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PHARMACY BENEFIT UPDATE
Spring 2014 Issue

Preferred Drug List (PDL) News

A. PDL Changes

This issue of the Pharmacy Benefit Updates contains recent changes to the MaineCare Preferred Drug List (PDL), as well as updates on MaineCare pharmacy benefit changes.

Non-preferred			
Adempas	Anoro Ellipta	Brintellix	Bromocriptine
Cyclosporine Sol Modified	Farxiga	Fetzima	Fycompa
Gilotrif	Khedezla	Neom/Poly/Dex Opth Oint 0.1%	Opsumit
Olysio	Ranitidine 150 Caps	Rilutrek	Selegiline HCL Tabs
Velphoro	Zohydro ER	Zorvolex	

Preferred			
Nor-QD Tabs	Norethindrone 0.35 Tabs	Maxitrol Opth Oint 0.1%	Neoral
Parlodel Caps	Ranitidine 150 Tabs	Riluzole	Rizatriptan Tabs
Selegiline HCL Caps			

The following medications have additional PDL clarifications or criteria
Xanax XR is now a step 9 and generic Alprazolam ER has been added as a step 8. Both are non-preferred.
Naratriptan HCL Tabs are now step 2 on the preferred side.
Donepezil Hydrochloride Tabs 23mg are now a step 7 on the non-preferred side.
Carisoprodol 250mg Tabs will be moved to a step 9.
Gardasil will be preferred under MaineCare for ages 19-26. Children who are 9- 18 years of age are eligible for this vaccine through the Maine Immunization Program. Please contact 1-800-867-4775 or 207-287-3746 for assistance.

Lyza and Maxair are not available and will be removed from the PDL.
Suprex will be preferred with dosing limits of one tablet per seven (7) days for prevention and treatment of STI gonorrhoea.
Sovaldi will be preferred and will require a clinical PA. Please see the MaineCare PDL for criteria.
Adempas will be non-preferred and will require previous trials/failure of multiple preferred medications. Dosing limits of one tablet daily. Drug-Drug Interations (DDI): PDE inhibitors should be avoided (including dypyridamole, adcira and tadalafil)
Brintellix will be non-preferred; requires previous trials/failure of multiple preferred medications. Dosing limits apply; please see the dose consolidation list.
Fetzima will be non-preferred and requires previous trials/failure of multiple preferred medications. Dosing limits apply; please see the dose consolidation list. Max daily dose of 80mg if used concomitantly with strong CYP3A4 inhibitor (including ketoconazole, itraconazole, clarithromycin, indinavir, nefazodone, nelfinavir, ritonavir, atazanavir, saquinavir and telithromycin).
Fycompa will be non-preferred and will require previous trials/failure of multiple preferred medications. Dosing limits apply; please see the dose consolidation list.
Gilotrif will be non-preferred and needs to be prescribed by an oncologist. Re-approval will require documentation of response without disease progression and tolerance to treatment. Dosing limits apply, please see the dose consolidation list.
Opsumit will be non-preferred and will require previous trials/failure of multiple preferred medications. Dosing limits of one tablet daily. DDI: CYP3A4 inhibitors should be avoided (including ketoconazole, itraconazole, clarithromycin, indinavir, nefazodone, nelfinavir, ritonavir, atazanavir, saquinavir and telithromycin).
Olysio will be non-preferred and DDI: CYP3A4 inhibitors should be avoided (including ketoconazole, itraconazole, clarithromycin, indinavir, nefazodone, nelfinavir, ritonavir, atazanavir, saquinavir and telithromycin).

