



*Dale R. Folwell, CPA*  
STATE TREASURER OF NORTH CAROLINA  
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## Pharmacy & Therapeutics Committee Meeting

*Formulary and Program Updates Effective 7/1/2020*

May 13, 2020  
6:30 – 8:00 PM

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*A Division of the Department of State Treasurer*

# Role Call

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## 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

- Natasha Davis
- Caroline Smart
- Dee Jones

### Segal Consulting

- Kautook Vyas, PharmD

### CVS Caremark

- Renee Jarnigan, RPh
- Stephanie Morrison, PharmD

# Ethics Awareness & Conflict of Interest Reminder

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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.

# Minutes from Previous Committee Meeting

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Instead of reading 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 7/1/2020

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## CVS Caremark's Quarterly Formulary Update:

- Product Exclusions
- Tier Changes (Uptier/Downtier)
- Formulary Additions (New molecule entries, line extensions)
- New Utilization Management Criteria

## Presented by:

- Renée 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

## Standard Control Formulary – Exclusions

- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Cardiovascular/ Antilipemics/ PCSK9 Inhibitors	REPATHA	Availability of an additional option for secondary prevention of cardiovascular events and treatment of high cholesterol. The preferred option is Praluent (alirocumab).	647
Anti-Infectives/ Antibacterials/ Tetracyclines	MINOCYCLINE Extended-Release TAB; COREMINO	Availability of additional generic tetracycline options. Preferred options include doxycycline hyclate 20 mg, doxycycline hyclate capsule, minocycline, and tetracycline.	198
Topical/ Dermatology/ Herpes Agents	ACYCLOVIR CREAM	Availability of generic options for the treatment of cold sores. Preferred options include acyclovir capsules, acyclovir tablets, and valacyclovir.	187

# Formulary Updates – Product Exclusions

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Antidepressants/ Selective Serotonin Reuptake Inhibitors (SSRIs)	FLUOXETINE TAB 60MG	Availability of additional selective serotonin reuptake inhibitors (SSRIs). Preferred options include citalopram, escitalopram, fluoxetine (except fluoxetine tablet 60 mg), paroxetine HCl, paroxetine HCl ext-rel, sertraline, Trintellix (vortioxetine), and Viibryd (vilazodone).	187
Anti-Infectives/ Antibacterials/ Tetracyclines	DOXYCYCLINE HYCLATE TAB 50MG (NDC 72143021160 - JG Pharma Only)	Availability of additional generic tetracycline options. Preferred options include doxycycline hyclate 20 mg, doxycycline hyclate capsule, minocycline, and tetracycline.	150

# Formulary Updates – Product Exclusions

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Migraine/ Selective Serotonin Agonist/ Nonsteroidal Anti- inflammatory Drug (NSAID) Combinations	SUMATRIPTAN-NAPROXEN SODIUM TAB; TREXIMET	Availability of additional options for the acute treatment of migraine headaches. Preferred options include diclofenac sodium, ibuprofen or naproxen (except naproxen CR or naproxen suspension) WITH eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, Nurtec ODT (rimegepant), Onzetra Xsail (sumatriptan nasal powder), Reyvow (lasmiditan), Ubrelvy (ubrogepant), Zembrace SymTouch (sumatriptan injection), or Zomig Nasal Spray (zolmitriptan).	136
Anti-Infectives/ Antibacterials/ Tetracyclines	DOXYCYCLINE HYCLATE 75MG and 150MG TABS	Availability of additional generic tetracycline options. Preferred options include doxycycline hyclate 20 mg, doxycycline hyclate capsule, minocycline, and tetracycline.	125



