With prior authorization approval, acute gout patients who are unresponsive to oral NSAIDs will be approved to receive up to ten Colcrys tabs per month. It is required that maximal doses of prophylactic medications are being utilized. FMF patients will qualify for up to one hundred and twenty tabs per month once the diagnosis has been confirmed via PA. Concomitant use of P-glycoprotein and strong CYP3A4 inhibitors may cause severe drug interactions with colchicine especially in patients with renal and hepatic impairment or advanced age.

D. COZAAR / HYZAAR UPDATE

MaineCare has maintained Cozaar 25mg (up to four per day) as a preferred medication for over a year as the exclusive preferred version of losartan. Beginning in February of 2011 Cozaar 25mg will become non-preferred. Losartan generic has finally come down enough cost wise to allow it to be preferred for the months of November and December. Both Losartan and Cozaar 25mg tabs will be co-preferred for several months to allow time for pharmacies to utilize current brand stocks and transition to the generic version. Hyzaar becomes non-preferred in January and Losartan HCT becomes the preferred version. Preferred ARB products are available without PA if patient on diabetic therapy or prior ACE therapy.

E. MAJOR PDL CHANGES DUE TO HEALTHCARE REFORM

The recent Healthcare Reform (HCR) Act will change the way certain medications are viewed by the Federal Government as product (line) extensions of the original product. For these drugs the Federal government will take back from the states a disproportionately larger share of the drug's rebate (paid by the manufacturer). Several historically preferred extended release versions of older drug products ("line extension" drugs) such as Detrol LA and Seroquel XR, have now become essentially unaffordable to the State. MaineCare, with input from the DUR committee, decided to remove these medications from the preferred status effective August 1st, 2010 while several of them were allowed for existing users until 10/1/10 for certain indications. Due to conflicting guidance from CMS over the past year, the assessment of these drugs has been both complicated and lengthy. Please see below for the most current PDL status of these drugs.

F.LINE EXTENSION DRUGS

Line Extension Drug	Preferred ?
Abilify ODT	No
Aricept ODT	Yes
Depakote ER	No
Detrol LA	No
Effexor XR	No
Focalin XR	Yes
Keppra XR	No
Lescol XL	Yes
Maxalt MLT	Yes
Opana ER	No
Paxil CR	No
Sanctura XR	No
Seroquel XR	No
Tegretol XR	No

G. MEDICARE GAP DISCOUNT PROGRAM

The Centers for Medicare & Medicaid Services (CMS) and drug manufacturers have reached agreements to develop this prescription drug discount program. Patients with Medicare who have Part D, but don't have Extra Help (the low-income subsidy), are eligible for the Medicare Coverage Gap Discount Program. Beginning January 1, 2011, claims made for participating manufacturer's "applicable" drugs will be automatically discounted by 50% at point-of-sale. This discount does not include the dispensing fee. For the purpose of out-of-pocket spending, the full cost of the drug will be accounted for in assisting the patient to reach catastrophic coverage. Furthermore, a 7% increase in coverage for all other covered drugs (e.g., generic drugs, insulin delivery supplies) will be applied while in the coverage gap. Over the next 10 years prescription drug coverage will continue to increase for all covered drugs in the coverage gap. Eventually, in 2020 people in the coverage gap will pay just 25%.

H. SUBOXONE

MaineCare has recently reviewed Suboxone utilization data, PA requests, Intensive Benefit Monitoring and overall cost to the MaineCare budget. The annual cost has climbed rapidly from \$0.5 million dollars in 2004 to an expected \$13 million in SFY 2011 (or nearly 7% of the drug budget). Diversion is on the upswing, as is dosing outside the manufacturer guidelines. In response, the State, with input from the DUR, has come up with the following recommendations to the MaineCare PDL with respect to Suboxone and will take effect on December 3, 2010.

1-Induction period for new starts of up to 60 days

2-Max dose of 32 mg per day during induction

3-Max dose of 16 mg per day for maintenance

4-PA will be necessary whenever there is more than one narcotic fill in a member's drug profile between today's fill of Suboxone and any prior Suboxone fill within the past 90 days.

5- Prescribers will be limited to those with X-DEAs

6- There should be evidence provided of monthly monitoring including periodic (not necessarily monthly) random pill counts, urine drug tests and Prescription Monitoring Program (PMP) reports.

I. LONG ACTING B₂ ADRENERGIC AGONIST (LABA)

LABAs are contraindicated if not being used concomitantly with another long term asthma control medication, inhaled corticosteroid (ICS). For pediatric and adolescent patients with asthma who require addition of a LABA to an ICS, a fixed-dose combination product should be used to ensure proper adherence for both drugs. After 90 days of separate concurrent LABA and ICS use, patients will be required to use a fixed-dose combination.

J. DRUG-DRUG INTERACTIONS

Onglyza 5mg will require a prior authorization if it is currently being used in combination with drugs known to be significant CYP3A4 inhibitors (ketoconazole, itraconazole, clarithromycin, indinavir, nefazodone, nelfinavir, ritonavir, atazanavir, saquinavir and telithromycin)

Cyclosporine will now require prior authorization when used with Livalo (pitavastatin).

