Formulary Updates

Published September 2, 2021

The formularies and pharmaceutical management procedures are updated on a bimonthly basis, and the following changes reflect the decisions made in **April 2021** 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:

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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 Program/Formularies** link from the menu on the left.

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Important Drug Safety Updates

Telmisartan Tablets, USP, 20 mg by Alembic Pharmaceuticals Limited: Recall – Label Mix-Up

On March 24th, 2021, Alembic Pharmaceuticals recalled the above product. The affected product was recalled due to a packaging error that resulted in a bottle labeled as Telmisartan 20 mg Tablets containing 40 mg Telmisartan Tablets.

Patients who could be on a doubled dose of telmisartan for a prolonged period could experience low blood pressure, worsening of kidney function, or an elevation of potassium which can be life-threatening. To date, Alembic Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

Guanfacine Extended-Release 2 mg Tablets by Apotex Corp: Recall – Trace Amounts of Quetiapine Fumarate

On March 31st, 2021, Apotex Corp recalled the above product. The affected product was recalled due to the detection of trace amounts of Quetiapine Fumarate in one lot.

Administration of Guanfacine Extended-Release Tablets containing trace amounts of Quetiapine Fumarate to a patient can result in the possibility of hypersensitivity reaction and may potentially have additive effects in lowering blood pressure, sleepiness/sedation, and dizziness. Pediatric patients, pregnant patients, and older adults may be more likely to experience low blood pressure and dizziness if exposed to the defective product. To date, Apotex Corp has not received any reports of adverse events related to this recall.

NP Thyroid 15 mg, 30 mg, 60 mg, 90 mg, 120 mg Tablets by Acella: Recall – Subpotency

On April 30th, 2021, Acella recalled the above products. The affected products were recalled because routine testing found certain lots to be sub potent.

Patients being treated for hypothyroidism (underactive thyroid), who receive sub potent NP Thyroid®, may experience signs and symptoms of hypothyroidism (underactive thyroid) which may include: fatigue, increased sensitivity to cold, constipation, dry skin, puffy face, hair loss, slow heart rate, depression, swelling of the thyroid gland, and/or unexplained weight gain or difficulty losing weight.

There is reasonable risk of serious injury in newborn infants or pregnant women with hypothyroidism including early miscarriage, fetal hyperthyroidism, and/or impairments to fetal neural and skeletal development.

In elderly patients and patients with underlying cardiac disease toxic cardiac manifestations of hyperthyroidism may occur, such as cardiac pain, palpitations or cardiac arrhythmia.

To date, Acella has received 43 reports of serious adverse events that could possibly be related to this recall.

Highmark Formulary Update – April 2021

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. 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
- Highmark Comprehensive Healthcare Reform Formulary

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 medication protocols and improve the overall health of our members.

Table 1. Products Added

All products added to the formulary effective May 2021, unless otherwise noted.

Brand Name	Generic Name	Comments
Plegridy prefilled syringe	peginterferon beta-1a intramuscular injection	Multiple Sclerosis
Edurant	rilpivirine	HIV-1 Infection
Vocabria*	cabotegravir	HIV-1 Infection

Coverage may be contingent upon plan benefits.

Table 2. Products Not Added**

Brand Name	Generic Name	Preferred Alternatives
Azstarys*	serdexmethylphenidate/dexmethylphenidate	methylphenidate er tablet, extended release 24 hr, dextroamphetamine-amphetamine
Lupkynis	voclosporin	Benlysta auto-injector (mL); Benlysta syringe (mL)
Verquvo	vericiguat	Entresto, spironolactone tablet
Tepmetko	tepotinib	Provider Discretion
Ukoniq	umbralisib	Provider Discretion

Coverage may be contingent upon plan benefits.

*Effective date to be determined.

**Physicians may request coverage of these products using the Request for Non-Formulary Drug Coverage Form.

Table 3. Additions to the Specialty Tier Copay Option

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

These changes are effective upon completion of internal review and implementation unless otherwise noted.

Brand Name	Generic Name
Plegridy prefilled syringe	peginterferon beta-1a intramuscular injection
Lupkynis	voclosporin
Tepmetko	tepotinib
Ukoniq	umbralisib

Table 4. Products to Be Removed or Shifted to Higher Tier— Effective July 2021

Brand name	Generic Name	Preferred Alternatives
Only Commercial Comprehensive products		
Apokyn	apomorphine hcl	Provider discretion
Contrave ER	naltrexone hcl/bupropion hcl	Provider discretion
Dipentum	olsalazine sodium	mesalamine ER
All commercial & healthcare reform comprehensive products		
Pentasa 250 mg	mesalamine	mesalamine ER
Pentasa 500 mg	mesalamine	mesalamine ER
Precision pcx	blood sugar diagnostic	Precision Xtra, One Touch Ultra test strips
Precision pcx plus	blood sugar diagnostic	Precision Xtra, One Touch Ultra test strips
Precision point of care	blood sugar diagnostic	Precision Xtra, One Touch Ultra test strips
Precision q-i-d	blood sugar diagnostic	Precision Xtra, One Touch Ultra test strips
Symfi	efavirenz/lamivu/tenofov disop	efavirenz-lamivu-tenofov disop

Brand name	Generic Name	Preferred Alternatives
Symfi Lo	efavirenz/lamivu/tenofov disop	efavirenz-lamivu-tenofov disop
Tecfidera 120 mg capsule	dimethyl fumarate	dimethyl fumarate
Tecfidera 240 mg capsule	dimethyl fumarate	dimethyl fumarate
Tecfidera starter pack	dimethyl fumarate	dimethyl fumarate
Timoptic 0.5.%	timolol maleate	timolol maleate
Timoptic 0.25.%	timolol maleate	timolol maleate
Truvada 100-150 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 133-200 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 167-250 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop

B. Changes to the Highmark Healthcare Reform 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 Program/Formularies** 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 Healthcare Reform Progressive Formulary

Table 1. Formulary Updates

All products added to the formulary effective May 2021, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below are preferred products			
Vocabria*	cabotegravir	2 - Preferred Brand	HIV-1 Infection
Plegridy prefilled syringe	peginterferon beta-1a	3 - Preferred Specialty	Multiple Sclerosis
Items listed below are non-preferred products			
Verquvo	vericiguat	3 - Nonpreferred Brand	spironolactone tablet
Azstarys*	serdexmethylphenidate/dexmethylphenidate	3 - Nonpreferred Brand	Methylphenidate ER Tablet, Extended Release 24 HR, Dextroamphetamine-Amphetamine
Lupkynis	voclosporin	4 - Nonpreferred Specialty	Benlysta auto-injector (mL); Benlysta syringe (mL)
Tepmetko	tepotinib	4 - Nonpreferred Specialty	Provider Discretion
Ukoniq	umbralisib	4 - Nonpreferred Specialty	Provider Discretion

Coverage may be contingent upon plan benefits.

*Effective date to be determined.

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 2. Products to Be Removed or Shifted to Higher Tier – Effective July 2021

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Progressive products		
levorphanol tartrate	levorphanol tartrate	morphine sulfate
Precision pcx	Blood sugar diagnostic	Precision Xtra, One Touch Ultra test strips
Precision pcx plus	Blood sugar diagnostic	Precision Xtra, One Touch Ultra test strips
Precision point of care	Blood sugar diagnostic	Precision Xtra, One Touch Ultra test strips
Precision q-i-d	Blood sugar diagnostic	Precision Xtra, One Touch Ultra test strips
Symfi	efavirenz/lamivu/tenofov disop	efavirenz-lamivu-tenofov disop
Symfi Lo	efavirenz/lamivu/tenofov disop	efavirenz-lamivu-tenofov disop
Tecfidera 120 mg	dimethyl fumarate	dimethyl fumarate
Tecfidera 240 mg	dimethyl fumarate	dimethyl fumarate
Tecfidera starter pack	dimethyl fumarate	dimethyl fumarate
Truvada 100-150 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 133-200 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 167-250 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop

C. Changes to the Highmark Healthcare Reform Essential Formulary

The Essential Formulary is a closed formulary for select Healthcare Reform (HCR) Individual plans. A list of drugs included on the Essential Formulary, listed by therapeutic class, is here.

