Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 1/1/2020

October 16, 2019
6:30 – 8:00 PM

A Division of the Department of State Treasurer
Role Call

P&T COMMITTEE MEMBERS

• David Konanc, MD
• Matthew K. Flynn, MD
• Jennifer Burch, PharmD
• Peter Robie, MD
• Tony Gurley, RPh, JD
• John B. Anderson, MD, MPH
• John Engemann, MD
• Joseph Shanahan, MD
• Sundhar Ramalingam, MD

PLAN STAFF & VENDORS

State Health Plan

• Carl Antolick III, PharmD
• Tracy Linton, MPH
• Dee Jones

CVS Caremark

• Renee Jarnigan, RPh
• Stephanie Morrison, PharmD
Ethics Awareness & Conflict of Interest Reminder

In accordance with the NC State Health Plan for Teachers and State Employees’ ethics policy, it is the duty of every member of the Pharmacy & Therapeutics Committee, whether serving in a vote casting or advisory capacity, to avoid both conflicts of interest and appearances of conflict.

Does any Committee member have any known conflict of interest or the appearance of any conflict with respect to any manufacturers of any medication to be discussed at today’s meeting?

Or, if during the course of the evaluation process if you identify a conflict of interest or the appearance of a conflict.

If so, please identify the conflict or appearance of conflict and refrain from any undue participation in the particular matter involved.
Recent Plan Formulary Decisions

All approved negative formulary changes from August's meeting went into effect 10/1/2019 and include the following:

Removed the following products from the formulary:

- SABRIL, COLCRYS, PERCOCET, TOPROL XL, XANAX IR/XR, LAMICTAL IR/ODT/CHEW/XR, ONFI, PRISTIQ, LEXAPRO, PROZAC, EVEKEO, SUBOXONE, BEYAZ, MINASTRIN 24 FE, YAZ, ORTHO TRI-CYCLIN LO, MINIVELLE, VIVELLE-DOT, LIALDA, ACIPHEX, RAPAFLO, CIALIS, COUMADIN, SINGULAIR, FINACEA, PREVIDENT, mupirocin cream 2%, metformin ER (Fortamet/Glumetza), glycopyrrolate 1.5mg, omeprazole/bicarb capsules/packets, fenoprofen 200mg, fenoprofen 400mg naproxen CR 375/500mg, naproxen 125mg/5mL, fenofibrate 120mg, fenoglide 120mg, VECTICAL, calcitriol ointment, diflorsalone cream, PSORCON, CORDRAN, flurandrenolide, lidocaine/tetracaine, LIDOTREX diflorsalone ointment, calcipotriene cream, doxepin cream, carbinoxamine 6mg, dihydroergotamine spray, & FOLIC-K.

Moved the following branded products to non-preferred status:

- FIORINAL, RANEXA, ANDROGEL, VESICARE, DIFFERIN, & ORACEA.

Adopted the following new utilization management criteria:

- MAVENCLAD SGM & SKYRIZI SGM.
Minutes from Previous Committee Meeting

Instead of having the Secretary read the minutes, copies were distributed prior to the meeting for your review.

• Are there any additions or corrections to the minutes?

• If not, the minutes will stand approved as is.
Formulary Updates – Effective 1/1/2020

CVS Caremark’s Quarterly Formulary Update:
- Product Exclusions
- Tier Changes
- New Drug Additions
- Utilization Management Criteria

Presented by:
- Heather Renee Jarnigan, RPh, Clinical Advisor, CVS Health
- Stephanie Morrison, PharmD, BCPS, Clinical Advisor, CVS Health

Formulary Exclusion Exception Process:
- This process is available to support Plan members who, per their provider, have a medical necessity to remain on an excluded drug.
- There may be circumstances in which the formulary alternatives may not be appropriate for some members. In this case, a member may be approved for the excluded drug with an exception process.
- An exception is defined as a situation where the member has tried and failed (that is, had an inadequate treatment response or intolerance) to the required number of formulary alternatives; or the member has a documented clinical reason such as an adverse drug reaction or drug contraindication that prevents them from trying the formulary alternatives.
- If a member’s exception is approved that drug will be placed into Tier 3 or Tier 6 and the member will be subject to the applicable cost share.
Formulary Updates – Product Exclusions

Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

DUROLANE® (hyaluronic acid)

- Availability of other viscosupplements for osteoarthritis.
- Preferred options include Gel-One (sodium hyaluronate), Gelsyn-3 (sodium hyaluronate), Supartz FX (sodium hyaluronate), and Visco-3 (sodium hyaluronate).
Formulary Updates – Product Exclusions

Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

**STRIBILD® (elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate)**

- Availability of other complete regimen options for the treatment of HIV-1 infection.
- Preferred options include Atripla (efavirenz-emtricitabine-tenofovir disoproxil fumarate), Biktarvy (bictegravir-emtricitabine-tenofovir alafenamide), Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide), Odefsey (emtricitabine-rilpivirine-tenofovir alafenamide), Symfi (efavirenz-lamivudine-tenofovir disoproxil fumarate), Symfi Lo (efavirenz-lamivudine-tenofovir disoproxil fumarate), and Triumeq (abacavir-dolutegravir-lamivudine).
Formulary Updates – Product Exclusions

Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

COMPLERA® (emtricitabine, rilpivirine, and tenofovir disoproxil fumarate)

- Availability of other complete regimen options for the treatment of HIV-1 infection.
- Preferred options include Atripla (efavirenz-emtricitabine-tenofovir disoproxil fumarate), Biktarvy (bictegravir-emtricitabine-tenofovir alafenamide), Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide), Odefsey (emtricitabine-rilpivirine-tenofovir alafenamide), Symfi (efavirenz-lamivudine-tenofovir disoproxil fumarate), Symfi Lo (efavirenz-lamivudine-tenofovir disoproxil fumarate), and Triumeq (abacavir-dolutegravir-lamivudine).
Formulary Updates – Product Exclusions

Advanced Control Specialty Formulary

• Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
• The following exclusions are only for branded products

AVONEX® (interferon beta-1a)

