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An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

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PHARMACY BENEFIT UPDATE
Summer/Fall 2013 Issue

Preferred Drug List (PDL) News

A. PDL Changes

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

Non-preferred			
Eliquis	Forfivo XL	Ilevro	Kazano
Methylphenidate ER Caps	Nesina	Oseni	Oxtellar
Pertzye	Prolensa	Vascepa	

Preferred			
Auvi-Q	Balsalazide	Delzicol	Epi-Pen
Proctocream-HC Cream	Proctosol HC Cream		

The following Medications have additional PDL clarifications or criteria
Tripase, Paokase Tabs, Ku-Zyme Caps, Lipram CR and Lipram are no longer available and have been removed from the PDL.
Reyataz dosing limits of one daily.
TOBI Podhaler is non-preferred and limited to patients with significant impairment from using nebulized version of medication.
Fulyzaq is non-preferred and requires a diagnosis of non-infectious diarrhea in patients with HIV/AIDS on anti-retroviral therapy, prior trials of preferred, more cost effective anti-diarrheals. Dosing limits of twice daily apply.
Gattex is non-preferred and requires a diagnosis of adult SBS who are dependent on parenteral support. Appropriate colonoscopy and lab assessments 6 months prior to starting.
Pomalyst is non-preferred and has a DDI with strong inhibitors of CYP1A2 and CYP3A4 drugs. Complete blood counts weekly for first 8 weeks, then monthly, patients have at least 2 prior therapies, including lenalidomide and bortezomib,female patients of reproductive potential must have 2 negative pregnancy tests and use 2 forms of contraception and providers must be certified with Pomalyst REMS Program.
Kynamro is non-preferred and requires a clinical PA for appropriate diagnosis, appropriate lab testing prior to starting (ALT<AST), Alkaline phosphatase and total bilirubin, monthly liver-related tests for the first year, then every three months.
Invokana is non-preferred and will be considered for patients who are unable to tolerate any preferred medications. Dosing limits of one daily apply.
Samsca Drug Warning- Avoid use in patients with underlying liver disease, including cirrhosis, because the ability to recover from liver injury may be impaired. Limit duration of therapy to 30 days to minimize the risk of liver

injury.
Aubagio is non-preferred and for adults with relapsing forms of MS. No concurrent use of leflunomide. Within 6 months of initiation of Aubagio, lab testing to look at (transaminase, bilirubin, CBC, TB) as boxed warning exists regarding hepatoxicity.
Binosto is non-preferred use preferred generic alendronate tablets.
Bosulif is non-preferred and requires a clinical PA, requiring diagnosis. Must have resistance or intolerance to prior therapy seen in drug profile, monthly hepatic enzyme tests should be preformed for the first three months of treatment as clinically indicated.
Giazo is non-preferred and only indicated for males, as the safety/efficacy for use in females has not been established. Prior trials of preferred products.
Juxtapid is non-preferred and contraindicated with strong CYP3A4 inhibitors. Juxtapid dosage should not exceed 30mg daily when it is used concomitantly with weak CYP3A4 inhibitors.
Linzess is non-preferred and for adults as treatment of IBS-Constipation and treatment of chronic idiopathic constipation in adults. Prior trials of preferred agents for constipation and IBS-constipation.
Lorzone is non-preferred and requires at least 4 preferred drugs (including tizanidine) and step care therapy (orphenadrine), and reasons for why chlorzoxazone is not acceptable.
Quillivant XR is non-preferred and only indicated for use in patients 6 years of age or older. Prior trials of preferred products.
Stivarga is non-preferred and for the treatment of metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine- oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and if KRAS wild type, an anti-EGFR therapy).
Xeljanz is non-preferred and limited to adults with moderately to severely active RA who have had an inadequate response or intolerance to methotrexate. Should not be used concomitantly with biologic DMARDs or potent Immunosuppressants. Therapy should not be started in those with lymphocyte count <500cells/mm^3, an ANC <1000cells/mm^3, or have a hemoglobin <9g/dl.
Xtandi is non-preferred and limited to treatment of metastatic castration-resistant prostate cancer in adults, with previous trials of docetaxel.