# Formulary Updates – Product Exclusions

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Antidepressants/ Miscellaneous Agents	BUPROPION TAB 450MG XL	Availability of additional generic options for the treatment of major depressive disorder. Preferred options include bupropion and bupropion ext-rel (except bupropion ext-rel tablet 450 mg).	118
Central Nervous System/ Musculoskeletal Therapy Agents	CYCLOBENZAPRINE TAB 7.5MG	Availability of a generic option for the management of muscle spasms. The preferred option is cyclobenzaprine (except cyclobenzaprine tablet 7.5 mg).	83
Anti-Infectives/ Antibacterials/ Tetracyclines	DOXYCYCLINE HYCLATE Delayed-Release TAB 200MG DR	Availability of additional generic tetracycline options. Preferred options include doxycycline hyclate 20 mg, doxycycline hyclate capsule, minocycline, and tetracycline.	76

# Formulary Updates – Product Exclusions

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Dermatology/ Acne/ Topical	CLINDAMYCIN GEL 1% (NDC 68682046275 - Oceanside Pharmaceuticals Only)	Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin gel (except NDC 68682046275), clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Epiduo (adapalene-benzoyl peroxide), Onexton (clindamycin-benzoyl peroxide), and Tazorac (tazarotene).	56
Topical/ Ophthalmic/ Prostaglandins	BIMATOPROST 0.03% OPTH	Availability of additional options for reducing elevated intraocular pressure. Preferred options include latanoprost, Lumigan (bimatoprost), and Travatan Z (travoprost).	52

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Gastrointestinal/ Antispasmodics	CHLORDIAZEPOXIDE/CLIDINIUM CAP 5-2.5MG	Availability of a generic antispasmodic option for various gastrointestinal disorders. The preferred option is dicyclomine.	42
Topical/ Dermatology/ Corticosteroids/ Medium Potency	TRIAMCINOLONE ACETONIDE AEROSOL SPRAY	Availability of additional generic medium-potency corticosteroids for the relief of inflammatory and pruritic conditions. Preferred options include hydrocortisone butyrate cream, hydrocortisone butyrate lotion, hydrocortisone butyrate ointment, hydrocortisone butyrate solution, mometasone, triamcinolone cream, triamcinolone lotion, and triamcinolone ointment.	39

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Musculoskeletal Therapy Agents	CHLORZOXAZONE TAB 375MG and 750MG; LORZONE	Availability of a generic option for the treatment of mild to moderate pain associated with acute musculoskeletal disorders. The preferred option is cyclobenzaprine (except cyclobenzaprine tablet 7.5 mg).	32
Central Nervous System/ Musculoskeletal Therapy Agents	CYCLOBENZAPRINE ER	Availability of an additional generic option for the treatment of mild to moderate pain associated with acute musculoskeletal disorders. The preferred option is cyclobenzaprine (except cyclobenzaprine tablet 7.5 mg).	25
Topical/ Dermatology/ Antifungals	KETOCONAZOLE FOAM 2%	Availability of other topical options for the treatment of seborrheic dermatitis. Preferred options include ketoconazole shampoo 2% and selenium sulfide lotion 2.5%.	21

# Formulary Updates – Product Exclusions

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Respiratory/ Antihistamines	RYCLORA SYRUP 2MG/5ML	Availability of a generic antihistamine option. The preferred option is levocetirizine.	18
Anti-infectives/ Antifungals	POSACONAZOLE Delayed-Rel TAB	Availability of generic options for prevention of fungal infections in those who are severely immunocompromised. Preferred options include fluconazole and itraconazole.	18

# Formulary Updates – Product Exclusions

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Dermatology/ Corticosteroids/ Medium Potency	HYDROCORTISONE BUTYRATE CREAM 0.1%	Availability of additional generic medium-potency corticosteroids for the relief of inflammatory and pruritic conditions. Preferred options include hydrocortisone butyrate cream, hydrocortisone butyrate lotion, hydrocortisone butyrate ointment, hydrocortisone butyrate solution, mometasone, triamcinolone cream, triamcinolone lotion, and triamcinolone ointment.	17
Endocrine and Metabolic/ Phosphate Binder Agents	LANTHANUM CHEWABLE TABS	Availability of additional phosphate binder options. Preferred options include calcium acetate, sevelamer carbonate, Phoslyra (calcium acetate), and Velphoro (sucroferric oxyhydroxide).	15