Table 1. Formulary Updates

All formulary changes effective May 2021, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Edurant	rilpivirine	3	HIV-1 Infection

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Vocabria*	cabotegravir	3	HIV-1 Infection
Items listed below were not added to the formulary			
Azstarys*	serdexmethylphenidate/dexmethylphenidate	NF	Methylphenidate ER tablet, Extended Release 24 HR,dextroamphetamine-amphetamine
Lupkynis	voclosporin	NF	Benlysta auto-injector (mL); Benlysta syringe (mL)
Plegridy prefilled syringe	peginterferon beta-1a intramuscular injection	NF	dimethyl fumarate capsule, delayed release (enteric coated)
Ukoniq	umbralisib	NF	Imbruvica Capsule, Zydelig
Verquvo	vericiguat	NF	Entresto, spironolactone tablet, eplerenone
Tepmetko	tepotinib	NF	Provider Discretion

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

*Effective date to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective July 2021

Brand Name	Generic Name	Preferred Alternatives
All Healthcare Reform Essential Products		
Alinia	nitazoxanide	nitazoxanide
Azopt	brinzolamide	brinzolamide
Banzel suspension	rufinamide	rufinamide
Bethkis	tobramycin	tobramycin sulfate
Kerydin	tavaborole	tavaborole
Monurol	fosfomycin tromethamine	fosfomycin tromethamine
Northera 100 mg	droxidopa	droxidopa
Northera 200 mg	droxidopa	droxidopa
Northera 300 mg	droxidopa	droxidopa
Saphris 10 mg	asenapine maleate	asenapine maleate
Saphris 2.5 mg	asenapine maleate	asenapine maleate
Saphris 5 mg	asenapine maleate	asenapine maleate
Sklice	ivermectin	ivermectin
Symfi	efavirenz/lamivu/tenofov disop	efavirenz-lamivu-tenofov disop
Symfi Lo	efavirenz/lamivu/tenofov disop	efavirenz-lamivu-tenofov disop
Truvada 100-150 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 133-200 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 167-250 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop

D. Changes to the Highmark Core Formulary

The Core Formulary is a closed formulary for select Commercial Individual plans. A list of drugs included on the Core Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates
All formulary changes effective May 2021, unless otherwise noted.

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary			
Edurant	rilpivirine	3	HIV-1 Infection
Vocabria*	cabotegravir	3	HIV-1 Infection
Plegridy prefilled syringe	peginterferon beta-1a intramuscular injection	4	Multiple Sclerosis
Items listed below were not added to the formulary			
Azstarys*	serdexmethylphenidate/dexmethylphenidate	NF	dextroamphetamine-amphet ER, methylphenidate HCL tablet
Lupkynis	voclosporin	NF	Benlysta auto-injector (mL); Benlysta syringe (mL)
Ukoniq	umbralisib	NF	Copiktra, Imbruvica Capsule, Zydelig
Verquvo	vericiguat	NF	Entresto, spironolactone tablet, eplerenone
Tepmetko	tepotinib	NF	Provider Discretion

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

*Effective date to be determined.

Table 2. Products to Be Removed or Shifted to Higher Tier – Effective July 2021

Brand Name	Generic Name	Preferred Alternatives
All Core Products		
Alinia	nitazoxanide	nitazoxanide
Colchicine capsule	colchicine	colchicine tablet
Contrave ER	naltrexone hcl/bupropion hcl	Provider discretion
Imbruvica 140 mg tablet	ibrutinib	Imbruvica 140 mg capsule
Imbruvica 280 mg tablet	ibrutinib	Imbruvica 140 mg capsule
Jynarque 15 mg tablet	tolvaptan	Jynarque tablet, Sequential
Jynarque 30 mg tablet	tolvaptan	Jynarque tablet, Sequential
Levorphanol tartrate	levorphanol tartrate	morphine sulfate
Mesalamine 800 mg DR tablet	mesalamine	mesalamine ER
Northera 100 mg	droxidopa	droxidopa
Northera 200 mg	droxidopa	droxidopa
Northera 300 mg	droxidopa	droxidopa

Sklice	ivermectin	ivermectin
Symfi	efavirenz/lamivu/tenofov disop	efavirenz-lamivu-tenofov disop
Symfi Lo	efavirenz/lamivu/tenofov disop	efavirenz-lamivu-tenofov disop
Tecfidera 120 mg	dimethyl fumarate	dimethyl fumarate
Tecfidera 240 mg	dimethyl fumarate	dimethyl fumarate
Tecfidera starter pack	dimethyl fumarate	dimethyl fumarate
Truvada 100-150 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 133-200 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 167-250 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop

E. Changes to the Highmark National Select Formulary

The National Select Formulary is an incentive formulary with a non-formulary drug list to manage products in therapeutic categories for which preferred alternatives are available. The National Select Formulary is available for select Commercial self-funded (ASO) plans. A list of drugs included on the National Select Formulary, listed by therapeutic class, is available here.

Table 1. Formulary Updates

Brand Name	Generic Name	Tier	Comments/Preferred Alternatives
Items listed below were added to the formulary (preferred)			
Plegridy prefilled syringe	peginterferon beta-1a intramuscular injection	2	Multiple Sclerosis
Verquvo	vericiguat	2	Heart failure
Items listed below were added to the formulary (non-preferred)			
Vocabria*	cabotegravir	3	Provider Discretion
Azstarys*	serdexmethylphenidate/dexmethylphenidate	3	methylphenidate ER 24 HR,dextroamphetamine-amphetamine
Ukoniq	umbralisib	3	Provider Discretion
Items listed below were not added to the formulary			
Lupkynis	voclosporin	NF	mycophenolate, prednisone
Tepmetko	tepotinib	NF	Tabrecta

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

*Effective date and final formulary position to be determined.

Table 2. Additions to the Specialty Tier Copay Option

Effective upon completion of internal review and implementation unless otherwise noted.

Brand Name	Generic Name
Plegridy prefilled syringe	peginterferon beta-1a intramuscular injection
Lupkynis	voclosporin
Tepmetko	tepotinib
Ukoniq	umbralisib

Table 3. Products to Be Removed or Shifted to Higher Tier – Effective April 2021

Brand Name	Generic Name	Preferred Alternatives
All National Select Products		
Afrezza	insulin regular, human	Novolog, Fiasp
Annovera	segesterone ac/ethin estradiol	Eluryng, etonogestrel-ethinyl estradio
Balcoltra	levonorgest/eth.estradiol/ iron	Levonorgestrel-eth estradiol, aviane
Bystolic	nebivolol hcl	Atenolol, carvedilol
Clenpiq	sod picosulf/mag ox/citric ac	Peg 3350-electrolyte, peg3350-sod sul-nacl-kcl-asb-c
Drysol	aluminum chloride	Certain dri otc, bromi-lotion otc
Edarbi	azilsartan medoxomil	Losartan potassium, irbesartan
Edarbyclor	azilsartan med/chlorthalidone	Losartan-hydrochlorothiazide, irbesartan-hydrochlorothiazide
Golytely	peg3350/sod sulf,bicarb,cl/kcl	Peg 3350-electrolyte, peg3350-sod sul-nacl-kcl-asb-c
Lo loestrin fe	norethindrone-e.estradiol-iron	Junel fe, larin fe
Natazia	estradiol valerate/dienogest	Drospirenone-ethinyl estradiol, norgestimate-ethinyl estradiol
Osphena	ospemifene	Estradiol
Pexeva	paroxetine mesylate	Paroxetine hcl, sertraline hcl
Plenvu	peg3350/sod sul/nacl/kcl/asb/c	Peg 3350-electrolyte, peg3350-sod sul-nacl-kcl-asb-c
Premarin	estrogens, conjugated	Estradiol
Premphase	estrogen,con/m-progest acet	Amabelz, fyavolv
Prempro	estrogen,con/m-progest acet	Amabelz, fyavolv
Slynd	drospirenone	Norethindrone acetate, camila
Suprep	sodium, potassium,mag sulfates	Peg 3350-electrolyte, peg3350-sod sul-nacl-kcl-asb-c

Taytulla	norethindrone-e.estradiol-iron	Gemmily, norethin-eth estra ferrous fum
Viibryd	vilazodone hcl	Citalopram hbr, sertraline hcl

