SPECIAL eBULLETIN

APRIL 2017

SECOND QUARTER 2017 UPDATE

CHANGES TO THE HIGHMARK DRUG FORMULARIES

Following is the Second Quarter 2017 update to the Highmark Drug Formularies and pharmaceutical management procedures. The formularies and pharmaceutical management procedures are updated on a quarterly basis, and the following changes reflect the decisions made in February 2017 by our Pharmacy and Therapeutics Committee. These updates are effective on the dates noted throughout this document.

Please reference the guide below to navigate this communication:

As an added convenience, you can also search our drug formularies and view utilization management policies on the Provider Resource Center (accessible via NaviNet® or our website). Click the Pharmacy/Formulary Information link from the menu on the left.

Important Drug Safety Updates

Chlorhexidine Gluconate: Drug Safety Communication – Rare but Serious Allergic Reactions
On February 2, 2017, the FDA warned that rare but serious allergic reactions have been reported with the widely used skin antiseptic products containing chlorhexidine gluconate. Although rare, the number of reports of serious allergic reactions to these products has increased over the last several years. As a result, we are requesting the manufacturers of over-the-counter (OTC) antiseptic products containing chlorhexidine gluconate to add a warning about this risk to the Drug Facts labels. Prescription chlorhexidine gluconate mouthwashes and oral chips used for gum disease already contain a warning about the possibility of serious allergic reactions in their labels.

FDA approves a generic of Xyrem with a REMS Program
On January 17, 2017, the FDA approved the first generic version of Xyrem (sodium oxybate) Oral Solution to treat cataplexy and excessive daytime sleepiness in patients with narcolepsy, which is a potentially debilitating disease. Because of the potential risks associated with Xyrem, it is subject to strict safety controls on prescribing and dispensing under a program called a Risk Evaluation and Mitigation Strategy (REMS). FDA's approval of generic sodium oxybate is subject to REMS with strict safety controls that are comparable to those currently required for Xyrem.

PNC-27 Products: FDA Warning – Do Not Use For Treatment or Cure for Cancer
On January 12, 2017, FDA began warning consumers not to purchase or use PNC-27, a product promoted and sold through http://PNC27.com, as a treatment or cure for cancer. PNC-27 is a small, nontoxic protein molecule that was designed in 2000 using a supercomputer at SUNI Downstate Medical Center in New York by Dr. Matthew Pincus and Dr. Josef Michl. Originally created to fight HIV, it was soon discovered that PNC-27 would attach to and kill cancer cells, leaving healthy cells to thrive. It is known to be most effective when used in conjunction with immune system boosters, proper hydration, and a vegan or near-vegan diet that avoids sugars and red meat. An FDA laboratory discovered the bacteria *Variovorax paradoxus* in a PNC-27 solution sample for inhalation. Consumers who use a contaminated product are at risk for serious, potentially life-threatening infections. Consumers at higher risk include vulnerable populations, such as young children, elderly people, pregnant women, and individuals with weakened immune systems.

Highmark Formulary Update – April 2017

SECTION I. Highmark Commercial and Healthcare Reform Formularies

A. Changes to the Highmark Comprehensive Formulary and the Highmark Comprehensive Healthcare Reform 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 also added to the Open Formulary. These updates are effective on the dates noted throughout this document. For your convenience, you can search the following formularies online:

Highmark Comprehensive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=8103967260)
Highmark Comprehensive Healthcare Reform Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4906449921)

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 to promote adherence to maintenance products and improve the overall health of our members.

Table 1. Products Added

(All products added to the formulary effective date to be determined in 1Q2017, unless otherwise noted.)

Brand Name	Generic Name	Comments
naloxone (solution for injection)*	naloxone	Indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
Epinephrine (EpiPen AG, Adrenaclick AG)**	epinephrine	Indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis.

*Naloxone solution for injection (syringes and vials) is a generic product.
**EpiPen AG and Adrenaclick AG are authorized generics.

Table 2. Products Not Added*

Brand Name	Generic Name	Preferred Alternatives
Rubraca	rucaparib	Provider discretion
Synjardy XR	empagliflozin/metformin ER	Invokamet XR, Xigduo XR
Eucrisa	crisaborole	hydrocortisone, triamcinolone
Arymo ER	morphine sulfate ER	morphine sulfate ER, oxymorphone ER
Colprep Kit	sodium/magnesium/potassium	PEG-3350 electrolyte, Suprep
Esbriet	pirfenidone	Provider discretion
Rhofade	oxymetazoline	metronidazole cream, lotion, and gel
Vantrela ER	hydrocodone bitartrate	morphine sulfate ER, oxymorphone ER

Brand Name	Generic Name	Preferred Alternatives
Tirosint-SOL	levothyroxine sodium solution	levothyroxine
Trulance	plecanatide	polyethylene glycol; lactulose
Vyvanse Chewable	lisdexamfetamine	methylphenidate ER
ArmonAir RespiClick	fluticasone propionate	Flovent Diskus, Flovent HFA
AirDuo RespiClick	fluticasone propionate/ salmeterol	Advair Diskus, Advair HFA, Symbicort

*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. 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 implementation unless otherwise noted.)

Brand Name	Generic Name
Rubraca	rucaparib
Esbriet	pirfenidone
Auvi-Q	epinephrine injection

Table 4. Products to be Removed — Effective July 1, 2017

Brand name	Generic Name	Preferred Alternatives
Only healthcare reform comprehensive products		
Zonatuss	benzonatate	benzonatate
Only commercial comprehensive products		
Accolate	zafirlukast	zafirlukast, montelukast sodium
Dibenzyline	phenoxybenzamine HCl	phenoxybenzamine HCl
Glyset	miglitol	miglitol, acarbose
Prandimet	repaglinide/metformin HCl	repaglinide/metformin HCl, metformin
Surmontil	trimipramine maleate	trimipramine maleate, amitriptyline HCl
All commercial & healthcare reform comprehensive products		
Evzio	naloxone	naloxone syringe/vial, Narcan nasal spray
Epipen/Epipen Jr	epinephrine	Provider discretion
Allegra-D Rx	fexofenadine/ pseudoephedrine	Provider discretion
Alphagan P 0.15%	brimonidine tartrate	brimonidine tartrate, apraclonidine HCl
Ancobon	flucytosine	flucytosine
Android	methyltestosterone	methyltestosterone
Cipro suspension	ciprofloxacin	ciprofloxacin, levofloxacin