# Formulary Updates – Product Exclusions

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Migraine/ Ergotamine Derivatives	ERGOT/CAFFEN TAB 1-100MG	Availability of additional options for the acute treatment of migraine headaches. Preferred options include eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, Nurtec ODT (rimegepant), Onzetra Xsail (sumatriptan nasal powder), Reyvow (lasmiditan), Ubrelvy (ubrogepant), Zembrace SymTouch (sumatriptan injection), and Zomig Nasal Spray (zolmitriptan).	10
Topical/ Dermatology/ Miscellaneous	VEREGEN	Availability of a generic option for the treatment of external genital and perianal warts.  The preferred option is imiquimod.	7

# Formulary Updates – Product Exclusions

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Nutritional/Supplements/ Vitamins and Minerals/ Miscellaneous	PRODIGEN CAP	Availability of additional supplementation options. Consult doctor.	6
Analgesics/ NSAIDs	KETOPROFEN CAP 25MG	Availability of additional generic NSAIDs for pain management. Preferred options include diclofenac sodium, ibuprofen, meloxicam, and naproxen (except naproxen CR or naproxen suspension).	6
Analgesics/ NSAIDs	KETOPROFEN CAP 200MG ER	Availability of generic nonsteroidal anti-inflammatory drugs (NSAID) options. Preferred options include diclofenac sodium, ibuprofen, meloxicam, and naproxen (except naproxen CR or naproxen suspension).	5



# Formulary Updates – Product Exclusions

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Anti-Infectives/ Antibacterials/ Tetracyclines	DOXYCYCLINE MONOHYDRATE 75 MG and 150 MG; OKEBO; MONODOXYNE NL	Availability of additional generic tetracycline options. Preferred options include doxycycline hyclate 20 mg, doxycycline hyclate capsule, minocycline, and tetracycline.	5
Anti-Infectives/ Antifungals	FLUCYTOSINE CAP 500MG	Availability of a generic antifungal option for the treatment of serious infections caused by susceptible strains of Candida and/or Cryptococcus. The preferred option is fluconazole.	3
Topical/ Dermatology/ Corticosteroids/ Low Potency	FLURANDRENOLIDE LOT 0.05% (NDC 24470092112 - Cintex Pharmaceuticals Only)	Availability of additional generic tetracycline options. Preferred options include doxycycline hyclate 20 mg, doxycycline hyclate capsule, minocycline, and tetracycline.	1

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- Removals of certain high-cost drugs such as multisource brands that have lower cost generic alternatives available or other clinically effective lower cost options.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Hematologic/ Platelet Aggregation Inhibitors	ZONTIVITY TAB	Availability of other options for the reduction of thrombotic cardiovascular events. Consult doctor.	0
Respiratory/ Antihistamines	DEXCHLORPHENIRAMINE SYRUP 2MG/5ML	Availability of a generic antihistamine option. The preferred option is levocetirizine.	0
Central Nervous System/ Migraine/ Ergotamine Derivatives	MIGERGOT SUPPOSITORY	Availability of additional options for migraine headaches. Preferred options include eletriptan, ergotamine-caffeine, naratriptan, rizatriptan, sumatriptan, zolmitriptan, Onzetra Xsail (sumatriptan nasal powder), Zembrace SymTouch (sumatriptan injection), and Zomig Nasal Spray (zolmitriptan).	0

