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

Department of Health and Human Services
MaineCare Services
Pharmacy Unit
11 State House Station
Augusta, Maine 04333-0011
Tel. (207) 287-7131; Fax (207) 287-8601
Toll Free (866) 796-2463; TTY (800) 423-4331

PHARMACY BENEFIT UPDATE
Fall 2011 Issue

Preferred Drug List (PDL) News

A. PDL CHANGES

MaineCare is working hard to make more and more medications available and reduce the impact on providers and MaineCare members. This issue of the Pharmacy Benefit Update will provide upcoming changes to the Preferred Drug list for 2012 as well as updates on MaineCare efforts to reduce waste in the pharmacy benefit, drug safety concerns and general drug information.

Preferred			
Amifostine	Coly-mycin Solr	Enbrel (all strengths)	Ella
Incivek	Intuniv	Latanoprost Sol 0.005%	Letrozole
Levonorgestrel	Maxalt	Methylphenidate ER	Metrgogel Vaginal Gel
Moxeza	Peg-Intron Kit	Plan B One Step	Seasonale
Tiazac CP24	Tradjenta	Travatan-Z	Tretinoin Cream
Tri-norinyl 28 Tab	Victrelis	Yaz	Nutropin AQ Nuspin
Tazorac	Imiquimod		

Non-preferred			
Adderall XR CP24	Advicor TBCR	Alfuzosin	Amphetamine/Dextroamphet ER
Amrix	Aralast	Aricept ODT	Aricept Tabs
Azor	Arcapta	Avelox ABC Pack tabs	Avelox Soln
Avelox tabs	Bromfenac	Budesonide EC	Caduet
Calcitonin NS	Calcium Acetate	Cimzia	Clarithromycin tabs
Colistimethate Sodium Solr	Concerta	Conzip	Cuvposa
Cyclobenzoprine ER	Edurant	Enoxaparin	Epinastine
Ethyol	Exelon	Femara	Firazyr
Fondaparinux	Gralise	Horizant	Lamictal
Loseasonique	Lotemax Susp	Metronidazole Vaginal Gel	Nicoderm CQ patch
Nicorette Gum	Nitrofurantoin macr Susp	Nucynta ER	Nuedexta
Nutropin	Optivar	Phoslyra	Prolia
Retin-A Gel	Revatio	Sanctura	Sprix
Sylatron	Teflaro	Travatan Soln	Trezix
Triamcinolone NS	Viibryd	Xarelto	Xgeva
Yervoy	Zelboraf	Zometa	Zyclara
Zytiga			

:

The following Medications have additional PDL clarifications or criteria		
Adcirca	Preferred with Clinical PA	Approvals will require WHO Group 1 diagnosis of PAH (Primary Pulmonary Hypertention) and NYHA functional class 2 or 3
Bactroban Cream	Preferred	Dosing limits added allowing 1 tube per 30 days.
Brilinta	Non-Preferred	A special PA may be obtained at the pharmacy for members schedule for"stent" placement or have had placement if in the last 12months. Please indicate on prescription date of stent placement
Eliphos	Preferred	Diagnosis required
Fluoxetine 60mg Caps	Non-Preferred	Use multiples of 20mg
Levemir	Non-preferred	Established Levemir users will have an additional 90 days (until March 31) to transition over to Lantus.
Lumigan	Non-preferred	All preferred medications tried and failed prior to approvals
Plan B One Step	Preferred	Allow 4 tablets per 30 days without a PA
Renagel	Preferred	All strengths preferred
Suboxone tablets	Non-preferred	The tablet version of Suboxone will become non-preferred. Suboxone film is the preferred buprenorphine product.
Incivek/Victrelis	Preferred with Clinical PA	Approvals will require clinical PA to establish genotype, baseline viral loads and will require periodic SVR's. Must have concurrent peg-a or peg-I and ribavirin therapies.

B. BASAL INSULIN UPDATE

Diabetic Insulins – Effective January 1, 2012 the long acting basal insulin Levemir will become non-preferred with Lantus designated as the sole preferred basal insulin. Established Levemir users will have an additional 90 days (until March 31) to transition over to Lantus. Novo-Nordisk, the makers of Levemir, declined to continue to providing a supplemental rebate to keep their product affordable.

C. ACETAMINOPHEN TOXICITY

MaineCare in conjunction with the Drug Utilization Review Committee has reviewed MaineCare claims specifically focusing on acetaminophen doses in combination pain relief products currently available through the MaineCare drug benefit. In its review of the claims it is apparent that MaineCare recipients receive total acetaminophen daily doses far exceeding safe levels recommended in current literature. Many of these members are not being tested for changes in liver function and potentially leave the members at risk for severe liver damage. In recent FDA safety communications, the FDA is asking drug manufacturers to limit the strength of acetaminophen in prescription drug products to 325mg per tablet, capsule or other dosage unit making these products safer for patients. In addition, a *Boxed Warning* highlighting the potential for severe liver injury is being added to the label of all prescription drug products that contain acetaminophen.

