



# Pharmacy & Therapeutics Committee Meeting

*Formulary and Program Updates Effective 7/1/2024*

May 15, 2024  
6:30PM – 8PM



*Dale R. Folwell, CPA*  
STATE TREASURER OF NORTH CAROLINA  
DALE R. FOLWELL, CPA

# Roll Call

## P&T COMMITTEE MEMBERS

- David Konanc, MD
- Jennifer Burch, PharmD, CDE
- John B. Anderson, MD, MPH
- Peter Robie, MD
- Phil Seats, RPh
- Sheel Desai Solomon, MD
- Sundhar Ramalingam, MD
- Ghassan Al-Sabbagh, MD
- W. Russell Laundon, PharmD, MS, BCPS

## PLAN STAFF & VENDORS

### State Health Plan

- Jenny Vogel, PharmD
- Sonya Dunn, MPA, BSPH, RN
- Caroline Smart
- Sam Watts

### CVS Caremark

- Renée Jarnigan, RPh
- Brian Hermreck

# Ethics Awareness & Conflict of Interest Reminder

In accordance with the [Recusal Guidelines for Public Servants](#), 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

# Cordavis Conflict of Interest Disclosure

*At this meeting the Committee may be presented for consideration information about one or more products co-manufactured and/or distributed by Cordavis. Cordavis is an affiliate of CaremarkPCS Health, L.L.C. (“CVS Caremark”) and so, in accordance with the conflicts of interest provision of the PBM services agreement in place between CVS Caremark and the North Carolina State Health Plan for Teachers and State Employee (the “Plan”), CVS Caremark hereby discloses that, should the Committee/Plan determine to include or continue to include a Cordavis product on the Plan’s formulary, CVS Caremark’s affiliate, Cordavis, will likely derive a direct financial benefit from the inclusion of such product on the formulary.*

Statement provided by CVS Caremark



# Minutes from Previous Committee Meeting

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 7/1/2024

## CVS Caremark's Quarterly Formulary Update:

- Formulary Additions (including add-backs, line extensions, and new molecular entities)
- Utilization Management
- Product Exclusions
- Tier Changes (Uptier/Downtier)

## Presented by:

- Renée Jarnigan, RPh, Clinical Advisor, CVS Health
- Jenny Vogel, PharmD, State Health Plan

# Formulary Updates- Add Backs

## Formulary Additions

- All Drugs, including line extensions, new formulations of existing formulary products and **add backs** (products not new to market that were previously blocked by the Plan and are now added to the formulary).

Drug	Therapeutic Category	Tier
XALKORI Oral Pellets (20MG, 50MG and 150MG)	Antineoplastic Agents/ Kinase Inhibitors	6

# Formulary Updates – Line Extensions

## Formulary Additions

- All Drugs, including **line extensions**, new formulations of existing formulary products and add backs (products not new to market that were previously blocked by the Plan and are now added to the formulary).

Drug	Therapeutic Category	Tier
CYCLOPHOSPHAMIDE INJ (500/5ML, 100MG, 200MG)	Antineoplastic Agents/ Alkylating Agents	3
HEMLIBRA INJ 300/2ML; HEMLIBRA SOL 12/0.04	Hematologic/ Hemophilia Agents	6
SPEVIGO INJ 150/1ML	Topical/ Dermatology, Antipsoriatic	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
ELFABRIO (pegunigalsidase alfa-iwxj)	Indicated for the treatment of adults with confirmed Fabry disease.	SGM	5
SKYCLARYS (omaveloxolone)	First treatment for Friedreich's ataxia, a rare, inherited, degenerative disease that damages the nervous system, characterized by impaired coordination and walking. This tends to develop in children and teenagers and gradually worsens over time.	SGM; Specialty QL	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
AUGTYRO (repotrectinib)	Indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)	SGM; Specialty QL	5
LAMZEDE (velmanase alfa-tycv)	Indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.	SGM	6
FABHALTA (iptacopan)	Indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).	SGM; Specialty QL	6

# Formulary Updates – Additions Questions?

# 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.
- **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

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Endocrine and Metabolic/ Gaucher Disease	VPRIV	0	CERDELGA, CEREZYME

# Formulary Updates – Exclusions Questions?

# Formulary Updates – Downtiers

## Movement to Preferred Status

- Typically, branded medications that are added as preferred products to provide additional treatment options.
- All the following products will be moving from a higher tier to a lower tier.

