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Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 10/1/19

August 14, 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 May's meeting went into effect 7/1/2019 and include the following:

Removed the following products from the formulary:

- EPIVIR HBV, VEMLIDY, ZARXIO, ZORTRESS, BARACLUDE tablets, HEPSERA, CHORIONIC GONADOTROPIN, NOVAREL, PREGNYL, FULPHILA, GRANIX, CELLCEPT, MYFORTIC, RAPAMUNE, ASTAGRAF XL, ENVARSUS XR, ZORVOLEX, RHEUMATE, FOSTEUM, FOSTEUM PLUS, VASCULERA, FML LIQUIFILM & LACTULOSE (NDC: 46600020003010), NAPROXEN (NDC: 66100060001805) & ALTABAX.

Moved the following branded products to non-preferred status:

- SAVELLA, RAPAFLO, CANASA, CARAFATE, TENORETIC, & CIALIS (2.5 and 5 mg).

Adopted the following new utilization management criteria:

- Opioid Policies for Age <19 (effective Oct. 1, 2019), XIIDRA Policy, Specialty Quantity Limit for HIV Medications, DIACOMIT Quantity Limit, & ELZONRIS Specialty Guideline Management.

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 10/1/2019

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 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

SABRIL® (vigabatrin)

- Availability of a generic option for treatment of refractory complex partial seizures and infantile spasms.
- The preferred option on the Advanced Control Specialty Formulary is vigabatrin.

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

COLCRYS® (colchicine)

- Availability of a generic option for the prophylaxis and treatment of gout and Familial Mediterranean fever (FMF).
- The preferred option is colchicine tablet.

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

PERCOCET® (oxycodone-acetaminophen)

- Availability of other options for pain management.
- Preferred options include hydrocodone-acetaminophen, hydromorphone, morphine, oxycodone-acetaminophen, and Nucynta (tapentadol).

TOPROL XL® (metoprolol succinate ext-rel)

- Availability of other beta-blocker options for various heart conditions.
- Preferred options include atenolol, carvedilol, carvedilol phosphate ext-rel, metoprolol succinate ext-rel, metoprolol tartrate, nadolol, pindolol, propranolol, propranolol ext-rel, and Bystolic (nebivolol).

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

XANAX® (alprazolam)

- Availability of generic options for the management of anxiety or panic disorder.
- Preferred options include alprazolam, clonazepam, diazepam, lorazepam, and oxazepam.

XANAX XR® (alprazolam ext-rel)

- Availability of generic options for the management of anxiety or panic disorder.
- Preferred options include alprazolam, clonazepam, diazepam, lorazepam, and oxazepam.

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

LAMICTAL® (lamotrigine)

- Availability of other anticonvulsant options.
- Preferred options include carbamazepine, carbamazepine ext-rel, divalproex sodium, divalproex sodium ext-rel, gabapentin, lamotrigine, lamotrigine ext-rel, levetiracetam, levetiracetam ext-rel, oxcarbazepine, phenobarbital, phenytoin, phenytoin sodium extended, primidone, tiagabine, topiramate, valproic acid, zonisamide, Fycompa (perampanel), Oxtellar XR (oxcarbazepine ext-rel), Trokendi XR (topiramate ext-rel), and Vimpat (lacosamide).
- All formulations including tablets, chewable dispersible tablets, orally disintegrating tablets, starter pack, and extended release.

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

ONFI® (clobazam)

- Availability of other anticonvulsant options for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome.
- Preferred options include clobazam, lamotrigine, topiramate, and Trokendi XR (topiramate ext-rel).

PRISTIQ® (desvenlafaxine)

- Availability of generic options for the for the treatment of adults with major depressive disorder (MDD).
- Preferred options include desvenlafaxine ext-rel, duloxetine, venlafaxine, and venlafaxine ext-rel capsule.

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

LEXAPRO® (escitalopram)

- Availability of other options for the treatment of major depressive disorder (MDD) and generalized anxiety disorder (GAD).
- Preferred options include citalopram, escitalopram, fluoxetine, paroxetine HCl, paroxetine HCl ext-rel, sertraline, Trintellix (vortioxetine), and Viibryd (vilazodone).

