4th QUARTER 2013 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the 4th Quarter 2013 update to the Highmark Drug Formularies and pharmaceutical management procedures. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the enclosed changes reflect the decisions made in September 2013 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference this guide to navigate this communication:

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

As an added convenience, you can also search the Highmark Drug Formularies online at **https://prc.highmarkblueshield.com/rscprc/hbs/pub?document=https%3A//www.highmarkblueshield.com/health/documents/pharm-form.html&docId=78**. This function allows you to search by the drug name or therapeutic class. (NaviNet® users: Simply click on the *Resource Center* button and select the *Pharmacy/Formulary Information* link.)

(continued)

HIGHMARK®

Camp Hill, PA 17089

Highmark Formulary Update – December 2013

SECTION I. Highmark Comprehensive and Progressive Formularies

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 Closed/Incentive Formulary is a complete subset of the Open Formulary; therefore, all medications added to the Comprehensive Closed/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 online at **http://highmark.formularies.com**.

Highmark is happy to inform you that Table 1 includes products that have been added to the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes this will promote adherence to maintenance products and improve the overall health of our members.

Table 1: Products Added (All products added to the formulary effective immediately unless otherwise noted)

Brand Name	Generic Name	Comments
Astagraf XL ™	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 ™	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[*]

Brand Name	Generic Name	Preferred Alternatives
Brisdelle™	paroxetine mesylate	paroxetine HCl
Clindesse®	clindamycin vaginal cream	clindamycin vaginal cream
Epaned™	enalapril maleate liquid	enalapril
Fetzima™	levomilnacipran HCl	venlafaxine ER
Gilotrif™	afatinib	Tarceva
Khedezla™	desvenlafaxine extended release	venlafaxine ER
Lo Minastin™ 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
Naftin®	naftifine hydrochloride	ketoconazole cream, ciclopirox cream, ciclopirox gel
Ravicti®	glycerol phenylbutyrate	Provider discretion

Simbrinza™	brinzolamide/bromonidine	Brimonidine drops, dorzolamide drops
Trokendi XR™	topiramate	topiramate
Zenzedi™ (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 in Highmark's 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

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

Table 4: Additions to the Specialty Tier Copay Option

*Note: The specialty tier does not apply to Highmark Delaware members; see Highmark Delaware's online Provider Resource Center and access the *Pharmacy/Formulary Information* link for details on the formularies and formulary options that apply to Highmark Delaware members.

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

Brand Name	Generic Name
Gilotrif™	afatinib
Ravicti®	glycerol phenylbutyrate

B. Changes to the Highmark Progressive Formulary

*Note: The Progressive Formulary does not apply to Highmark Delaware members; see Highmark Delaware's online Provider Resource Center and access the *Pharmacy/Formulary Information* link for details on the formularies and formulary options that apply to Highmark Delaware members.

For your convenience, you may search the Highmark Progressive Formulary online at **http://highmark.formularies.com**. Note: You must click the hyperlink for the Progressive Formulary.

Table 1: Formulary Updates (All products added to the formulary effective immediately unless otherwise noted)

Brand Name	Generic Name	Tier[*]	Comments
Astagraf XL™	tacrolimus	3 - Preferred Brand	Calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving a kidney transplant.
Oxymorphone Extended-Release	oxymorphone extended-release	1 - Formulary Generic	Long acting opiate receptor agonist indicated for the management of pain.
Tecfidera® *(effective 1/1/14)*	dimethyl fumarate	3 – Formulary Specialty	Oral agent indicated for the treatment of relapsing forms of multiple sclerosis.
TOBI® Podhaler™	tobramycin	3 – Formulary Specialty	Aminoglycoside oral inhalation indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa.
Items listed below are non-preferred products			
Brisdelle™	paroxetine mesylate	3 – Non-formulary Brand	paroxetine HCL, paroxetine ER HCl