Effective 10/7/2011, MaineCare began implementing dosing limits on many of the common preferred acetaminophen combination analgesics to limit acetaminophen doses to 4 grams or less. While this is a stepped approach, these initial selections constitute the majority of drugs responsible for exceeding the recommended daily 4 gram acetaminophen limit. Prescription claims submitted for total daily dosages exceeding 4 grams of acetaminophen will require prior authorization.

Drug Combination	Acetaminophen Dose	Quantity limits/day
Hydrocodone/Acetaminophen Tab	**325 MG**	**12**
Hydrocodone/Acetaminophen Tab	**500 MG**	**8**
Hydrocodone/Acetaminophen Tab	**650 MG**	**6**
Hydrocodone/Acetaminophen Tab	**750 MG**	**5**
Oxycodone/Acetaminophen Tab	**325 MG**	**12**
Oxycodone/Acetaminophen Tab/Cap	**500 MG**	**8**
Oxycodone/Acetaminophen Tab	**650 MG**	**6**

D. CDC CONFIRMS NOVEL H3N2 VIRUS

The US Centers for Disease Control and Prevention (CDC) first identified a novel swine origin H3N2 virus in July of 2011 that has now infected 10 people of which 9 of these infections were in children. Most illnesses were mild, but three people were hospitalized and recovered. The states affected by this novel virus include: Maine, Iowa, Indiana, and Pennsylvania. The cases in Iowa were not all associated with swine exposure and likely represent limited human-to-human transmission.

The H3N2 virus isolated is a triple recombinant strain that is of swine origin and includes the matrix gene from the H1N1 virus. The CDC has stated that this novel H3N2 strain is related to a strain circulated before 1990 and therefore the population that may be more susceptible to it would be people under 20 years old. Only 18 cases of swine origin H3N2 infection have been identified since 2009.

It should be noted that the current seasonal flu vaccination would not be expected to protect against this strain of H3N2. It is expected that current commercially available diagnostic testing will be able to diagnose these infections as influenza, but will not be specific to show the novel virus. There are, however, two antiviral drugs-oseltamivir (Tamiflu) and zanamivir (Relenza)-which can be used for treatment which are covered under MaineCare and do not require prior authorization for a usual course of therapy.

E. RSV SEASON UPDATE

MaineCare has updated the Synagis prior authorization requirements for the upcoming RSV season. MaineCare will approve Synagis® PA requests for infants who meet the following guidelines. PA requests will be approved starting at the onset of RSV season for a maximum of 5 doses and a dosing interval not less than 30 days between injections. For MaineCare members, PA requests began November 1, 2011 for dates of service starting November 28, 2011. Synagis® were not to be authorized for administration prior to this date. Synagis® dosing authorizations will extend for the recommended number of doses or until the end of epidemic RSV season as defined by CDC - whichever occurs first. For a complete list of Synagis criteria please refer to the Synagis prior authorization form at www.mainecarepdl.org

F. NEW HEPATITIS C THERAPIES OFF TO POOR START

Summary of Utilization from May 2011 through Late November 2011

This is a very early but disturbing set of findings concerning a promising class of very expensive medications for Hepatitis C. These drugs cost from $5,000 to $16,000 per month per member. We will be sharing these results with the prescribing providers and working with them to hopefully improve this dismal start.

Incivek requires twelve weeks of consecutive therapy with concurrent interferon and ribavirin followed by at least twelve more weeks of the interferon and ribavirin alone.

Victrelis requires a four week lead-in with interferon and ribavirin. The shortest complete course of Victrelis is twenty four weeks with concurrent interferon and ribavirin.

The following chart summarizes the data collected since May

	Victrelis	Incivek
Starts	11	33
Starts with 4 week interferon/ribavirin lead-in	10	N/A
Discontinuation after 1 month	2 (18%)	14 (42%)
Discontinuation after 2 months	1	2
Therapy for 3 months but interferon and/or ribavirin discontinued	N/A	2
Therapy ongoing and complying with standard of care	8	15
Ongoing for 1 month	4	3
Ongoing for 2 months	2	4
Ongoing for 3+ months	2	8
Therapy started without interferon and/or ribavirin	1	N/A
Raw discontinuation rate	27%	48%
Discontinuation or wasted/substandard therapy	36%	54%