B. Pharmacy Care Management:

The Department, in conjunction with Goold Health Systems (GHS), continues to fully implement the Pharmacy Care Management (PCM) program that was initiated in October. The MaineCare PCM program is a new pilot program intended to provide increased management of both high-cost drugs and high-cost pharmacy users that have the potential to increase MaineCare's pharmacy spend exponentially over the next few years. The clinical staff at GHS have reviewed MaineCare data to identify high-cost members and medications, which has led to individualized interventions. The interventions have not only been member-centric, but also included provider participation. The clinicians at GHS have been looking at medication adherence, proper medication utilization, FDA approved durations, indications, dosing and proper metabolic monitoring. The Department has analyzed many recent high-cost therapies, and as reported to the Drug Utilization Review Committee, there have been frequent issues with adherence, discontinuation, and lack of proper monitoring. This has led to a significant concern regarding the potential loss of the clinical benefit due to incomplete therapy course or, in some cases, medication waste. The cost of pharmaceuticals over the next few years is expected to rise dramatically with the release of bio-similars, oral oncology medications and other specialty medications. The expectation is that there will be a rising number of highly specialized medications that are available for a relatively small number of MaineCare members. However, these medications are expected to represent an ever increasing proportion of the cost associated for the pharmacy program. Many of these newer medications are expected to cost as much as $400,000 - $800,000 per member each year.

- Over the last few months, the clinical staff at GHS have contacted hundreds of providers and members as part of this PCM program. Some results seen in the past few months have included: discovery of several Mirena IUD devices that were ordered for patients and never implanted. These devices have been returned and claims reversed.
- Creation of guidelines for management of Hepatitis C inclusive of the new medication, Sovaldi
    - Deferral of several Prior Authorization requests for a more cost-effective regimen including Sovaldi, Pegylated-Interferon and Ribavirin (where medically appropriate) resulting in avoidance of unnecessary spend on lengthier regimens.
- Discontinuation of several ongoing Mepron prescriptions in which the duration had become inappropriate for the diagnosis, or in which sulfamethoxazole/trimethoprim could be used in its place.
- Working with specialty providers (i.e. those for Cystic Fibrosis, HIV, and Rheumatoid Arthritis) to improve patient adherence to complex medication regimens.

Our goal will be to work with providers and MaineCare members to ensure that the drug is taken as intended and that the medication is used and monitored appropriately. If you have any questions, please contact Goold Health System at 207-622-7153 ext. 1362

C. Hepatitis C Update

In late 2013, Olysio and Sovaldi, both oral antivirals drugs indicated for the treatment of hepatitis C, were approved by the FDA. Numerous other anti-HCV drugs are in the late stage pipeline with approvals for these products starting in late 2014, and continuing throughout 2015 and 2016. Relative to the treatment in use over the past several years, these new medications show potential for better tolerability and shorter duration of therapy. However, they come at an extreme cost and it is expected that the State could spend $3.4 million on Hepatitis C drugs in the final two quarters of SFY14. It is expected that these easier and better tolerated regimens, along with the CDC's 2012 recommendation that all baby boomers be tested for HCV, will result in an increased number of individuals being treated for HCV. Additionally, patients whose treatment has been delayed ("warehoused") until these new drugs are available will now begin to seek treatment.

With this in mind, the State reached out to GHS to develop clinical PDL criteria for these high-cost HCV medications. After careful consideration, the following criteria, which were subsequently approved by the Maine DUR Board, have been established and GHS has been working with individual prescribers as new prior authorization requests are received.

Prior authorization is required for direct-acting oral antiviral agents against the hepatitis C virus.

- Patient is ≥ 18 years of age; AND
- Documentation of HCV active infection verified by positive viral load performed within the last year and must be submitted with request; AND
- Genotype is verified by lab submitted with initial request; AND
- Treatment regimen has been prescribed by, or based on, a documented consult that included a recommendation for the requested treatment by a gastroenterologist, hepatologist, infectious disease specialist or other practitioner specializing in the treatment of hepatitis. Consult must be within the year prior to request and include a recommendation for the requested therapy and be

