SPECIAL BULLETIN

FOR PROFESSIONAL PROVIDERS **DECEMBER 2, 2013**

CHANGES TO THE HIGHMARK DRUG FORMULARIES

4TH QUARTER UPDATE

The 4th 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 the decisions made in September 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, **www.highmarkbcbsde.com**). Click the *Pharmacy/Formulary Information* link from the menu on the left.

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

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Highmark Delaware

Highmark Formulary Update – December 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, **www.highmarkbcbsde.com**). 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
Astagraf XL TM	tacrolimus	Calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving a kidney transplant.
Lialda®	mesalamine	Locally acting 5-aminosalicylic acid (5-ASA) indicated for the induction and maintenance of remission in adults with ulcerative colitis.
Oxymorphone Extended-Release	oxymorphone extended-release	Long acting opiate receptor agonist indicated for the management of pain.
Tecfidera® (effective 1/1/14)	dimethyl fumarate	Oral agent indicated for the treatment of relapsing forms of multiple sclerosis.
Tivicay®	dolutegravir	Human immunodeficiency virus (HIV) integrase strand transfer inhibitor (INSTI) indicated for the treatment of HIV type 1 infection.
TOBI® Podhaler TM	tobramycin	Aminoglycoside oral inhalation indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa.
Uloric ® (effective 1/1/14)	febuxostat	Xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout.

Table 2: Products Not Added*

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

Brand Name	Generic Name	Preferred Alternative
BrisdelleTM	paroxetine mesylate	paroxetine HCl
Clindesse®	clindamycin vaginal cream	clindamycin vaginal cream
EpanedTM	enalapril maleate liquid	enalapril
FetzimaTM	levomilnacipran HCl	venlafaxine ER
Gilotrif™	afatinib	Tarceva
KhedezlaTM	desvenlafaxine extended release	venlafaxine ER
Lo MinastinTM Fe	ethinyl estradiol and norethindrone, ethinyl estradiol, and ferrous fumarate	Junel Fe, Microgestin Fe, Gildess Fe
Mirvaso®	brimonidine topical gel	metronidazole topical gel/cream/lotion

Brand Name	Generic Name	Preferred Alternative
Naftin®	naftifine hydrochloride	ketoconazole cream, ciclopirox cream, ciclopirox gel
Ravicti®	glycerol phenylbutyrate	Provider discretion
SimbrinzaTM	brinzolamide/bromonidine	Brimonidine drops, dorzolamide drops
Trokendi XRTM	topiramate	topiramate
ZenzediTM (2.5mg and 5mg)	dextroamphetamine sulfate	dextroamphetamine, amphetamine salt combo

*Physicians may request coverage of these products using the Prescription Drug Medication Request Form, which can be accessed online via the Provider Resource Center; under *Provider Forms*, select *Miscellaneous Forms*, and select the form titled *Request for Non-Formulary Drug Coverage*.

Table 3: Products Removed * - effective 1/1/2014

Brand Name	Generic Name	Preferred Alternatives
Advicor ®	niacin ER/ lovastatin	lovastatin, Niaspan®
Kombiglyze™ XR	saxagliptin/metformin	Janumet, Janumet XR, Jentadueto
Onglyza®	saxagliptin	Januvia, Tradjenta
Oxycontin®	oxycodone	Morphine sulfate extended release
Rilutek®	riluzole	riluzole
Temodar®	temozolomide	temozolmide
Valcyte®	valganciclovir	Provider discretion
Vectical®	calcitriol	calcitriol topical ointment
Vivelle-Dot®	Estradiol transdermal system	estradiol patch; Climara

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
Anti-Obesity: Belviq and Qsymia	9/5/2013	When a benefit, initial coverage for phentermine/topiramate extended-release will be approved if members meet the following criteria: 1. The member is ≥18 years of age and is obese, with a documented BMI ≥30 kg/m^2 ***OR*** 2. The member is ≥18 years of age and is overweight, with a documented BMI ≥27 kg/m^2 AND at least one weight-related comorbidity (e.g., hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea, symptomatic osteoarthritis of lower extremities, gastroesophageal reflux, coronary heart disease)**.** For members with a closed formulary in which the requested medication is non-formulary, the medication requested will only be approved if the member has tried and failed at least two (2) formulary alternatives (if available) while still meeting the other criteria outlined within this policy. Use of lorcaserin or phentermine/topiramate extended-release for disease states outside of its FDA-approved indications should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.
EGFR Tyrosine Kinase	10/18/2013	When a benefit and prescribed under the supervision of an

