SPECIAL BULLETIN

FOR PROFESSIONAL PROVIDERS **SEPTEMBER 19, 2013**

CHANGES TO THE HIGHMARK HEALTH SERVICES DRUG FORMULARIES

3RD QUARTER UPDATE

The 3rd 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 March 2013 by the Highmark Health Services 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 Health Services Comprehensive Formulary

A. Changes to the Highmark Health Services 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 Specialist.

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Highmark Delaware

Highmark Health Services Formulary Update – September 2013

SECTION I. Highmark Health Services Comprehensive Formulary

A. Changes to the Highmark Health Services Comprehensive Formulary

The Highmark Health Services Pharmacy and Therapeutics Committee has reviewed the medications listed in the tables below. Please note that the Highmark Health Services 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 Health Services 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
Cystaran™	cysteamine	Ophthalmic aminothiol indicated for the treatment of nephropathic cystinosis.
Mekinist™	trametinib	Signal Transduction Inhibitor indicated for the treatment of unresectable or metastatic malignant melanoma in patients with BRAF V600E or V600K mutations.
Tafinlar®	dabrafenib	Kinase inhibitor indicated for the treatment of unresectable or metastatic malignant melanoma in patients with BRAF V600E mutation.

Table 2: Products Not Added* - effective 8/9/2013

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

Brand Name	Generic Name	Preferred Alternative
AcipHex® Sprinkle™	rabeprazole	omeprazole, pantoprazole
Belviq®	lorcaserin	Xenical®
Breo™ Ellipta™	fluticasone/ vilanterol	Advair®, Dulera®, Symbicort®
Diclegis®	doxylamine/ pyridoxine	Provider discretion
Eliquis®	apixaban	Xarelto®, Pradaxa®
Fulyzaq™	crofelemer	Provider discretion
Ilevro®	nepafenac	diclofenac, flurbiprofen, ketorolac
Invokana™	canagliflozin	Various Diabetes medications
Juxtapid™	lomitapide	Provider discretion
Karbinal™ ER	carbinoxamine maleate	diphenhydramine
Kynamro®	mipomersen sodium	Provider discretion
Linzess™	linaclotide	Amitiza®
Liptruzet™	ezetimibe/ atorvastatin	Zetia®, atorvastatin, simvastatin
Minastrin™ 24 Fe	Ethinyl estradiol and norethindrone	Gianvi®
Myrbetriq®	mirabegron	oxybutynin, Vesicare®, Toviaz®
Nymalize™	nimodipine	nimodipine

Onfi®	clobazam	lamotrigine, topiramate
Osphena™	ospemifene	Provider discretion
Oxtellar XR™	oxcarbazepine	carbamazepine ER, divalproex ER
Pertzye®	pancrelipase	Viokase®, Creon®, Zenpep®
Procysbi™	cysteamine bitartrate	Provider discretion
Prolensa™	bromfenac	diclofenac, flurbiprofen, ketorolac
Qsymia™	phentermine/topiramate	Xenical®
Quartette™	ethinyl estradiol/levonorgestrel	Seasonique®
Sirturo ™	bedaquiline	Provider discretion
Sitavig®	acyclovir	acyclovir, famciclovir, valacyclovir
Tecfidera™	dimethyl fumarate	Avonex®, Rebif®, Copaxone®
TOBI® Podhaler®	tobramycin	TOBI®
Topicort®	desoximetasone	Desoximetasone, fluocinonide, betamethasone dipropionate
Tudorza™ Pressair™	aclidinium bromide	Spiriva®
Versacloz™	clozapine	clozapine
Vituz®	hydrocodone bitartrate and chlorpheniramine maleate	hydrocodone/acetaminophen oral solution, diphenhydramine oral solution