Brand name	Generic Name	Preferred Alternatives
CitraNatal DHA	PNV no.22/iron (ferrous gluconate/folic acid/ docusate sodium /DHA	PNV OB+DHA, Prenaissance DHA
CitraNatal Rx	PNV no. 22/ Iron (carbonyl iron, ferrous gluconate) / folic acid / docusate sodium	Prenatal Plus, PNV OB+DHA
Cleocin palmitate solution	clindamycin palmitate HCl	clindamycin palmitate HCl, azithromycin
Cleocin phosphate 2%	clindamycin phosphate	clindamycin phosphate, metronidazole
Cordran cream	flurandrenolide	flurandrenolide, mometasone furoate
Cyclogyl 2%	cyclopentolate HCl	cyclopentolate HCl, tropicamide
DDAVP tablet/ampule/vial	desmopressin acetate	desmopressin acetate
Differin gel/cream	adapalene	adapalene, tretinoin
Dilaudid oral liquid	hydromorphone HCl	hydromorphone HCl, morphine sulfate
Disalcid	salsalate	salsalate, diclofenac sodium
Drisdol	ergocalciferol (vitamin D2)	ergocalciferol
Drysol	aluminum chloride	Hypercare
Edecrin tablet	ethacrynic acid	ethacrynic acid, furosemide
Efudex	fluorouracil	fluorouracil
Epivir solution	lamivudine	lamivudine, zidovudine
Estrostep Fe	ethinyl estradiol; norethindrone acetate; ferrous fumarate	Tilia Fe, Tri-Legest Fe
Evista	raloxifene HCl	raloxifene HCl, tamoxifen citrate
Femara	letrozole	letrozole, anastrozole
Femhrt	ethinyl estradiol; norethindrone acetate	ethinyl estradiol; norethindrone acetate, Jevantique Lo
Feosol 45 mg	iron; carbonyl	Perfect Iron
Fergon	ferrous gluconate	ferrous gluconate
Fer-in-sol	ferrous sulfate	Provider discretion
Grifulvin V	griseofulvin	griseofulvin, terbinafine
Gyne-lotrimin	clotrimazole	clotrimazole, terconazole
Haldol decanoate	haloperidol decanoate	haloperidol decanoate, fluphenazine decanoate
Halflytely-bisacodyl	PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride	Peg-prep, Gavilyte-H and bisacodyl
Hard nails	biotin	biotin
Hemocyte	ferrous fumarate	ferrous fumarate
Hemocyte-F	ferrous fumarate/ folic acid	hematinic with folic acid
ICAR tablet	iron(as carbonyl)	iron chews

Brand name	Generic Name	Preferred Alternatives
ICAR-C	iron(as carbonyl)/ ascorbic acid (vitamin C)	Fe C
ICAR-C Plus	iron (ascarbonyl)/vitamin C/vitamin B12/folic acid	Fe C
Isopto carpine	pilocarpine HCl	pilocarpine HCl
Isopto homatropine 5%	homatropine hydrobromide	homatropine hydrobromide, homatropaire
Kenalog spray	triamcinolone acetonide	triamcinolone acetonide, mometasone furoate
Loestrin Fe	ethinyl estradiol; norethindrone acetate; ferrous fumarate	ethinyl estradiol; norethindrone acetate; ferrous fumarate, Junel Fe
Loprox cream	ciclopirox olamine	ciclopirox, Ciclodan
LoSeasonique	ethinyl estradiol; levonorgestrel	ethinyl estradiol; levonorgestrel, Camrese Lo
Macrodantin 25 mg	nitrofurantoin macrocrystal	nitrofurantoin, sulfamethoxazole/trimethoprim
Medrol 8, 16, 32 mg	methylprednisolone	methylprednisolone, prednisone
Meribin	biotin	biotin
Mestinon ER	pyridostigmine bromide	pyridostigmine bromide
Mircette	ethinyl estradiol; desogestrel	ethinyl estradiol; desogestrel, Viorele
Modicon	ethinyl estradiol; norethindrone	Necon, Nortrel
Monistat 3 combo pack	miconazole nitrate	miconazole 3, terconazole
Monistat 7 cream	miconazole nitrate	miconazole 3, terconazole
Navelbine	vinorelbine tartrate	vinorelbine tartrate
Neosporin drops	neomycin/polymyxin b/gramicidin	neomycin/polymyxin b/gramicidin, neomycin/bacitracin/polymyxin
Nephrocaps	B-complex w-C no.20/folic acid	renal caps, Triphrocaps
Neurontin solution	gabapentin	gabapentin, levetiracetam
Nilandron	nilutamide	nilutamide
Nitrolingual	nitroglycerin	nitroglycerin
Nu-Iron	iron polysaccharide complex	Iferex 150
Oncovite	multivitamin; therapeutic	Thera
Orapred	prednisolone sod phosphate	prednisolone sodium phosphate, prednisone
Ortho Micronor	norethindrone	norethindrone acetate, Camila
Ortho Tri-Cyclen	ethinyl estradiol; norgestimate	ethinyl estradiol; norgestimate, Tri-Estarylla
Ortho-Cept	ethinyl estradiol;	ethinyl estradiol; desogestrel, Apri

