PR 13-32

SPECIAL BULLETIN

JULY 2013

CHANGES TO THE HIGHMARK DRUG FORMULARIES

2ND QUARTER UPDATE

The 2nd Quarter 2013 update to our Drug Formularies and pharmaceutical management procedures is attached to this *Special Bulletin*. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the attached changes reflect that decisions made in March 2013 by the Highmark Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout the document.

Please reference the guide below to navigate this communication:

Section 1: Highmark Comprehensive Formulary

A. Changes to the Highmark Comprehensive Formulary
B. Updates to the Pharmacy Utilization Management Programs
    1. Updates to the Prior Authorization Program
    2. Updates to the Managed Prescription Drug Coverage (MRxC) Program

As an added convenience, you can also search our Drug Formularies on the Provider Resource Center (accessible via NaviNet® or our website). Click the *Pharmacy/Formulary Information* link from the menu on the left, and then choose *SEARCH the Formulary*.

If you have any questions regarding this pharmacy communication or the formularies, please contact your Highmark Delaware Provider Relations Specialist.

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Highmark Delaware

FDA ISSUES WARNING ABOUT ZOLPIDEM-CONTAINING PRODUCTS

The FDA has announced that it is requiring manufacturers of products containing zolpidem (e.g., Ambien, Ambien CR, Edular, and Zolpimist), a commonly-used medication for the treatment of insomnia, to lower the recommended dose. These recommendations are based on studies of zolpidem in men and women, which found that approximately 15 percent of women and 3 percent of men had zolpidem concentrations exceeding 50 ng/mL at approximately 8 hours post-dose. Blood concentrations of zolpidem of above 50 ng/mL have been associated with impaired driving and increased risk of motor vehicle accidents.

As a result, the FDA has required manufacturers of zolpidem-containing products to lower the recommended initial dose for women and to provide a suggestion to use a lower initial dose for men. The new dosing recommendations are shown in the following table:

Drug	Previous Dosing Recommendation	New Dosing Recommendation
Immediate-release zolpidem (e.g., Ambien, Edular, Zolpimist)	**Men and Women:** 10 mg once daily immediately before bedtime (short-term treatment is recommended)	**Women:** 5 mg once daily immediately before bedtime (short-term treatment is recommended) **Men:** 5 or 10 mg once daily immediately before bedtime (short-term treatment is recommended)
Extended-release zolpidem (e.g., Ambien CR)	**Men and Women:** 12.5 mg once daily immediately before bedtime (short-term treatment is recommended)	**Women:** 6.25 mg once daily immediately before bedtime (short-term treatment is recommended) **Men**: 6.25 or 12.5 mg once daily immediately before bedtime (short-term treatment is recommended)

Highmark Formulary Update – June 2013

SECTION I. Highmark Comprehensive Formulary

A. Changes to the Highmark Comprehensive Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. Please note that the Highmark Comprehensive Incentive Formulary is a complete subset of the Open Formulary; therefore, all medications added to the Comprehensive Incentive Formulary are automatically added to the Open Formulary. These updates are effective as of the dates noted throughout this document. For your convenience, you can search the Highmark Comprehensive Formulary on the Provider Resource Center (accessible via NaviNet® or our website). Click the *Pharmacy/Formulary Information* link from the menu on the left.

Table 1: Products Added to Preferred Brand Tier

(All products added to the formulary effective immediately unless otherwise noted)

Brand Name	Generic Name	Comments
Delzicol™	mesalamine	Aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance and remission of ulcerative colitis
Gattex®	teduglutide	Recombinant analog of human glucagon-like peptide 2 indicated for the treatment of adult patients with short bowel syndrome (SBS)
Iclusig™	ponatinib	Kinase inhibitor indicated for the treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy

Table 2: Products added to Non-Preferred Brand Tier - effective 5/1/2013

Brand Name	Generic Name	Preferred Alternatives
Kazano®	alogliptin/metformin	Jentadueto®, Kombiglyze®, Janumet®
Nesina®	alogliptin	Tradjenta®, Onglyza®, Januvia®
Oseni®	alogliptin/pioglitazone	Tradjenta®, Onglyza®, Januvia®, pioglitazone
Pomalyst®	pomalidomide	Revlimid®
Signifor®	pasireotide	ketoconazole, metapyrone
Suclear™	sodium sulfate/potassium sulfate/magnesium sulfate oral solution, peg-3350/sodium chloride/ sodium bicarbonate/ potassium chloride for oral solution	PEG, Trilyte®, Halflytely®, Suprep®
Uceris™	budesonide ER	prednisone
Zecuity™	sumatriptan iontophoretic transdermal system	sumatriptan

Table 3: Products to be moved from Preferred Brand Tier to Non-Preferred Brand Tier Effective 7/1/2013

(Effective upon completion of internal review and operationalization unless otherwise noted)