Brand Name	Policy Effective Date	Approval Criteria
Inhibitors- Policy Revision		oncologist/hematologist, gefitinib, afatinib, or erlotinib may be approved when the following criteria have been met: 1. Erlotinib is being used for the treatment of non-small cell lung cancer ***OR*** 2. Erlotinib is being used for the treatment of pancreatic cancer as first-line treatment when used in combination with gemcitabine ***OR*** 3. Gefitinib is being used for the treatment of advanced NSCLC after the failure of both platinum and docetaxel-based chemotherapies ***OR*** 4. Gefitinib is being used for the treatment of advanced NSCLC in a member who is or has previously benefitted from gefitinib ***OR*** 5. Afatinib is being used for the treatment of non-small cell lung cancer in adult patients that express EGFR exon 19 deletion mutations or exon 21 (L858R) mutations as detected by an FDA-approved test. Coverage of tyrosine kinase inhibitors as salvage therapy for disease states outside of their FDA-approved indications should be evaluated based on the member's diagnosis, documented failure of all FDA-approved therapies for their diagnosis and in accordance with Highmark Medical Policy G-16. Coverage of tyrosine kinase inhibitors for disease states outside of their FDA-approved indications should be denied based on the lack of clinical data to support their effectiveness and safety in other conditions.
Jakafi (ruxolitinib)- Policy Update	9/5/2013	When a benefit and prescribed under the supervision of an oncologist/hematologist, ruxolitinib may be approved when the following criterions have been met: 1. Ruxolitinib is being used for the treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults 18 years of age or older **AND** 2. If ruxolitinib is being used for the continuation of therapy, there is documentation supporting the reduction in spleen size or the improvement of symptoms **AND** 3. The starting dose of ruxolitinib does not exceed 5 mg orally twice daily for patients whose platelet count is between 50 X 10^9/L and 100 X 10^9/L **OR** 4. The starting dose of ruxolitinib does not exceed 15 mg orally twice daily for patients whose platelet count is between 100 X 10^9/L and 200 X 10^9/L **OR** 5. The starting dose of ruxolitinib does not exceed 20 mg orally twice daily for patients whose platelet count is greater than 200 X 10^9/L Coverage of ruxolitinib for disease states outside of its FDA-approved indication should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.
Provigil (modafinil) &	9/5/2013	When a benefit, modafinil/armodafinil may be approved when the

Brand Name	Policy Effective Date	Approval Criteria
Nuvigil (armodafinil)-Policy Revision		following are met for each diagnosis: • Modafinil/armodafinil are to be used in the treatment of documented narcolepsy for patients meeting the ICD-9 and American Sleep Disorders Association criteria as follows and no medical or mental disorders accounts for symptoms: 1. Recurrent daytime naps or lapsed into sleep that occur almost daily for at least 3 months **AND** 2. Sudden bilateral loss of postural muscle tone in association with intense emotion (cataplexy) **OR** 3. A complaint of excessive sleepiness or sudden muscle weakness with associated features such as sleep paralysis, hypnagogic hallucinations, automatic behaviors, or disrupted major sleep episode **AND** 4. A polysomnography demonstrating at least one of the following should be included: • Sleep latency less than 10 minutes **OR** • REM sleep latency less than 20 minutes **AND** • An MSLT that demonstrates a mean sleep latency of less than 5 minutes **AND** • Two or more sleep-onset REM periods. • Modafinil/armodafinil are to be used in the treatment of fatigue associated with multiple sclerosis ***OR*** • Modafinil/armodafinil are to be used as an adjunctive treatment of obstructive sleep apnea / hypopnea syndrome (OSAHS) with obstructive apneas documented by objective polysomnographic testing in patients who must be currently receiving and compliant with continuous positive airway pressure (CPAP) therapy who must meet the following ICSD criteria: 1. Excessive sleepiness or insomnia **AND** 2. Frequent episodes of impaired breathing during sleep **AND** 3. Associated features such as loud snoring, morning headaches and dry mouth upon awakening **AND** 4. Polysomnography demonstrating more than 5 obstructive apneas, each greater than 10 seconds in duration per hour of sleep and one or more of the following: • Frequent arousals from sleep associated with apneas • Bradytachycardia • Arterial oxygen desaturation in association with apneas • Modafinil/armodafinil are to be use in the treatment of SWSD in Highmark Delaware patients who meet the following criteria: 1. A minimum of 5 night shifts per month with at least 3 of the nights being consecutive night shifts. 2. Night shifts are defined by at least 6 hours occurring between 2200h and 0800h 3. Night shifts no more than 12 hours in duration.