Brand name	Generic Name	Preferred Alternatives
	desogestrel	
Ortho-Cyclen	ethinyl estradiol; norgestimate	ethinyl estradiol; norgestimate, Sprintec
Ortho-Novum	ethinyl estradiol; norethindrone	Nortrel, Alyacen
Ovide	malathion	malathion, permethrin
Pic 200	iron polysaccharide complex	EZFE
Prevident gel and cream	sodium fluoride	Dentagel, SF
Pulmicort 1 mg/2 ml	budesonide	budesonide
Pyridoxine HCL 50 mg and 500 mg	pyridoxine HCl	vitamin B-6
Right step prenatal vitamins	prenatal vitamin/iron fumarate/folic acid	Mynatal, Preplus
Rocaltrol solution	calcitriol	calcitriol
Rosanil	sulfacetamide sodium/sulfur	sodium sulfacetamide/sulfur, erythromycin-benzoyl peroxide
Sandostatin ampoules and vials	octreotide acetate	octreotide acetate
Seasonique	ethinyl estradiol; levonorgestrel	ethinyl estradiol; levonorgestrel, Camrese
Select-OB	prenatal vitamins without calcium /iron ps complex/folic acid	Prenatal-U, PNV-VP-U
Stress Formula vitamins w/ zinc	multivitamin; stress formula/zinc	Provider discretion
Strovite Forte	multivitamin; iron; min #5; folic acid	V-C Forte, Strovite Plus
Stuart Prenatal	prenatal vitamin /iron fumarate/folic acid	Mynatal, Preplus
Support capsule	B-complex with vitamin C	Strovite
Terazol	terconazole	terconazole, miconazole 3
Testred	methyltestosterone	methyltestosterone
Theramill Forte	multivitamin; theramill and minerals	V-C Forte, Strovite Plus
Tigan capsule	trimethobenzamide HCl	trimethobenzamide HCl
Ultra-antioxidant	beta-carotene(A)- vitamin C; vitamin E/ selenium	super antioxidant
Verelan 360 mg	verapamil HCl	verapamil HCl, diltiazem HCl
Vfend suspension	voriconazole	voriconazole, itraconazole
Videx ec	didanosine	didanosine, zidovudine
Vision plus lutein	multivitamin with	Corvita

Brand name	Generic Name	Preferred Alternatives
	minerals/ lutein	
Vitabee W-C	B-complex with vitamin C	Strovite
Yasmin	drospirenone; ethinyl estradiol	drospirenone; ethinyl estradiol, Ocella
Yaz	drospirenone; ethinyl estradiol	drospirenone; ethinyl estradiol, Gianvi
Zantac Rx syrup	ranitidine HCl	ranitidine HCl, famotidine
Zarontin	ethosuximide	ethosuximide, lamotrigine
Zithromax packet	azithromycin	azithromycin, clarithromycin
Tikosyn	dofetilide	dofetilide
Tamiflu capsules	oseltamivir phosphate	oseltamivir phosphate
Ziagen solution	abacavir sulfate	lamivudine
Kaletra solution	lopinavir/ritonavir	lopinavir/ritonavir, Prezista
Zetia	ezetimibe	ezetimibe
Azilect	rasagiline mesylate	selegiline HCl
Cafergot	ergotamine tartrate/ caffeine	ergotamine-caffeine, sumatriptan succinate

B. Changes to the Highmark Progressive Formulary and the Highmark Progressive Healthcare Reform 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 following formularies online:

Highmark Progressive Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=1176922773)
Highmark Progressive Healthcare Reform Formulary:
(https://client.formularynavigator.com/Search.aspx?siteCode=4909431197)

Table 1. Products Added

(All products added to the formulary effective date to be determined in 1Q2017 unless otherwise noted.)

Brand Name	Generic Name	Comments
Narcan nasal spray, naloxone (solution for injection)	naloxone	Indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
Epinephrine (EpiPen AG, Adrenaclick AG)**	epinephrine	Indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis.

*Naloxone solution for injection (syringes and vials) is a generic product.
**EpiPen AG and Adrenaclick AG are authorized generics.

Table 2. Products Not Added

(All products added to the formulary effective date to be determined in 1Q2017 unless otherwise noted.)

Brand Name	Generic Name	Tier*	Preferred Alternatives
Items listed below are non-preferred products			
Rubraca	rucaparib	4 - Non-preferred Specialty	Provider discretion
Synjardy XR	empagliflozin/ metformin ER	3 - Non-preferred Brand	Invokamet XR, Xigduo XR
Eucrisa	crisaborole	3 - Non-preferred Brand	hydrocortisone, triamcinolone
Arymo ER	morphine sulfate ER	3 - Non-preferred Brand	morphine sulfate ER, oxymorphone ER
Colprep Kit	sodium/magnesium/ potassium	3 - Non-preferred Brand	PEG-3350 electrolyte, Suprep
Esbriet	pirfenidone	4 - Non-preferred Specialty	Provider discretion
Rhofade	oxymetazoline	3 - Non-preferred Brand	metronidazole cream, lotion, and gel
Vantrela ER	hydrocodone bitartrate	3 - Non-preferred Brand	morphine sulfate ER, oxymorphone ER
Tirosint-SOL	levothyroxine sodium solution	3 - Non-preferred Brand	levothyroxine
Trulance	plecanatide	3 - Non-preferred Brand	polyethylene glycol, lactulose
Vyvanse Chewable	lisdexamfetamine	3 - Non-preferred Brand	dextroamphetamine ER, methylphenidate ER
ArmonAir RespiClick	fluticasone propionate	3 - Non-preferred Brand	Asmanex
AirDuo RespiClick	fluticasone propionate/ salmeterol	3 - Non-preferred Brand	Symbicort, Breo Ellipta

***Tier 1:** Preferred generic drugs. **Tier 2:** Preferred brand drugs. **Tier 3:** Non-preferred generic drugs, non-preferred brand drugs, preferred specialty drugs. **Tier 4:** Non-preferred specialty drugs.

Table 3. Products to be Removed – Effective July 1, 2017

Brand Name	Generic Name	Preferred Alternatives
Only commercial progressive products		
Epivir solution	lamivudine	lamivudine, zidovudine
Gris-peg	griseofulvin ultramicrosize	griseofulvin ultramicrosize, terbinafine HCl
All commercial & healthcare reform progressive products		
Epipen/Epipen Jr	epinephrine	Provider discretion
CitraNatal DHA	PNV no.22/iron (ferrous gluconate/folic acid/ docusate sodium /DHA	Prenaissance DHA, PNV OB+DHA
CitraNatal Rx	PNV no. 22/ Iron (carbonyl iron, ferrous gluconate) /	Vinacal, Prenatal Plus

Brand Name	Generic Name	Preferred Alternatives
	folic acid / docusate sodium	
Cleocin palmitate solution	clindamycin palmitate HCl	clindamycin palmitate HCl, azithromycin
Evista	raloxifene HCl	raloxifene HCl, tamoxifen citrate
Femara	letrozole	letrozole, anastrozole
Fer-in-sol	ferrous sulfate	Provider discretion
Grifulvin V	griseofulvin	griseofulvin, terbinafine HCl
Halflytely-bisacodyl	PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride	Peg-Prep, Gavilyte-H and bisacodyl
Hemocyte-F	ferrous fumarate/folic acid	hematinic with folic acid
ICAR-C plus	iron; carbonyl/vitamin C/vitamin B12/folic acid	Fe C
Nephrocaps	B complex w-C no.20/folic acid	Triphrocaps, Renal Caps
Neurontin solution	gabapentin	gabapentin, carbamazepine
Nilandron	nilutamide	nilutamide
Strovite Forte	multivitamin; iron; min #5; folic acid	Strovite Plus
Tamiflu capsules	oseltamivir phosphate	oseltamivir phosphate

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans in Pennsylvania and West Virginia. A list of drugs included on the Essential Formulary, listed by therapeutic class, is available at HighmarkEssentialFormulary.com.