• Availability of other options for the treatment of relapsing forms of multiple sclerosis (MS).
• Preferred options include glatiramer, Aubagio (teriflunomide), Betaseron (interferon beta-1b), Copaxone (glatiramer), Gilenya (fingolimod), Mayzent (siponimod), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate delayed release), and Tysabri (natalizumab).
Formulary Updates – Product Exclusions

Advanced Control Specialty Formulary

• Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
• The following exclusions are only for branded products

PLEGRIDY® (peginterferon beta-1a)

• Availability of other options for the treatment of relapsing forms of multiple sclerosis (MS).
• Preferred options include glatiramer, Aubagio (teriflunomide), Betaseron (interferon beta-1b), Copaxone (glatiramer), Gilenya (fingolimod), Mayzent (siponimod), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate delayed release), and Tysabri (natalizumab).
Formulary Updates – Product Exclusions

Advanced Control Specialty Formulary
- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

**SIMPONI® (golimumab)**
- Now excluded for ulcerative colitis.
- Simponi remains excluded for ankylosing spondylitis, psoriatic arthritis, and rheumatoid arthritis.
- Preferred options include Humira (adalimumab).
Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

VERZENIO® (abemaciclib)

- Availability of other options for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
- Preferred options include Ibrance (palbociclib) and Kisqali (ribociclib).
Standard Control Formulary – Low Net Cost Strategy

• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

ASMANEX TWISTHALER & HFA® (mometasone furoate)

• Availability of other inhaled corticosteroid for prophylactic treatment in asthma
• Preferred options include Arnuity Ellipta (fluticasone furoate), Flovent Diskus (fluticasone propionate), Flovent HFA (fluticasone propionate, CFC-free aerosol), Pulmicort Flexhaler (budesonide), and Qvar RediHaler (beclomethasone breath-activated aerosol).

BUTRANS® (buprenorphine)

• Availability of another option for severe pain.
• The preferred option is Belbuca (buprenorphine).
Standard Control Formulary – Low Net Cost Strategy

• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

**HYSINGLA ER® (hydrocodone bitartrate)**

• Availability of other long-acting options for pain management.
• Preferred options include fentanyl transdermal, hydromorphone ext-rel, methadone, morphine ext-rel, Embeda (morphine-naltrexone ext-rel), Nucynta ER (tapentadol ext-rel), and Xtampza ER (oxycodone ext-rel).

**OXYCONTIN® (oxycodone hydrochloride)**

• Availability of other long-acting options for pain management.
• Preferred options include fentanyl transdermal, hydromorphone ext-rel, methadone, morphine ext-rel, Embeda (morphine-naltrexone ext-rel), Nucynta ER (tapentadol ext-rel), and Xtampza ER (oxycodone ext-rel).
Formulary Updates – Product Exclusions

Standard Control Formulary – Low Net Cost Strategy

• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

ZOHYDRO ER® (hydrocodone bitartrate)

• Availability of other long-acting options for pain management.
• Preferred options include fentanyl transdermal, hydromorphone ext-rel, methadone, morphine ext-rel, Embeda (morphine-naltrexone ext-rel), Nucynta ER (tapentadol ext-rel), and Xtampza ER (oxycodone ext-rel).

QTERN® (dapagliflozin and saxagliptin)

• Availability of another combination SGLT2/DPP-4 inhibitor combination option for improving glycemic control in adults with type 2 diabetes mellitus.
• The preferred option is Glyxambi (empagliflozin-linagliptin).
Formulary Updates – Product Exclusions

Standard Control Formulary – Low Net Cost Strategy

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
- The following exclusions are only for branded products

**ALREX® (loteprednol etabonate)**

- Availability of other ophthalmic options for treating seasonal allergic conjunctivitis.
- Preferred options include azelastine, cromolyn sodium, olopatadine, Lastacaft (alcaftadine), and Pazeo (lopatadine).

**FLAREX® (fluorometholone)**

- Availability of other ophthalmic anti-inflammatory options.
- Preferred options include dexamethasone, loteprednol, prednisolone acetate 1%, Durezol (difluprednate), FML Forte (fluorometholone), FML S.O.P. (fluorometholone), Maxidex (dexamethasone), and Pred Mild (prednisolone acetate).
Formulary Updates – Product Exclusions

Standard Control Formulary – Low Net Cost Strategy

• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

LOTEMAX® (loteprednol etabonate)

• Availability of other ophthalmic anti-inflammatory options.
• Preferred options include dexamethasone, loteprednol, prednisolone acetate 1%, Durezol (difluprednate), FML Forte (fluorometholone), FML S.O.P. (fluorometholone), Maxidex (dexamethasone), and Pred Mild (prednisolone acetate).

TIMOPTIC OCUDOSE® (timolol maleate)

• Availability of other ophthalmic beta-blocker options for the reduction of elevated intraocular pressure.
• Preferred options include timolol maleate solution, Betimol (timolol hemihydrate), and Betoptic S (betaxolol).
Standard Control Formulary – Low Net Cost Strategy

• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

ZYLET® (loteprednol etabonate 0.5% and tobramycin 0.3%)

• Availability of other ophthalmic anti-infective and anti-inflammatory products.
• Preferred options include neomycin-polymyxin B-bacitracin-hydrocortisone, neomycin-polymyxin B-dexamethasone, tobramycin-dexamethasone, TobraDex Ointment (tobramycin-dexamethasone), and TobraDex ST (tobramycin-dexamethasone).

CARAFATE® (sucralfate)

• Availability of a generic option for the treatment and maintenance therapy of duodenal ulcers.
• The preferred option is generic sucralfate.
Standard Control Formulary – Low Net Cost Strategy

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
- The following exclusions are only for branded products

**COMBIVENT RESPIMAT® (ipratropium bromide & albuterol)**
- Availability of other anticholinergic-beta agonist option for the treatment of chronic obstructive pulmonary disease (COPD).
- Preferred options include ipratropium-albuterol inhalation solution, Anoro Ellipta (umeclidinium-vilanterol), Bevespi Aerosphere (glycopyrrolate-formoterol), and Stiolto Respimat (tiotropium-olodaterol).