Table 3.1 Products to Be Removed or Shifted to Higher Tier – Effective July 2021

Brand Name	Generic Name	Preferred Alternatives
All National Select Products		
Apokyn	apomorphine HCL	kynmobi
Besivance	besifloxacin HCL	ciprofloxacin hcl, ofloxacin
Betimol 0.25%	timolol	Alphagan P, Combigan
Betimol 0.5%	timolol	Alphagan P, Combigan
Bijuva	estradiol/progesterone	amabelz, fyavolv
Bromsite	bromfenac sodium	bromfenac sodium, diclofenac sodium
Canasa	mesalamine	mesalamine
Colcrys	colchicine	colchicine
Corlanor 5 mg	ivabradine HCL	carvedilol, metoprolol succinate
Corlanor 7.5 mg	ivabradine HCL	carvedilol, metoprolol succinate
Corlanor 5 mg/5 ml oral soln	ivabradine HCL	carvedilol, metoprolol succinate
Cosopt pf	dorzolamide/timolol/pf	dorzolamide-timolol
Daliresp 250 mg	roflumilast	Asmanex, Flovent HFA
Daliresp 500 mg	roflumilast	Asmanex, Flovent HFA
Divigel 0.25 mg	estradiol	estradiol
Divigel 0.5 mg	estradiol	estradiol
Divigel 0.75 mg	estradiol	estradiol
Divigel 1 mg	estradiol	estradiol
Divigel 1.25 mg	estradiol	estradiol
Envarsus xr 1 mg	tacrolimus	tacrolimus
Envarsus xr 4 mg	tacrolimus	tacrolimus
Envarsus xr 0.75 mg	tacrolimus	tacrolimus
Estring	estradiol	Premarin cream, estradiol
Evamist	estradiol	estradiol
Flarex	fluorometholone acetate	Inveltys, prednisolone acetate
Imvexxy 4 mcg	estradiol	Premarin cream, estradiol
Imvexxy 10 mcg	estradiol	Premarin cream, estradiol
Menest 0.3mg	estrogens, esterified	estradiol
Menest 0.625 mg	estrogens, esterified	estradiol
Menest 1.25 mg	estrogens, esterified	estradiol
Menest 2.5 mg	estrogens, esterified	estradiol
Northera 100 mg	droxidopa	droxidopa
Northera 200 mg	droxidopa	droxidopa
Northera 300 mg	droxidopa	droxidopa

Novoseven rt 1 mg	coagulation factor viia, recomb	Sevenfact
Novoseven rt 2 mg	coagulation factor viia, recomb	Sevenfact
Novoseven rt 5 mg	coagulation factor viia, recomb	Sevenfact
Novoseven rt 8 mg	coagulation factor viia, recomb	Sevenfact
Pliaglis	lidocaine/tetracaine	lidocaine-prilocaine
Pulmicort 90 mcg flexhaler	budesonide	Asmanex, Flovent HFA
Pulmicort 180 mcg flexhaler	budesonide	Asmanex, Flovent HFA
Qnasl 40 mcg	beclomethasone dipropionate	fluticasone propionate, flunisolide
Qnasl 80 mcg	beclomethasone dipropionate	fluticasone propionate, flunisolide
Rhopressa	netarsudil mesylate	latanoprost, timolol maleate
Rocklatan	netarsudil mesylat/latanoprost	latanoprost, timolol maleate
Saphris 2.5 mg	asenapine maleate	asenapine maleate
Saphris 5 mg	asenapine maleate	asenapine maleate
Saphris 10 mg	asenapine maleate	asenapine maleate
Suboxone 2 mg-0.5 mg	buprenorphine hcl/naloxone HCL	buprenorphine-naloxone
Suboxone 4 mg-1 mg	buprenorphine hcl/naloxone HCL	buprenorphine-naloxone
Suboxone 8 mg-2 mg	buprenorphine hcl/naloxone HCL	buprenorphine-naloxone
Suboxone 12 mg-3 mg	buprenorphine hcl/naloxone HCL	buprenorphine-naloxone
Tirosint 13mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 25 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 50 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 75 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 88 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 100 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 112 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 125 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 137 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 150 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 175 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint 200 mcg	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 13 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox

Tirosint-sol 25 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 50 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 75 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 88 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 100 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 112 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 125 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 137 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 150 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 175 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tirosint-sol 200 mcg/ml	levothyroxine sodium	levothyroxine sodium, euthyrox
Tobradex st	tobramycin/dexamethasone	Tobradex ointment, tobramycin-dexamethasone
Truvada 100-150 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 133-200 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 167-250 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Truvada 200-300 mg	emtricitabine/tenofovir (tdf)	emtricitabine-tenofovir disop
Welchol	colesevelam hcl	colesevelam hcl
Zylet	tobramycin/lotepred etab	Tobradex Ointment, tobramycin-dexamethasone
Zytiga 500 mg	abiraterone acetate	abiraterone acetate

F. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors - Commercial and Healthcare Reform	4/14/2021	Policy revised for heterozygous familial hypercholesterolemia (HeFH) that untreated low-density lipoprotein cholesterol (LDL-C) level is > 190 mg/dL or ≥ 160 mg/dL before age 20 to meet along with physical signs.
ALK-Targeting Kinase Inhibitors - Commercial and Healthcare Reform	4/14/2021	Policy revised for Xalkori (crizotinib) for use in pediatric patients 1 year of age to 21 years of age with relapsed or refractory, systemic anaplastic large cell lymphoma that is ALK-positive. Policy revised for Lorbrena (lorlatinib) for use in metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
Anabolic Steroids - Commercial and Healthcare Reform	5/3/2021	Policy revised for anabolic steroids to add reauthorization criteria attesting positive clinical response to therapy and member requires additional therapy with an anabolic steroid product.
Anti-Angiogenesis and VEGF Kinase Inhibitors - Commercial and Healthcare Reform	4/15/2021	Policy revised for Cabometyx (cabozantinib) for use in members with a diagnosis of advanced renal cell carcinoma, as first-line treatment in combination with nivolumab.
BCR-ABL Kinase Inhibitors - Commercial and Healthcare Reform	4/15/2021	Policy revised for Bosulif (bosutinib) to add criteria for approval in members 18 years of age or older. Policy revised for Iclusig (ponatinib) for use in members 18 years of age or older in chronic myeloid leukemia (CML) and acute lymphoblastic leukemia; and to update criteria for when the member has T3151+ CML in the chronic phase (CP), accelerated phase (AP), or blast phase (BP); when the member has a diagnosis of CP CML and has experienced resistance or intolerance to at least two prior kinase inhibitors; and when the member has a diagnosis of AP or BP CML when no other kinase inhibitor is indicated for the member.
Bynfezia (octreotide acetate) - Commercial and Healthcare Reform	4/15/2021	Policy revised for Bynfezia (octreotide acetate) to require high pretreatment insulin like growth factor-I (IGF-1) based on laboratory reference range if used for acromegaly and that the member has tried and failed or cannot be treated with surgical resection or pituitary irradiation and bromocriptine mesylate. Reauthorization criteria for acromegaly include decreased or normalized IGF-1 from baseline.
CDK Inhibitors - Commercial and Healthcare Reform	4/16/2021	Policy revised to add age limitation for Kisqali (ribociclib) and Kisqali Femara Co-Pack (ribociclib, letrozole) for 18 years of age and older; to clarify age limitation of 18 years and older for Ibrance (palbociclib) and Verzenio (abemaciclib); for Ibrance (palbociclib), to clarify that Ibrance (palbociclib) is used as initial endocrine-based therapy or following

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		endocrine-based therapy; to clarify that Kisqali (ribociclib) is used as initial endocrine-based therapy or following disease progression on endocrine-based therapy; and to clarify that Verzenio (abemaciclib) is used as initial endocrine-based therapy.
Chronic Inflammatory Diseases - Commercial and Healthcare Reform	TBD	Policy revised for Actemra (tocilizumab) for new indication of systemic sclerosis-asssociated interstitial lung disease (SSc-ILD) to require member to be 18 years of age or older, a diagnosis of SSc-ILD, and therapeutic failure or intolerance to at least 1 immunosuppressant or all immunosuppressants are contraindicated. Maintenance therapy quantity limit (QL) for Actemra (tocilizumab) in SSc-ILD added for 4 prefilled syringes every 4 weeks. Policy revised for Humira (adalimumab) for ulcerative colitis (UC) for the member to be 5 years of age or older. Pediatric UC induction QL (44 pounds (lbs)-88lbs): 4 prefilled syringes within the first 4 weeks of therapy; (≥88lbs): 8 prefilled syringes within the first 4 weeks of therapy or 1 starter package kit. Pediatric UC maintenance dosing QL (44lbs-88lbs): 2 prefilled syringes every 4 weeks or 4 prefilled syringes (20mg) every 4 weeks; (≥88lbs): 4 prefilled syringes every 4 weeks.
Chronic Inflammatory Diseases - Commercial National Select Formulary	4/16/2021	Policy revised for Actemra (tocilizumab) for new indication of systemic sclerosis-asssociated interstitial lung disease (SSc-ILD) to require member to be 18 years of age or older, a diagnosis of SSc-ILD, and therapeutic failure or intolerance to at least 1 immunosuppressant or all immunosuppressants are contraindicated. Maintenance therapy quantity limit (QL) for Actemra (tocilizumab) in SSc-ILD added for 4 prefilled syringes every 4 weeks. Policy revised for Cosentyx (secukinumab) in psoriatic arthritis to require therapeutic failure or intolerance to at least 3 step 1 different products from 2 or more classes; and in plaque psoriasis to require member to experience therapeutic failure or intolerance to at least 4 step 1 different