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Nutritional/Supplements/ Vitamins and Minerals/ Folic Acid/ Combinations	FOLVITE-D TAB	Availability of an additional supplementation option. The preferred option is folic acid.	0
Topical/ Dermatology/ Wound Care Products	ATOPADERM CREAM	Availability of generic options to manage and relieve the burning, itching and pain experienced with various types of dermatoses. Preferred options include desonide and hydrocortisone.	0
Cardiovascular/ Calcium Channel Blocker/ Nonsteroidal Anti- Inflammatory Drug (NSAID) Combinations	CONSENSI	Availability of the individual components of this combination product for the treatment of high blood pressure and osteoarthritis. Preferred options include amlodipine WITH celecoxib.	0

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Musculoskeletal Therapy Agents	NORGESIC FORTE	Availability of a generic option for the treatment of mild to moderate pain associated with acute musculoskeletal disorders. The preferred option is cyclobenzaprine (except cyclobenzaprine tablet 7.5 mg).	0
Central Nervous System/ Musculoskeletal Therapy Agents	ORPHENGESIC FORTE; ORPHENADRINE/ASPIRIN/CAFF EINE TAB	Availability of a generic option for the treatment of mild to moderate pain associated with acute musculoskeletal disorders. The preferred option is cyclobenzaprine (except cyclobenzaprine tablet 7.5 mg).	0
Central Nervous System/ Musculoskeletal Therapy Agents	FEXMID TAB 7.5MG	Availability of a generic option for the management of muscle spasms. The preferred option is cyclobenzaprine (except cyclobenzaprine tablet 7.5 mg).	0

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Dermatology/ Antifungals	KETODAN	Availability of other topical options for the treatment of seborrheic dermatitis. Preferred options include ketoconazole shampoo 2% and selenium sulfide lotion 2.5%.	0
Central Nervous System/ Migraine/ Ergotamine Derivatives	DIHYDROERGOT SPR 4MG/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). Previously reviewed/approved for exclusion at the NDC-level effective 10/1/2019; this applies to all generic NDCs within the GPI.	0

# Formulary Updates – Product Exclusions

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QUESTIONS?

# 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 non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand).

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Endocrine and Metabolic/ Contraceptives/ Vaginal	NUVARING	Availability of a generic vaginal contraceptive option. The preferred option is ethinyl estradiol-etonogestrel.	1,274
Endocrine and Metabolic/ Antiobesity	BELVIQ XR	Product withdrawn from the market.	550
Endocrine and Metabolic/ Antiobesity	BELVIQ	Product withdrawn from the market.	406

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Central Nervous System/ Fibromyalgia	LYRICA CAPSULES and SOLUTION	Availability of a generic option for the management of neuropathic pain associated with diabetic peripheral neuropathy or spinal cord injury, postherpetic neuralgia, partial-onset seizures, and fibromyalgia. Preferred options include: carbamazepine w/ ext-rel, divalproex sodium w/ext-rel, gabapentin, lamotrigine w/ext-rel, levetiracetam w/ext-rel, oxcarbazepine, phenobarbital, phenytoin w/ext-rel, pregabalin, primidone, tiagabine, topiramate, valproic acid, zonisamide, FYCOMPA, GRALISE, OXTELLAR XR, TROKENDI XR, VIMPAT	404



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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Gastrointestinal/ Inflammatory Bowel Disease/ Oral Agents	APRISO	Availability of additional options for the maintenance treatment of UC. Preferred options include balsalazide, mesalamine delayed-rel, mesalamine ext-rel, sulfasalazine, sulfasalazine delayed-rel, and Pentasa (mesalamine ext-rel).	222
Analgesics/ Gout	ULORIC	Product has a required Boxed Warning, as the U.S. Food and Drug Administration (FDA) has noted an increased risk of death upon comparison to allopurinol. The preferred option is allopurinol.	118

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Analgesics/ Opioid Analgesics	ULTRAM	Availability of additional generic options for the management of mild to moderate pain. Preferred options include tramadol (except NDC 52817019610) and tramadol ext-rel.	6
Cardiovascular/ Nitrates/ Oral	ISORDIL TITRADOSE	Availability of generic nitrates for angina. Preferred options include isosorbide dinitrate oral, isosorbide mononitrate, and isosorbide mononitrate ext-rel.	3