attached; AND

- Patient is not a pregnant female, not planning to become pregnant during treatment (or within six months of stopping treatment), or a male with a pregnant female partner; AND
- Women of childbearing potential and their male partners must agree to use two forms of effective non-hormonal contraception during treatment and for at least six months after treatment has concluded; AND
- Documentation that monthly pregnancy tests will be performed during this time; AND
- Documentation of counseling regarding abstinence from alcohol and education on how to prevent the transmission of HCV to others AND
- Patient is not receiving dialysis and has CrCl ≥ 30 ml/min, (lab result documenting renal function meeting this criteria within the last 6 months must be submitted with this request)
- Must be taken along with required concomitant meds as outlined below. Sovaldi will not be refilled for those non-compliant with required concomitant medications.
- Patient must not be on any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's wort or tipranavir.
- All Sovaldi dosing is 400 mg once daily
- Olysio dosing is 150 mg once daily
- Ribavirin dosing must be weight-based
- Sovaldi is subject to MaineCare's Initial Script Limit. Once approved, the first two fills will be for 14-day supplies, with remaining refills of 28-day supplies to complete the treatment course.
- Compliance with all medications on regimen will be followed and must have > 85% compliance for authorization of continued treatment. For continuation of treatment, we require some indicator of compliance to be submitted - either by lab values (i.e significant log decrease in HepC viral load) or documentation from an office visit provider-patient discussion that indicates full patient compliance.

Please refer to the MaineCare PDL at www.mainecarepdl.org for further criteria and the Hepatitis PA form.

D. Stimulant, Benzodiazepine and Opiate Use

MaineCare previously sent communications about the increasing concern regarding the use of certain medication classes which are associated with a high risk of diversion. Controlled substances, including stimulants (methylphenidate, amphetamines), benzodiazepines (diazepam, clonazepam, alprazolam) and opiates (hydrocodone, oxycodone) have become an increasing source of concern in terms of abuse potential and diversion with the State of Maine Drug Utilization Review Board (DUR).

Careful and rigorous assessment and documentation of disorders requiring treatment with stimulants, benzodiazepines and opiates is frequently warranted. Urine monitoring for drugs of abuse is helpful in assessing whether a patient is using these medications as prescribed. Requests for early refills should also be monitored represents a warning sign of possible drug misuse or abuse. Medications sometimes are legitimately lost or accidentally destroyed, but multiple requests for early refills should be treated as evidence of potential misuse and handled accordingly. It is also recommended that the prescription monitoring program (PMP) be routinely queried. The combined use of stimulants, benzodiazepines and opiates should be approached carefully, with a thorough consideration of the potential risks and benefits.

Detecting that a patient is abusing any prescribed controlled medications presents a therapeutic opportunity. The clinician should meet with the patient and family, develop a treatment plan for the abuse or addiction, and treat any co-existing medical conditions.

In the fall of 2013, MaineCare began contacting providers identified as high co-prescribers of these medications and requesting a re-evaluation of their patients' needs for these combinations of benzodiazepines, stimulants, and opiates. Since that initial outreach, little change has occurred in the utilization of these medication combinations the as a majority of these medications are preferred. Beginning 06/01/2014, when a member is prescribed all three of these medications, a Point of Sale edit at the pharmacy will be triggered, requiring a prior authorization for the clinical review of the appropriateness of these combinations of medications.

E. Lyme Disease Update

Recently, the Maine Drug Utilization Review (DUR) Committee looked at long-term antibiotic use of patients with a diagnosis of Lyme disease. The concern of the committee was that some providers believe there is a chronic undiagnosable form of Lyme disease for which multiple antibiotics are indicated. In reviewing the data, there were many instances of multiple prescribed antibiotics or general long-term use and, since many of these medications are of low cost and frequently used antibiotics, the prolonged use may go undetected. After much discussion, the DUR recommended the following limitations for antibiotic use.

- Require a prior authorization for any member on an anti-infective drug for more than 12 weeks in the past 365 days (consecutive or not).
- Includes members 22-64 years of age
- Includes antibacterial and anti-parasitic agents
- Excludes antiviral and antifungal agents
- Excludes TMP/SMX and Macrodantin used for UTI prophylaxis

Prior authorization requirements will be effective 05/30/2014.