**LO LOESTRIN FE® (norethindrone/ethinyl estradiol/ferrous fumarate)**
- Availability of generic combination oral contraceptives.
- Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-levonorgestrel, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron, ethinyl estradiol-norgestimate.
Formulary Updates – Product Exclusions

Standard Control Formulary – Low Net Cost Strategy
• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

NATAZIA® (estradiol valerate/dienogest)
• Availability of generic combination oral contraceptives.
• Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-levonorgestrel, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron, ethinyl estradiol-norgestimate.

TAYTULLA® (norethindrone/ethinyl estradiol/ferrous fumarate)
• Availability of generic monophasic oral contraceptive options.
• Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-norethindrone acetate, and ethinyl estradiol-norethindrone acetate-iron.
Formulary Updates – Product Exclusions

Standard Control Formulary – Low Net Cost Strategy

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
- The following exclusions are only for branded products

MOVIPREP® (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid)

- Availability of other options for colon cleansing prior to a colonoscopy.
- Preferred options include peg 3350-electrolyes and Suprep (sodium sulfate-potassium sulfate-magnesium sulfate).

OSMOPREP® (sodium phosphate monobasic monohydrate, and sodium phosphate dibasic anhydrous)

- Availability of other options for colon cleansing prior to a colonoscopy.
- Preferred options include peg 3350-electrolyes and Suprep (sodium sulfate-potassium sulfate-magnesium sulfate).
Formulary Updates – Product Exclusions

Standard Control Formulary – Low Net Cost Strategy

• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

PROAIR HFA & RESPICLICK® (albuterol sulfate)

• Availability of generic short-acting beta-agonist options for the management of asthma.
• Preferred options include generics albuterol sulfate CFC-free aerosol and levalbuterol tartrate CFC-free aerosol.

TRANSDERM SCOP® (scopolamine)

• Availability of generic options for the treatment of nausea and vomiting.
• Preferred options include meclizine and scopolamine transdermal.
Formulary Updates – Product Exclusions

Standard Control Formulary – Low Net Cost Strategy

• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

BEAU RX® (silicone scar gel)

• Availability of other options for the management of scarring.
• Consult doctor for preferred options.

RECEDO® (medical-grade topical silicone)

• Availability of a generic option for the management of scarring.
• The preferred option is imiquimod.

SIL-K PAD® (silicone gel matrix)

• Availability of a generic option for the management of scarring.
• The preferred option is imiquimod.
Formulary Updates – Product Exclusions

Standard Control Formulary – Low Net Cost Strategy

• Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available
• The following exclusions are only for branded products

EPICERAM® (controlled-release skin-barrier-repair emulsion)

• Availability of generic options for managing and relieving the burning and itching experienced with various types of skin conditions.
• Preferred options include desonide and hydrocortisone.

KAMDOY® (skin emulsion)

• Availability of generic options for managing and relieving the burning and itching experienced with various types of skin conditions.
• Preferred options include desonide and hydrocortisone.
Formulary Updates – Product Exclusions

Custom Formulary Exclusions

• Targets drugs with limited clinical value, with more cost-effective alternatives available

ABSORICA® (isotretinoin)

• Availability of generic and brand-named options for the treatment of acne.
• Suggested alternatives include generic isotretinoin, Amnesteem, Claravis, Zenatane and Myorisan.

APLENZIN® (bupropion)

• Availability of generic and brand-named options for the treatment of depression.
• Suggested alternatives include generic bupropion, bupropion ext-rel
Formulary Updates – Product Exclusions

Custom Formulary Exclusions

- Targets drugs with limited clinical value, with more cost-effective alternatives available

**DUEXIS® (famotidine/ibuprofen)**
- Availability of generic and brand-named options for the treatment of arthritis with ulcer prophylaxis.
- Suggested alternatives include generic famotidine with a generic or brand-named NSAID.

**VIMOVO® (esomeprazole/naproxen)**
- Availability of generic and brand-named options for the treatment of arthritis with ulcer prophylaxis.
- Suggested alternatives include generic esomeprazole with a generic or brand-named NSAID.
Custom Formulary Exclusions

• Targets drugs with limited clinical value, with more cost-effective alternatives available

**JUBLIA® (efinaconazole)**

• Availability of generic and brand-named options for the treatment of onychomycosis.
• Suggested alternatives include generic itraconazole and terbinafine.

**KERYDIN® (tavaborole)**

• Availability of generic and brand-named options for the treatment of onychomycosis.
• Suggested alternatives include generic itraconazole and terbinafine.
Custom Formulary Exclusions

• Targets drugs with limited clinical value, with more cost-effective alternatives available

**SITAVIG® (acyclovir)**

• Availability of generic and brand-named options for the treatment of cold sores.
• Suggested alternatives include generic acyclovir and valacyclovir.

**XERESE® (acyclovir/hydrocortisone)**

• Availability of generic and brand-named options for the treatment of cold sores.
• Suggested alternatives include generic acyclovir and valacyclovir.
Custom Formulary Exclusions

• Targets drugs with limited clinical value, with more cost-effective alternatives available

NASCOBAL® (cyancobalamin)

• Availability of generic and brand-named options for the treatment of B12 deficiency and/or anemia.
• Suggested alternatives include generic cyanocobalamin injection.

ZIPSOR® (diclofenac)

• Availability of generic and brand-named options for the treatment of acute pain.
• Suggested alternatives include generic diclofenac.
Formulary Updates – Product Exclusions

Custom Formulary Exclusions

• Targets drugs with limited clinical value, with more cost-effective alternatives available

ZYFLO® (zileuton)

• Availability of generic and brand-named options for the treatment of asthma.
• Suggested alternatives include generic zileuton CR and montelukast.

BENZEPRO® Foaming Cloths (benzoyl peroxide 6%)

• Availability of generic and brand-named options for acne.
• Suggested alternative include generic benzoyl peroxide wash.
Formulary Updates – Uptiers

Movement to Non-preferred Status

• Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.

• All the following products are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

SAFYRAL® (drospirenone/ethinyl estradiol/levomefolate)

• Availability of generic monophasic oral contraceptive options.

• Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-norethindrone acetate, and ethinyl estradiol-norethindrone acetate-iron.

TEKTURNA® (aliskiren)

• Availability of a generic direct renin inhibitor option for the treatment of hypertension.