Brand Name	Policy Effective Date	Approval Criteria
		Coverage for armodafinil will be granted only after the documented trial and failure of modafinil, when prescribed for an approved indication. Coverage for modafinil and armodafinil will not be approved when the main purpose is to counteract the sedating effects of another medication.
Valchlor (mechlorethamine)	11/8/2013	When a benefit, initial coverage for mechlorethamine gel may be approved when all of the following criteria are met: 1. Mechlorethamine gel is to be used for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have limited localized or generalized skin involvement who received at least one (1) prior skin directed therapy alone **OR** 2. The member is using mechlorethamine gel in combination with other skin directed therapies. Skin directed therapies include the following: i. Topical corticosteroids ii. Topical chemotherapy (e.g., carmustine) iii. Local radiation iv. Topical retinoids (e.g., bexarotene, tazarotene) v. Phototherapy vi. Topical imiquimod Use of mechlorethamine gel for disease states outside of its FDA-approved indications should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.
Xyrem (sodium oxybate)- Policy Update	9/5/2013	When a benefit, sodium oxybate may be approved when the following criteria are met: • Sodium oxybate is to be used in the treatment of documented narcolepsy for patients meeting the ICD-9 and American Sleep Disorders Association criteria as follows and no medical or mental disorders accounts for symptoms: 1. Recurrent daytime naps or lapsed into sleep that occur almost daily for at least 3 months ***AND*** 2. Sudden bilateral loss of postural muscle tone in association with intense emotion (cataplexy) **OR** 3. A complaint of excessive sleepiness or sudden muscle weakness with associated features such as sleep paralysis, hypnagogic hallucinations, automatic behaviors, or disrupted major sleep episode **AND** 4. A polysomnography demonstrating at least one of the following should be included: • Sleep latency less than 10 minutes ***OR*** • REM sleep latency less than 20 minutes **AND** • An MSLT that demonstrates a mean sleep latency of less than 5 minutes **AND** • Two or more sleep-onset REM periods. Use of sodium oxybate for disease states outside of its FDA-approved indication should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.

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*
Doxycycline Acne Products	TBD	Members who meet the criteria as outlined below will receive automatic authorization at the pharmacy point of service without documentation of additional information. Claims will automatically adjudicate on-line, with no prior authorization required. • The day supply is less than or equal to 21 days ***OR*** • The member is 8 years of age or older ***AND*** • The member has at least one prescription drug claim for a doxycycline immediate release product ***AND*** one prescription drug claim for a different oral antibiotic indicated for the treatment of acne (e.g., dapsone, tetracycline, minocycline, demeclocycline, erythromycin), ***AND*** one prescription drug claim for a topical agent for the treatment of acne within the previous 12 months. Members who do not meet the above criteria will require prior authorization.
Interferon Beta-Commercial Only	1/1/2014	Members who meet the criteria as outlined below will receive automatic authorization at the pharmacy point of service without documentation of additional information. Claims will automatically adjudicate on-line, with no prior authorization required. 1. The member has at least one prescription drug claim within the past 720 days for the non-preferred interferon beta product being requested, Betaseron (interferon beta-1b) or Extavia (interferon beta-1b) **OR** 2. The member has at least one prescription drug claim within the past 720 days for both Avonex (interferon beta-1a) AND Rebif (interferon beta-1a). Members who do not meet the above criteria will require prior authorization.
Opioid Dependence Therapy- Policy updated to include Zubsolv	9/16/13	Members who meet the criterion as outlined below will receive automatic authorization at the pharmacy point of service without documentation of additional information. Claims will automatically adjudicate on-line, with no prior authorization required. • The prescribed dose of Subutex does not exceed a 5 day supply (160mg) within 60 days. Members who do not meet the above criterion will require prior authorization.
Select Serotonin-Norepinephrine Reuptake Inhibitors- Policy updated to include Fetzima, Khedezla, and Pristiq	11/1/13	Members who meet the criteria as outlined below will receive automatic authorization at the point of service without documentation of additional information. Claims will adjudicate automatically online. 1. The member has at least one claim for 2 different antidepressant agents (e.g., SNRI, SSRI, TCA, MAOI) in their prescription drug claims history within the past 24 months ***OR*** 2. The member has a previous paid claim for Fetzima, Khedezla, or Pristiq within the previous 120 days. Coverage of Fetzima, Khedezla, or Pristiq for disease states outside of those listed above should be denied based on the lack of clinical data to support their effectiveness and safety in such conditions. For members with a closed formulary, Fetzima, Khedezla, or Pristiq will only be approved if the "2 other antidepressants" listed above in the

		Approval Criteria are two formulary (preferred) anti-depressants (e.g., SNRI, SSRI, TCA, MAOI), while still meeting the other criteria outlined within this policy.

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

3. Updates to the Quantity Level Limit Program

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

Drug Name	Up to 34-Day Supply Limit (retail)	35- to 90-Day Supply Limit (retail or mail)
Ampyra	68 tablets	180 tablets
Aubagio	68 tablets	180 tablets
Auvi Q	2 devices	2 devices
Belviq	68 tablets	180 tablets
Butrans	5 patches	13 patches
Erivedge	34 capsules	90 capsules
Gilenya	34 capsules	90 capsules
Kalydeco	68 tablets	180 tablets
Qsymia	68 capsules	180 capsules
Tecfidera	68 capsules	180 capsules
Xeljanz	68 tablets	180 tablets
Xenical	102 capsules	270 capsules

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