F. Lipid Guidelines

New guidelines from the American College of Cardiology and the American Heart Association no longer recommend using specific cholesterol targets in the treatment of hyperlipidemia. HMG-CoA reductase inhibitors (statins) are the lipid lowering drugs of first choice for the treatment of most patients with atherosclerotic cardiovascular disease. They can decrease the incidence of major coronary events and death in such patients. Taken as an adjunct to diet, exercise and smoking cessation, statins can also reduce the risk of first cardiovascular events and death in patients with certain risk factors.

MaineCare and the DUR Committee recently reviewed MaineCare pharmacy and medical data of MaineCare members with atherosclerotic cardiovascular disease in comparison to the newly released guidelines. In its review of a year's worth of data, the DUR found that of 25,000+ members, only 30-35% were being dosed with appropriate doses of statins in accordance with the new guidelines, and only 24% of those members diagnosed with stroke are following the recommendations. There is a high level of evidence that high-intensity statin therapy with atorvastatin 40mg and 80mg and rosuvastatin 20mg and 40mg reduces ASCVD risk more than moderate-intensity statin therapy with atorvastatin 10mg pravastatin, lovastatin or simvastatin. As a result of this review of clinical data, the Department and the DUR will be sending out specific provider letters discussing the new guidelines to prescribers with the

largest number of affected patients not in compliance with the new guidelines. In the communication, the DUR will seek to promote a thoughtful discussion to identify reasons these high-risk patients are not utilizing high–intensity statins. Please look for these provider letters in the coming weeks.

G. Antipyschotic Utilization in Children

Back in the summer of 2012, MaineCare and the DUR Committee reviewed MaineCare data regarding atypical antipsychotic use. Many MaineCare members on atypical antipsychotics were found to not be monitored for weight or metabolic changes as is recommended while receiving atypical antipsychotics. Monitoring of weight and metabolic parameters, including blood pressure, fasting glucose and a fasting lipid profile are in accordance with the American Diabetes Association Screening Guidelines for patients on Second-Generation (atypical) Antipsychotics. Routine monitoring of the above parameters at baseline, 12 weeks, and annually are considered the standard of care and represent best clinical practice.

Also in 2013 MaineCare implemented a monthly survey process to providers regarding members who were newly started on antipsychotic medication to assure proper baseline monitoring. In an effort to simplify the process, the providers of those surveys were given 20 weeks to submit the relevant clinical information for review. If this documentation was not received, ongoing prescribing of atypical antipsychotics would require prior authorization to assure proper monitoring of these parameters.

Recent legislation (LD 338), mandated that the Department adopt policies for children under 17 years of age enrolled in MaineCare to require that prescribers justify continued long- term utilization of antipsychotics and require ongoing monitoring of metabolic and neurological variables in accordance with the ADA/APA monitoring guidelines. As a result, **beginning June 1st, 2014,** MaineCare will require that providers submit a prior authorization for these children under 17 years of age if appropriate documentation of proper monitoring at baseline and 12 weeks later has not been submitted or attest that either they are meeting the guidelines or that the risk of using the medication without monitoring outweighs the risk of not using the medication. Please review the updated Atypical Antipsychotic prior authorization form at www.mainecarepdl.org or contact GHS at 1-888-445-0497 with any questions.

H. PA Statistics

For the first quarter of 2014, there were 30,672 unique PA requests, and 82.35% were approved. The top five most frequently requested drugs were: Buprenorphine HCL- Naloxone HCL Dihydrate/Suboxone (1,826), Oxycodone HCL (1,549), Omeprazole (1,545), Amphetamine- Dextroamphetamine (1,373), and Duloxetine HCl (1,042). The average determination time was 2.09 hours.

I. Next DUR Committee Meeting:

The next DUR meeting will be held Sept. 9th from 6:00 pm to 8:00 pm at the Augusta Armory 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:
Roger Bondeson, Director of Operations, OMS Roger.Bondeson@maine.gov

For PA/PDL questions you may contact:
Michael Ouellette, R.Ph at mouellette@ghsinc.com
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