PROZAC® (fluoxetine)

- Availability of other options for the treatment of major depressive disorder (MDD), obsessive compulsive disorder (OCD), bulimia nervosa, and panic disorder.
- Preferred options include citalopram, escitalopram, fluoxetine, paroxetine HCl, paroxetine HCl ext-rel, sertraline, Trintellix (vortioxetine), and Viibryd (vilazodone).

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

EVEKEO® (amphetamine)

- Availability of other amphetamine options.
- Preferred options include amphetamine-dextroamphetamine mixed salts and methylphenidate.

SUBOXONE® film (buprenorphine-naloxone)

- Availability of other options for the treatment of opioid dependence.
- Preferred options include buprenorphine-naloxone sublingual and Zubsolv (buprenorphine-naloxone sublingual tablet).

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

BEYAZ® (drospirenone/ethinyl estradiol/levomefolate)

- Availability of other oral contraceptive options for preventing pregnancy, treating premenstrual dysphoric disorder, treating moderate acne, and raising folate levels.
- Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron, and Safyral (ethinyl estradiol-drospirenone-levomefolate).

MINASTRIN® 24 FE (norethindrone/ethinyl estradiol/ferrous fumarate)

- Availability of other monophasic oral contraceptive options.
- Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron, and Safyral (ethinyl estradiol-drospirenone-levomefolate).

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

YAZ® (drospirenone/ethinyl estradiol)

- Availability of other oral contraceptive options for preventing pregnancy, treating premenstrual dysphoric disorder, and treating moderate acne.
- Preferred options include ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron, and Safyral (ethinyl estradiol-drospirenone-levomefolate).

ORTHO TRI-CYCLN LO® (norgestimate/ethinyl estradiol)

- Availability of a generic triphasic oral contraceptive option.
- The preferred option is 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

MINIVELLE® (estradiol transdermal patch)

- Availability of other options for the treatment of vasomotor symptoms associated with menopause.
- Preferred options include estradiol, Divigel (estradiol), and Evamist (estradiol).

VIVELLE-DOT® (estradiol transdermal system)

- Availability of other options for the treatment of vasomotor symptoms associated with menopause.
- Preferred options include estradiol, Divigel (estradiol), and Evamist (estradiol).

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

LIALDA® (mesalamine)

- Availability of other options for the induction of remission in patients with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.
- Preferred options include balsalazide, sulfasalazine, sulfasalazine delayed-rel, Apriso (mesalamine ext-rel), and Pentasa (mesalamine ext-rel).

ACIPHEX® (rabeprazole)

- Availability of other proton pump inhibitors for the acute or maintenance treatment of gastroesophageal disease (GERD), duodenal ulcers, and hypersecretory conditions.
- Preferred options include esomeprazole, lansoprazole, omeprazole, pantoprazole, and Dexilant (dexlansoprazole).

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

RAPAFLO® (silodosin)

- Availability of generic options for the treatment of benign prostatic hyperplasia (BPH).
- Preferred options include alfuzosin ext-rel, doxazosin, silodosin, tamsulosin, and terazosin.

CIALIS® (tadalafil)

- Availability of generic phosphodiesterase inhibitor options.
- Preferred options are sildenafil and tadalafil.

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

COUMADIN® (warfarin)

- Availability of a generic oral anticoagulant for the prevention and/or treatment of clots.
- The preferred option is warfarin.
- Because this is a narrow therapeutic index drug, we will be grandfathering coverage for the 100 current utilizers.

SINGULAIR® (montelukast)

- Availability of generic options for the asthma, exercise-induced bronchoconstriction, and allergic rhinitis.
- Preferred options include montelukast, zafirlukast, and zileuton 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

FINACEA® (azelaic acid)

- Availability of other topical options for the treatment of rosacea.
- Preferred options include metronidazole, Finacea foam (azelaic acid), and Soolantra (ivermectin).