Brand Name	Generic Name	Preferred Alternative
Bactroban® Cream	mupirocin calcium 2% cream	mupirocin calcium 2% cream
Dovonex®	calcipotriene	calcipotriene
Duetact®	Pioglitazone HCL/ glimepiride	pioglitazone HCL/glimepiride
Evoxac®	cevimeline HCL	cevimeline HCL
Gabitril®	tiagabine HCL	tiagabine HCL
Lysteda®	tranexamic acid	tranexamic acid
Maxalt®/Maxalt MLT®	rizatriptan benzoate	rizatriptan benzoate
Plan B One Step®	levonorgestrel	levonorgestrel
Revatio®	sildenafil citrate	sildenafil citrate
Rhinocort Aqua®	budesonide	Nasonex®; fluticasone nasal spray
Tricor®	fenofibrate nanocrystals	fenofibrate nanocrystals
Viramune®	nevirapine	nevirapine
Ziagen®	abacavir	abacavir

B. Updates to the Pharmacy Utilization Management Programs

1. Updates to the Prior Authorization Program

(If approved, authorization may be granted for up to one year unless otherwise noted.)

Brand Name	Policy Effective Date	Approval Criteria
Gattex®	5/1/2013	• Teduglutide is to be used for the treatment of patients with short bowel syndrome (SBS) ***AND*** • The member is dependent on parenteral nutrition/intravenous nutrition support for at least 12 months and requiring parenteral nutrition at least three times per week.
Iclusig™	5/1/2013	• Ponatinib is to be used for the treatment of chronic phase, accelerated phase, or blast phase CML in patients who are no longer responding to, or are intolerant of, prior tyrosine kinase inhibitor therapy [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib)] ***OR*** • Ponatinib is to be used for the treatment of Ph+ALL in patients who are no longer responding to, or are intolerant of prior tyrosine kinase inhibitor therapy [e.g., Gleevec (imatinib) or Sprycel (dasatinib)]. • If approved, up to a lifetime authorization may be granted.
Juxtapid™/Kynamro®	5/1/2013	• Lomitapide or mipomersen is to be used for the treatment of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: o Genetic testing to confirm functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL

		receptor functionality ***AND*** o LCL-C concentration >300 mg/dL after at least six months of maximally-tolerated drug therapy, which is defined as a trial of drugs from at least two separate classes of hypolipidemic agents such as bile acid sequestrants, HMG-CoA reductase inhibitors, fibric acid derivatives, or niacin/nicotinic acids ***OR*** o Untreated LDL-C concentration >500 mg/dL with the presence of Xanthomas in the first decade of life • If approved, up to a lifetime authorization may be granted.
Pomalyst®	5/1/2013	The Miscellaneous Immunomodulators policy has been updated to include coverage for pomalidomide in the following situation: • Pomalidomide is to be used for the treatment of multiple myeloma when a patient has tried at least two other therapies, including lenalidomide and bortezomib, and whose disease has progressed on or within 60 days of the last therapy. • If approved, up to a lifetime authorization may be granted.
Signifor®	5/1/2013	• Pasireotide is being used for the treatment of adult patients with Cushing's disease ***AND*** • The member is not a candidate for pituitary surgery, or surgery has not been curative ***AND*** • The member has experienced intolerance, failure, or inadequate response with ketoconazole or metyrapone. • If approved, up to a lifetime authorization may be granted.
Stivarga	5/1/2013	The prior authorization policy for Stivarga has been updated to include coverage for the following indication: • Regorafenib is to be used for the treatment of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) after treatment with both Gleevec (imatinib) and Sutent (sunitinib). • If approved, up to a lifetime authorization may be granted.

2. Updates to the Managed Prescription Drug Coverage (MRxC) Program
(If approved, authorization may be granted for up to one year unless otherwise noted.)

Brand Name	Policy Effective Date	Automatic Approval Criteria*
Zecuity™	5/1/2013	The Migraine Therapies policy has been updated to include a quantity limit for Zecuity of 4 patches per 25 days at retail and 12 patches per 75 days at mail order. Additional quantities of up to double the quantity limit may be authorized in the following situations: • The medication is used concurrently with a prophylactic medication or upon failure of two prophylactic medications in different therapeutic classes. Migraine prophylaxis therapeutic classes include:

		o Beta-blockers (e.g., atenolol, propranolol, etc.) o Calcium-channel blockers (e.g., diltiazem, verapamil, etc.) o Anti-epileptic drugs (e.g., topiramate, carbamazepine, etc.) o Selective serotonin reuptake inhibitors (SSRIs) (e.g., fluoxetine, paroxetine, etc.) o Tricyclic antidepressants (TCAs) (e.g., amitriptyline, nortriptyline, etc.)

* Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

All effective dates are tentative and subject to delay, pending internal review.