Clindesse®	clindamycin vaginal cream	3 – Non-formulary Brand	clindamycin vaginal cream
Epaned™	enalapril maleate liquid	3 – Non-formulary Brand	enalapril
Fetzima™	levomilnacipran HCl	3 – Non-formulary Brand	venlafaxine ER
Gilotrif™	afatinib	4 - Non-formulary Specialty	Tarceva
Khedezla™	desvenlafaxine extended release	3 – Non-formulary Brand	venlafaxine ER
Kombiglyze™ XR	saxagliptin/metformin	3 – Non-formulary Brand	Preferred product: Jentadueto, effective 1/1/14
Lo Minastin™ Fe	ethinyl estradiol and norethindrone, ethinyl estradiol, and ferrous fumarate	3 – Non-formulary Brand	Junel Fe, microgestin Fe, Gildess Fe
Mirvaso®	Brimonidine topical gel	3 – Non-formulary Brand	Metronidazole topical gel/cream/lotion
Naftin®	naftifine hydrochloride	3 – Non-formulary Brand	ketoconazole cream, ciclopirox cream, ciclopirox gel
Onglyza®	saxagliptin	3 – Non-formulary Brand	Preferred product: Tradjenta, effective 1/1/14
Ravicti®	dlycerol phenylbutyrate	4 – Non-formulary Specialty	Provider discretion
Simbrinza™	brinzolamide/bromonidine	3 – Non-formulary Brand	Brimonidine drops, dorzolamide drops
Tivicay®	dolutegravir	3 – Non-formulary Brand	Provider discretion
Trokendi XR™	topiramate	3 – Non-formulary Brand	Topiramate
Vectical®	calcitriol	3 – Non-formulary Brand	Preferred product: calcitriol topical ointment, effective 1/1/14
Zenzedi™	dextroamphetamine sulfate	3 – Non-formulary Brand	dextroamphetamine, amphetamine salt combo
Ziagen®	abacavir	3 – Non-formulary Brand	Preferred product: abacavir, effective 1/1/14

*Tier 1: Formulary generic drugs; **Tier 2:** Formulary brand drugs; **Tier 3:** Non-formulary generic drugs, non-formulary brand drugs, formulary specialty drugs; **Tier 4:** Non-formulary specialty drugs

C. Updates to the Pharmacy Utilization Management Programs
1. Updates to the Prior Authorization Program

Drug 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 Inhibitors Policy Revision	10/18/2013	When a benefit and prescribed under the supervision of an 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 criteria 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 50×10^9/L and 100×10^9/L **OR** 4. The starting dose of ruxolitinib does not exceed 15 mg orally twice daily for patients whose platelet count is between 100×10^9/L and 200×10^9/L **OR** 5. The starting dose of ruxolitinib does not exceed 20 mg orally twice daily for patients whose platelet count is greater than 200×10^9/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) & Nuvigil (armodafinil) Policy Revision	9/5/2013	When a benefit, modafinil/armodafinil may be approved when the 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 account for symptoms: 1. Recurrent daytime naps or lapses 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 used 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.
		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 account for symptoms:
  1. Recurrent daytime naps or lapses 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.)

Drug 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 online, 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 online, 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 online, 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.

SECTION II. Highmark Medicare-approved Formularies

A. Changes to the Highmark Medicare-approved Closed 2-Tier Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare-approved Formularies online at **http://highmark.medicare-approvedformularies.com.**

Highmark is happy to inform you that Table 1 includes products that have been added to the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes this will promote adherence to maintenance products and improve the overall health of our members.

Table 1: Products Added (All products added to the formulary effective immediately upon CMS approval unless otherwise noted)

Brand Name	Generic Name	Comments
Astagraf XL™	tacrolimus	Calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving a kidney transplant.
Fetzima™	levomilnacipran HCl	Serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of Major Depressive Disorder (MDD).
Gilotrif™	afatinib	Oral tyrosine kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC).
Khedezla™	desvenlafaxine extended release	SNRI indicated for the treatment of MDD.
Tivicay®	dolutegravir	Human immunodeficiency virus (HIV) integrase strand transfer inhibitor (INSTI) indicated for the treatment of HIV type 1 infection.
Trokendi XR™	topiramate	Antiepileptic indicated for the treatment of partial onset seizures, primary onset generalized tonic-clonic seizures, and Lennox-Gastaut Syndrome associated seizures.
Zenzedi™ (2.5 mg and 5 mg)	dextroamphetamine sulfate	Amphetamine indicated for the treatment of narcolepsy and attention deficit disorder with hyperactivity.

Table 2: Products Not Added*

Brand Name	Generic Name	Preferred Alternatives/Comments
Brisdelle™	paroxetine mesylate	paroxetine HCl, paroxetine ER HCl
Clindesse®	clindamycin vaginal cream	clindamycin vaginal cream
Epaned™	enalapril maleate liquid	enalapril
Lo Minastin™ Fe	ethinyl estradiol and norethindrone, ethinyl estradiol, and ferrous fumarate	Junel Fe, Microgestin Fe
Mirvaso®	brimonidine topical gel	metronidazole topical gel/cream/lotion
Naftin®	naftifine hydrochloride	ketoconazole cream, ciclopirox cream, ciclopirox gel
Simbrinza™	brinzolamide/bromonidine	brimonidine drops, dorzolamide drops
Simponi® Aria™	golimumab	Simponi SubQ

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

B. Changes to the Highmark Medicare-approved Incentive Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare-approved Formularies online at **http://highmark.medicare-approvedformularies.com.**

Highmark is happy to inform you that Table 1 includes products that have been added to the preferred tiers on the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes this will promote adherence to maintenance products and improve the overall health of our members.