PREVIDENT® (fluoride)

- Availability of other options for dental caries prevention.
- Preferred options include over-the-counter products.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

MUPIROCIN 2% CREAM

- Availability of generic topical antibiotics.
- Preferred options include gentamicin and mupirocin ointment.

GLYCOPYRROLATE 1.5MG TABLETS

- Availability of other options for adjunctive therapy in the treatment of peptic ulcer such as dicyclomine.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

METFORMIN ER TABLETS (Fortamet®)

- Availability of other generics: metformin, metformin ext-rel (except generic FORTAMET, GLUMETZA)

METFORMIN ER TABLETS (Glumetza®)

- Availability of other generics: metformin, metformin ext-rel (except generic FORTAMET, GLUMETZA)

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

OMEPRAZOLE/SODIUM BICARBONATE CAPSULES

- Availability of other options for the treatment of active duodenal ulcers, active benign gastric ulcers, GERD, and maintenance of healing of erosive esophagitis including esomeprazole, lansoprazole, omeprazole, pantoprazole, and Dexilant (dexlansoprazole).

OMEPRAZOLE/BICARBONATE PACKETS 40-1680MG

- Availability of other options for the treatment of active duodenal ulcers, active benign gastric ulcers, GERD, and maintenance of healing of erosive esophagitis including: esomeprazole, lansoprazole, omeprazole, pantoprazole, and Dexilant (dexlansoprazole).

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

FENOPROFEN 200MG CAPSULES

- Availability of other generic NSAIDs including: diclofenac sodium, meloxicam, and naproxen (except naproxen CR or suspension).

FENOPROFEN 400MG CAPSULES

- Availability of other generic NSAIDs including diclofenac sodium, meloxicam, and naproxen (except naproxen CR or suspension).
- NDCs by Gentex and Xspire Pharma.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

NAPROXEN 375 & 500MG CONTROLLED RELEASE TABLETS

- Availability of other generic NSAIDs including diclofenac sodium, meloxicam, naproxen (except naproxen CR or suspension).

NAPROXEN SUSPENSION 125/5ML

- Availability of other generic NSAIDs including ibuprofen suspension.
- NDC by Key Therapeutics in addition to already excluded Palmetto Pharmaceuticals.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

FENOFIBRATE 120MG TABLETS

- Availability of generic options for the treatment of high triglycerides.
- Preferred options include fenofibrate (except 120 mg tablet) and fenofibric acid.

FENOGLIDE® 120MG TABLETS (fenofibrate)

- Availability of generic options for the treatment of high triglycerides.
- Preferred options include fenofibrate (except 120 mg tablet) and fenofibric acid.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

VECTICAL® OINTMENT 3MCG/GM (calcitriol)

- Availability of generic options for the topical treatment of plaque psoriasis.
- Preferred options include calcipotriene ointment and solution.

CALCITRIOL OINTMENT 3MCG/GM

- Availability of generic options for the topical treatment of plaque psoriasis.
- Preferred options include calcipotriene ointment and solution.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

PSORCON® CREAM 0.05% (diflorasone)

- Availability of generic high-potency corticosteroids for the relief of inflammatory and pruritic conditions.
- Preferred options include desoximetasone and fluocinonide (except fluocinonide cream 0.1%).

DIFLORASONE CREAM & OINTMENT 0.05%

- Availability of generic high-potency corticosteroids for the relief of inflammatory and pruritic conditions.
- Preferred options include desoximetasone and fluocinonide (except fluocinonide cream 0.1%).

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

CORDRAN® OINTMENT 0.05% (flurandrenolide)

- Availability of generic medium-potency corticosteroids for the relief of inflammatory and pruritic conditions.
- Preferred options include clocortolone, hydrocortisone butyrate, mometasone, and triamcinolone.

FLURANDRENOLIDE OINTMENT 0.05%

- Availability of generic medium-potency corticosteroids for the relief of inflammatory and pruritic conditions.
- Preferred options include clocortolone, hydrocortisone butyrate, mometasone, and triamcinolone.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

LIDOCAINE/TETRACAINE CREAM

- Availability of a generic option for topical local analgesia.
- The preferred option is lidocaine-prilocaine.

