Department of Health and Human Services
Maine People Living Safe, Healthy and Productive Lives
John E. Baldacci, Governor
Brenda M. Harvey, Commissioner

Department of Health and Human Services
MaineCare Services
442 Civic Center Drive
11 State House Station
Augusta, Maine 04333-0011
Tel: (207) 287-2674; Fax: (207) 287-2675
TTY: 1-800-423-4331

PHARMACY BENEFIT UPDATE
Spring 2010 Issue

Preferred Drug List (PDL) News

A. PDL CHANGES

Preferred	Notes
Necon 1/50	*Will be preferred since OrthoNovum 1/50 not available*
Dexilant	*New name change for the former Kapidex due to reports of med errors with Casodex and Kadian.*

Non-preferred	Notes/PA Criteria
Migergot Supp	
VFend	*Consider using other preferred agents*
Fluoxetine 90mg	
Doxepin 150mg	*Please use multiples of 50mg*

B. ATYPICAL ANTIPSYCHOTIC PRIOR AUTHORIZATION

Recent studies show that atypical antipsychotic medications are being prescribed inappropriately. One study found that of 279,778 patients who received an antipsychotic, 60.2% had no diagnosis for an FDA approved indication. Manufacturers of atypical antipsychotics have been fined for fraudulently marketing these products, and promoting inappropriate use. The off label use of these drugs have made them the most costly to MaineCare. – has MaineCare studied whether members have appropriate diagnoses for these drugs? Or is this assumed since larger studies show inappropriate use?
These drugs have been inappropriately used for

- insomnia,
- dementia related psychosis,
- attention deficit disorder, and
- anxiety disorders.

Not only are these drugs expensive, they have serious side effects. Side effects are weight gain, diabetes, lipid abnormalities, and potentially irreversible movement disorders such as tardive dyskinesia.

Starting July 1, 2010, all prescribers who are not psychiatrists will need a prior authorization (PA) for atypical antipsychotics. The PA will require that the drug be used in accordance with FDA approval or literature-supported evidence-based best practices. These drugs are appropriately used to treat

- schizophrenia,
- bipolar disorder,
- agitation related to autism, and
- severe behavioral dyscontrol with risk of imminent need for emergency services such as the emergency room, crisis services, or an inpatient psychiatric facility.

Atypical antipsychotics are also used along with antidepressants to treat major depression. This use will be permitted if the patient has previously tried antidepressants from two distinct classes (SSRIs, SNRIs, TCAs, bupropion).

The goal is to ensure appropriate use of these medications reduce costs for inappropriate use and improve patient care.

C. ABILIFY SPLITTING AND COMPLIANCE

In the spring of 2009 the Psychiatric Work Group made a recommendation to the State that would allow Abilify to be a preferred antipsychotic if pill splitting was employed. Pill splitting is endorsed by a number of insurers and it was felt that it would be a safe and effective process in appropriate candidates. Indeed, many patients including stable adults, children with responsible parents/caregivers, and institutionalized members would be considered potentially appropriate recipients. As a follow up study, compliance was assessed for patients treated pre- and post-policy. Medication possession ratio (MPR) is a measurement of medication compliance. MPR rates did not differ comparing 2007 to 2009 demonstrating that splitting doses of Abilify did not impair medication compliance. Simultaneously, this process achieved significant cost savings. Our findings demonstrate that pill splitting an atypical antipsychotic was associated with substantial cost savings with no negative impact on medication compliance. Pill splitting appears to be a safe and effective technique in achieving cost savings without degradation of compliance and may be employed in the future as indicated.

D. ATYPICAL ANTIPSYCHOTICS IN CHILDREN LESS THAN 5

Atypical antipsychotics are used for bipolar disorder, schizophrenia, and the management of agitation and aggression in children and adolescents. Some of these medications have FDA approved indications for this age group. Concerns regarding weight gain, diabetes, and abnormal movement disorders such as tardive dyskinesia have emerged particularly pertaining to pediatric use. In addition, utilization rates of atypical antipsychotics have substantially increased nationally. Between December 1, 2009 and March 31, 2010 35 MaineCare members under age 5 have been identified (range 2 yrs 3 months – 5 years 2 months, mean = 4 years 2 months). The DUR board at its March 2010 meeting defined an initiative to analyze reasons for the use of this drug class in patients under 5 years of age. An analysis to determine demographic factors and diagnoses is underway. Chart notes are being obtained from prescribers with results to be shared with the Psychiatric Work Group and DUR board. The ultimate goal is to define parameters for appropriate use of these medications given the above risks in treating patients in this age range. Beginning 6/1/10 MaineCare will begin requiring PA's for all children under the age of 5 to verify appropriate diagnosis in treating these patients.

E. VALPROATE (DEPAKOTE) AND BIRTH DEFECTS

Valproic acid (Depakote and others) is an anticonvulsant approved for the treatment of seizures, migraine headache, and bipolar disorder. This agent is associated with major birth defects including neural tube defects such as spina bifida, various cardiovascular malformations, and craniofacial defects. Additionally, measures of intelligence can be impaired by maternal exposure to valproic acid. Healthcare professionals are wise to warn patients about these risks. Valproic acid should only be used if the potential benefits of treatment outweigh the risks of teratogenicity and appropriate and reliable contraception is employed. The risks of birth defects are highest early in pregnancy, a time when most women are not aware of being pregnant. The State of Maine DUR board is considering an initiative to educate prescribers of the risk of valproic acid in pregnancy by identifying patients of childbearing age who are not receiving concomitant oral contraceptives or who have not had prior sterilization procedures. Clearly, decreasing exposure to valproic acid in pregnancy will have positive impact upon decreasing the risk of birth defects.