Table 1: Preferred Products Added (All products added to the formulary effective immediately upon CMS approval unless otherwise noted).

Brand Name	Generic Name	Comments
Astagraf XL ™	tacrolimus	Calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving a kidney transplant.

Table 2: Non-Preferred Products

Brand Name	Generic Name	Alternatives/Comments
Brisdelle™	paroxetine mesylate	paroxetine HCl, paroxetine ER HCl
Clindesse®	clindamycin vaginal cream	clindamycin vaginal cream
Epaned™	Enalapril maleate liquid	enalapril
Fetzima™	levomilnacipran HCl	Cymbalta, venlafaxine ER
Khedezla™	desvenlafaxine extended release	Cymbalta, venlafaxine ER
Lo Minastin™ Fe	ethinyl estradiol and norethindrone, ethinyl estradiol, and ferrous fumarate	Junel Fe, Microgestin Fe
Mirvaso®	Brimonidine topical gel	metronidazole topical gel/cream/lotion
Naftin®	Naftifine hydrochloride	ketoconazole cream, ciclopirox cream, ciclopirox gel
Simbrinza™	Brinzolamide/bromonidine	Azopt®, brimonidine drops, dorzolamide drops
Trokendi XR™	Topiramate	topiramate
Zenzedi™ (2.5 mg and 5 mg)	Dextroamphetamine sulfate	dextroamphetamine, amphetamine salt combo

C. Changes to the Highmark Medicare-approved 5-Tier Closed Formulary

The Highmark Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. For your convenience, you can search the Highmark Medicare-approved Formularies online at **http://highmark.medicare-approvedformularies.com.**

Highmark is happy to inform you that Table 1 includes products that have been added to the preferred tiers on the formulary. Adding products to the formulary may mean lower copays or coinsurance rates for members. By adding products to the formulary, Highmark hopes this will promote adherence to maintenance products and improve the overall health of our members.

Table 1: Preferred Products Added (All products added to the formulary effective immediately upon CMS approval unless otherwise noted).

Brand Name	Generic Name	Comments
Astagraf XL ™	tacrolimus	Calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving a kidney transplant.

Table 2: Non-Preferred Products

Brand Name	Generic Name	Comments
Fetzima™	levomilnacipran HCl	Cymbalta, venlafaxine ER
Khedezla™	desvenlafaxine extended release	Cymbalta, venlafaxine ER
Mirvaso®	brimonidine topical gel	metronidazole topical gel/cream/lotion
Simbrinza™	brinzolamide/bromonidine	Azopt®, brimonidine drops, dorzolamide drops
Zenzedi™ (2.5 mg and 5 mg)	dextroamphetamine sulfate	dextroamphetamine, amphetamine salt combo

Table 3: Products Not Added[*]

Brand Name	Generic Name	Preferred Alternatives/Comments
Brisdelle™	paroxetine mesylate	paroxetine HCl, paroxetine ER HCl
Clindesse®	clindamycin vaginal cream	clindamycin vaginal cream
Epaned™	enalapril maleate liquid	enalapril
Lo Minastin™ Fe	ethinyl estradiol and norethindrone, ethinyl estradiol, and ferrous fumarate	Junel Fe, Microgestin Fe
Naftin®	naftifine hydrochloride	ketoconazole cream, ciclopirox cream, ciclopirox gel
Trokendi XR™	topiramate	topiramate

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

D. Additions to the Specialty Tier (applicable to the Medicare-approved Incentive Formulary and the Medicare-approved 5-Tier Closed Formulary)
(Effective immediately upon CMS approval)

Brand Name	Generic Name
Gilotrif™	afatinib
Simponi® Aria™	golimumab
Tivicay®	dolutegravir

E. 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.)

Drug Name	Policy Effective Date	Approval Criteria
Cimzia (certolizumab pegol) Policy Update	11/1/2013	When a benefit, certolizumab pegol may be approved when the following criteria are met: 1. Certolizumab is to be used in reducing the signs and symptoms of patients with Crohn's disease who have failed two immunosuppressant therapies or monotherapy with Remicade® *OR* 2. Certolizumab is to be used alone or in combination with methotrexate for the treatment of adult patients with rheumatoid arthritis. 3. Certolizumab is to be used for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis. For Medicare Part D beneficiaries, certolizumab pegol may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).