LIDOTREX® GEL 2% (lidocaine)

- Availability of a generic option for topical local analgesia.
- The preferred option is lidocaine-prilocaine.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

CALCIPOTRIENE CREAM 0.005%

- Availability of generic options for the topical treatment of plaque psoriasis.
- Preferred options include calcipotriene ointment and solution.

DOXEPIN HCL CREAM 5%

- Availability of other options for the short-term management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus including: desonide, hydrocortisone, tacrolimus, Elidel (pimecrolimus), and Eucrisa (crisaborole).
- NDCs by Mylan.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

XOLEGEL® GEL 2% (ketoconazole)

- Availability of generic options for the treatment of seborrheic dermatitis.
- Preferred options include ciclopirox and ketoconazole.

CARBINOXAMINE 6MG TABLETS

- Availability of another antihistamine agent, levocetirizine.
- NDC by Foxland Pharmaceuticals.

Formulary Updates – Product Exclusions

Hyperinflation Strategy

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

DIHYDROERGOTAMINE SPRAY 8X4MG/ML

- Availability of other options for the acute treatment of migraine headaches with or without aura including: eletriptan, ergotamine-caffeine, naratriptan, rizatriptan, sumatriptan, zolmitriptan, Onzetra Xsail (sumatriptan nasal powder), Zembrace Symtouch (sumatriptan injection), and Zomig Nasal Spray (zolmitriptan).
- NDC by Oceanside Pharmaceuticals.

FOLIC-K® CAPSULES (folic acid)

- Availability of other generic folic acid formulations.

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)

FIORINAL® (butalbital/aspirin/caffeine)

- Availability of other treatment options for the relief of symptom complex of tension (or muscle contraction) headache.
- The preferred options are generic alternatives diclofenac sodium, ibuprofen, & naproxen (except naproxen CR or suspension).

RANEXA® (ranolazine ext-rel)

- Availability of a generic option for the treatment of chronic angina.
- The preferred option is ranolazine extended-release tablet.

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)

ANDROGEL® 1.62% (testosterone gel)

- Availability of other options for the treatment of hypogonadism.
- Preferred options include testosterone gel, testosterone solution, and Androderm (testosterone transdermal).

VESICARE® (solifenacin)

- Availability of other options for the treatment of overactive bladder.
- Preferred options include darifenacin ext-rel, oxybutynin ext-rel, solifenacin, tolterodine, tolterodine ext-rel, trospium, trospium ext-rel, Myrbetriq (mirabegron), and Toviaz (fesoterodine).

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)

DIFFERIN® (adapalene)

- Availability of other options for the treatment of acne vulgaris.
- Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microspheres), and Tazorac (tazarotene).

ORACEA® (doxycycline)

- Availability of a generic oral option for the treatment of rosacea.
- The preferred option is doxycycline monohydrate delayed-release capsule.

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).

NONE

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
- Only occurs once a year
 - 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

Formulary Updates – New Drug Additions

Therapeutic Category/ Subcategory	Drug	Specialty Flag	GPI	CVS Block Removal Date	Proposed NCSHP Tier	Comments	New Molecular Entity
Immunologic Agents/ Autoimmune Agents	SKYRIZI INJECTION 150 DOSE (Risankizumab)	Y	9025057070F820	8/7/2019	5	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	Yes
Central Nervous System/ Multiple Sclerosis Agents	MAVENCLAD PAK 10MG (cladribine)	Y	6240101500B718	8/9/2019	6	Treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults	Yes
Topical/ Dermatology/ Miscellaneous Skin and Mucous Membrane	QBREXZA PAD 2.4% (glycopyrronium)	N	90970030204320	8/14/2019	3	Treatment of primary axillary hyperhidrosis in ages 9 and older.	Yes
Respiratory/ Cystic Fibrosis	KALYDECO PAK 25MG (ivacaftor)	Y	45302030003010	5/22/19	6	Line extension - new form (granules)	No
Antineoplastic Agents/ Kinase Inhibitors	ZYKADIA TABLET 150MG (ceritinib)	Y	21534014000330	6/5/19	6	Line extension - new strength	No
Nutritional/Supplements/ Vitamins and Minerals/ Prenatal Vitamins	PRENATAL PLUS MIS MV + DHA	N	78512018006310	6/5/19	3	Additional prenatal vitamin product	No
Analgesics/ Opioid Analgesics	KADIAN 20MG ER CAPSULES (morphine extended-release)	N	65100055107020	6/5/19	3	Line extension - new strength	No
Analgesics/ Opioid Analgesics	KADIAN 60MG ER CAPSULES (morphine extended-release)	N	65100055107045	6/5/19	3	Line extension - new strength	No