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

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Analgesics/ NSAIDs	MOBIC	Availability of additional NSAIDs for pain management. Preferred options include diclofenac sodium delayed-rel, diflunisal, etodolac, ibuprofen, meloxicam, nabumetone, naproxen sodium, naproxen sodium tabs, naproxen tabs, oxaprozin, sulindac,	3
Endocrine and Metabolic/ Contraceptives/ Biphasic	MIRCETTE TAB 28	Availability of additional options for oral contraceptives including ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-levonorgestrel, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron, ethinyl estradiol-norgestimate, LO LOESTRIN FE	3

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Analgesics/ Non-Opioid Analgesics	ESGIC	Availability of generic options for the acute treatment of tension headaches. Preferred options include butalbital-acetaminophen-caffeine tabs and butalbital-aspirin-caffeine.	1
Hematologic/ Anticoagulants/ Injectable	LOVENOX INJ	Availability of additional injectable anticoagulants. Preferred options include enoxaparin and Fragmin (dalteparin).	0

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Analgesics/ NSAIDs	DAYPRO	Availability of additional NSAIDs for pain management. Preferred options include diclofenac sodium delayed-rel, diflunisal, etodolac, ibuprofen, meloxicam, nabumetone, naproxen sodium, naproxen sodium tabs, naproxen tabs, oxaprozin, sulindac, Advil (ibuprofen), and Aleve (naproxen sodium).	0
Central Nervous System/ Musculoskeletal Therapy Agents	ZANAFLEX TAB 4MG	Availability of generic alternatives for muscle spasticity including cyclobenzaprine (except cyclobenzaprine tablet 7.5 mg) and tizanidine.	0

# 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).

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Endocrine and Metabolic/ Calcium Receptor Antagonists	SENSIPAR	Availability of a generic option for the management of secondary hyperparathyroidism and hypercalcemia in specific circumstances. The preferred option is cinacalcet.	11

# Formulary Updates – Uptiers

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QUESTIONS?

# Formulary Updates – Formulary Additions

## Formulary Additions

- All Drugs, including add backs, that are not new to market but medications that were previously blocked by the plan and are now added to the formulary.
- The following products are on tier 2 (preferred brand) for non-specialty or tier 5 (non-preferred brand) for specialty.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Selective Estrogen Receptor Modulators	OSPHENA	Osphena was an elected Plan Exclusion in January 2017. Re-evaluation for formulary addition due to P&T approved addition of Intrarosa in 2019.	0
Endocrine and Metabolic/ Contraceptives/ Biphasic	LO LOESTRIN	To provide an additional combination oral contraceptive option.	0
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	SYMTUZA	To provide an additional combination option for the treatment of HIV-1. Fixed-dose combination of darunavir, cobicistat, emtricitabine and TAF, active ingredients contained in other products already on formulary.	0



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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Cardiovascular/ Antilipemics/ PCSK9 Inhibitors	PRALUENT	To provide an option for secondary prevention of cardiovascular events and high cholesterol.	0
Immunologic Agents/ Hereditary Angioedema	TAKHZYRO	To provide an option for prophylactic treatment of HAE. - See New Drug Entity for Review -	0
Antineoplastic Agents/ Kinase Inhibitors	VERZENIO	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).	0

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Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Immunologic Agents/ Autoimmune Agents/ Ulcerative Colitis	STELARA VIA 5MG/ML (IV)	Addition of a preferred product for ulcerative colitis (UC) after failure of Humira (adalimumab).	0
Central Nervous System/ Migraine/ Preventive Migraine Agents/ Monoclonal Antibodies	EMGALITY PFS 100MG/ML	To provide an option for the treatment of cluster headaches. - See New Drug Entity for Review -	0
Endocrine and Metabolic/ Glucose Elevating Agents	BAQSIMI	To provide an additional option for the treatment of severe hypoglycemia.	0
Topical/ Dermatology/ Acne/ Topical	ONEXTON GEL 1.2-3.75	To provide an additional option for the topical treatment of acne.	0

# Formulary Updates – Formulary Additions

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QUESTIONS?