Drug	Indication	Tier Change
FABRAZYME	Indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.	6 → 5
GALAFOLD	Indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.	6 → 5
RADICAVA ORS	Indicated for the treatment of amyotrophic lateral sclerosis (ALS).	6 → 5

# 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 will be moving from a lower tier to a higher tier.

Therapeutic Category	Drug	# Utilizers (6 mo)	Alternatives	Tier Change
Anti-Infectives/ Antitubercular Agents	MYAMBUTOL	0	Preferred option is <b>generic ethambutol</b> .	2 → 3
Anti-Infectives/ Miscellaneous	CLEOCIN Oral Capsule	2	Preferred option is <b>generic clindamycin</b> .	2 → 3
Anti-Infectives/ Miscellaneous	CLEOCIN Pediatric Solution	0	Preferred option is <b>generic clindamycin oral solution</b> .	2 → 3
Anti-Infectives/ Miscellaneous	VANCOCIN Capsule	0	Preferred option is <b>generic vancomycin capsules</b> .	2 → 3
Antineoplastic Agents/ Alkylating Agents	ALKERAN	0	Preferred option is <b>generic melphalan</b> .	2 → 3
Antineoplastic Agents/ Hormonal Antineoplastic Agents	ARIMIDEX	2	Preferred options are <b>generics anastrozole</b> (tier 0), exemestane (tier 0), and letrozole (tier 1).	2 → 3
Antineoplastic Agents/ Hormonal Antineoplastic Agents	AROMASIN	3	Preferred options are <b>generics anastrozole</b> (tier 0), <b>exemestane</b> (tier 0), and letrozole (tier 1).	2 → 3
Antineoplastic Agents/ Hormonal Antineoplastic Agents	FEMARA	1	Preferred options are <b>generics anastrozole</b> (tier 0), exemestane (tier 0), and <b>letrozole</b> (tier 1).	2 → 3
Antineoplastic Agents/ Miscellaneous	HYDREA	0	Preferred option is <b>generic hydroxyurea</b> .	2 → 3
Cardiovascular/ ACE Inhibitor Combinations	LOTREL	4	Preferred option is generic <b>amlodipine-benazepril</b> .	2 → 3



# Formulary Updates – Uptiers (continued)

Therapeutic Category	Drug	# Utilizers (6 mo)	Alternatives	Tier Change
Cardiovascular/ Aldosterone Receptor Antagonists	INSPRA	0	Preferred options include <b>generics eplerenone</b> and spironolactone.	2 → 3
Cardiovascular/ Diuretics	ALDACTONE	3	Preferred options include <b>generics eplerenone</b> and <b>spironolactone (Aldactone generic)</b> .	2 → 3
Cardiovascular/ Miscellaneous	CATAPRES TTS (transdermal patch)	4	Preferred option is its <b>generic clonidine patch</b> .	2 → 3
Cardiovascular/ Nitrates	NITRO-DUR (nitroglycerin) transdermal patch	2	Preferred options include isosorbide dinitrate (except isosorbide dinitrate 40 mg), isosorbide mononitrate, isosorbide mononitrate ext-rel and <b>nitroglycerin patch (Nitro-Dur generic)</b> .	2 → 3
Central Nervous System/ Antianxiety	ANAFRANIL	0	Preferred options include its <b>generic, clomipramine</b> , as well fluoxetine (except fluoxetine tablet 60mg, fluoxetine tablet [generics for SARAFEM]), fluoxetine delayed-rel, fluvoxamine, fluvoxamine ext-rel, paroxetine oral suspension and tablet, and sertraline oral concentrate and tablet.	2 → 3
Central Nervous System/ Antidepressants	NARDIL	0	Preferred options include <b>phenelzine (Nardil generic)</b> and tranylcypromine.	2 → 3
Central Nervous System/ Antidepressants	NORPRAMIN	0	Preferred options include amitriptyline, <b>desipramine (Norpramin generic)</b> , doxepin, imipramine hydrochloride, imipramine pamoate, and nortriptyline.	2 → 3
Central Nervous System/ Antidepressants	PAMELOR	0	Preferred options include amitriptyline, desipramine, doxepin, imipramine hydrochloride, imipramine pamoate and <b>nortriptyline (Pamelor generic)</b> .	2 → 3

# Formulary Updates – Uptiers (continued)

Therapeutic Category	Drug	# Utilizers (6 mo)	Alternatives	Tier Change
Central Nervous System/ Antiseizure Agents	TROKENDI	174	Preferred options include carbamazepine, carbamazepine ext-rel, clobazam, clonazepam, divalproex sodium, divalproex sodium ext-rel, gabapentin, lacosamide, lamotrigine, lamotrigine ext-rel, levetiracetam, levetiracetam ext-rel, oxcarbazepine, phenobarbital, phenytoin, phenytoin sodium ext-rel, pregabalin, primidone, rufinamide, tiagabine, topiramate, <b>topiramate ext-rel</b> , valproic acid, zonisamide, Aptiom (eslicarbazepine), Carbatrol (carbamazepine ext-rel), Fycompa (perampanel), Mysoline (primidone), Neurontin (gabapentin), Oxtellar XR (oxcarbazepine ext-rel), Topamax (topiramate), Topamax Sprinkle (topiramate), and Xcopri (cenobamate).	2 → 3
Central Nervous System/ Miscellaneous	LITHOBID	1	Preferred options include lithium carbonate and <b>lithium carbonate ext-rel (Lithobid generic)</b> .	2 → 3
Central Nervous System/ Musculoskeletal Therapy Agents	DANTRIUM	0	Preferred options include baclofen, <b>dantrolene (Dantrium generic)</b> , tizanidine, and Zanaflex (tizanidine).	2 → 3
Endocrine and Metabolic/ Antidiabetics, Alpha-Glucosidase Inhibitors	PRECOSE	0	Preferred option includes <b>acarbose (Precose generic)</b> .	2 → 3
Endocrine and Metabolic/ Contraceptives	DEPO-PROVERA; DEPO-SQ PROVERA	26	Preferred option is <b>medroxyprogesterone injection</b> (Tier 0 /ACA).	2 → 3
Endocrine and Metabolic/ Estrogens	DIVIGEL	22	Preferred options include <b>estradiol gel (Divigel generic)</b> and estradiol transdermal.	2 → 3
Endocrine and Metabolic/ Miscellaneous	FORTEO	79	<b>teriparatide</b> , PROLIA, TYMLOS	5 → 6