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		products from 3 or more classes. Policy revised for Humira (adalimumab) for ulcerative colitis (UC) for the member to be 5 years of age or older. Pediatric UC induction QL (44 pounds (lbs)-88lbs): 4 prefilled syringes within the first 4 weeks of therapy; (≥88lbs): 8 prefilled syringes within the first 4 weeks of therapy or 1 starter package kit. Pediatric UC maintenance dosing QL (44lbs-88lbs): 2 prefilled syringes every 4 weeks or 4 prefilled syringes (20mg) every 4 weeks; (≥88lbs): 4 prefilled syringes every 4 weeks.
Clotting Factor Products - Commercial and Healthcare Reform	4/19/2021	Policy revised that step therapy is for new starts (no prior therapy considered as initiation) to non-preferred factor products. For all products except Hemlibra (emicizumab-kxwh), allow for members who have received previous clotting factor product(s) (history of previous therapy considered maintenance) to not require diagnosis if member is tolerating therapy and experienced therapeutic response defined as one (1) of the following: disease stability, disease improvement, or delayed disease progression. Hemlibra (emicizumab-kxwh) reauthorization changed to member is tolerating therapy and experienced therapeutic response defined as one (1) of the following: disease stability, disease improvement, or delayed disease progression.
Cystic Fibrosis Inhaled Medications - Commercial and Healthcare Reform	4/19/2021	Policy revised for Bethkis (tobramycin inhalation solution), Cayston (aztreonam inhalation solution), Kitabis Pak (tobramycin inhalation solution), Tobi (tobramycin inhalation solution), Tobi Podhaler (tobramycin inhalation solution), and tobramycin inhalation solution reauthorization criteria to require a decrease in sputum density of Pseudomonas aeruginosa, or an increase in forced expiratory volume in 1 second (FEV1), or a decrease in the number of hospitalizations or exacerbations. Policy revised for Pulmozyme (dornase alfa) reauthorization criteria to require an increase in

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		FEV1, or a decrease in the number of hospitalizations or exacerbations.
Cystic Fibrosis Inhaled Medications - Commercial National Select	4/19/2021	Policy revised for Bethkis (tobramycin inhalation solution) initial authorization to require a step through generic tobramycin inhalation solution. Policy revised for Bethkis, Cayston (aztreonam inhalation solution), Kitabis Pak (tobramycin inhalation solution), Tobi (tobramycin inhalation solution), Tobi Podhaler (tobramycin inhalation solution), and tobramycin inhalation solution reauthorization criteria to require a decrease in sputum density of Pseudomonas aeruginosa, or an increase in forced expiratory volume in 1 second (FEV1), or a decrease in the number of hospitalizations or exacerbations. Policy revised for Pulmozyme (dornase alfa) reauthorization criteria to require an increase in FEV1, or a decrease in the number of hospitalizations or exacerbations.
Daraprim (pyrimethamine) - Commercial and Healthcare Reform	4/20/2021	Policy revised for Daraprim (pyrimethamine) to combine Commercial and HCR LOBs. Acute Toxoplasmosis gondii infection criteria revised to require member to step through generic pyrimethamine if requesting brand Daraprim. Primary prophylaxis of Toxoplasmosis gondii infection criteria revised to require member to have a CD4 count of less than 100 cells/mm3 and to be Toxoplasma IgG positive. Cystoisosporiasis criteria revised to require member to have either a diagnosis of acute cystoisosporiasis infection or secondary prophylaxis/chronic maintenance of cystoisosporiasis with a CD4 count of less than 200 cells/mm3. Pneumocystis jirovecii pneumonia criteria revised to require member to have diagnosis of primary prophylaxis of Pneumocystis jirovecii pneumonia.
Daraprim (pyrimethamine) - Healthcare Reform	4/20/2021	Policy for Daraprim (pyrimethamine) Healthcare Reform terminated as it was combined into J-0802 Daraprim (pyrimethamine) - Commercial and Healthcare Reform due to identical criteria.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Dupixent (dupilumab) - Commercial and Healthcare Reform	04/20/21	Policy revised to require either forced expiratory volume in one second (FEV1) reversibility of at least 12% and 200 milliliters after albuterol or FEV1 less than predicted depending on the member's age for asthma indication. Reauthorization criteria revised to include one more approvable criterion: attestation of reduction in reported asthma-related symptoms. Reauthorization for nasal polyposis indication revised to require either a decrease in the nasal polyp score or a reduction in nasal congestion/obstruction severity score. Reauthorization duration is increased to up to 12 months.
Entresto (sacubitril/valsartan) - Commercial and Healthcare Reform	4/21/2021	Policy revised to require a diagnosis of chronic heart failure with New York Heart Association (NYHA) Class II, III, or IV, the member is 18 years or older, and the member is not receiving an angiotensin-converting enzyme inhibitor or another angiotensin II receptor blocker for the adult chronic heart failure indication. Documentation of left ventricular ejection fraction (LVEF) criterion was removed from the adult chronic heart failure indication.
FLT3 Kinase Inhibitors - Commercial and Healthcare Reform	4/26/2021	Policy revised for Rydapt (midostaurin) to require the member to be 18 years of age or older.
Gocovri and Osmolex ER (amantadine ER) - Commercial and Healthcare Reform	5/01/2021	Policy revised for Gocovri (amantadine ER) to include expanded indication for off episodes. Member has Parkinson’s disease, experiencing “off” episodes despite optimized levodopa/carbidopa therapy, receiving concurrent levodopa/carbidopa therapy, tried and failed immediate-release amantadine, and two (2) of the following generic agents: entacapone, pramipexole, rasagiline, ropinirole, or selegiline. Policy revised for Osmolex ER (amantadine ER) that if used for drug-induced extrapyramidal reactions the member is 18 years of age or older. Reauthorization criteria added for positive response.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Hedgehog Pathway Inhibitors - Commercial and Healthcare Reform	4/29/2021	Policy revised for Daurismo (glasdegib) for prescriber attestation that the member with newly-diagnosed acute myeloid leukemia (AML) is not a candidate for intensive induction therapy.
Hepatitis C Oral Therapy - Commercial and Healthcare Reform	4/29/2021	Policy revised for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks to update to preferred product for sofosbuvir-based treatment failures with or without compensated cirrhosis without liver transplant. Mavyret (glecaprevir/pibrentasvir) treatment duration updated to 16 weeks for sofosbuvir-based treatment failures with or without compensated cirrhosis (except genotype 3) without liver transplant. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks updated to preferred product for glecaprevir/pibrentasvir treatment failures in no cirrhosis (+ ribavirin in compensated cirrhosis) without liver transplant. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 24 weeks updated to preferred product for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) treatment failure with or without compensated cirrhosis without liver transplant. Mavyret (glecaprevir/pibrentasvir) x 16 weeks added to preferred product for genotype 2 with or without compensated cirrhosis for Sofosbuvir + NS5A Inhibitor treatment failure.
Hepatitis C Oral Therapy - Commercial Core	5/1/2021	Policy revised for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks to update to preferred product for sofosbuvir-based treatment failures with or without compensated cirrhosis without liver transplant. Mavyret (glecaprevir/pibrentasvir) treatment duration updated to 16 weeks for sofosbuvir-based treatment failures with or without compensated cirrhosis (except genotype 3) without liver transplant. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks updated to preferred product for glecaprevir/pibrentasvir treatment failures in no cirrhosis (+ ribavirin in compensated cirrhosis)

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		without liver transplant. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 24 weeks updated to preferred product for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) treatment failure with or without compensated cirrhosis without liver transplant. Mavyret (glecaprevir/pibrentasvir) x 16 weeks added to preferred product for genotype 2 with or without compensated cirrhosis for Sofosbuvir + NS5A Inhibitor treatment failure.
Hepatitis C Oral Therapy - Commercial National Select Formulary	5/12/2021	Policy revised for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks to update to preferred product for sofosbuvir-based treatment failures with or without compensated cirrhosis without liver transplant. Mavyret (glecaprevir/pibrentasvir) treatment duration updated to 16 weeks and non-preferred product for sofosbuvir-based treatment failures with or without compensated cirrhosis (except genotype 3) without liver transplant. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x 12 weeks preferred product for genotype 5 and, with or without compensated cirrhosis, without liver transplant for glecaprevir/pibrentasvir treatment failure. Mavyret (glecaprevir/pibrentasvir) + sofosobuvir + ribavirin x 16 weeks non-preferred for sofosbuvir/velpatasvir/voxilaprevir treatment failure.
Homozygous Familial Hypercholesterolemia - Commercial and Healthcare Reform	4/29/2021	Policy revised for homozygous familial hypercholesterolemia (HoFH) that untreated low-density lipoprotein cholesterol (LDL-C) level is > 400 mg/dL or total cholesterol > 500 mg/dL (previously untreated LDL-C > 500 mg/dL), Juxtapid (lomitapide) is used concurrently with other lipid-lowering therapies, and member has tried and failed ezetimibe.
Interleukin-1b blockers - Commercial and Healthcare Reform	4/29/2021	Policy revised for Arcalyst (rilonacept) to add new indication for deficiency of Interleukin-1 receptor antagonist (DIRA) to require the member to weigh at least 10 kg; a diagnosis of DIRA requiring maintenance of remission; and