# Formulary Updates – New Molecular Entities

## Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
ASPARLAS INJ	Indicated for treatment of acute lymphoblastic leukemia (ALL) in ages 1 month to 21 years old as a component of a multi-agent chemotherapeutic regimen.	<ul style="list-style-type: none"> <li>• The requested medication will be used in conjunction with multi-agent chemotherapy.</li> <li>• The member is 21 years of age or younger.</li> </ul>	6
TRIKAFTA TAB	Indicated for treatment of cystic fibrosis (CF) in patients 12 years of age and older who have at least one F508del mutation in the CF transmembrane conductance regulator (CFTR) gene.	<ul style="list-style-type: none"> <li>• Genetic testing was conducted to detect a mutation in the CFTR gene.</li> <li>• The member is positive for at least one F508del mutation in the CFTR gene.</li> <li>• The member is at least 12 years of age.</li> <li>• Trikafta will not be used in combination with other ivacaftor containing medications.</li> </ul>	6

# Formulary Updates – New Molecular Entities

## Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
PRETOMANID TAB	Indicated as part of a combination regimen with Sirturo (bedaquiline) and Zyvox (linezolid) for treatment of adults with pulmonary extensive drug-resistant (XDR) or treatment intolerant or nonresponsive multi-drug resistant (MDR) tuberculosis (TB).	N/A	3
RECARBRIO INJ	Indicated in adults who have limited or no alternative treatment options for complicated urinary tract infections (cUTIs) or complicated intra-abdominal infections (cIAIs) caused by susceptible organisms.	N/A	3

# Formulary Updates – New Molecular Entities

## Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
ADAKVEO INJ	Indicated to reduce the frequency of vaso-occlusive crises (VOCs) in patients 16 years of age and older with sickle cell disease (SCD).	<ul style="list-style-type: none"> <li>• 16 years of age or older with sickle cell disease and prior vaso-occlusive crises.</li> </ul>	6
FETROJA INJ	Indicated in adults who have limited or no alternative treatment options for complicated urinary tract infections (cUTIs) caused by susceptible Gram-negative microorganisms.	N/A	3
VUMERITY	Indicated for treatment of relapsing forms of MS, including CIS, RRMS and active SPMS.	<ul style="list-style-type: none"> <li>• Diagnose with a relapsing form of multiple sclerosis</li> <li>• Treatment of clinically isolated syndrome</li> </ul>	6

# Formulary Updates – New Molecular Entities

## Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
NURTEC ODT REYVOW UBRELVY	Indicated for acute treatment of migraine with or without aura in adults.	<ul style="list-style-type: none"> <li>• The requested drug is being prescribed for the acute treatment of migraine in an adult patient AND</li> <li>• The patient experienced an inadequate response or an intolerance to two triptan 5-HT1 receptor agonists OR</li> <li>• The patient has a contraindication that would prohibit a trial of triptan 5-HT1 receptor agonistsN/A</li> </ul>	2

# Formulary Updates – New Molecular Entities

## Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
YUPELRI SOL	Indicated as a maintenance treatment for COPD.	N/A	2
KOSELUGO CAP	Indicated for the treatment of pediatric patients 2-years old and older with neurofibromatosis type-1 (NF1) who have symptomatic inoperable plexiform neurofibromas	<ul style="list-style-type: none"><li>• Pending</li></ul>	6



# Formulary Updates – New Molecular Entities

## Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
TEGSEDI INJ	Indicated for the treatment of polyneuropathy of hereditary ATTR (hATTR) amyloidosis in adults.	<ul style="list-style-type: none"> <li>• The diagnosis with mutation of the TTR gene.</li> <li>• Member exhibits clinical manifestations of ATTR-FAP (e.g., amyloid deposition in biopsy specimens, TTR protein variants in serum, progressive peripheral sensory-motor polyneuropathy).</li> <li>• The member is not a liver transplant recipient.</li> <li>• The requested medication will not be used in combination with patisiran (Onpattro) or tafamidis.</li> </ul>	6

# Formulary Updates – New Molecular Entities

## Formulary Additions

- These are new formulary medications for the State Health Plan that are eligible for formulary inclusion as the CVS new drug to market block strategy has been satisfied.