B. Pharmacy Care Management:

The Department in conjunction with Goold Health Systems will be rolling out a new Pharmacy Care Management (PCM) program 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 will review MaineCare data to identify high cost members and medications, which will lead to individualized interventions. The interventions will not only be member-centric but also include provider participation. The clinicians at GHS will be 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 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 400-800 thousand dollars per member each year.

Over the next few weeks, a small number of members, prescribers, or pharmacies may be contacted to be involved in this pilot PCM program. Our goal will be to work with you and the MaineCare member to be certain 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 855-208-0862

C. Suboxone Limit Update:

Effective on 1/01/2013, MaineCare implemented a 24 month lifetime limit for members prescribed Suboxone for the treatment of opioid addiction. These changes were part of the Department of Health and Human Services' Supplemental Budgets and Administrative Savings Initiatives that were signed by Governor LePage. See Public Law 2011, c. 477 and c. 657.

Over the last 9 months, providers have been sent information by MaineCare about members who have exceeded or will soon meet their 24 month lifetime limit of Suboxone. Prior authorization requests will be reviewed for dose titration downward, whether the patient is engaged in recovery oriented support services, periodic urine drug screens, film counts, factors that threaten stability of recovery or evidence of improvement in social, physical and occupational areas. Members that stop treatment and require a restart of Suboxone treatment after completion of treatment will also require prior authorization. This prior authorization will assess the patient risk of relapsing or evidence that the patient has relapsed.

In reviewing the first six months of the new policy, we have seen an overall decrease in average dose per member per day of greater than 6%. The larger changes are seen when we look at the overall trending with members at specific daily dosage bands. The number of members with greater than 16mg per day has decreased by over 25% when comparing to the same period for 2012. Dosages per members at specific months in the 24 month timeframe have also shown a consistent decrease from 2012 in dosages 16-24mg/day and those greater than 24mg/day. MaineCare continues to review data including responses to prior authorization requests and will have further information in the months to come.

Prescriptions for Suboxone will require a diagnosis designating that they are being prescribed for the treatment of addiction. Pharmacies, when transmitting prescription claims, will be required to submit this diagnosis for payment of claims, no other diagnosis will be allowed. Please review the MaineCare Preferred Drug List for complete criteria on Suboxone limitations. Prior Authorization forms for Suboxone can be found at www.mainecarepdl.org or providers may log in to the MaineCare Rx Portal at www.mainerxportal.org to submit prior authorizations electronically.

D. Opiate Limits Update

In January of 2013, MaineCare implemented a 45 day limit for members prescribed opiates for their treatment of pain. These changes were part of the Department of Health and Human Services' Supplemental Budgets and Administrative Savings Initiatives that were signed by Governor LePage. See Public Law 2011, c. 477 and c. 657.

MaineCare members are allowed over a rolling 12 month period up to a 15 day supply of an opiate without prior authorization. Members requiring longer than 15 days will require a PA for continuation of therapy and providers may provide medical necessity. Members may be eligible for up to three prior authorizations of up to 14 day supplies of opiates during the 12 month period. Recently MaineCare reviewed the impact of the implementation and would like to share the following. The patient counts for members classified as Acute Pain users are all trending downward when comparing member utilization over the same time frame of previous years when looking at the prior authorization (PA) criteria over the various Days Supply bands.

Report Period	<=15 Days	16-29 Days	30-43 Days	44-57 Days
1/1/12-6/30/12	21,600	1,912	1,247	591
1/1/13-6/30/13	19,032	1,507	1,118	572
Decrease	**12%**	**21%**	**10%**	**3%**

For patients that are defined as Chronic Pain users (duration of therapy longer than eight weeks), new policies and PA criteria that require other treatment options such as physical therapy, cognitive behavioral therapy and others, were also implemented. In reviewing the same time period compared to the previous year MaineCare has seen a ***29% decrease*** in utilization of long term opiate use. Lastly, patients' average daily dose of morphine sulfate equivalents has also decreased by 11% over the first six months of the implementation especially those receiving members receiving in excess of 300mg of MSE's.

MaineCare would like to thank all the providers for their efforts to curb one of the highest per capita user rates of opioid medications in the country and help work towards a solution which includes a focus on other treatment options and serial evaluations of pain management with the member.