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
		previously experienced clinical benefit from Kineret (anakinra) for the induction treatment of DIRA.
Lupkynis (voclosporin) - Commercial and Healthcare Reform	5/3/2021	New policy for Lupkynis (voclosporin) requiring the member to be 18 years of age or older; a diagnosis of active lupus nephritis; documentation of systemic lupus erythematous by positive antinuclear antibody (ANA) ≥1:80 or anti-double stranded DNA (anti-ds DNA) ≥ 30 IU/mL; therapeutic failure, intolerance, insufficient response to two (2) of the following: corticosteroid, antimalarials, or immunosuppressives; and concurrent therapy of both corticosteroid and mycophenolate mofetil. Reauthorization criteria created for the prescriber to attest the member has experienced a therapeutic response to therapy by disease stability or disease improvement. Initial authorization duration of 24 weeks and reauthorization duration of 12 months.
MET Kinase Inhibitors – Commercial and Healthcare Reform	5/3/2021	Policy revised to add criteria for Tepmetko (tepotinib) for the treatment of adult patients aged 18 years of age or older with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal epithelial transition (MET) exon 14 skipping alterations.
Oral Isotretinoin Therapy - Commercial and Healthcare Reform	5/4/2021	Policy revised to specify list of oral antibiotics that member must try at least one of or the list of which all must be contraindicated. Policy also revised to include contraindication to all topical combination products. Policy also revised to combine Commercial and Health Care Reform.
Orgovyx (relugolix) - Commercial and Healthcare Reform	5/4/2021	Policy revised to add approval criteria for loading dose of 3 tablets on day 1.
Oxbryta (voxelotor) - Commercial and Healthcare Reform	5/4/2021	Policy revised for Oxbryta (voxelotor) to require member to experience therapeutic failure, contraindication, or intolerance to hydroxyurea for the Commercial LOB only. Limitations of Coverage revised to prohibit use of Oxbryta in combination with Adakveo (crizanlizumab-tmca).

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
PCSK9 Inhibitors - Commercial and Healthcare Reform	TBD	Policy revised for homozygous familial hypercholesterolemia (HoFH) for initiation and maintenance that untreated low-density lipoprotein cholesterol (LDL-C) level is > 400 mg/dL or total cholesterol > 500 mg/dL (previously untreated LDL-C > 500 mg/dL), member has LDL-C > 135 mg/dL for children, member has tried and failed ezetimibe, and moved from limitations of coverage to approval criteria that drug is used concurrently with other lipid-lowering therapies. For initiation and maintenance of heterozygous familial hypercholesterolemia (HeFH), hypercholesterolemia with atherosclerotic cardiovascular disease (ASCVD), and primary hyperlipidemia, member has tried and failed ezetimibe.
PI3K Inhibitors - Commercial and Healthcare Reform	5/6/2021	Policy revised for all PI3K Inhibitors. For Copiktra (duvelisib) and Piqray (alpelisib), member must be 18 years of age or older. Ukoniq (umbralisib) added to the policy, and approval requires member to be 18 years of age or older and have a diagnosis of either Follicular Lymphoma (FL) or Marginal Zone Lymphoma (MZL). For Follicular Lymphoma (FL), member must have received at least three (3) prior lines of systemic therapy. For Marginal Zone Lymphoma (MZL), member must have received at least one (1) prior anti-CD20-based regimen.
Pizensy (lactitol) - Commercial and Healthcare Reform	TBD	Policy revised for Pizensy (lactilol) to require the member has experienced an increase in the mean number of bowel movements per week for reauthorization. Shortened the initial authorization duration to 12 weeks and added the reauthorization duration of 12 months.
Procysbi (cysteamine bitartrate) - Commercial and Healthcare Reform	5/6/2021	Reauthorization criteria for Procysbi (cysteamine bitartrate) revised to verify member is still unable to swallow capsules or has a gastrostomy tube (g-tube) in place if they continue using the Granules dosage form.

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Sabril and Vigadrone (vigabatrin) - Commercial	5/6/2021	Policy revised to change reauthorization criteria to a reduction in seizure frequency from baseline.
Sabril and Vigadrone (vigabatrin) - Healthcare Reform	5/6/2021	Policy revised to change reauthorization criteria to a reduction in seizure frequency from baseline.
Sympazan and Onfi (clobazam) - Commercial and Healthcare Reform	TBD	Policy revised to include brand Onfi (clobazam) tablets and suspension. Policy also revised into initiation and maintenance criteria. Initiation requires age 2 years or older, diagnosis of Lennox-Gastaut syndrome, using as adjunct therapy, therapeutic failure, contraindication, or intolerance to at least one standard of care treatment (valproic acid, lamotrigine, topiramate, or rufinamide), and therapeutic failure or intolerance to generic clobazam. Maintenance criteria requires age 2 years or older, diagnosis of Lennox-Gastaut syndrome, using as adjunctive therapy, and prescriber attestation that the patient has experienced a reduction in seizure frequency from baseline.
Testosterone (Androgens) - Commercial and Healthcare Reform	5/7/2021	Policy revised for testosterone products to remove Androxy, First-Testosterone, Striant, and testosterone propionate solution as off-market. Removed age if used for gender dysphoria or gender identity disorder and added prescriber specialty. Removed testosterone propionate oil for injection as option for palliative treatment in metastatic breast cancer as off-market. Removed vulvar dystrophies criteria as all topical testosterone propionate products off-market. Lab values for hypogonadism in males changed to 2 morning testosterone levels < 264 ng/dL, and for those with total testosterone levels not below normal but considered near, near is defined as < 300 ng/dL or the bottom 20% of the reference range.
Tibsovo (ivosidenib) – Commercial and Healthcare Reform	5/7/2021	Policy revised for Tibsovo (ivosidenib) for use in members 18 years of age or older with newly-diagnosed acute myeloid leukemia (AML).
Urea Cycle Disorder Medications -	5/7/2021	Policy revised to include criteria for a new indication for Carbaglu (carglumic acid):

Policy Name*	Policy Effective Date**	Updates and/or Approval Criteria
Commercial and Healthcare Reform		adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) in adults and pediatric patients
Venclexta (venetoclax) – Commercial and Healthcare Reform	5/7/2021	Policy revised for Venclexta (venetoclax) for use in members 18 years of age or older with prescriber attestation that the member is not a candidate for intensive induction therapy.
Verquvo (vericiguat) - Commercial and Healthcare Reform	5/7/2021	New policy created for Verquvo (vericiguat) requiring members to have a diagnosis of heart failure, New York Heart Association (NYHA) Class II, III, or IV, with left ventricular ejection fraction less than 45%; must be taking in conjunction with an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB) or an angiotensin receptor neprilysin inhibitor (ARNI), as well as a beta blocker indicated for heart failure (HF), unless contraindicated, and the member must have either been hospitalized for heart failure in the past 6 months or have received intravenous (IV) diuretics in the past 3 months.

*For Commercial and Healthcare Reform policies, an exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

**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
Acute Migraine Therapies - Commercial	4/13/2021	Policy revised to include oral ergotamines in criteria requiring diagnosis of acute migraine with or without aura and therapeutic failure, contraindication, or intolerance to generic oral sumatriptan, rizatriptan, and zolmitriptan.
Acute Migraine Therapies - Healthcare Reform	4/14/2021	Policy revised to include oral ergotamines in criteria requiring diagnosis of acute migraine with or without aura and therapeutic failure, contraindication, or intolerance to generic oral sumatriptan, rizatriptan, and zolmitriptan.