Formulary Updates – New Drug Additions

Therapeutic Category/ Subcategory	Drug	Specialty Flag	GPI	CVS Block Removal Date	Proposed NCSHP Tier	Comments	New Molecular Entity
Immunologic Agents/ Autoimmune Agents	RITUXAN INJECTION 100MG (rituximab)	Y	21353060002020	6/20/2019	6	Line extension - packaging	No
Antineoplastic Agents/ Monoclonal Antibodies	AVASTIN INJECTION (bevacizumab)	Y	21335020002025	6/20/2019	6	Line extension - packaging	No
Antineoplastic Agents/ Monoclonal Antibodies	AVASTIN INJECTION 400/16ML (bevacizumab)	Y	21335020002030	6/20/2019	6	Line extension - packaging	No
Antineoplastic Agents/ Monoclonal Antibodies	HERCEPTIN INJECTION 150MG (trastuzumab)	Y	21353070002110	6/20/2019	6	Line extension - packaging	No
Central Nervous System/ Potassium Channel Blocker	RUZURGI TABLET 10MG (amifampridine)	Y	76000012000320	6/26/2019	6	Same active ingredient (amifampridine) as contained in Firdapse	No
Analgesics/ Viscosupplements	KENALOG-80 INJECTION (triamcinolone)	N	22100050101835	7/3/2019	3	Line extension - new strength	No
Antidiabetics/ Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor / Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Combinations	QTERN TABLET 5-5MG (dapagliflozin/saxagliptin)	N	27996502200320	7/3/2019	2	Line extension - new strength	No
Respiratory/ Cystic Fibrosis	SYMDEKO TAB 50-75MG (tezacaftor/ivacaftorand ivacaftor)	Y	4530990280B710	7/17/2019	6	Line extension - new strength	No
Antineoplastic Agents/ Miscellaneous	LEVOLEUCOVORIN SOLUTION 250MG/25	Y	21755050102030	7/26/2019	4	Line extension - new strength	No
Anti-Infectives/ Miscellaneous	VANCOMYCIN SOLUTION 2G/400ML	N	16280080102073	8/7/2019	3	Line extension - packaging	No

Formulary Updates – New Molecular Entities

SKYRIZI (risankizumab)

Indication:

- Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Mechanism of Action:

- Interleukin-23 antagonist

Drug Facts:

- 150 mg (two 75 mg injections) administered by subcutaneous injection at Week 0, Week 4 and every 12 weeks thereafter.
- Warnings: Infections, Tuberculosis (TB).

Place in Therapy:

- Four doses per year; 3-month dosing after 2 initiation doses at Weeks 0 and 4 (150 mg/dose).
- Most patients achieved a 90% improvement in Psoriasis Area and Severity Index (PASI) at Week 16 and maintained it at Week 52.