EGFR Tyrosine Kinase Inhibitors Policy Revision	11/1/2013	When a benefit and prescribed under the supervision of an 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. For Medicare Part D beneficiaries, erlotinib, gefitinib, or afatinib may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).
Immediate Release Fentanyl Citrate Policy Update	1/1/2014	When a benefit, oral transmucosal fentanyl may be approved when the following criteria are met: 1. The immediate release fentanyl is being used for the management of breakthrough cancer pain in patients who are currently receiving and tolerant to long-acting opioid therapy. 2. Upon approval, coverage will be limited to 124 units total (Actiq or Fentora or Onsolis or Abstral) per 31 days. Upon approval, coverage for Lazanda will be limited to 31 bottles per 31 days. Upon approval, coverage of Subsys will be limited to 124 units total per 31 days. If more units are required on a daily basis for the management of breakthrough cancer pain, an increase in the around-the-clock opioid dose for persistent pain should be considered. Immediate release fentanyl citrate should not be used for acute pain conditions, chronic pain conditions which are not related to cancer, or in situations involving chronic pain in which the patient is not receiving maintenance doses of long-acting opioid analgesics.
Jakafi (ruxolitinib) Policy Update	TBD	When a benefit and prescribed under the supervision of an oncologist/hematologist, ruxolitinib may be approved when the following criteria 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 50×10^9/L and 100×10^9/L **OR** 4. The starting dose of ruxolitinib does not exceed 15 mg orally twice daily for patients whose platelet count is between 100×10^9/L and 200×10^9/L **OR** 5. The starting dose of ruxolitinib does not exceed 20 mg orally twice daily for patients whose platelet count is greater than 200×10^9/L For Medicare Part D beneficiaries, ruxolitinib may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).
Provigil (modafinil) & Nuvigil (armodafinil) Policy Update	TBD	When a benefit, modafinil/armodafinil may be approved when the following criteria 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 account for symptoms: 1. Recurrent daytime naps or lapses 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) for those patients currently receiving and compliant with continuous positive airway pressure (CPAP) 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 used in the treatment of SWSD in 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.
		    • Night shifts are defined by at least 6 hours occurring between 2200h and 0800h
		    • Night shifts no more than 12 hours in duration.
		For Medicare Part D beneficiaries, modafinil or armodafinil may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).

Valchlor (mechlorethamine)	TBD	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:
		  ▪ Topical corticosteroids
		  ▪ Topical chemotherapy (e.g., carmustine)
		  ▪ Local radiation
		  ▪ Topical retinoids (e.g., bexarotene, tazarotene)
		  ▪ Phototherapy
		  ▪ Topical imiquimod
		For Medicare Part D beneficiaries, mechlorethamine gel may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).

| Xyrem (sodium oxybate) Policy Update | TBD | 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 account for symptoms:
  1. Recurrent daytime naps or lapses 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.
For Medicare Part D beneficiaries, sodium oxybate may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS). |

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

Drug Name	Policy Effective Date	Automatic Approval Criteria*
Extended Release Opioid Management – Medicare Only	1/1/2014	This policy was modified to accommodate a 31-day supply retail edit limit and a 93-day supply mail order edit limit.
Immediate Release Opioid Management	1/1/2014	This policy was modified to accommodate a 31-day supply retail edit limit and a 93-day supply mail order edit limit.
Migraine Therapies	1/1/2014	This policy was modified to accommodate a 31-day supply retail edit limit and a 93-day supply mail order edit limit.
Opioid Dependence Therapy Policy updated to include Zubsolv	TBD	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 online, with no prior authorization required. • The prescribed dose does not exceed a 5-day supply 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	TBD	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.

Uloric	1/1/2014	Policy terminated.

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

3. Updates to the Quantity Level Limit Program*

Drug Name	Up to 31-Day Supply Limit (retail)	93-Day Supply Limit (retail or mail)	Policy Effective Date
Acetaminophen (APAP) brand and generic containing products: Additional products were added to this policy, including liquid medications.	Limits are based on a maximum daily dose of 4 grams of APAP/day. These limits are based upon safe maximum daily dosages of APAP.	Limits are based on a maximum daily dose of 4 grams of APAP/day. These limits are based upon safe maximum daily dosages of APAP.	1/1/2014
This policy was modified to a 31-day supply retail edit limit and a 93-day supply mail order edit limit.			1/1/2014

*Physicians may request coverage of additional quantities for members with a Medicare-approved Formulary by using the Prescription Drug Medication Request Form, which can be accessed online in Highmark's Provider Resource Center; under *Provider Forms*, select *Miscellaneous Forms*, and select the form titled *Request for Non-Formulary Drug Coverage*.

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