Table 1. Formulary Updates
(All formulary changes effective date to be determined in 1Q2017 unless otherwise noted.)

Brand Name	Generic Name	Tier	Preferred Alternatives
Items listed below were added to the formulary			
Epinephrine (Epipen AG)	epinephrine	Tier 2	Indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis.
Narcan nasal spray	naloxone	Tier 3	Indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
Colprep Kit	sodium/magnesium/ potassium	Tier 3	Indicated for cleansing of the colon in preparation for a colonoscopy in adults.
Vyvanse	lisdexamfetamine	Tier 3	Indicated for the treatment of attention deficit

Brand Name	Generic Name	Tier	Preferred Alternatives
Chewable			hyperactivity disorder (ADHD) and moderate to severe binge eating disorder (BED) in adults.
Esbriet	pirfenidone	Tier 4	Indicated for the treatment of idiopathic pulmonary fibrosis (IPF).
Rubraca	rucaparib	Tier 4	Indicated as monotherapy for the treatment of patients with deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies.
Items listed below were not added to the formulary			
Synjardy XR	empagliflozin/metformin ER	NF	Invokamet XR
Eucrisa	crisaborole	NF	hydrocortisone, triamcinolone
Arymo ER	morphine sulfate ER	NF	morphine sulfate ER, oxymorphone ER
Rhofade	oxymetazoline	NF	metronidazole cream, lotion, and gel
Vantrela ER	hydrocodone bitartrate	NF	morphine sulfate ER, oxymorphone ER
Tirosint-SOL	levothyroxine sodium solution	NF	levothyroxine, liothyronine, Unithroid, Levoxyl
Trulance	plecanatide	NF	polyethylene glycol; lactulose
ArmonAir RespiClick	fluticasone propionate	NF	Flovent Diskus, Flovent HFA
AirDuo RespiClick	fluticasone propionate/ salmeterol	NF	Breo Ellipta, Dulera

Formulary options: Tier 1, Tier 2, Tier 3, Tier 4, Non-formulary (NF).

Table 2. Products to be Removed or Shifted to Higher Tier – Effective July 1, 2017

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Evzio*	naloxone	naloxone syringe/vial, Narcan nasal spray
Epzicom	abacavir sulfate/ lamivudine	abacavir sulfate/lamivudine, lamivudine/zidovudine
Nilandron	nilutamide	nilutamide
Edecrin	ethacrynic acid	ethacrynic acid, furosemide
Ziagen solution	abacavir sulfate	lamivudine
Sabril solution, tablet	vigabatrin	phenytoin
Kaletra solution	lopinavir/ritonavir	lopinavir/ritonavir, Prezista
Pristiq	desvenlafaxine succinate	venlafaxine, duloxetine
Strattera	atomoxetine HCl	guanfacine HCl ER

*Only product being shifted from Tier 3 to Tier 4. The remaining products are being removed from the formulary.

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Bonjesta (doxylamine; pyridoxine) – Healthcare Reform	TBD	New policy created to separate Healthcare Reform (Bonjesta only) from previously approved Commercial policy.
Evzio Step Therapy – Commercial and Healthcare Reform	02/10/2017	New policy created to require contraindication to or inappropriate candidate for treatment with Narcan nasal spray and generic naloxone vial/syringe. *Commercial effective date 02/10/2017: Evzio 2 mg/0.4 ml and 0.4 mg/0.4 ml* *Healthcare Reform effective date 03/20/2017: Evzio 2 mg/0.4 ml*
Topical Non-Steroid Therapy for Atopic Dermatitis – Commercial and Healthcare Reform	TBD	New policy created to require therapeutic failure, intolerance or contraindication to two topical corticosteroids to receive Protopic, Elidel, or Eucrisa. Pediatric patients or members requesting for use on the face will only require therapeutic failure, intolerance, or contraindication to one non-fluorinated topical corticosteroid. Policy already in place for Protopic and Elidel for Healthcare Reform.
Epinephrine Auto Injectors – Commercial and Healthcare Reform	TBD	New policy created to ensure appropriate utilization of cost-effective products for emergency treatment of allergic reactions including anaphylaxis.
Intra-articular hyaluronan (Medical Injectable Policy) – Commercial and Healthcare Reform	02/09/2017	Policy revised to include three new hyaluronan products (Gel-Syn, Hymovis, and Gen-Visc 850), but the criteria remains the same.
Diclegis and Bonjesta (doxylamine; pyridoxine) – Commercial	03/20/2017	Policy revised to remove Healthcare Reform line of business. Healthcare Reform coverage for Bonjesta falls under new policy.
Enbrel (etanercept) – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on European League Against Rheumatism (EULAR) 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic disease-modifying antirheumatic drugs (DMARDs).
Otezla (apremilast) – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on EULAR 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic DMARDs.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Cosentyx (secukinumab) – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on EULAR 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic DMARDs.
Cimzia (certolizumab) – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on EULAR 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic DMARDs.
Simponi (golimumab) – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on EULAR 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic DMARDs.
Stelara (ustekinumab) – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on EULAR 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic DMARDs.
Humira (adalimumab) – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on EULAR 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic DMARDs.
Erelzi (etanercept-szzs) *Biosimilar* – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on EULAR 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic DMARDs. Etanercept-szzs (Erelzi) is a biosimilar to Enbrel.
Amjevita (adalimumab-atto) *Biosimilar* – Commercial and Healthcare Reform	02/09/2017	Policy revised to allow coverage for axial disease, enthesitis and dactylitis associated with psoriatic arthritis based on EULAR 2015 updated guidelines. Following NSAID first line therapy, these conditions respond to TNF inhibitors rather than non-biologic DMARDs. Adalimumab-atto (Amjevita) is a biosimilar to Humira.
Kinase Inhibitors – Commercial, Healthcare Reform and Medicare	TBD	Policy revised to include criteria for rucaparib (Rubraca) for the treatment of BRCA mutated advanced ovarian cancer in patients treated with two or more prior lines of chemotherapy. Policy revised to include new indication for