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

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
MAP Kinase Inhibitors Medications: Mekinist™ (trametinib), Tafinlar® (dabrafenib), Zelboraf® (vemurafenib)	8/9/2013	When a benefit, MAP kinase inhibitors may be approved when the following criterion is met: • Vemurafenib and dabrafenib are being used for the treatment of patients with unresectable or metastatic melanoma with BRAFV600E mutation as detected by an FDA-approved test **OR** • Trametinib is being used for the treatment of patients with unresectable or metastatic melanoma with BRAFV600E or BRAFV600K mutation as detected by an FDA-approved test **AND** • Trametinib is not being used in patients who have received prior BRAF inhibitor therapy (e.g. Zelboraf, Tafinlar). Use of MAP kinase inhibitors 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.
Procysbi™ (cysteamine bitartrate)	8/9/2013	When a benefit, Procysbi may be approved when all of the following criteria are met: 1. The member is at least 6 years of age and has a documented diagnosis of nephropathic cystinosis ***AND*** 2. The member has had an adequate trial and failure of or

		intolerance to immediate-release cysteamine bitartrate (Cystagon®) .
Tecfidera™ (dimethyl fumarate)	8/9/2013	When a benefit, dimethyl fumarate may be approved when the following criteria are met: 1. Members must have a documented diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting, relapsing secondary progressive, or progressive relapsing multiple sclerosis) ***AND*** 2. The prescribed dose of dimethyl fumarate does not exceed 240 mg twice daily. Combination use of disease modifying MS agents (dimethyl fumarate, fingolimod, interferons, Copaxone, Tysabri, etc.) will not be authorized. Use of dimethyl fumarate for disease states outside of its FDA-approved indications will be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.
Urea Cycle Disorder Medications: Buphenyl® (sodium phenylbutyrate), Carbaglu® (carglumic acid), Ravicti™ (glycerol phenylbutyrate)	8/9/2013	When a benefit, coverage for a hyperammonium agent may be approved if members met the following criteria: 1. Buphenyl is being prescribed as an adjunct therapy to dietary protein restriction for *chronic management* of urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), argininosuccinic acid synthetase (ASS), or ornithine transcarbamylase (OTC) OR 2. Carbaglu is being prescribed as an adjunct therapy for acute hyperammonemia or maintenance therapy for chronic hyperammonemia due to hepatic enzyme N-acetylglutamate synthase (NAGS) deficiency OR 3. Ravicti is being prescribed with dietary protein restriction for chronic management of a urea cycle disorders (UCDs) when the condition cannot be managed by dietary protein restriction alone. Coverage of Buphenyl, Carbaglu, or Ravicti 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.

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***
Brand Statin Edit: addition of LIPTRUZET™ (atorvastatin/ezetimibe)	8/15/2013	When a benefit, coverage for a brand HMG-CoA Reductase Inhibitors (Statins) may be approved if members meet the following criteria: 1. The member has a documented trial and failure of at least one generic Statin (e.g. pravastatin, simvastatin, lovastatin, atorvastatin, etc.).

		Additional Approval Criteria 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 24 months for a generic Statin.
Butrans™ (buprenorphine) non-opioid dependence use	9/6/13	When a benefit, buprenorphine may be approved when the following criteria are met: 1. The product is being used for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time **AND** The member has tried and failed at least two (2) previous federal legend medications for pain, including NSAIDs (ibuprofen, meloxicam, naproxen, etc.), tramadol, or opioids. 2. Upon approval, coverage will be limited to 4 units of Butrans™ every 28 days. Exceptions to the quantity limit may be approved to accommodate dose titration, but will not be approved to accommodate doses greater than 20mcg/hour or the application of multiple transdermal systems. Subutex® (buprenorphine) and Suboxone® (buprenorphine/naloxone) are indicated for the treatment of opioid dependence and are not eligible for coverage when used for the treatment of chronic pain. For coverage criteria associated with the use of buprenorphine for the treatment of opioid dependence, please refer to Highmark Health Services Pharmacy Policy J-23. For Medicare Part D beneficiaries, buprenorphine transdermal patches may be approved when used for a medically accepted indication (identified in Drugdex, AFHS Drug Information, or Clinical Pharmacology) as defined by the Centers for Medicare & Medicaid Services (CMS). **Additional Approval Criteria** 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 for two unique federal legend medications for pain, including NSAIDs (ibuprofen, meloxicam, naproxen, etc.), tramadol, or opioids, within the last 6 months. 2. The member has at least one paid claim for Butrans (buprenorphine)

		within the last 6 months. Members who do not meet the above criteria will require prior authorization.

* 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.