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
Azstarys (serdexmethylphenidate/ dexmethylphenidate) – Commercial and Healthcare Reform	TBD	New policy created for Azstarys (serdexmethylphenidate/dexmethylphenidate) requiring members to be 6 years of age or older with a diagnosis of ADHD and a trial and failure of an immediate-release ADHD product and an extended-release ADHD product.
Brand Statins - Select Healthcare Reform Plans	4/15/2021	Policy for brand statins terminated as it was combined to J-0874 Generic Step Therapy Edit - Healthcare Reform.
Brand Statins- Select Commercial Plans	4/15/2021	Policy terminated- coverage criteria captured in J-0303 Generic Step Therapy Edit - Commercial.
Generic Step Therapy Edit - Commercial	4/27/2021	Policy revised to reduce authorization duration to 12 months and add reauthorization criteria. Policy revised to remove within 24 months in approval criteria for trial and failure of a generic. Commercial benefits updated to include members previously captured under J-0320 Brand Statins - Select Commercial.
Generic Step Therapy Edit - Select Healthcare Reform Plans	4/27/2021	Policy revised to remove brand step therapy for selective serotonin (norepinephrine) reuptake inhibitors (SSRI/SSNRI). Policy revised for statins to remove within 24 months in approval criteria for trial and failure of a generic statin. Authorization duration revised to 12 months.
Lidoderm (lidocaine patch) and ZTLido (lidocaine 1.8% topical system) - Commercial and Healthcare Reform	5/4/2021	Policy revised to allow for adjuvant use with an opioid for diagnosis of neuropathic pain associated with cancer.
Lubiprostone - Commercial and Healthcare Reform	5/3/2021	Policy revised for lubiprostone (authorized generic only) for the member to experience therapeutic failure or intolerance to brand Amitiza (removed contraindication).
Mesalamine Ulcerative Colitis Treatments – Commercial and Healthcare Reform	TBD	Policy revised for Lialda (mesalamine) to remove age criteria requiring the member to be 18 years of age or older. Reauthorization criteria revised to state prescriber attests to demonstrated disease stability or beneficial response to therapy. If the request is for Asacol HD (mesalamine), Canasa (mesalamine), Rowasa (mesalamine), or Pentasa (mesalamine), the prescriber must attest additional courses for UC induction of remission or treatment are necessary. Authorization durations revised to

Policy Name	Policy Effective Date	Updates and Automatic Approval Criteria
		change from 2 months to 6 weeks for Asacol HD (mesalamine), Canasa (mesalamine), Rowasa (mesalamine); 8 weeks for Pentasa (mesalamine); and 6 months for Apriso (mesalamine), Delzicol (mesalamine) and Lialda (mesalamine).
Mupirocin Cream - Commercial and Healthcare Reform	5/3/2021	Policy revised to remove impetigo from the diagnosis criteria. Policy also revised to combine Commercial and Health Care Reform.
Mupirocin Cream - Healthcare Reform	5/3/2021	Policy retired and combined with J-0289 Mupirocin Cream - Commercial.
Nonpreferred Topical Antifungals- Commercial and Healthcare Reform	5/4/2021	Combined Commercial and Healthcare Reform into one policy, archiving previous HCR policy. Under FDA-approved indications, policy revised to remove brand name Naftin 1% and 2% Cream and change age for naftifine 1% and 2% Cream and 1% gel to 12 years of age. Under the criteria required for approval, removed age restrictions from criteria for all products.
Nonpreferred Topical Antifungals- Healthcare Reform	5/3/2021	Policy terminated and combined with J-0291 Nonpreferred Topical Antifungals - Commercial. Commercial and HCR now one policy
Oral Isotretinoin Therapy - Healthcare Reform	5/4/2021	Policy retired and combined with J-0695 Oral Isotretinoin Therapy - Commercial.
Xifaxan 550mg (rifaximin) - Commercial and Healthcare Reform	5/7/2021	Policy revised for Xifaxan (rifaximin) for irritable bowel syndrome with diarrhea (IBS-D) criteria from a double step to a single step through loperamide or a tricyclic antidepressant. Removed cholestyramine, colestipol, dicyclomine, hyoscamine, and selective serotonin reuptake inhibitors as qualifying agents.
Zelnorm (tegaserod) - Commercial and Healthcare Reform	5/7/2021	Policy revised for Zelnorm (tegaserod) to update initial authorization duration to 6 weeks and reauthorization duration to 12 months.
Zelnorm (tegaserod) - Healthcare Reform	5/7/2021	Policy for Zelnorm (tegaserod) Healthcare Reform terminated as it was combined to J-0940 Zelnorm (tegaserod) - Commercial and Healthcare Reform.

*For Commercial and Healthcare Reform policies, an exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

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. Formulary Program
No changes at this time.

4. 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
Mayzent (siponimod) Starter Pack	1 starter pack per 720 days	1 starter pack per 720 days

*Effective date to be determined.

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

Drug Name	Retail Edit Limit	Mail Edit Limit
Lindane 1% Shampoo*	60 mL (1 bottle) per dispensing event	60 mL (1 bottle) per dispensing event
Natroba (spinosad) 0.9% Topical Suspension*	120 mL (1 bottle) per dispensing event	120 mL (1 bottle) per dispensing event
Ovide (malathion) 0.5% Topical Lotion*	59 mL (1 bottle) per dispensing event	59 mL (1 bottle) per dispensing event
Sklice (ivermectin) 0.5% Topical Lotion*	117 mL (1 bottle) per dispensing event	117 mL (1 bottle) per dispensing event
Vocabria (cabotegravir)	30 tablets per dispensing event	30 tablets per dispensing event

*Effective date to be determined.

Quantity per dispensing event limits the quantity of medication that can be dispensed per each fill. If the submitted day supply on a claim is 34 days or less, the retail limit will apply. If the submitted day supply on a claim is greater than 34 days, the mail limit will apply.

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

Drug Name	Daily Limit
Azstarys (serdexmethylphenidate/dexmethylphenidate)	1 tablet per day
Iclusig (ponatinib) 15 mg*	1 tablet per day
Lupkynis (voclosporin)	6 capsules per day

Drug Name	Daily Limit
Myrbetriq (mirabegron)*	1 tablet per day
Tepmetko (tepotinib)	2 tablets per day
Ukoniq (umbralisib)	4 capsules per day
Verquvo (vericiguat)	1 tablet per day

* Effective date to be determined.

Members can receive up to the maximum day supply according to their benefits, but the daily limit must not be exceeded for each individual day.

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:

- **Performance Formulary**
- **Venture Formulary**
- **Incentive Formulary**

Table 1. 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	Comments
Amondys 45	casimersen	Duchenne Muscular Dystrophy
Cabenuva	cabotegravir/rilpivirine	HIV-1 Infection
Evkeeza	evinacumab-dgnb	Homozygous Familial Hypercholesterolemia
Lupkynis	voclosporin	Lupus Nephritis
Nulibry	fosdenopterin	MoCD type A
Pepaxto	melphalan flufenamide	Multiple myeloma
Plegridy intramuscular injection	peginterferon beta-1a intramuscular injection	Multiple Sclerosis
Tepmetko	tepotinib	Non-small cell lung cancer
Ukoniq	umbralisib	Marginal Zone Lymphoma; Follicular Lymphoma

Vocabria	cabotegravir	HIV-1 Infection

Table 2. Non-Preferred Products
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Azstarys	serdexmethylphenidate/ dexmethylphenidate	amphetamine sulfate tablets, methylphenidate ER tablets
Verquvo	vericiguat	Entresto, spironolactone, eplerenone

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:

- **Performance Formulary**
- **Venture Formulary**
- **Incentive Formulary**

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

Brand Name	Generic Name	Comments
Amondys 45	casimersen	Duchenne Muscular Dystrophy
Cabenuva	cabotegravir/rilpivirine	HIV-1 Infection
Evkeeza	evinacumab-dgnb	Homozygous Familial Hypercholesterolemia
Lupkynis	voclosporin	Lupus Nephritis
Nulibry	fosdenopterin	MoCD type A
Pepaxto	melphalan flufenamide	Multiple myeloma
Plegridy intramuscular injection	peginterferon beta-1a intramuscular injection	Multiple Sclerosis
Tepmetko	tepotinib	Non-small cell lung cancer
Ukoniq	umbralisib	Marginal Zone Lymphoma; Follicular Lymphoma
Vocabria	cabotegravir	HIV-1 Infection

Table 2. Non-Preferred Products
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Verquvo	vericiguat	Entresto, spironolactone, eplerenone

Table 3. Products Not Added*
Effective immediately pending CMS approval and upon completion of internal review and implementation.

Brand Name	Generic Name	Preferred Alternatives
Azstarys	serdexmethylphenidate/ dexmethylphenidate	amphetamine sulfate tablets, methylphenidate ER tablets

*Physicians may request coverage of these products using the Request for Non-Formulary Drug Coverage form.