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		ibrutinib (Imbruvica) for the treatment of marginal zone lymphoma. For commercial line of business, only included requirement of documentation of generic imatinib (intolerance or ineffectiveness) for brand Gleevec.
Idiopathic Pulmonary Fibrosis – Commercial, Healthcare Reform and Medicare	TBD	Policy revised to include new dosage form pirfenidone (Esbriet) tablets.
Kuvan (sapropterin) – Commercial and Healthcare Reform	02/09/2017	Policy revised to align with most current guidelines regarding diagnosis and continuation of therapy.
Firazyr (icatibant) – Commercial and Healthcare Reform	TBD	Policy revised to include approval criteria to authorize additional quantities for icatibant (Firazyr), which has a retail limit of three pre-filled syringes per 31 days, for acute treatment of Hereditary angioedema (HAE) attacks, since select agents are weight-based and are utilized for on-demand treatment. The policy was revised to ensure that supporting documentation includes that the patient has been evaluated for treatable trigger attacks, attestation to benefits of therapy and monitoring plan.
C1 Esterase Inhibitors – Commercial and Healthcare Reform	TBD	Policy revised to include approval criteria to authorize additional quantities for C1 esterase inhibitors for acute treatment HAE attacks, since select agents are weight-based and are utilized for on-demand treatment. Retail quantity limitations for the following at point of sale are: • Cinryze: 20 vials for injection per 30 days • Berinert: 30 vials for injection per 30 days • Ruconest: 30 vials for injection per 28 days The policy was revised to ensure that supporting documentation includes that the patient has been evaluated for treatable trigger attacks, attestation to benefits of therapy and monitoring plan.

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

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
Non-Stimulant Treatment of ADHD/ADD –	TBD	New policy created to require the step therapy of generic guanfacine ER for the Commercial and Healthcare Reform lines

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
Commercial and Healthcare Reform		of business. The separate Medicare policy criteria will remain the same.
Xeloda (capecitabine) – Commercial	TBD	New policy created to require trial and failure of generic capecitabine prior to use of Xeloda.
Branded Aromatase Inhibitors – Commercial	TBD	New policy created to require trial and failure of the generic equivalent aromatase inhibitor (anastrazole, exemestane, letrozole) prior to use of the branded formulation (Arimidex, Aromasin, Femara).
Branded Antiandrogen Therapy – Commercial	TBD	New policy created to require trial and failure of the generic equivalent antiandrogen therapy (bicalutamide, nilutamide) prior to use of the branded formulation (Casodex, Nilandron).
Tirosint-SOL (levothyroxine sodium oral solution) – Commercial and Healthcare Reform	TBD	New policy created to require trial and failure of generic levothyroxine therapy prior to use of branded liquid oral formulation (Tirosint-SOL). Additional criteria considerations are implemented to allow Tirosint-SOL coverage in patients with GI conditions such as celiac disease or gluten sensitivity, irritable bowel syndrome, lactose intolerance, or prior gastric bypass surgery.
Vanos (fluocinonide) – Commercial and Healthcare Reform	TBD	Policy revised to include Commercial plans. The policy was initially created for Healthcare Reform to ensure that fluocinonide (Vanos) is being prescribed for the treatment of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses (including psoriasis and atopic dermatitis), in patients 12 years and older. The policy requires trial and failure of at least two generic topical corticosteroids (e.g., betamethasone, clobetasol, triamcinolone, halobetasol), one of which must be fluocinonide.
Lorzone, Parafon Forte DSC (chlorzoxazone) – Commercial and Healthcare Reform	TBD	Policy revised to include Commercial plans. The policy was initially created for Healthcare Reform to ensure that chlorzoxazone (Lorzone, Parafon Forte DSC) is being prescribed as adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The policy requires trial and failure of at least two generic muscle relaxers (e.g., baclofen, carisoprodol, cyclobenzaprine, or methocarbamol), one of which must be generic chlorzoxazone.
Antiviral Therapy (Sitavig & Denavir) – Commercial and Healthcare Reform	TBD	Policy revised to include Commercial plans.The policy was initially created for Healthcare Reform to ensure that acyclovir buccal tablets (Sitavig) and penciclovir 1% cream (Denavir) are being prescribed for the treatment of recurrent herpes labialis (cold sores). The policy requires trial and failure of at least two

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria**
		formulary antiviral agents (e.g., acyclovir, valacyclovir, or famciclovir), one of which must be acyclovir.
Oleptro (trazodone ER) – Commercial and Healthcare Reform	TBD	Policy revised to include Commercial plans. The policy was initially created for Healthcare Reform to ensure that trazodone hydrochloride extended release (Oleptro ER) is being prescribed for major depressive disorder. The policy requires trial and failure or intolerance to generic immediate-release trazodone and trial and failure of at least two other generic antidepressants (e.g., sertraline, paroxetine, and other antidepressants in the SSRI, SNRI, TCA, and MAOI classes).
Atypical Antipsychotics – Commercial and Healthcare Reform	TBD	Policy revised to require therapeutic failure or intolerance to generic aripiprazole to receive brand Abilify, Rexulti and Vraylar if there is a shared indication. Policy revised to remove aripiprazole from the prior authorization policy.
Topical Rosacea Treatments – Commercial	TBD	Policy revised with the addition of oxymetazoline (Rhofade). The member must be 18 years of age or older, have a diagnosis of persistent facial erythema associated with rosacea in adults, and have experienced therapeutic failure or intolerance to generic metronidazole for the approval of Rhofade.
Extended Release Opioid Management – Commercial and Healthcare Reform	TBD	Policy revised to include two products: hydrocodone bitartrate (Vantrela ER) and morphine sulfate (Arymo ER). Quantities may be prescribed up to the limits outlined in the policy.
Combination Prescription Drug Safety – Medicare and Commercial	TBD	Policy revised to add additional opioid agonists, including codeine, codeine combinations, dihydrocodeine, fentanyl, methadone, levorphanol, hydromorphone combinations, morphine sulfate, and morphine sulfate combinations. In order to ensure that all corresponding brand names would be addressed, the policy was revised to remove all product names; only generic names will be listed.