• The preferred option is aliskiren.
Formulary Updates – Uptiers

Movement to Non-preferred Status

• Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.
• All the following products are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

DICLEGIS® (doxylamine succinate & pyridoxine)
• Availability of a generic option for the treatment of nausea and vomiting in women during pregnancy.
• The preferred option is doxylamine-pyridoxine delayed-rel.

ELIDEL® (pimecrolimus)
• Availability of other options for the treatment of mild to moderate atopic dermatitis.
• Preferred options include pimecrolimus, tacrolimus, and Eucrisa (crisaborole).
Formulary Updates – Uptiers

Movement to Non-preferred Status

• Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.

• All the following products are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

MESTINON® (pyridostigmine)

• Availability of generic options for the treatment of myasthenia gravis.

• Preferred options include pyridostigmine and pyridostigmine ext-rel.

NAPROSYN® (naproxen)

• Availability of other NSAIDs for pain management.

• Preferred options include diclofenac sodium delayed-rel, diflunisal, etodolac, ibuprofen, meloxicam, nabumetone, naproxen sodium tabs, naproxen tabs, oxaprozin, sulindac, Daypro (oxaprozin), and Mobic (meloxicam).
Movement to Non-preferred Status

• Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.

• All the following products are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

MIGRANAL® (dihydroergotamine mesylate)

• Availability of other options for the acute treatment of migraine headaches.

• Preferred options include dihydroergotamine injection, eletriptan, ergotamine-caffeine, naratriptan, rizatriptan, sumatriptan, sumatriptan-naproxen sodium, zolmitriptan, D.H.E. 45 (dihydroergotamine injection), Imitrex (sumatriptan), Maxalt (rizatriptan), Onzetra Xsail (sumatriptan nasal powder), Relpax (eletriptan), Treximet (sumatriptan-naproxen sodium), Zembrace SymTouch (sumatriptan injection), Zomig (zolmitriptan), and Zomig Nasal Spray (zolmitriptan).

ABSTRAL® (fentanyl)

• Availability of additional options for managing breakthrough pain in cancer patients.

• Preferred options include fentanyl transmucosal lozenge and Subsys (fentanyl sublingual spray).
Formulary Updates – Uptiers

Movement to Non-preferred Status

• Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.

• All the following products are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

RETIN-A MICROSPHERE® (tretinoin gel)

• Availability of other options for the treatment of acne vulgaris.

• Preferred options include adapalene, benzoyl peroxide, clindamycin gel, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Epiduo (adapalene-benzoyl peroxide), and Tazorac (tazarotene).
Formulary Updates – Uptiers

Movement to Non-preferred Status

- Typically branded medications that have readily available generic alternatives or, other preferred formulary alternatives in the therapeutic class.
- All the following products are specialty, but retain custom non-specialty formulary tiering and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand)

REYATAZ® (atazanavir)
- Availability of other protease inhibitor options for the treatment of HIV-1 infection.
- Preferred options include atazanavir and Prezista (darunavir).

VIREAD® (tenofovir disoproxil)
- Availability of a generic nucleotide reverse transcriptase inhibitor option for the treatment of HIV-1 infection or chronic hepatitis B infection.
- The preferred option is tenofovir disoproxil fumarate.
Formulary Updates – Uptiers

Movement to Non-preferred Status

- Typically branded medications that have readily available generic alternatives, biosimilars or other preferred formulary alternatives in the therapeutic class.
- All the following products are specialty and will be moving from tier 5 (preferred brand) to tier 6 (non-preferred brand).

NEXAVAR® (sorafenib)

- Availability of other options for the treatment of hepatocellular carcinoma, renal cell carcinoma, or thyroid carcinoma.
- Preferred options include Cabometyx (cabozantinib), Sutent (sunitinib), and Votrient (pazopanib).

PEG-INTRON® (peginterferon alfa-2b)

- Availability of other options for the treatment of chronic hepatitis C infection.
- Consult doctor for preferred options.
Formulary Updates – Uptiers

Movement to Non-preferred Status

- Typically branded medications that have readily available generic alternatives, biosimilars or other preferred formulary alternatives in the therapeutic class.
- All the following products are specialty and will be moving from tier 5 (preferred brand) to tier 6 (non-preferred brand).

**TARCEVA® (erlotinib)**
- Availability of other options for the treatment of metastatic non-small cell lung cancer or pancreatic cancer.
- Preferred options include erlotinib and Iressa (gefitinib).

**TRACLEER® (bosentan)**
- Availability of other endothelin receptor antagonist options for the treatment of pulmonary arterial hypertension.
- Preferred options include ambrisentan, bosentan, and Opsumit (macitentan).
Movement to Non-preferred Status

• Typically branded medications that have readily available generic alternatives, biosimilars or other preferred formulary alternatives in the therapeutic class.

• All the following products are specialty and will be moving from tier 5 (preferred brand) to tier 6 (non-preferred brand).

LETAIRIS® (ambrisentan)

• Availability of other endothelin receptor antagonist options for the treatment of pulmonary arterial hypertension.

• Preferred options include ambrisentan, bosentan, and Opsumit (macitentan).

LUPRON DEPOT-PED® (leuprolide acetate)

• Availability of other options for the treatment of central precocious puberty.

• Consult doctor for preferred options.
Formulary Updates – Uptiers

Movement to Non-preferred Status

• Typically branded medications that have readily available generic alternatives, biosimilars or other preferred formulary alternatives in the therapeutic class.
• All the following products are specialty and will be moving from tier 5 (preferred brand) to tier 6 (non-preferred brand).

ARALAST® (alpha1-proteinase inhibitor [human])

• Availability of another option for the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency.
• The preferred option is Prolastin-C (alpha-1 proteinase inhibitor).

GLASSIA® (alpha1-proteinase inhibitor [human])

• Availability of another option for the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency.
• The preferred option is Prolastin-C (alpha-1 proteinase inhibitor).
Formulary Updates – Downtiers

Movement to Preferred Status

• Typically branded medications that are added as preferred products to provide additional treatment options.
• Non-specialty drugs will move from tier 3 (non-preferred brand) to tier 2 (preferred brand) while specialty drugs will move from tier 6 (non-preferred specialty) to tier 5 (preferred specialty).