# Formulary Updates – Uptiers (continued)

Therapeutic Category	Drug	# Utilizers (6 mo)	Alternatives	Tier Change
Gastrointestinal/ Anticholinergics	LEVSIN/LEVSIN SL	4	Preferred option includes dicyclomine. <b>Levsin generic, hyoscyamine</b> , is also an available option.	2 → 3
Gastrointestinal/ Antidiarrheals	LOMOTIL	0	Preferred options include <b>diphenoxylate-atropine (Lomotil generic)</b> and loperamide.	2 → 3
Gastrointestinal/ Miscellaneous	CYTOTEC	0	Preferred option is <b>misoprostol (Cytotec generic)</b> .	2 → 3
Gastrointestinal/ Rectal, Corticosteroids	ANUSOL-HC Cream 2.5%	0	Preferred options include <b>hydrocortisone cream</b> and ProctoFoam-HC (hydrocortisone-pramoxine).	2 → 3
Genitourinary/ Vaginal Anti-Infectives	CLEOCIN 2% Vaginal Cream	1	Preferred option is <b>clindamycin vaginal cream (Cleocin generic)</b> .	2 → 3
Hematologic/ Anticoagulants	ARIXTRA	0	Preferred options include enoxaparin and <b>fondaparinux (Arixtra generic)</b> .	2 → 3
Immunologic Agents/ Disease-Modifying Anti-Rheumatic Drugs (DMARDs)	PLAQUENIL	37	Preferred options include <b>hydroxychloroquine (Plaquenil generic)</b> , leflunomide, methotrexate, sulfasalazine delayed-rel, and Rasuvo (methotrexate).	2 → 3
Immunologic Agents/ Disease-Modifying Anti-Rheumatic Drugs (DMARDs)	ARAVA	1	Preferred options include hydroxychloroquine, <b>leflunomide (Arava generic)</b> , methotrexate, sulfasalazine delayed-rel, and Rasuvo (methotrexate).	2 → 3

# Formulary Updates – Uptiers (continued)

Therapeutic Category	Drug	# Utilizers (6 mo)	Alternatives	Tier Change
Immunologic Agents/ Immunosuppressants	IMURAN	1	Preferred option is <b>azathioprine (Imuran generic)</b> .	2 → 3
Topical Dermatology, Scabicides and Pediculicides	OVIDE 0.5% Lotion	0	Preferred options include ivermectin and <b>malathion (Ovide generic)</b> .	2 → 3
Topical/ Dermatology, Antibiotics	SILVADENE	3	Preferred option is <b>silver sulfadiazine (Silvadene generic)</b> .	2 → 3
Topical/ Dermatology, Corticosteroids	CLOBEX Lotion	0	Preferred options include betamethasone dipropionate augmented gel and ointment, <b>clobetasol</b> cream, foam (except clobetasol emollient foam), gel, <b>lotion (Clobex lotion generic)</b> , ointment, and shampoo, clobetasol propionate solution, and halobetasol cream and ointment.	2 → 3
Topical/ Dermatology, Corticosteroids	CLOBEX Shampoo	1	Preferred options include betamethasone dipropionate augmented gel and ointment, <b>clobetasol</b> cream, foam (except clobetasol emollient foam), gel, lotion, ointment, and <b>shampoo (Clobex shampoo generic)</b> , clobetasol propionate solution, and halobetasol cream and ointment.	2 → 3
Topical/ Dermatology, Local Anesthetics	LIDODERM 5% Patch	0	Preferred option is <b>lidocaine patch (Lidoderm generic)</b> .	2 → 3
Topical/ Mouth/Throat/Dental Agents	EVOXAC	0	Preferred options include <b>cevimeline (Evoxac generic)</b> and pilocarpine.	2 → 3

# Formulary Updates – Downtiers/Uptiers Questions?

# Summary of Formulary Changes Effective 7/1/24

## NEW MOLECULAR ENTITIES

- 5 new drug products were added to the formulary

## OTHER FORMULARY ADDITIONS

- 4 additional products were added to the formulary

## UTILIZATION MANAGEMENT

- SGM/Specialty QL for SKYCLARYS, AUGTYRO, and FABHALTA
- SGM for LAMZEDE and ELFABRIO

## PRODUCT EXCLUSIONS

- 1 product was excluded impacting 0 members

## UPTIERS/DOWNTIERS

- 43 products had tier movements

# New Business?

# Upcoming Meeting Dates for 2024

- Wednesday, August 14, 2024
- Wednesday, October 16, 2024