*All effective dates are tentative and subject to delay pending internal review or approval.
**Standard prior authorization criteria will apply for members who do not meet the automatic approval criteria.

3. Quantity Level Limit (QLL) Programs*
(Effective immediately upon completion of internal review and implementation, unless otherwise noted.)

Table 1. Quantity Level Limits – Quantity per Duration for Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Arymo ER (morphine sulfate)	90 tablets/25 days	270 tablets/75 days
Esbriet (pirfenidone) 267 mg	270 tabs or caps/365 days	270 tabs or caps/365 days

Drug Name	Retail Edit Limit	Mail Edit Limit
Cinryze [C1 Esterase inhibitor (Human)]	20 vials/30 days	60 vials/90 days
Firazyr (icatibant)	9 ml (3 vials)/28 days	27 ml (9 vials)/84 days
Berinert [C1 Esterase inhibitor (Human)]	30 vials/28 days	90 vials/84 days
Ruconest [C1 Esterase inhibitor (Recombinant)]	20 vials/28 days	60 vials/84 days
ArmonAir RespiClick (fluticasone propionate)	1 inhaler/30 days	3 inhalers/90 days
AirDuo RespiClick (fluticasone propionate/salmeterol) 55/14, 113/14 mcg	1 inhaler/30 days	3 inhalers/90 days
AirDuo RespiClick (fluticasone propionate/salmeterol) 232/14 mcg	2 inhalers/30 days	6 inhalers/90 days
Farydak (panobinostat)	6 capsules/21 days	18 capsules/63 days
Cotellic (cobimetinib)	63 tablets/28 days	189 tablets/84 days
Stivarga (regorafenib)	84 tablets/28 days	252 tablets/84 days
Vantrela ER (hydrocodone)	60 tablets/25 days	180 tablets/75 days

Table 2. Quantity Level Limits – Quantity per Dispensing Event – Commercial and Healthcare Reform Plans

Drug Name	Retail Edit Limit	Mail Edit Limit
Eucrisa (crisaborole)	100 grams/31 days	300 grams/90 days
Ibrance (palbociclib)	21 capsules/28 days	63 capsules/84 days

Table 3. Maximum Daily Quantity Limits – Commercial and Healthcare Reform Plans

Drug Name	Daily Limit
Synjardy XR (empagliflozin/metformin ER)	2 tablets/day
Xeljanz XR (tofacitinib)	1 tablet/day
Esbriet (pirfenidone) 267 mg*	9 tablets/day
Esbriet (pirfenidone) 801 mg*	3 tablets/day
Trulance (plecanatide) 3 mg	1 tablet/day
Bosulif (bosutinib) 100 mg	4 tablets/day
Bosulif (bosutinib) 500 mg	1 tablet/day
Gleevec (imatinib) 100 mg	6 tablets/day
Gleevec (imatinib) 400 mg	2 tablets/day
Imbruvica (ibrutinib)	4 tablets/day
Iclusig (ponatinib)	1 tablets/day
Leukeran (chlorambucil)	5 tablets/day
Ninlaro (ixazomib)	1 capsule/day
Pomalyst (pomalidomide)	1 capsule/day

Drug Name	Daily Limit
Revlimid (lenalidomide)	1 capsule/day
Sprycel (dasatanib)	1 tablets/day
Tasigna (nilotinib)	2 capsules/day
Thalomid (thalidomide) 50, 100 mg	1 capsule/day
Thalomid (thalidomide) 150, 200 mg	2 capsules/day
Venclexta (venetoclax) 10 mg	2 tablets/day
Venclexta (venetoclax) 50, 100 mg	4 tablets/day
Zolinza (vorinostat)	4 capsules/day
Zydelig (idelalisib)	2 tablets/day
Odomzo (sonidegib)	1 capsule/day
Zelboraf (vemurafenib)	8 tablets/day
Mekinist (trametinib) 0.5 mg	3 tablets/day
Mekinist (trametinib) 2 mg	1 tablet/day
Xtandi (enzalutamide)	4 capsules/day
Zytiga (abiraterone)	4 tablets/day
Votrient (pazopanib)	4 tablets/day
Nexavar (sorafenib)	4 tablets/day
Alecensa (alectinib)	8 capsules/day
Lynparza (olaparib)	16 capsules/day
Tykerb (lapatinib)	6 tablets/day
Tafinlar (dabrafenib)	4 capsules/day
Gilotrif (afatinib)	1 tablet/day
Tarceva (erlotinib) 25 mg	3 tablets/day
Tarceva (erlotinib) 100, 150 mg	1 tablet/day
Cabometyx (cabozantinib)	1 tablet/day
Xalkori (crizotinib)	2 capsules/day
Caprelsa (vandetanib) 100 mg	2 tablets/day
Caprelsa (vandetanib) 300 mg	1 tablet/day
Cometriq (cabozantinib) 140 mg/day	4 capsules/day
Cometriq (cabozantinib) 100 mg/day	2 capsules/day
Cometriq (cabozantinib) 60 mg/day	3 capsules/day
Rubraca (rucaparib)	4 tablets/day
Sutent (sunitinib)	1 capsule/day
Afinitor (everolimus)	1 tablet/day
Inlyta (axitinib) *1 mg*	8 tablets/day
Inlyta (axitinib) *5 mg*	4 tablets/day
Lenvima (lenvatinib) 10 mg/day	1 capsule/day
Lenvima (lenvatinib) 8, 14, 20 mg/day	2 capsules/day
Lenvima (lenvatinib) *18, 24 mg/day*	3 capsules/day
Tagrisso (osimertinib)	1 tablet/day

*Quantity per Duration (QD) rule also applies to this medication (refer to Table 1).
Requests for coverage of select medications exceeding the defined quantity level limits may be submitted for clinical review. Maximum-day supply on certain medications may vary depending on member's benefit design.

SECTION II. Highmark Medicare Part D Formularies

A. Changes to the Highmark Medicare Part D 5-Tier 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 Part D Formularies online at: https://client.formularynavigator.com/Search.aspx?siteCode=9001272798

Table 1. Preferred Products*
(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Comments
Anoro Ellipta	umeclidinium/vilanterol	Indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

*Modified from tier 4 (non-preferred) to tier 3 (preferred brand) status.