F. CHRONIC OPIATE USE MONITORING

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

G. PLAVIX DDI

In November, 2009 the FDA issued a warning regarding the interaction between clopidogrel (Plavix®) and omeprozole (generic, Prilosec®.) This is based upon a study demonstrating that concomitant use resulted in a decrease of 45% in the level of the active metabolite of clopidogrel and a 47% decrease in the effect on platelets. This effect was seen even if the medications were taken 12 hours apart. Additionally, the FDA states that other potent CYP2C19 inhibitors would be expected to have the same effect and therefore the combination with clopidorgrel should be avoided. These include omeprazole, esomeprazole, cimetidine, fluconazole, ketoconazole, voriconazole, etravirine, felbamate, fluoxetine, fluvoxamine, and ticlopidine.

H. ANXIETY DIAGNOSIS WITH SSRI'S

Beginning June 4th 2010 MaineCare will allow the use of a diagnosis code for the treatment of anxiety with preferred SSRI's in MaineCare members under the age of 18. Currently members under the age of 18 are required to use fluoxetine prior to any other preferred or non-preferred medication. Once initiated, providers may utilize other preferred SSRI's without prior authorization if indicated for anxiety on the prescription. Pharmacies will now be able to use AX in the diagnosis field if a prescription indicates the use for anxiety. The following preferred drugs, Paroxetine, Sertraline, Cymbalta, Lexapro, Venlafaxine ER, and Fluvoxamine, will accept AX diag on the pharmacy claim and bypass the fluoxetine requirements for members under the age of 18.

I. BUPROPION AND ADHD

Beginning June 4th 2010 MaineCare will allow the use of a diagnosis code for the treatment of ADHD with bupropion. Once initiated providers may write on the prescription the ADHD indication and the pharmacy will be able to process the claim online utilizing the ADHD diagnosis code of 5. Until that time pharmacies may call the GHS Pharmacy Help Desk to get help processing the claim or the physician may continue to submit prior authorization for the ADHD indication.

J. STATINS UPDATE

All patients on statins need to be cautioned regarding the increased risk of myopathy. Myopathy risk with 80mg doses of simvastatin is much greater than lower doses and may possibly be higher than other statins. Simvastatin 80mg doses lowers LDL just 6% more than 40mg doses but increases myopathy risk by 6 times. If a patient needs more LDL lowering than can be obtained from simvastatin at a dose greater than 40 mg per day please consider using Lipitor, another MaineCare preferred statin. Simvastatin dosing should be tailored to avoid inappropriate doses when used in combination with medications such as cyclosporine, amiodorone, verapamil, diltiazem and avoiding in patients taking strong CYP3A4 ihibitors such as eyrthro, clartih, itraconazole, ketoconazole and HIV protease inhibitors.

K. MAINECARE INITIAL 15 DAY SUPPLY

Late in the summer of 2009 MaineCare began a policy for a 15 day supply limit on initial prescriptions for certain medications. The medications chosen reflect those that have low compliance rates for the first 30 days. The purpose of this policy is to decrease the quantity of medications that are wasted during their initial use (first prescription) by patients. This will result in cost savings, less diversion, and a reduction in the negative environmental impact. The 15 day supply only involves initial prescriptions and does NOT involve subsequent dose increases. Meaning, if a MaineCare member has had a generic or brand version of the medication in the past year then they will not be subjected to a 15 day limit. For schedule 2 medications, the prescriber must write out an initial 15 day prescription and may write a second prescription, noting the date to be filled on the latter. The following is a list of the medications currently subjected to 15 day limit: Suboxone, Subutex, Chantix and Nicotine replacement products, Bethanechol, Detrol, Flavoxate, Oxybutynin, Sanctura, Urispas, Vesicare, Detrol LA, Ditropan XL, Enablex, Oxytrol, Toviaz, Opana, Oxycodone, Avinza, Duragesic, Fentanyl, Kadian, Methadone, Morphine sulfate, Opana ER, Oramorph, Oxycontin, , Cymbalta, Effexor, Effexor XR, Lexapro, Luvox CR, Paxil CR, paroxetine ER, Pristiq, Abilify, Geodon, Invega, Risperdal, risperidone, Seroquel, Seroquel XR, Zyprexa, Adderall, amphetamine combo's, Concerta, dextroamphetamine, Dextrostat, Focalin, Focalin XR, Metadate, Methylin, methylphenidate, Provigil, Ritalin, Ritalin LA, Vyvanse, Strattera, Cafcit, Ultram ER, and Equetro.

L. 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

M. PA STATISTICS

For the first quarter of 2010, there were 19,372 unique PA requests, 80% were approved. The top five most frequently requested drugs were: omeprazole/Prilosec (1,616), aripiprazole/Abilify (1,282), pantoprazole/Protonix (1,262), duloxetine/Cymbalta (1,188), and quetiapine/Seroquel (1,026). The average determination time was 3.12 hours.

N. 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

O. NEXT DUR COMMITTEE MEETING

The next scheduled DUR meetings will be held on May 11th, 2010 and June 8th, 2010 (subject to change) 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:
Jennifer Palow, Pharmacy Unit Manager at OMS jennifer.palow@maine.gov
Timothy Clifford, MD at tclifford@ghsinc.com

For PA/PDL questions you may contact:
Laureen Biczak, DO at lbiczak@ghsinc.com
Michael Ouellette, R.Ph at mouellette@ghsinc.com
Jeffrey Barkin, MD at jbarkin@ghsinc.com