**XULTOPHY® (insulin degludec & liraglutide)**

• To provide an additional option to improve glycemic control in adults with type 2 diabetes mellitus.

**XTAMPZA ER® (oxycodone ext-rel)**

• To provide an additional option for severe pain management.

**FIRAZYR® (icatibant)**

• Off-cycle tiering change for CVS effective 10/1/19; Availability of additional option for the treatment of hereditary angioedema (HAE).
Movement to Preferred Status

- Typically branded medications that are added as preferred products to provide additional treatment options.
- Non-specialty drugs will move from tier 3 (non-preferred brand) to tier 2 (preferred brand) while specialty drugs will move from tier 6 (non-preferred specialty) to tier 5 (preferred specialty).

**ADEMPAS® (riociguat)**
- To provide an option for the treatment of persistent/recurrent chronic thromboembolic pulmonary hypertension and pulmonary arterial hypertension.

**YONSA® (abiraterone acetate)**
- To provide an additional option for the treatment of prostate cancer.

**XOLAIR® (omalizumab)**
- To provide an additional option for the treatment of severe asthma and chronic idiopathic urticaria.

**LYNPARZA® (olaparib)**
- To provide an option for the treatment of ovarian cancer.
Formulary Updates – New Drug Additions

New-to-Market Block Removals
• CVS Health program that initially blocks new drugs from being added to the formulary and evaluates:
  • Drug’s place in therapy
  • Potential market share
  • Cost
  • Appropriate utilization management
• CVS adds new drugs to their formulary throughout the year; however the Plan only adds these medications on a quarterly basis

Add-Backs
• Medications that were previously removed from the formulary but are now being added back
• Occurs on a quarterly basis
  • Xeljanz, & Xeljanz XR were added back this year beginning 1/1/2019

New Molecular Entities
• Are also initially placed on CVS’s New-to-Market Block
• These medications are reviewed by the members of the Plan’s P&T Committee to determine:
  • Satisfactory tier position
  • Appropriate utilization management
Add-Backs

- Medications that were previously removed from the formulary but are now being added back
- Only occurs once a year

FASENRA® (benralizumab)
- To provide an additional option for the treatment of asthma.

RELISTOR® (methylnaltrexone bromide)
- To provide an additional option for the treatment of opioid-induced constipation with chronic noncancer pain.
## Formulary Updates – New Drug Additions

<table>
<thead>
<tr>
<th>Therapeutic Category/ Subcategory</th>
<th>Drug</th>
<th>Specialty Flag</th>
<th>CVS Block Removal Date</th>
<th>Proposed NCSHP Tier</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory/ Severe Asthma Agents</td>
<td>FASENRA 30MG/ML syringe (benralizumab)</td>
<td>Y</td>
<td>01/01/20</td>
<td>5</td>
<td>Indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.</td>
</tr>
<tr>
<td>Central Nervous System/ Narcolepsy</td>
<td>SUNOSI 75 &amp; 150MG tab (solriamfetol)</td>
<td>N</td>
<td>10/1/19</td>
<td>2</td>
<td>Indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).</td>
</tr>
<tr>
<td>Central Nervous System/ Multiple Sclerosis Agents</td>
<td>MAYZENT 0.25 &amp; 2MG tab (siponimod)</td>
<td>Y</td>
<td>10/1/19</td>
<td>5</td>
<td>Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Same class as Gilenya.</td>
</tr>
<tr>
<td>Anti-Infectives/ Antifungals</td>
<td>XENLETA 600MG tabs &amp; 150MG/ML inj (leflunomide)</td>
<td>N</td>
<td>10/1/19</td>
<td>3</td>
<td>Indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP). Same class as Atabax but for internal use.</td>
</tr>
<tr>
<td>Antineoplastic Agents/ Hormonal</td>
<td>NUBEQA 300MG tab (darolutamide)</td>
<td>Y</td>
<td>10/1/19</td>
<td>6</td>
<td>Indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. Same class as Erleada, Casodex, Xtandi, &amp; Nilandron.</td>
</tr>
<tr>
<td>Antineoplastic Agents/ Antiandrogens</td>
<td>RINVOQ ER 15MG tab (upadacitinib)</td>
<td>Y</td>
<td>11/15/19</td>
<td>5</td>
<td>Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. Same class as Olumiant &amp; Xeljanz.</td>
</tr>
<tr>
<td>Central Nervous System/ Movement Disorders</td>
<td>INGREZZA 40 &amp; 80MG cap (valbenazine)</td>
<td>Y</td>
<td>01/01/20</td>
<td>5</td>
<td>Indicated for the treatment of adults with tardive dyskinesia. Same class as Austedo &amp; Xenazine.</td>
</tr>
</tbody>
</table>
## Formulary Updates – New Drug Additions