Table 2. Non-Preferred Products
(Effective immediately pending Centers for Medicare and Medicaid Services (CMS) approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Synjardy XR	empagliflozin/metformin ER	Invokamet XR, Xigduo XR
Eucrisa	crisaborole	hydrocortisone, triamcinolone
Arymo ER	morphine sulfate ER	morphine sulfate ER, oxymorphone ER
Colprep Kit	sodium/magnesium/ potassium	PEG-3350 electrolyte, Suprep
Rhofade	oxymetazoline	metronidazole cream, lotion, and gel
Vantrela ER	hydrocodone bitartrate	morphine sulfate ER, oxymorphone ER
Tirosint SOL	levothyroxine sodium solution	levothyroxine, Unithroid, Levoxyl
Trulance	plecanatide	polyethylene Glycol, lactulose
Vyvanse Chewable	lisdexamfetamine	dextroamphetamine ER, methylphenidate ER
ArmonAir RespiClick	fluticasone propionate	Asmanex, Qvar
AirDuo RespiClick	fluticasone propionate/ salmeterol	Symbicort, Breo Ellipta

B. Changes to the Highmark Medicare Part D 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 Part D Formularies online at: https://client.formularynavigator.com/Search.aspx?siteCode=3589973640

Table 1. Preferred Products*

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Comments
Anoro Ellipta	umeclidinium/vilanterol	Indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

*Modified from tier 4 (non-preferred) to tier 3 (preferred brand) status.

Table 2. Non-Preferred Products

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Vyvanse Chewable	lisdexamfetamine	dextroamphetamine ER, methylphenidate ER

Table 3. Products Not Added*

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name	Preferred Alternatives
Synjardy XR	empagliflozin/metformin ER	Invokamet XR, Xigduo XR
Eucrisa	crisaborole	hydrocortisone, triamcinolone
Arymo ER	morphine sulfate ER	morphine sulfate ER, oxymorphone ER
Colprep Kit	sodium/magnesium/ potassium	PEG-3350 electrolyte, Suprep
Rhofade	oxymetazoline	metronidazole cream, lotion, and gel
Vantrela ER	hydrocodone bitartrate	morphine sulfate ER, oxymorphone ER
Tirosint-SOL	levothyroxine solution	levothyroxine, Unithroid, Levoxyl
Trulance	plecanatide	polyethylene glycol, lactulose
ArmonAir RespiClick	fluticasone propionate	Asmanex, Qvar
AirDuo RespiClick	fluticasone propionate/ salmeterol	Symbicort, Breo Ellipta

*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**.

C. Additions to the Specialty Tier

(Effective immediately pending CMS approval and upon completion of internal review and implementation.)

Brand Name	Generic Name
Rubraca	rucaparib
Spinraza	nusinersen
Esbriet	pirfenidone

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Amjevita (adalimumab-atto) *Biosimilar* – Medicare Restrictive	TBD	New policy created to align with Commercial policy to ensure appropriate use of adalimumab-atto (Amjevita), a biosimilar to adalimumab (Humira), in patients with all of the same chronic inflammatory conditions in which Humira is approved for except pediatric Crohn's disease (CD), hidradenitis suppurativa, and uveitis. Policy step therapy criteria include an adequate trial of the following products for the respective indications: • Juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), or rheumatoid arthritis (RA): An adequate trial of one least one non-biologic DMARD (e.g., methotrexate, lefluonide, etc.). • Ulcerative colitis (UC): An adequate trial of two immunosuppressants (e.g., corticosteroids, azathioprine, or 6-mercaptopurine). • CD: An adequate trial of two immunosuppressants or Remicade. • Chronic plaque psoriasis: An adequate trial of phototherapy or at least one systemic therapy (e.g., cyclosporine, methotrexate, etc.). • Ankylosing spondylitis: An adequate trial of at least one non-steroidal anti-inflammatory drug.
Erelzi (etanercept-szzs) *Biosimilar* – Medicare Restrictive	TBD	New policy created to align with Commercial policy to ensure appropriate use of Erelzi, a biosimilar to etanercept (Enbrel), in patients with all of the same chronic inflammatory conditions in which Enbrel is currently approved. Policy step therapy criteria include an adequate trial of the following products for the respective indications:

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		• Juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), or rheumatoid arthritis (RA): At least one non-biologic DMARD (e.g., methotrexate, lefluonide, etc.). • Ulcerative colitis (UC): Two immunosuppressants (e.g., corticosteroids, azathioprine, or 6-mercaptopurine). • Crohn's disease (CD): Two immunosuppressants or Remicade. • Chronic plaque psoriasis: Phototherapy or at least one systemic therapy (e.g., cyclosporine, methotrexate, etc.) • Ankylosing spondylitis: At least one non-steroidal anti-inflammatory drug.
Spinraza (nusinersen) – Medicare	TBD	New policy created to ensure appropriate utilization based on FDA-approved label for spinal muscle atrophy (SMA) caused by mutations in chromosome 5q.
Zinplava (bezlotoxumab) – Medicare	03/01/2017	New policy created to ensure the member is using bezlotoxumab (Zinplava) for the prevention of *Clostridium difficile* (*C. diff*) recurrence with standard of care antibacterial drugs such as metronidazole, vancomycin, or fidaxomycin. The policy also ensures that the member is 18 years of age or older and is defined as high risk for *C. diff* infections.
Inflectra (infliximab-dyyb) – Medicare	TBD	New policy created for Inflectra, the biosimilar to Remicade. Policy criteria created to match the current policy for Remicade.
Darzalex (daratumumab) – Medicare	02/09/2017	Policy revised to include new FDA indication of use in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.
Kinase Inhibitors – Commercial, Healthcare Reform and Medicare	TBD	Policy revised to include criteria for rucaparib (Rubraca) for the treatment of BRCA mutated advanced ovarian cancer in patients treated with two or more prior lines of chemotherapy. Policy revised to include new indication for ibrutinib (Imbruvica) for the treatment of marginal zone lymphoma. For commercial line of business, only included requirement of documentation of generic imatinib (intolerance or ineffectiveness) for brand Gleevec.
Idiopathic Pulmonary Fibrosis – Commercial, Healthcare Reform and Medicare	TBD	Policy revised to include new dosage for pirfenidone (Esbriet) tablets.