C. Additions to the Specialty Tier

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

Brand Name	Generic Name
Amondys 45	casimersen
Cabenuva	cabotegravir/rilpivirine
Evkeeza	evinacumab-dgnb
Lupkynis	voclosporin
Nulibry	fosdenopterin
Pepaxto	melphalan flufenamide
Plegridy intramuscular injection	peginterferon beta-1a intramuscular injection
Tepmetko	tepotinib
Ukoniq	umbralisib
Vocabria	cabotegravir

D. Updates to the Pharmacy Utilization Management Programs

1. Prior Authorization Program

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
Administrative Prior Authorizations for Medicare Part D Plans - Medicare	4/14/2021	Policy revised to align ICD-10 codes related to Part B coverage of intravenous immune globulin in home for the treatment of primary immune deficiency diseases with Chapter 15 of the Medicare Benefit Policy Manual. Addition of Nulibry (fosdenopterin) as a target for infusion pump criteria.
ALK-Targeting Kinase Inhibitors - Medicare	4/15/2021	Policy revised for Xalkori (crizotinib) for use in pediatric patients 1 year of age to 21 years of age with relapsed or refractory, systemic anaplastic large cell lymphoma that is ALK-positive. Policy revised for Lorbrena (lorlatinib) for use in metastatic non-small cell lung cancer (NSCLC)

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		whose tumors are anaplastic lymphoma kinase (ALK)-positive.
Amondys 45 (casimersen) - Medicare	4/15/2021	New policy for Amondys 45 (casimersen) requiring the member to have a diagnosis of Duchenne muscular dystrophy with a confirmed mutation of the DMD gene that is amenable to exon 45 skipping, member has been on stable doses of oral corticosteroids for at least 6 months prior to initiating therapy, and member is ambulatory (with or without assistance), not wheelchair dependent.
Anti-Angiogenesis and VEGF Kinase Inhibitors - Medicare	4/15/2021	Policy revised for Cabometyx (cabozantinib) for use in members with a diagnosis of advanced renal cell carcinoma, as first-line treatment in combination with nivolumab.
Anti-EGFR and HER2 Kinase Inhibitors - Medicare	TBD	Policy updated to remove limitations of coverage for Tykerb (lapatinib).
BCR-ABL Kinase Inhibitors - Medicare	4/15/2021	Policy revised for Iclusig (ponatinib) to add criteria for use in members with a diagnosis of CP CML and after experience of resistance or intolerance to at least two prior kinase inhibitors.
CDK Inhibitors - Medicare	TBD	Policy revised to clarify age limitation of 18 years and older for Ibrance (palbociclib) and Verzenio (abemaciclib); for Ibrance (palbociclib), to clarify that Ibrance (palbociclib) is used as initial endocrine-based therapy or following endocrine-based therapy; to clarify that Kisqali (ribociclib) is used as initial endocrine-based therapy or following disease progression on endocrine-based therapy; and to clarify that Verzenio (abemaciclib) is used as initial endocrine-based therapy.
Chloroquine Therapy - Medicare	4/16/2021	Policy revised for chloroquine to require duration of travel if using for malaria prophylaxis.
Chronic Inflammatory Diseases - Medicare	4/16/2021	Policy revised for Actemra (tocilizumab) for new indication of systemic sclerosis-associated interstitial lung disease (SSc-ILD) to require member to be 18 years of age or older, a diagnosis of SSc-ILD, and therapeutic failure or intolerance to at least 1 immunosuppressant or all immunosuppressants are contraindicated. Maintenance therapy quantity limit (QL) for

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		Actemra (tocilizumab) in SSc-ILD added for 4 prefilled syringes every 4 weeks. Policy revised for Humira (adalimumab) for ulcerative colitis (UC) for the member to be 5 years of age or older. Pediatric UC induction QL (44 pounds (lbs)-88lbs): 4 prefilled syringes within the first 4 weeks of therapy; (≥88lbs): 8 prefilled syringes within the first 4 weeks of therapy or 1 starter package kit. Pediatric UC maintenance dosing QL (44lbs-88lbs): 2 prefilled syringes every 4 weeks or 4 prefilled syringes (20mg) every 4 weeks; (≥88lbs): 4 prefilled syringes every 4 weeks.
Cosela (trilaciclib) - Medicare	TBD	New policy for new drug, Cosela (trilaciclib), requiring age of 18 years or older, diagnosis of extensive stage small cell lung cancer, using to decrease the incidence of myelosuppression, and will be receiving a chemotherapy regimen containing platinum and etoposide or topotecan.
Darzalex (daratumumab) and Darzalex Faspro (daratumumab and hyaluronidase-fihj) - Medicare	4/21/2021	Policy revised for Darzalex Faspro (daratumumab and hyaluronidase-fihj) to add criteria for treatment of members with newly diagnosed light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone.
Dupixent (dupilumab) - Medicare	5/4/2021	Policy revised to require either forced expiratory volume in one second (FEV1) reversibility of at least 12% and 200 milliliters after albuterol or FEV1 less than 80% predicted for asthma indication. Reauthorization duration is increased to up to 12 months.
Emflaza (deflazacort) - Medicare	TBD	Policy revised to allow for therapeutic failure, intolerance, or contraindication to prednisone.
Exondys 51 (eteplirsen) - Medicare	4/22/2021	Policy revised to remove criterion stating that Exondys 51 should be prescribed by or in consultation with a physician who specializes in the treatment of muscular dystrophy (e.g., neurologist). Moved it to prescribing considerations in the background section
Gamifant (emapalumab-lzsg) - Medicare	4/27/2021	New policy for Gamifant (emapalumab-lzsg) requiring diagnosis of primary hemophagocytic lymphohistiocytosis (HLH). The diagnosis must be confirmed by genetic testing or the patient

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		must have 5 symptoms (fever, enlarged spleen, cytopenia of two lineages, elevated triglycerides or low fibrinogen, hemophagocytosis, decreased or absent natural killer cells, increased ferritin, or increased soluble CD25 levels), the member must have refractory disease, recurrent disease, progressive disease, or intolerant to conventional therapy, and the member must use concomitantly with dexamethasone. Reauthorization requires improvement in clinical or laboratory parameters.
Gaucher Disease - Medicare	4/27/2021	Policy revised for both Zavesca (miglustat) and Cerdelga (eliglustat) to add a step of thrombocytopenia with platelet count of less than or equal to 120,000/mm3 that would meet definition of bone marrow complications.
Gocovri and Osmolex ER (amantadine ER) - Medicare	4/27/2021	Policy revised for Gocovri (amantadine ER) to include expanded indication for off episodes. Member has Parkinson's disease, experiencing "off" episodes despite optimized levodopa/carbidopa therapy, receiving concurrent levodopa/carbidopa therapy, tried and failed immediate-release amantadine, and two (2) of the following generic agents: entacapone, pramipexole, rasagiline, ropinirole, or selegiline. Policy revised for Osmolex ER (amantadine ER) that if used for drug-induced extrapyramidal reactions the member is 18 years of age or older.
Hepatitis C Oral Therapy - Medicare	5/1/2021	Policy revised for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks to update to preferred product for sofosbuvir-based treatment failures with or without compensated cirrhosis without liver transplant. Mavyret (glecaprevir/pibrentasvir) treatment duration updated to 16 weeks for sofosbuvir-based treatment failures with or without compensated cirrhosis (except genotype 3) without liver transplant. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks updated to preferred product for glecaprevir/pibrentasvir treatment failures in no cirrhosis (+ ribavirin in compensated cirrhosis) without liver transplant. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) + ribavirin x

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		24 weeks updated to preferred product for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) treatment failure with or without compensated cirrhosis without liver transplant. Mavyret (glecaprevir/pibrentasvir) x 16 weeks added to preferred product for genotype 2 with or without compensated cirrhosis for Sofosbuvir + NS5A Inhibitor treatment failure.
Homozygous Familial Hypercholesterolemia - Medicare	5/1/2021	Policy revised to add new criteria for new medication Evkeeza (evinacumab-dgnb) requiring member to be 12 years of age or older, a diagnosis of homozygous familial hypercholesterolemia (HoFH) by genetic confirmation of two mutant alleles or untreated low density lipoprotein cholesterol (LDL-C) > 400 mg/dL or untreated total cholesterol (TC) > 500 mg/dL and cutaneous or tendon xanthomas before age 10 or evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents. Current LDL > 100 mg/dL (18 years of age or older) or >135 mg/dL (17 years of age or younger) despite maximally tolerated statin or member defined as statin intolerant. Member must experience therapeutic failure, contraindication, or intolerance to Repatha (evolocumab) and continue to receive concurrent lipid-lowering therapies for HoFH.
Interleukin-1b blockers - Medicare	5/1/2021	Policy revised for Arcalyst (rilonacept) to add new indication for deficiency of Interleukin-1 receptor antagonist (DIRA) to require the member to weigh at least 10 kg and a diagnosis of DIRA requiring maintenance of remission.
Korlym (mifepristone) - Medicare	TBD	Policy revised for Korlym (mifepristone) to remove limitations of coverage that it should not be used in members who are pregnant as not filed.
Lubiprostone - Medicare	TBD	New policy created for lubiprostone (authorized generic only) for members 18 years of age or older with a diagnosis of chronic idiopathic constipation (CIC), opioid-induced constipation (OIC), or irritable bowel syndrome with constipation (IBS-C). The member has experienced therapeutic failure or intolerance to