F. Stimulant and Benzodiazepines

There has been increasing concern regarding the use of certain medication classes which are associated with a high risk of diversion. Controlled substances, including stimulants (methylphenidate, amphetamines) and benzodiazepines (diazepam, clonazepam, alprazolam) have become an increasing source of concern in terms of abuse potential and diversion.

Careful and rigorous assessment and documentation of disorders requiring treatment with stimulants and benzodiazepines 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 and are a warning sign of drug misuse or abuse. Drugs sometimes are legitimately lost or accidentally destroyed, but multiple requests for early refills

should be treated as evidence of atypical medication use and handled accordingly. It is also recommended that the prescription monitoring program (PMP) be routinely queried.

The combination use of stimulants and benzodiazepines 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.

MaineCare will be reaching out to providers identified in the co-prescribing of these medications for re-evaluation of their patient's necessity or potential risk and benefits

G. Butalbital Overuse

Mild to moderate tension type headaches (TTH) should be treated with simple analgesics such as acetaminophen or NSAIDs while parenteral administration with NSAIDs is recommended for headaches that are considered to be moderate to severe. Trends show that prescribers are continually issuing prescriptions for combination analgesics containing the medication butalbital for the treatment of TTH.

Although indicated for the treatment of moderate to severe TTH, overutilization of butalbital containing analgesic products may potentially cause overuse headaches. Susceptible patient populations are those who suffer from chronic daily headaches and have a history of two to three per week. In addition to overuse headaches, patients over utilizing butalbital containing analgesics are at risk for tolerance, dependence, and toxicity related concerns.
Evidence upholding the efficacy and safety of frequent and chronic use of butalbital containing products is unavailable. In an effort to prevent the overuse of these medications, it is our recommendation that their use should be limited to three or fewer days per month. Patient education regarding medication safety is the optimal first line defense against potential adverse events.

Three months of non-reversed, paid pharmacy claims over the first quarter of 2013 have been queried and analyzed identifying members in this overuse patient population (members with more than 61 units of butalbital in a month). MaineCare will be reaching out to corresponding parties involved in the near future to discuss and will soon be instituting quantity limits on the Preferred Drug List over the coming month to further limit overutilization of these medications.

H. Antimicrobial Resistance

The correlation between inappropriate antimicrobial use and development of drug resistant species has been established for years. Despite this association, improper antibiotic use appears to be increasing. A recent MaineCare analysis of the prescribing of antibiotics has shown that a substantial portion of the antibiotics prescribed in the outpatient setting are given for viral illnesses or bacterial diseases where the benefit of antibacterial therapy is uncertain. The CDC estimates that about one half of the antibiotics prescribed by office-based physicians are unnecessary.

Most antibiotics prescribed in the ambulatory setting are for respiratory infections. Almost 50% of office visits for colds and upper respiratory infections, and 80% of visits for acute bronchitis are treated with antibacterial agents. Despite the fact that antibacterial agents have no effect against a viral disease such as the common cold and numerous studies have also found that antibacterial agents do not significantly shorten the duration of illness in acute bronchitis.

According to the CDC, over-prescribing antibiotics, using a broad-spectrum therapy when a more specific drug would be better, an incomplete antibiotic treatment course, and patient's distributing antibiotics amongst friends and family who appear to have the same ailment, all contribute to the problem of antibiotic resistance. Many physicians agree that these issues are major factors contributing to antimicrobial resistance; however the trend in prescribing persists. We are asking healthcare providers to take the time to educate their patients about this issue and the risks they present when antibiotics are not used appropriately.

For treatment guidelines for Upper Respiratory Tract Infections, see
http://www.cdc.gov/getsmart/campaign-materials/adult-treatment.html

H. PA Statistics

For the third quarter of 2013 there were 29,790 unique PA requests, 89.03% were approved. The top five most frequently requested drugs were: Buprenorphine HCL- Naloxone HCL Dihydrate/Suboxone (1,988), Omeprazole/Prilosec (1,742), Oxycodone HCL (1,727), Amphetamine/Adderall XR (1,335), and Lisdexamfetamine/Vyvanse (974). The average determination time was 1.57 hours.

I. Next DUR Committee Meeting

The next DUR meeting will be held November 12th, 2013 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:
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