Tracleer may induce the metabolism of atorvastatin, lovastatin, and simvastatin leading to significantly decreased serum concentrations and possible loss of efficacy. Furthermore, Tracleer may induce the metabolism of warfarin leading to decreased anticoagulant effects, INR should be closely monitored and warfarin doses should be increased accordingly during concurrent use. Tracleer is a pregnancy category X and is contraindicated in women who are or may become pregnant. Since bosentan induces the metabolism of hormonal contraceptive therapies, possibly resulting in subtherapeutic serum levels, alternative contraceptive methods must be used during concurrent use. Prior authorization is required if oral contraceptives are in a member's drug profile.

K. CHRONIC OPIATE USE MONITORING UPDATE

Due to increasing concerns regarding the appropriate and, safe use of long-term opiates, the Pharmacy Unit of the Office of MaineCare Services will expand the scope of its *chronic opiate* prescription monitoring efforts. The specific goal is to promote the widespread adoption of key elements of the existing standards of care (most notably the joint Rule 11 of the Boards of Licensure in Medicine and Osteopathy) as they pertain to "new" chronic opiate patients. This effort will require a prior authorization (PA) for any member who has had 90 days of opiates in the past 100 days (no chronic, sustained opiate prescriptions previously; i.e. **new starters**). A PA will **not** be required for hospice patients or for those members being actively treated for a life threatening illness such as AIDS or cancer.

The PA will concentrate on determining how thoroughly the following principles of pain management have been addressed:

- Confirming an appropriate indication for chronic opiates;
- Reviewing non-pharmacologic and non-opioid treatments considered and/or tried;
- Verification that an opiate/controlled substance contract exists;
- Reviewing the intended monitoring plan (such as whether Urine Screens and Random Pill Counts may be appropriate);
- Verification that Prescription Monitoring Program reports are used routinely and not misinterpreted.

It is anticipated that only a handful of Chronic Narcotic Use Prior Authorizations will be required of each provider and most providers will not have to fill out more than 5 PAs. Some patients will require a follow-up PA 3 to 12 months later to see how well actual monitoring results and contract violations are handled. Exemptions will be granted quickly once it is clear that appropriate selection and reevaluation/monitoring of chronic opiate patients is occurring. The overall PA volume is estimated to be 50-100 per month.

Monitored patients are less likely to abuse prescription medications. Robert J. Meyer, M.D., Director for the FDA's Office of Drug Evaluation, on February 9, 2004 while addressing the Subcommittee on criminal Justice, Drug Policy, and Human Resources House Committee on Government Reform stated:
"States that have monitoring programs have shown lower levels of abuse and misuse of scheduled drugs compared to states that do not have such programs. These programs facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled prescription drugs. Approximately 18 states have some kind of monitoring program in effect. While they vary in resources, methods, and data access by health care professionals, the programs share the objective of preventing and reducing inappropriate prescribing and dispensing, drug diversion, and drug abuse. FDA strongly supports state-based prescription drug monitoring programs."¹

¹ <http://www.fda.gov/NewsEvents/Testimony/ucm114804.htm>

Preventing Prescription Drug Abuse
Statement by
Robert J. Meyer, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

L. MAINECARE 15 DAY INITIAL SCRIPT LIMIT: UPDATE

In the summer of 2009, MaineCare introduced a fifteen day initial prescription supply limit. The original concept was brought forth from Eastern Maine Medical Center. MaineCare staff and associates began developing the program for various medications that have been identified with high side effect profiles, high discontinuation rates, or frequent dose adjustments to ensure cost effectiveness without "wasting" or "discarding" of used medications.

The medications selected for this program will be maintained on the Mainecarepdl.org web site. For those who may be interested in what MaineCare may be implementing for cost saving or safety measures, you may attend the Drug Utilization Review Committee meetings. These meetings are held 9 times a year, the second Tuesday of the month, excluding December, July and August from 6-8pm. The location is 442 Civic Center Drive at the Office of MaineCare Services.

M. ACADEMIC DETAILING

The State of Maine in conjunction with the Maine Medical Association has launched an innovative pilot program called MiCiS (The Maine Independent Clinical Information Service). This Academic Detailing program is designed to provide physicians and healthcare providers with objective, evidence based information on prescription medications. By providing outreach visits to practitioners with licensed clinicians, the MiCiS program hopes to present education and support with evidence based information about common prescribing choices without the commercial and marketing approach employed by drug manufacturers. While academic detailing is primarily a quality driven endeavor it has also demonstrated an ability to control costs. For further information please see www.mainemed.com

N. PA STATISTICS

For the third quarter of 2010, there were 25,618 unique PA requests, 83% were approved. The top five most frequently requested drugs were: omeprazole/Prilosec (1,193), aripiprazole/Abilify (1,074),

duloxetine/Cymbalta (1,042), pantoprazole/Protonix(912), and quetiapine/Seroquel (813). The average determination time was 3.16 hours.

O. MAIL ORDER

The Department would like to once again remind providers of the mail-order option that is available to MaineCare members. Prescriptions may be obtained in quantities up to a 90 day supply. Cost savings and conveniences to the MaineCare members are greater when prescriptions are written in 90 day quantities when using mail-order.

MaineCare Mail Order Pharmacies

I-Care Pharmacy: 1-888-422-7319

Wal-Mart Mail Order: 1-800-273-3455

P. NEXT DUR COMMITTEE MEETING

The next DUR meeting will be the annual PDL review and will be held January 11th at 6:00 pm to 8:00 pm at OMS (442 Civic Center Drive) in Augusta. Comments on the PDL or any PA's, 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:

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