Drug	Indication	Criteria for Approval	Tier
TAKHZYRO	Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older.	<ul style="list-style-type: none"> <li>• Member has C1 inhibitor deficiency confirmed by laboratory testing.</li> <li>• Member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:               <ol style="list-style-type: none"> <li>1. Member has an F12, angiotensin-converting enzyme, or plasminogen gene mutation</li> <li>2. Member has a documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine (e.g., cetirizine) for at least one month.</li> </ol> </li> </ul>	5

# Formulary Updates – New Molecular Entities

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QUESTIONS?

# Formulary Updates – Line Extensions

## Line Extensions

- These are new formulations or strengths of existing formulary medications being added to the formulary. Current SGM or UM will apply to all line extensions.

Drug	Tier	Drug	Tier
AJOVY INJ 225/1.5	2	EGRIFTA SOL 2MG	6
ATROPINE SOL 0.01%	3	EXTINA AER 2%	3
BRYHALI LOT 0.01%	3	EYLEA INJ 2/0.05ML	5
CALDOLOR INJ 4MG/ML	3	FASENRA PEN INJ 30MG/ML	5
CHLORZOXAZON TAB (375MG; 750MG)	1	FIASP PENFIL INJ U-100	2
CORLANOR SOL 5MG/5ML	3	HIZENTRA INJ 1GM/5ML; 2GM/10ML	5
DIVIGEL GEL 1.25MG	2	HIZENTRA SOL 20%	5
D-PENAMINE TAB 125MG	3	IBRANCE TAB (75MG;100MG, 125 MG)	5

# Formulary Updates – Line Extensions

## Line Extensions

- These are new formulations or strengths of existing formulary medications being added to the formulary. Current SGM or UM will apply to all line extensions.

Drug	Tier	Drug	Tier
MESALAMINE TAB 800MG DR	1	SUBLOCADE SYN (100/0.5; 300/1.5)	3
METOCLOPRAMI ODT 10MG TAB	3	SYMJEPI INJ (0.15MG; 0.3MG)	2
NOC DURNA SUB 27.7MCG; 55.3 MCG	3	TALICIA CAP	3
NUWIQ KIT (250U; 500U; 1000U; 2000U; 2500U; 3000U; 4000U)	5	TRAMADOL HCL TAB 100MG	3
NUWIQ VIAL (2500UNIT; 3000UNIT)	5	VANCOMYCIN INJ 500MG	3
PROMACTA PAK 25MG	6	XELJANZ XR TAB 22MG	5
ROMIDEPSIN INJ 27.5MG	6	ZINC SULFATE INJ 3MG/ML	3
RYBELSUS TAB (3MG; 7MG;14MG)	2		

# Formulary Updates – Line Extensions

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QUESTIONS?

# Formulary Updates – New SGM Additions

## New Specialty Guideline Management Additions

- There are 16 specialty medications that will have newly applied SGM criteria effective 8/1/2020.
- Four of the sixteen medications are part of therapy classes that have utilization and therefore are included for review. Current utilizers will be grandfathered.