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Programmed Death Receptor Therapies – Medicare	02/09/2017	Policy revised to include expanded indication for nivolumab (Opdivo), treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
Exondys 51 (eteplirsen) – Medicare	03/01/2017	Policy revised to add more specific criteria for appropriate use of eteplirsen (Exondys 51). Criteria include use for Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene amenable to exon 51 skipping. Member should be a pediatric patient less than 18 years of age with documented use of stable doses of oral corticosteroids for at least 6 months prior to initiating therapy. Member should be ambulatory (with or without assistance), not wheelchair dependent, and the medication should be prescribed by or in consultation with a physician who specializes in treatment of muscular dystrophy (e.g., neurologist).
Firazyr (icatibant) – Medicare	TBD	Policy revised to include approval criteria to authorize additional quantities for icatibant (Firazyr), which has a retail limit of three pre-filled syringes per 31 days, for acute treatment of hereditary angioedema (HAE) attacks, since select agents are weight-based and are utilized for on-demand treatment. The policy was revised to ensure that supporting documentation includes that the patient has been evaluated for treatable trigger attacks, attestation to benefits of therapy and monitoring plan.
C1 Esterase Inhibitors – Medicare	TBD	Policy revised to include approval criteria to authorize additional quantities for C1 esterase inhibitors for acute treatment HAE attacks, since select agents are weight-based and are utilized for on-demand treatment. Retail quantity limitations for the following at point of sale are: • Cinryze: 20 vials for injection per 30 days • Berinert: 30 vials for injection per 30 days • Ruconest: 30 vials for injection per 28 days The policy was revised to ensure that supporting documentation includes that the patient has been evaluated for treatable trigger attacks, attestation to benefits of therapy and monitoring plan.

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

2. Managed Prescription Drug Coverage (MRxC) Program

Policy Name	Policy Effective Date*	Updates and Automatic Approval Criteria
Non-Stimulant Treatment of ADHD/ADD – Medicare	TBD	Policy revised to remove Commercial and Healthcare Reform. New policy created for those lines of business.
Extended Release Opioid Management – Medicare	TBD	Policy revised to include two products: hydrocodone bitartrate (Vantrela ER) and morphine sulfate (Arymo ER). Quantities may be prescribed up to the limits outlined in the policy.
Combination Prescription Drug Safety – Medicare and Commercial	TBD	Policy revised to add additional opioid agonists, including codeine, codeine combinations, dihydrocodeine, fentanyl, methadone, levorphanol, hydromorphone combinations, morphine sulfate and morphine sulfate combinations. In order to ensure that all corresponding brand names would be addressed, the policy was revised to remove all product names; only generic names will be listed.

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

3. Quantity Level Limit (QLL) Program*

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Synjardy XR (empagliflozin/metformin ER)	62 tablets/31 days	180 tablets/90 days
Eucrisa (crisaborole)	100 grams/31 days	300 grams/90 days
Vantrela ER (hydrocodone)**	62 tablets/25 days	186 tablets/75 days
Esbriet (pirfenidone) 267 mg	279 tablets/31 days	837 tablets /93 days
Esbriet (pirfenidone) 801 mg	93 tablets /31 days	279 tablets/93 days
Trulance (plecanatide)	31 tablets/31 days	90 tablets/90 days
Cinryze [C1 Esterase inhibitor (Human)]	20 vials/31days	60 vials/90 days
Firazyr (icatibant)	3 syringes/31 days	9 syringes/90 days
Berinert [C1 Esterase inhibitor (Human)]	30 vials/31 days	90 vials/90 days
Ruconest [C1 Esterase inhibitor (Recombinant)]	20 vials/31 days	60 vials/90 days
ArmonAir RespiClick (fluticasone propionate)	1 inhaler/30 days	3 inhalers/90 days
AirDuo RespiClick (fluticasone propionate/salmeterol) 55/14, 113/14 mcg	1 inhaler/30 days	3 inhalers/90 days
AirDuo Respiclick (fluticasone propionate/salmeterol) 232/14 mcg	2 inhalers/30 days	6 inhalers/90 days
bupropion HCl SR *150 mg*¥	62 tablets/31 days	124 tablets/93 days
Mytesi (crofelemer)¥	62 tablets/31 days	124 tablets/93 days
Lorcet (hydrocodone bitartrate and acetaminophen) *10-325 mg*¥	372 tablets/31 days	1116 tablets/93 days

Drug Name	Retail Quantity Limit	Mail Order Quantity Limit
Levalbuterol tartrate HFA**¥**	30 grams/30 days	90 grams/90 days
Adlyxin (lixisenatide)****¥**	6 mL/28 days	12 mL/84 days
Orkambi (lumacaftor/ivacaftor) *100-125 mg***¥**	124 tablets/31 days	372 tablets/93 days
Relistor (methylnaltrexone) *150 mg***¥**	93 tablets/31 days	279 tablets/93 days
Methylphenidate ER *20 mg***¥**	93 capsules/31 days	279 capsules/93 days
Methylphenidate ER *40 mg***¥**	62 capsules/31 days	186 capsules/93 days
Ocaliva (obeticholic acid)**¥**	31 tablets/31 days	93 tablets/93 days
Olmesartan *20 mg, 40 mg***¥**	31 tablets/31 days	93 tablets/93 days
Olmesartan *5 mg***¥**	93 tablets/31 days	279 tablets/93 days
Olmesartan/Hydrochlorthiazide *20-12.5, 40-25, 40-12.5 mg***¥**	31 tablets/31 days	93 tablets/93 days
Treximet (sumatriptan/naproxen) *10-60 mg***¥**	9 tablets/31 days	27 tablets/93 days
Epclusa (sofosbuvir/velpatasvir)**¥**	28 tablets/28 days	93 tablets/93 days
Sumatriptan succinate**¥**	6 mL/31 days	18 mL/93 days
Stelara (ustekinumab)**¥**	104 mL/180 days	104 mL/180 days
Bevespi aerosphere (glycopyrrolate/ formoterol)**¥**	10.7 mL/30 days	32.1 mL/90 days

*Requests for coverage exceeding the defined quantity level limits can be submitted for clinical review.
**Limits only applicable to Medicare Incentive Formulary.
¥ Effective date of 3/01/17.

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