<table>
<thead>
<tr>
<th>Therapeutic Category/ Subcategory</th>
<th>Drug</th>
<th>Specialty Flag</th>
<th>CVS Block Removal Date</th>
<th>Proposed NCSHP Tier</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunologic Agents/ Autoimmune Agents/ Psoriasis</td>
<td>TREMFYA 100MG/ML pen &amp; syringe (guselkumab)</td>
<td>Y</td>
<td>01/01/20</td>
<td>5</td>
<td>Indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Same class as Skyrizi, Ilumya, &amp; Stelara.</td>
</tr>
<tr>
<td>Central Nervous System/ Migraine/ Monoclonal Antibodies</td>
<td>AIMOVIG 70MG/ML inj &amp; 140 MG/ML pen (erenumab)</td>
<td>N</td>
<td>01/01/20</td>
<td>2</td>
<td>Indicated for the preventive treatment of migraine in adults. Same class as Ajovy, &amp; Emgality.</td>
</tr>
<tr>
<td>Gastrointestinal/ Opioid-Induced Constipation</td>
<td>SYMPROIC 0.2MG tab (naldemedine)</td>
<td>N</td>
<td>01/01/20</td>
<td>2</td>
<td>Indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Same class as Entereg, Relistor, &amp; Movantik.</td>
</tr>
<tr>
<td>Respiratory/ Severe Asthma Agents</td>
<td>NUCALA 100MG/ML inj (mepolizumab)</td>
<td>Y</td>
<td>8/21/2019</td>
<td>5</td>
<td>Prefilled syringe form to join vial form already on formulary.</td>
</tr>
<tr>
<td>Genitourinary/ Renal Agents</td>
<td>THIOLA EC 100 &amp; 300MG tab (tiopronin)</td>
<td>N</td>
<td>8/21/2019</td>
<td>3</td>
<td>Enteric-coated formulation</td>
</tr>
<tr>
<td>Hematologic/ Miscellaneous</td>
<td>FERRIPROX 1000MG tab (deferiprone)</td>
<td>Y</td>
<td>8/21/2019</td>
<td>6</td>
<td>Tablet formulation (Solution on formulary)</td>
</tr>
<tr>
<td>Anti-Infectives/ Antiretroviral Agents/ Antiretroviral</td>
<td>TEMIXYS (lamivudine/tenofovir disoproxil fumarate)</td>
<td>Y</td>
<td>9/3/2019</td>
<td>2</td>
<td>Shares GPI with Cimduo (same active ingredients)</td>
</tr>
<tr>
<td>Combinations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topical/ Dermatology/ Local Anesthetics</td>
<td>QUTENZA KIT 8% 1-PCH (capsaicin)</td>
<td>Y</td>
<td>9/4/2019</td>
<td>6</td>
<td>Capsaicin topical patch and cleansing gel kit- Limited distribution</td>
</tr>
</tbody>
</table>

![North Carolina State Health Plan Logo](image1.png)

*North Carolina State Health Plan*

*A Division of the Department of State Treasurer*
### Formulary Updates – New Drug Additions

<table>
<thead>
<tr>
<th>Therapeutic Category/ Subcategory</th>
<th>Drug</th>
<th>Specialty Flag</th>
<th>CVS Block Removal Date</th>
<th>Proposed NCSHP Tier</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocrine and Metabolic/ Estrogens/ Vaginal</td>
<td>IMVEXXY 4 &amp; 10MCG suppos (estradiol vaginal)</td>
<td>N</td>
<td>9/11/2019</td>
<td>3</td>
<td>Lower dose (4mcg) vag tablet formulation of estradiol; Additional 10 mcg vag tablet formulation of estradiol.</td>
</tr>
<tr>
<td>Anti-Infectives/ Miscellaneous</td>
<td>VANCOMYCIN INJ 1GM/200M</td>
<td>N</td>
<td>9/18/2019</td>
<td>3</td>
<td>1000mg/200ml IV solution</td>
</tr>
<tr>
<td>Anti-Infectives/ Antivirals/ Hepatitis B Agents</td>
<td>VEMLIDY 25MG tab (tenofovir alafenamide fumarate)</td>
<td>Y</td>
<td>10/1/2019</td>
<td>5</td>
<td>Brand of tenofovir alafenamide</td>
</tr>
<tr>
<td>Topical/ Ophthalmic/ Rho Kinase Inhibitor / Prostaglandin Combinations</td>
<td>ROCKLATAN drops (netarsudil/latanoprost)</td>
<td>N</td>
<td>10/1/2019</td>
<td>2</td>
<td>Combination of Netarsudil (Rho kinase inhibitor) and Latanoprost (Prostaglandin) - products already on formulary.</td>
</tr>
<tr>
<td>Antineoplastic Agents/ Hormonal Antineoplastic Agents/ Antiandrogens</td>
<td>YONSA 125MG tab (abiraterone)</td>
<td>Y</td>
<td>10/1/2019</td>
<td>5</td>
<td>Abiraterone formulation - Zytiga already on formulary.</td>
</tr>
<tr>
<td>Endocrine and Metabolic/ Androgens</td>
<td>XYOSTED 50/0.5, 75/0.5, 100/0.5 inj (testosterone)</td>
<td>N</td>
<td>10/2/2019</td>
<td>3</td>
<td>Testosterone enathate solution for injection whereas only the oil formulation previously available.</td>
</tr>
<tr>
<td>Cardiovascular/ Antilipemics/ PCSK9 Inhibitors</td>
<td>REPATHA SURE PEN &amp; INJ 140MG/ML, PUSH CRT 420-3.5 (evolocumab)</td>
<td>Y</td>
<td>1/1/2020</td>
<td>2</td>
<td>Additional NDCs</td>
</tr>
</tbody>
</table>
**FASENRA (benralizumab)**

**Indication:**
- Add-on maintenance treatment of severe asthma in adults and children ≥12 years of age with an eosinophilic phenotype.
- Limitations: not for treatment of other eosinophilic conditions, not for relief of acute bronchospasm or status asthmaticus.

**Mechanism of Action:**
- Interleukin-5 Receptor Antagonist; Monoclonal Antibody

**Drug Facts:**
- 30 mg subcutaneously every 4 weeks for the first 3 doses, and then once every 8 weeks.
- Warnings: Helminth infections, not for acute asthma, do not discontinue corticosteroids abruptly.
- ADRs: Antibody development, Headache, Pharyngitis, Fever

**Place in Therapy:**
- 74% of patients who continued on Q8W dosing from SIROCCO or CALIMA had 0 exacerbations during BORA (56 weeks).

**Proposed Tier Placement:**
- Tier 5 – Preferred Specialty
Formulary Updates – New Molecular Entities

FASENRA (benralizumab)

Criteria for Initial Approval:

• Authorization of 6 months may be granted for treatment of asthma when all of the following criteria are met:

A. Member is 12 years of age or older.
B. Member has a baseline blood eosinophil count of at least 150 cells per microliter.
C. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
   1. Inhaled corticosteroid
   2. Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
D. Member will not use Fasenra as monotherapy.
E. Member does not currently smoke.
F. Member will not use Fasenra concomitantly with other biologics (e.g., Cinqair, Dupixent, Nucala, Xolair).
FASENRA (benralizumab)

Continuation of Therapy:

- Authorization of 12 months may be granted for treatment of asthma when all of the following criteria are met:
  - A. Member is 12 years of age or older.
  - B. Asthma control has improved on Fasenra treatment as demonstrated by at least one of the following:
    1. A reduction in the frequency and/or severity of symptoms and exacerbations
    2. A reduction in the daily maintenance oral corticosteroid dose
  - C. Member will not use Fasenra as monotherapy.
  - D. Member does not currently smoke.
  - E. Member will not use Fasnera concomitantly with other biologics (e.g., Cinqair, Dupixent, Nucala, Xolair).
FASENRA (benralizumab)

Specialty Quantity Limit Program:
- The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. If the member’s plan allows a quantity limit exception review for the requested medication, coverage of an additional quantity may be provided up to the exception limit with prior authorization. The recommended dosing parameters for the treatment of severe eosinophilic asthma fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.
- Covered Quantities:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Standard Limit</th>
<th>Exception Limit*</th>
<th>FDA-recommended dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasenra 30 mg/mL single-dose prefilled syringe</td>
<td>1 syringe per 56 days</td>
<td>3 syringes per 84 days</td>
<td>Initial: 30 mg every 4 weeks for the first 3 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maintenance: 30 mg every 8 weeks</td>
</tr>
</tbody>
</table>

*Coverage up to the exception limits may be provided with prior authorization via the Specialty Post Limit Quantity Exception Criteria for approval.
SUNOSI (solriamfetol)

**Indication:**
- To improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).
- Limitations: not indicated to treat the underlying airway obstruction in OSA. Patients should be treated for underlying airway obstruction for at least 1 month prior to and during therapy.

**Mechanism of Action:**
- Dopamine and Norepinephrine - Reuptake Inhibitor

**Drug Facts:**
- 37.5 mg or 75 mg to start increasing to the maximum dose of 150 mg/day
- Warnings: Cardiovascular effects, Psychiatric effects, Drug-drug interactions.
- ADRs: Headache, Anxiety, Decreased appetite, Nausea, Palpitations

**Place in Therapy:**
- Proven effective across key clinical measures: maintenance of wakefulness test, Epworth Sleepiness Scale, & Patient Global Impression of Change scale.

**Proposed Tier Placement:**
- Tier 2 – Preferred Brand
SUNOSI Initial Prior Authorization Criteria with Quantity Limit

Affected Medications:
• SUNOSI (solriamfetol)

Coverage Criteria:
The requested drug will be covered with prior authorization when the following criteria are met:
• The patient has narcolepsy confirmed by sleep lab evaluation
  AND
  o The patient has experienced an inadequate treatment response, intolerance or contraindication to a CNS stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate)
  AND
  o The patient has experienced an inadequate treatment response, intolerance or contraindication to modafinil OR armodafinil

OR
• The patient has obstructive sleep apnea (OSA) confirmed by polysomnography
  AND
  o The patient has been receiving treatment for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) for at least one month
  AND
  o The patient has experienced an inadequate treatment response, intolerance or contraindication to modafinil OR armodafinil
Formulary Updates – New Molecular Entities

TREMFYA (guselkumab)

Criteria for Initial Approval:

Moderate to severe plaque psoriasis
A. Authorization of 24 months may be granted for members who are 18 years of age or older who have previously received Tremfya, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis.
B. Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis for members who are 18 years of age or older when all of the following criteria are met:
   1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   2. Member meets any of the following criteria:
      a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
      b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix).
      c. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.
TREMFYA (guselkumab)

Specialty Quantity Limit Program:
The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. If member’s plan allows a quantity limit exception review for the requested medication, coverage of an additional quantity may be provided up to the exception limit with prior authorization.

Covered Quantities

<table>
<thead>
<tr>
<th>Medication</th>
<th>Standard Limit</th>
<th>Exception Limit*</th>
<th>FDA-recommended dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tremfya (guselkumab) 100 mg/mL</td>
<td>1 syringe per 56 days</td>
<td>2 syringes per 28 days</td>
<td>• Loading doses: 100 mg at week 0 and 4</td>
</tr>
<tr>
<td>prefilled syringe</td>
<td></td>
<td></td>
<td>• Maintenance dose: 100 mg every 8 weeks thereafter</td>
</tr>
</tbody>
</table>

*Coverage up to the exception limits may be provided with prior authorization via the Specialty Post Limit Quantity Exception Criteria for approval.
INGREZZA (valbenazine)

Criteria for Initial Approval:

**Tardive dyskinesia**
- Authorization of 3 months may be granted for members requesting Ingrezza for the treatment of tardive dyskinesia related to drug use.

Continuation of Therapy:
- Coverage may be renewed for 12 months in situations where there has been an improvement in signs and symptoms of tardive dyskinesia.

**Specialty Quantity Limit Program:**
- The initial limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the initial limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Standard Limit</th>
<th>FDA-recommended dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingrezza 40 mg capsule</td>
<td>30 per 30 days</td>
<td>Initial: 40 mg orally once daily x 1 week</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maintenance: 80 mg orally once daily</td>
</tr>
<tr>
<td>Ingrezza 80 mg capsule</td>
<td>30 per 30 days</td>
<td></td>
</tr>
</tbody>
</table>
MAYZENT (siponimod)

Criteria for Initial Approval:

Relapsing forms of multiple sclerosis
- Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically isolated syndrome
- Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome.

Continuation of Therapy:
- Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Mayzent.
MAYZENT (siponimod)

Specialty Quantity Limit Program:
• The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. If the member’s plan allows a quantity limit exception review for the requested medication, coverage of an additional quantity may be provided up to the exception limit with prior authorization.

• Covered Quantities:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Standard Limit*#</th>
<th>Exception Limit*</th>
<th>FDA-recommended dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mayzent (siponimod) 0.25mg tablets starter pack</td>
<td>12 per 5 days</td>
<td>Not applicable</td>
<td>• Titration to reach 2 mg maintenance dosage:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 1: 0.25mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 2: 0.25mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 3: 0.50mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 4: 0.75mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 5: 1.25mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Do not use the starter pack for patients who will be titrated to the 1-mg maintenance dosage</td>
</tr>
<tr>
<td>Mayzent (siponimod) 0.25mg tablets</td>
<td>112 per 28 days</td>
<td>Not applicable</td>
<td>• Titration to reach 1 mg maintenance dosage:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 1: 0.25mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 2: 0.25mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 3: 0.50mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 4: 0.75mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o  Day 5 and after: 1 mg</td>
</tr>
<tr>
<td>Mayzent (siponimod) 2mg tablets</td>
<td>30 per 30 days</td>
<td>Not applicable</td>
<td>• 2 mg daily after starter pack</td>
</tr>
</tbody>
</table>
NUBEQA (darolutamide)

**Exclusions:**
- Coverage will not be provided if the requested medication is used in combination with a second-generation oral anti-androgen (e.g., apalutamide [Erleada]) or an oral androgen metabolism inhibitor (e.g., abiraterone acetate [Zytiga]).