Drug	Indication	Criteria for Approval	# of Utilizers
ARIKAYCE SUS	Treatment of Mycobacterium avium complex (MAC) lung disease	<ul style="list-style-type: none"> <li>• The patient has refractory disease with limited or no other treatment options.</li> <li>• The requested medication will be used as part of a combination antibacterial drug regimen.</li> <li>• The patient has not achieved negative sputum cultures after being treated with a multidrug background regimen therapy for a minimum of 6 consecutive months.</li> </ul>	3

# Formulary Updates – New SGM Additions

## New Specialty Guideline Management Additions

- These are 16 specialty medications that will have SGM criteria applied to them effective 8/1/2020 that did not have them before.
- 4 medications have utilization currently and therefore are presented for review. Current utilizers will be grandfathered.

Drug	Indication	Criteria for Approval	# of Utilizers
PURIXAN SUS 20MG/ML	<ul style="list-style-type: none"> <li>• acute lymphoblastic leukemia (ALL) as a component of a combination maintenance therapy regimen</li> <li>• acute promyelocytic leukemia (APL) as post-consolidation maintenance therapy, if included in the initial treatment protocol</li> </ul>	<ul style="list-style-type: none"> <li>• Documented intolerable adverse event with mercaptopurine and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information</li> <li>OR</li> <li>• Member is unable to swallow the tablet formulation.</li> </ul>	4



# Formulary Updates – New SGM Additions

## New Specialty Guideline Management Additions

- These are 16 specialty medications that will have SGM criteria applied to them effective 8/1/2020 that did not have them before.
- 4 medications have utilization currently and therefore are presented for review. Current utilizers will be grandfathered.

Drug	Indication	Criteria for Approval	# of Utilizers
XIAFLEX VIA 0.9MG	Adult patients with Dupuytren's contracture or adult men with Peyronie's disease	<ul style="list-style-type: none"> <li>• The member has a finger flexion contracture with a palpable cord in a metacarpophalangeal joint or a proximal interphalangeal joint</li> <li>• The contracture is at least 20 degrees</li> <li>• The member had a positive table top test, defined as the inability to simultaneously place the affected finger(s) and palm flat against a table</li> <li>• The member will receive a maximum of 3 injections per cord (4 weeks apart) as part of the current treatment.</li> </ul>	18

# Formulary Updates – New SGM Additions

## New Specialty Guideline Management Additions

- These are 16 specialty medications that will have SGM criteria applied to them effective 8/1/2020 that did not have them before.
- 4 medications have utilization currently and therefore are presented for review. Current utilizers will be grandfathered.

Drug	Indication	Criteria for Approval	# of Utilizers
FASLODEX	Treatment of Breast cancer, Ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer/Epithelial ovarian cancer, Endometrial cancer or Uterine sarcoma	<ul style="list-style-type: none"> <li>• Breast Cancer- recurrent, advanced, or stage IV hormone receptor-positive breast cancer.</li> <li>• Ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer/Epithelial ovarian cancer-recurrent low grade serous carcinoma</li> <li>• Endometrial cancer - treatment of endometrial cancer</li> <li>• Uterine sarcoma- low-grade endometrial stromal sarcoma and uterine leiomyosarcoma</li> </ul>	0

# Formulary Updates – New SGM Additions

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QUESTIONS?

# Summary of Formulary Changes Effective 7/1/20

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## PRODUCT EXCLUSIONS

- 45 products were excluded impacting 2,264 members

## UPTIERS

- 15 products had movement to a higher tier impacting 3,001 members

## FORMULARY ADDITIONS

- 12 products that were previously excluded were added to the formulary including formulary add backs.

## NEW MOLECULAR ENTITIES

- 14 new drug products were added to the formulary.

## LINE EXTENSIONS

- 45 products had additional strengths and formulations added to the formulary.

## NEW SGM ADDITIONS

- 4 new SGM policies were proposed to be added to the formulary



Next meeting: **August 12<sup>th</sup>, 2020**



*North Carolina*  
**State Health Plan**

FOR TEACHERS AND STATE EMPLOYEES

*A Division of the Department of State Treasurer*



*Dale R. Folwell, CPA*

STATE TREASURER OF NORTH CAROLINA  
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