G. TNF BLOCKERS GET BOXED WARNINGS

The US Food and Drug Administration (FDA) announced recently that the boxed warnings on the labels of tumor necrosis factor alpha (TNF-alpha) inhibitors will be updated to warn about the risk for serious and sometimes fatal infection from two bacterial pathogens, Legionella and Listeria. This announcement is in addition to the 2008 warnings on the risk for histoplasmosis and other invasive fungal infection. This announcement follows a recent FDA review of bacterial infections in patients treated with TNF-alpha blockers and reports of 80 patients who developed Legionella pneumonia after receiving the drug between 1999 and 2010. Fourteen patients died. The FDA is advising clinicians to consider the risk and benefits of these drugs in patients who already have a chronic or recurring infection, or who have underlying medical conditions that make them prone to infections. The risk for an opportunistic infection may be higher for patients older than 65 years and for those taking a concomitant immunosuppressant. More information may be obtained on the FDA agency's website.

H. ATYPICAL ANTIPSYCHOTICS IN THE VERY YOUNG

The utilization of psychotropic medications have soared in the very young both nationally and in Maine. Atypical antipsychotics are associated with potentially severe and irreversible adverse events including abnormal movement disorders such as tardive dyskinesia, weight gain, diabetes, and other metabolic abnormalities. While this class of medication has established efficacy in schizophrenia and mood disorders, the majority of utilization in the very young, defined as less than 6 years of age, is for aggression and irritability. Aggression and irritability are symptoms of multiple psychiatric disorders such as attention deficit disorder, major depression, and bipolar disorder, amongst others.

Though atypical antipsychotics have demonstrated efficacy in decreasing aggression in the very young, they frequently do not treat the underlying psychiatric diagnosis, assuming one is even present. Given the high risk of adverse effects, the use of the atypical antipsychotics in the very young should be considered when:

- The underlying cause of aggression is identified and pharmacologic treatment for the underlying psychiatric disorder has been ineffective;
- An effort of non-pharmacologic treatment alternatives including psychotherapy and family intervention have been unsuccessful;
- In those patients where atypical antipsychotics have been successful in alleviating aggressive symptoms, an effort of tapering and discontinuing the medication should be attempted after three to six months.

Following the above suggestions will allow identification and treatment of the underlying psychiatric disorder. This facilitates the optimal balance of treatment efficacy and risk mitigation.

I. SIGNIFICANT NEW GENERICS UPDATE

The following list is a provider update to upcoming releases of significant brand name medications. MaineCare will monitor these releases and notify providers when generics are available on the Preferred Drug List. Initial pricing of generics often make them more costly than their original brand products but eventually become preferred products for MaineCare.

Year	Period	Brand Name	Generic Name
2011	4Q (Oct)	Zyprexa and Zyprexa Zydis	Olanzapine
2011	4Q (Nov)	Lipitor	Atorvastatin
2012	1q (Jan)	Clarinex & Clarinex D (planning OTC prior to generic availability)	Desloratadine & Desloratadine/Pseudoephedrine
2012	1Q (Mar)	Lexapro	Escitalopram
2012	1Q (Mar)	Seroquel	Quetiapine
2012	1Q (Mar)	Gabitril	Tiagabine
2012	1Q (Mar)	Avapro	Irbesartan
2012	1Q (Mar)	Avalide	Irbesartan/HCTZ
2012	2Q (May)	Plavix	Clopidogrel
2012	3Q (July)	Tricor	Fenofibrate
2012	3Q (Aug)	Singulair	Montelukast
2012	3Q (Aug)	Actos	Pioglitazone
2012	3Q (Aug)	Xopenex (not HFA)	Levalbuterol inh. Solution

2012	3Q (Sept)	Diovan and Diovcan HCT	Valsartan and Valsartan/HCTZ
2012	3Q (Sept)	Geodon	Ziprasidone
2012	4Q (Dec)	Atacand and Atacand HCT (16/12.5 and 23/12.5 strengths)	Candesartan and Candesartan/HCTZ
2012	4Q (Dec)	Maxalt and Maxalt MLT	Rizatriptan

J. 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

K. PA STATISTICS

For the third quarter of 2011 there were 27,007 unique PA requests, 77% were approved. The top five most frequently requested drugs were: omeprazole/Prilosec (1,620), duloxetine/Cymbalta (1,224), aripiprazole/Abilify (1,086), pantoprazole/Protonix(944), and methylphenidate (830). The average determination time was 2.66 hours.

L. 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

M. NEXT DUR COMMITTEE MEETING

The next DUR meeting will be held January 10th from 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:
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:
Michael Ouellette, R.Ph at mouellette@ghsinc.com
Laureen Biczak, DO at lbiczak@ghsinc.com