Proposed Tier Placement:

- Tier 5 – Preferred Specialty

Formulary Updates – New Molecular Entities

SKYRIZI (risankizumab)

Criteria for Initial Approval:

Moderate to severe plaque psoriasis

- A. Authorization of 12 months may be granted for members who are 18 years of age or older who have previously received Skyrizi, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis.
- B. Authorization of 12 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 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 and acitretin (see Appendix).
 - c. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Formulary Updates – New Molecular Entities

SKYRIZI (risankizumab)

Continuation of Therapy:

Moderate to severe plaque psoriasis

Authorization of 12 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Skyrizi as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Formulary Updates – New Molecular Entities

MAVENCLAD (cladribine)

Indication:

- Treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of MAVENCLAD is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS.
- Not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

Mechanism of Action:

- Purine antimetabolite

Drug Facts:

- Cumulative dosage of 3.5 mg/kg administered orally and divided into 2 treatment courses (1.75 mg/kg per treatment course). Each treatment course is divided into 2 treatment cycles. Separate administration from any other oral drug by at least 3 hours.
- Warnings: Lymphopenia, Infections, Hematologic toxicity, Graft-versus-host-disease with blood transfusion, & Liver injury.

Place in Therapy:

- First and only short-course oral therapy for relapsing forms of MS. Proven results with no more than 10 oral treatment days a year over 2 years.

Proposed Tier Placement:

- Tier 6 – Non-preferred Specialty

Formulary Updates – New Molecular Entities

MAVENCLAD (cladribine)

Specialty Guideline Management:

Multiple Sclerosis

A. Initial requests

- Authorization of 45 days may be granted for treatment of relapsing forms of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapses) and when all of the following criteria are met:
 1. Inadequate response or unable to tolerate an alternative drug indicated for the treatment of multiple sclerosis.
 2. Member does not have clinically isolated syndrome (CIS).
 3. Member has not received 2 courses (i.e., 4 cycles) of Mavenclad.
 4. Members will not use Mavenclad concomitantly with other medications used for the treatment of multiple sclerosis, excluding Ampyra.

B. Subsequent requests

- Authorization of 45 days may be granted for treatment of relapsing forms of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapses) and when all of the following criteria are met:
 1. Member has not received 2 courses (i.e., 4 cycles) of Mavenclad.
 2. Members will not use Mavenclad concomitantly with other medications used for the treatment of multiple sclerosis, excluding Ampyra.
 3. The member has not received Mavenclad in the last 43 weeks.

Formulary Updates – New Molecular Entities

QBREXZA PAD 2.4% (glycopyrronium)

Indication:

- Topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

Mechanism of Action:

- Anticholinergic agent

Drug Facts:

- Apply once daily to both axillae using a single cloth.
- Warnings: Worsening of urinary retention, Control of body temperature, & Operating machinery or an automobile.

Place in Therapy:

- First and only prescription cloth towelette approved to treat excessive underarm sweating (primary axillary hyperhidrosis) in people 9 years of age and older.
- 60% of patients achieved significant improvements in patient-reported sweat severity vs 28% with alcohol-based vehicle.

Proposed Tier Placement:

- Tier 3 – Non-preferred Brand

Utilization Management Policy Review

DUPIXENT Enhanced Specialty Guideline Management

Affected Medications:

- DUPIXENT (dupilumab)

Documentation:

- Submission of the following information is necessary to initiate the prior authorization review:
 - A. Atopic dermatitis (initial requests): Member's chart or medical record showing prerequisite therapies and affected area(s) and body surface area (see section IV.A.1).
 - B. Asthma (initial requests): Member's chart or medical record showing pretreatment blood eosinophil count and prerequisite therapies. For oral glucocorticoid use history, the documentation must also include drug, dose, frequency and duration.
 - C. Chronic rhinosinusitis with nasal polyposis (for initial requests): Member's chart or medical record showing nasal endoscopy or anterior rhinoscopy details (e.g., location, size).

Utilization Management Policy Review

DUPIXENT Enhanced Specialty Guideline Management

Prescriber Specialties:

- This medication must be prescribed by or in consultation with one of the following:
 - A. Atopic dermatitis: dermatologist or allergist/immunologist
 - B. Asthma: allergist/immunologist or pulmonologist
 - C. Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist

Criteria for Initial Approval:

Moderate-to-severe atopic dermatitis

- Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:
 1. Affected body surface area is greater than or equal to 10% OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 2. Member has had an inadequate treatment response to topical tacrolimus (Protopic) AND at least two medium or high potency topical corticosteroids OR a single very high potency topical corticosteroid in the past 180 days, OR topical corticosteroids or topical tacrolimus are not advisable for the member.