**Criteria for Initial Approval:**

**Prostate Cancer**
- Authorization of 12 months may be granted to members for the treatment of non-metastatic castration-resistant prostate cancer when the member has had a bilateral orchiectomy or will be using the requested medication in combination with a GnRH analog.

**Continuation of Therapy:**
- Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Criteria for Initial Approval above who have not experienced disease progression or an unacceptable toxicity.
RINVOQ (upadacitinib)

Criteria for Initial Approval:

Moderately to severely active rheumatoid arthritis (RA)

A. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Xeljanz, Olumiant) indicated for moderately to severely active rheumatoid arthritis.

B. Authorization of 12 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:
   1. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
   2. Member has an intolerance or contraindication to methotrexate (See Appendix A).

Continuation of Therapy:

- Authorization of 12 months may be granted for all members (including new members) who are using Rinvoq for an indication outlined in Criteria for Initial Approval and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.
RINVOQ (upadactinib)

Specialty Quantity Limit Program:
• The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

• Covered Quantities:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Standard Limit</th>
<th>FDA-recommended dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rinoq 15 mg extended-release tablet</td>
<td>30 tablets per 30 days</td>
<td>Rheumatoid arthritis: 15 mg once daily</td>
</tr>
</tbody>
</table>
ROCKLATAN (netarsudil/latanoprost)

Criteria for Initial Approval:
Branded prostaglandin analogues will be covered with post step therapy prior authorization when the following criteria are met:

• Patient has experienced an inadequate treatment response, intolerance, contraindication or potential drug interaction to at least one generic prostaglandin analogue.
AIMOVIG (erenumab-aooe)

**Initial Step Therapy:**
- If the patient has filled a prescription for at least a 56 day supply of divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, or venlafaxine within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**Criteria for Initial Approval:**
The requested drug will be covered with prior authorization when the following criteria are met:
- The requested drug is being prescribed for the preventive treatment of migraine in an adult patient
  - The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline
  - OR
  - The patient experienced an inadequate treatment response with an 8-week trial of any of the following: Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), Antidepressants (e.g., amitriptyline, venlafaxine)
  - OR
  - The patient experienced an intolerance or has a contraindication that would prohibit an 8-week trial of any of the following: Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), Antidepressants (e.g., amitriptyline, venlafaxine)
MOVANTIK Initial Prior Authorization Criteria

Affected Medications:

- MOVANTIK (naloxegol)

Coverage Criteria:

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of opioid-induced constipation (OIC) in an adult patient with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
SYMPROIC Initial Prior Authorization Criteria

Affected Medications:
- SYMPROIC (naldemedine)

Coverage Criteria:
The requested drug will be covered with prior authorization when the following criteria are met:
- The requested drug is being prescribed for the treatment of opioid-induced constipation (OIC) in an adult patient with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
RELISTOR Initial Prior Authorization Criteria

Affected Medications:
- RELISTOR (methylnaltrexone bromide)

Coverage Criteria:
The requested drug will be covered with prior authorization when the following criteria are met:
- The requested drug is being prescribed for opioid-induced constipation in an adult patient with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
  OR
- The requested drug is being prescribed for opioid-induced constipation in an adult patient with advanced illness or pain caused by active cancer who requires opioid dosage escalation for palliative care
  AND
- The request is for the injectable formulation of the requested drug
Summary of Formulary Changes Effective 1/1/20

DRUG EXCLUSIONS

- ASMANEX, BUTRANS, HYSINGLA, OXYCONTIN, ZOHYDRO, QTERN, ALREX, FLAREX, LOTEMAX, TIMOPTIC OCUDOSE, ZYLET, CARAFATE, COMBIVENT, LO LOESTRIN, NATAZIA, TAYTULLA, MOVIPREP, OSMOPREP, PROAIR, TRANSDERM, VERZENIO, BEAU RX, RECEDO, EPICREAM, KAMDOY, SIL-K PAD, DUROLANE, STRIBILD, COMPLERA, AVONEX, PLEGRIDY, SIMPONI, ABSORICA, APLENZIN, DUEXIS, VIMOVO, JUBLIA, KERYDIN, SITAVIG, XERESE, NASCOBAL, ZIPSOR, ZYFLO and BENZEPRO.

UPTIERS

- RETIN-A MICROSPHERE, SAFYRAL, TEKTURNA, DICLEGIS, ELIDEL, MESTINON, NARPOSYN, MIGRANAL, ABSTRAL, ARALAST, GLASSIA, NEXAVAR, TARCEVA, TRACLEER, LETAIRIS, REYATAZ, VIREAD, LUPRON DEPOT-PED, & PEG-INTRON.

DOWNTIERS

- XULTOPHY, XTAMPZA, FIRAZYR, ADEMPAS, YONSA, XOLAIR, & LYNPARZA.

NEW DRUG ADDITIONS

- FASENRA, SUNOSI, MAYZENT, XENLETA, NUBEQA, RINVOQ, INGREZZA, TREMFYA, AIMOVIG, SYMPROIC, NUCALA, THIOLA EC, FERRIPROX, TEMIXYS, QUTENZA, IMVEXXY, VANCOMYCIN, VEMLIDY, ROCKLATAN, YONSA, XYOSTED, REPATHA & RELISTOR.

UTILIZATION MANAGEMENT

- PA for MOVANTIK, RELISTOR, and SYMPROIC; PA and QL for SUNOSI; Step Therapy for Prostaglandin Analogues & Combinations; SGM and Specialty QL for MAYZENT, RINVOQ, INGREZZA, TREMFYA, FASENRA; SGM for NUBEQA.
Next meeting: **February 12, 2020**