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		brand Amitiza. Authorization duration for 12 months.
Lupkynis (voclosporin) - Medicare	5/3/2021	New policy for Lupkynis (voclosporin) requiring the member to be 18 years of age or older; a diagnosis of active lupus nephritis; documentation of systemic lupus erythematous by positive antinuclear antibody (ANA) ≥1:80 or anti-double stranded DNA (anti-ds DNA) ≥ 30 IU/mL; therapeutic failure, intolerance, insufficient response to two (2) of the following: corticosteroid, antimalarials, or immunosuppressives; and concurrent therapy of both corticosteroid and mycophenolate mofetil. Reauthorization criteria created for the prescriber to attest the member has experienced a therapeutic response to therapy by disease stability or disease improvement. Initial authorization duration of 24 weeks and reauthorization duration of 12 months.
MET Kinase Inhibitors – Medicare	5/3/2021	Policy revised to add criteria for Tepmetko (tepotinib) for the treatment of adult patients aged 18 years of age or older with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymalepithelial transition (MET) exon 14 skipping alterations.
Myalept (metreleptin) - Medicare 2022	5/3/2021	Policy revised for Myalept (metreleptin) to remove absence or loss of subcutaneous body fat as that is the definition of lipodystrophy making it duplicative. Added step therapy that member has experienced therapeutic failure to one (1) previous therapy for diabetes (e.g., metformin, insulin) or hypertriglyceridemia (e.g., statin, fibrate). Reauthorization added that member meets one (1) of the following: decreased HbA1c from baseline, decreased fasting plasma glucose from baseline, decreased fasting triglycerides from baseline.
Nulibry (fosdenopterin) - Medicare	5/4/2021	New policy for new drug, Nulibry (fosdenopterin), with criteria for presumed or confirmed molybdenum cofactor deficiency (MoCD) type A. For presumed MoCD type A, prescribers must attest that the patient will undergo genetic confirmation of diagnosis and for reauthorization

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		the diagnosis must have been confirmed by genetic testing. For confirmed MoCD type A, the diagnosis must have been confirmed by genetic testing. For confirmed or presumed MoCD type A, use must be determined to be eligible under Medicare Part D.
Orgovyx (relugolix) - Medicare	5/4/2021	Policy revised to add approval criteria for loading dose of 3 tablets on day 1.
PI3K Inhibitors - Medicare	5/6/2021	Policy revised for all PI3K Inhibitors. For Copiktra (duvelisib) and Piqray (alpelisib), member must be 18 years of age or older. Ukoniq (umbralisib) added to the policy, and approval requires member to be 18 years of age or older and have a diagnosis of either Follicular Lymphoma (FL) or Marginal Zone Lymphoma (MZL). For Follicular Lymphoma (FL), member must have received at least three (3) prior lines of systemic therapy. For Marginal Zone Lymphoma (MZL), member must have received at least one (1) prior anti-CD20-based regimen.
Pizensy (lactitol) - Medicare	TBD	Policy revised for Pizensy (lactilol) to require the member has experienced an increase in the mean number of bowel movements per week for reauthorization. Shortened the initial authorization duration to 12 weeks and added the reauthorization duration of 12 months.
Programmed Death Receptor Therapies - Medicare	5/6/2021	Policy revised for Opdivo (nivolumab) to add criteria for advanced renal cell carcinoma in which Opdivo is used as first-line treatment in combination with cabozantinib, and to specify advanced RCC for first-line treatment in members who have received prior anti-angiogenic therapy. Policy revised for Keytruda (pembrolizumab) to remove criteria for small cell lung cancer; and for Imfinzi (durvalumab) to remove criteria for urothelial carcinoma following removal of the indications per FDA.
Rocklatan (netarsudil and latanoprost) - Medicare	TBD	Termination of policy
Testosterone (Androgens) - Medicare	5/7/2021	Policy revised for delayed puberty to allow for use of Testopel.
Urea Cycle Disorder Medications - Medicare	5/7/2021	Policy revised to include criteria for a new indication for Carbaglu (carglumic acid):

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) in adults and pediatric patients
Verquvo (vericiguat) - Medicare	TBD	New policy created for Verquvo (vericiguat) requiring members to have a diagnosis of heart failure, New York Heart Association (NYHA) Class II, III, or IV, with left ventricular ejection fraction less than 45%; must be taking in conjunction with an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB) or an angiotensin receptor neprilysin inhibitor (ARNI), as well as a beta blocker indicated for heart failure (HF), unless contraindicated, and the member must have either been hospitalized for heart failure or have received intravenous (IV) diuretics
Welchol (colesevelam) chewable bars - Medicare	TBD	Policy revised for Welchol (colesevelam) chewable bars that if member has primary hyperlipidemia, low-density lipoprotein cholesterol (LDL-C) > 70 mg/dL and if member is intolerant to statins it is demonstrated by rhabdomyolysis or skeletal-related muscle symptoms while receiving two (2) separate trials of different statins which resolved upon discontinuation of the statins or the member experienced one (1) of the following: Creatinine kinase increase to 10 times upper limit of normal (ULN), liver function tests increase to 3 times ULN, or hospitalization due to severe statin-related adverse event, such as rhabdomyolysis. If member has heterozygous familial hypercholesterolemia it is supported by one (1) of the following: genetic confirmation, high elevated LDL-C ≥ 190 mg/dL (or ≥ 160 mg/dL before 20 years of age) with physical signs, meets Dutch Lipid Clinical Network, or meets Simon Broome register, and member has LDL-C > 135 mg/dL.
Xolair (omalizumab) - Medicare	5/7/2021	Policy revised to include a new indication for Xolair (omalizumab) for treating nasal polyps. The criteria require the member to be 18 years of age or older, have a diagnosis of nasal polyps, have tried and failed both intra-nasal

Policy Name	Policy Effective Date*	Updates and/or Approval Criteria
		corticosteroid and a 14-day course of oral corticosteroid. Reauthorization criteria require attestation of a reduction in nasal polyp score or nasal congestion/obstruction severity score.

*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/or Approval Criteria
Brand ADHD Step Therapy – Medicare	TBD	Policy revised to add Azstarys (serdexmethylphenidate/dexmethylphenidate) requiring use for a medically accepted indication and trial and failure of 2 generic medications if the member has a diagnosis of ADHD.
Nonpreferred Topical Antifungals- Medicare	5/4/2021	Under FDA-approved indications, policy revised to remove brand name Naftin 1% and 2% Cream, and change age for naftifine 1% and 2% Cream and 1% gel to 12 years. Under the criteria required for approval, removed age restrictions from criteria for all products.
Xifaxan 550mg (rifaximin) - Medicare 2022	5/7/2021	Policy revised for Xifaxan (rifaximin) for irritable bowel syndrome with diarrhea (IBS-D) criteria from a double step to a single step through loperamide. Removed cholestyramine, colestipol, dicyclomine, tricyclic antidepressants, and selective serotonin reuptake inhibitors as qualifying agents.

3. Quantity Level Limit (QLL) Program*

Effective date pending CMS approval, completion of internal review and implementation, unless otherwise noted.

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Azstarys (serdexmethylphenidate/dexmethylphenidate)	31	90
Lupkynis (voclosporin)	186	540
Mayzent (siponimod) Starter Pack	2 starter packs per year	2 starter packs per year
Plegridy (peginterferon beta-1a) intramuscular injection	2 prefilled syringes per 28 days	6 prefilled syringes per 84 days

Drug Name	Retail Quantity Limit (31 days)	Mail Order Quantity Limit (90 days)
Tepmetko (tepotinib)	62	180
Ukoniq (umbralisib)	124	360
Verquvo (vericiguat)	31	90
Vocabria (cabotegravir)	31	90

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