Utilization Management Policy Review

DUPIXENT Enhanced Specialty Guideline Management

Criteria for Initial Approval:

Moderate-to-severe asthma

- Authorization of 6 months may be granted for treatment of moderate-to-severe asthma in members 12 years of age or older when all of the following criteria are met:
- Member meets one of the following criteria:
 - a. Member has inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with all of the following medications at optimized doses*:
 - i. High-dose inhaled corticosteroid
 - ii. Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
 - iii. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)
**Members should be receiving treatment with inhaled corticosteroid and additional controller for at least the previous 3 months, and oral glucocorticoids for most days during the previous 6 months (e.g. 50% of days, 3 steroid bursts in the previous 6 months)⁸.*
 - b. Member has a baseline blood eosinophil count of at least 150 cells per microliter and asthma is inadequately controlled despite treatment for at least 3 months with both of the following at optimized doses:
 - i. Medium-to-high-dose inhaled corticosteroid
 - ii. Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
- Member will not use Dupixent as monotherapy
- Member does not currently smoke.
- Member will not use Dupixent concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair).

Utilization Management Policy Review

DUPIXENT Enhanced Specialty Guideline Management

Criteria for Initial Approval:

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Authorization of 6 months may be granted for treatment of CRSwNP in members 18 years of age or older when all of the following criteria are met:

1. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated; and
2. The member has CRSwNP despite one of the following:
 - a. Prior sino-nasal surgery; or
 - b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated; and
3. Member has a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril; and
4. Member has nasal obstruction plus one additional symptom:
 - a. Rhinorrhea (anterior/posterior); or
 - b. Reduction or loss of smell; and
5. Member will be using a daily intranasal corticosteroid while being treated with Dupixent, unless contraindicated or not tolerated.

Utilization Management Policy Review

DUPIXENT Enhanced Specialty Guideline Management

Continuation of Therapy:

Moderate-to-severe atopic dermatitis

Authorization of 6 months may be granted for members 12 years of age or older who achieve or maintain positive clinical response with Dupixent therapy for moderate-to-severe atopic dermatitis as evidenced by low disease activity (i.e., clear or almost clear skin) or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Moderate-to-severe asthma

Authorization of 12 months may be granted for members 12 years of age or older when all of the following criteria are met:

1. Member has achieved and maintained positive clinical response with Dupixent therapy for asthma as evidenced by at least one of the following:
 - a. A reduction in the frequency and/or severity of symptoms and exacerbations
 - b. A reduction in the daily maintenance oral corticosteroid dose
2. Member will not use Dupixent as monotherapy
3. Member does not currently smoke.
4. Member will not use Dupixent concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair)

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Authorization of 12 months may be granted for members 18 years of age or older who achieve or maintain positive clinical response to Dupixent therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).

Summary of Formulary Changes Effective 10/1/19

DRUG EXCLUSIONS

- 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, diflorasone cream, PSORCON, CORDRAN, flurandrenolide, lidocaine/tetracaine, LIDOTREX diflorasone ointment, calcipotriene cream, doxepin cream, carbinozamine 6mg, dihydroergotamine spray, & FOLIC-K.

UPTIERS

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

DOWNTIERS

- None

NEW DRUG ADDITIONS

- SKYRIZI, MAVENCLAD, QBREXA, KALYDECO, ZYKADIA, PRENATAL PLUS + DHA, KADIAN, RITUXAN, AVASTIN, HERCEPTIN, RUZURGI, KENALOG-80, QTERN, SYMDEKO, LEVOLEUCOVORIN, & VANCOMYCIN.

UTILIZATION MANAGEMENT

- DUPIXENT Custom Enhanced SGM, MAVENCLAD SGM & SKYRIZI SGM.



Next meeting: **October 16, 2019**



North Carolina
State Health Plan
FOR TEACHERS AND STATE EMPLOYEES

A Division of the Department of State Treasurer



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