



# Pharmacy & Therapeutics Committee Meeting

*Formulary and Program Updates Effective 04/01/2023*

**February 8, 2023  
6:30 – 8:00 PM**



*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  
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
- Laura Rachal, MD

## PLAN STAFF & VENDORS

### State Health Plan

- Stephanie Craycroft-Andrews, PharmD, BCACP
- Sonya Dunn, MPA, BSPH, RN
- Caroline Smart

### CVS Caremark

- Renée Jarnigan, RPh

# 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

# 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?

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- Are there any additions or corrections to the minutes?
- If not, the minutes will stand approved as is.

# Formulary Updates – Effective 04/01/2023

## CVS Caremark's Quarterly Formulary Update:

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

## Presented by:

- Renée Jarnigan, RPh, Clinical Advisor, CVS Health
- Stephanie Craycroft-Andrews, PharmD, BCACP, State Health Plan

# 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
CAMZYOS (mavacamten)	Treatment option for adults with symptomatic NYHA class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.	SGM: Specialty QL	6
ENHERTU (Fam-trastuzumab deruxtecan)	Treatment option for some forms of HER-2 breast cancer, NSCLC and stomach cancer.	SGM	6

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Drug	Indication	Criteria for Approval	Tier
LIVTENCITY (maribavir)	Treatment option for post-transplant CMV infection.	Specialty QL	6
ULTOMIRIS (ravulizumab)	Treatment option for the following conditions: paroxysmal nocturnal hemoglobinuria (PNH); atypical hemolytic uremic syndrome (aHUS); generalized myasthenia gravis (gMG).	SGM: Specialty QL	6
VOXZOGO (vosoritide)	Treatment option for achondroplasia.	SGM: Specialty QL	6



# Formulary Updates- Additions

## 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	Tier
AMJEVITA	4
CORTROPHIN GEL	6
DHIVY	3
diclofenac powder 50 mg	1
JATENZO	3
ketorolac inj 30 mg/ml	1
levamlodipine	1

Drug	Tier
LOREEV XR	3
METHADONE INJ 10MG/ML	3
SEZABY INJ	3
SKYRIZI INJ 180/1.2	5
TIVICAY PD 5 MG TAB	5
XACIATO GEL 2%	3

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# Humira biosimilar pipeline

	Biosimilar drug name	Manufacturer	Projected launch date	Concentration*	Seeking interchangeability	Citrate free	Indications parity
FDA Approved	<u>Amjevita</u> (adalimumab- <u>atto</u> )	Amgen	Jan 31, 2023	Low	In development	Yes	All indications except pediatric hidradenitis suppurativa, uveitis and ulcerative colitis**
	<u>Cyltezo</u> (adalimumab- <u>adbm</u> )	Boehringer Ingelheim	July 1, 2023	Low	Yes/approved	Yes	
	<u>Hadlima</u> (adalimumab- <u>bwwd</u> )	Samsung Bioepis/Organon	July 1, 2023	Low and high	In development	Yes, only 100 mg/mL	
	<u>Abrilada</u> (adalimumab- <u>afzb</u> )	Pfizer	July 1, 2023	Low	Pending approval	Yes	
	<u>Yusimry</u> (adalimumab- <u>aqvh</u> )	<u>Coherus BioSciences</u>	July 1, 2023	Low	No	Yes	
	<u>Idacio</u> (adalimumab)	Fresenius Kabi	July 1, 2023	Low	No	Yes	
	<u>Hulio</u> (adalimumab- <u>fkip</u> )	Biocon/ <u>Viartis</u>	July 31, 2023	Low	No	Yes	
	<u>Hyrimoz</u> (adalimumab- <u>adaz</u> )	Sandoz	Sep 30, 2023	Low and high (Pending approval)	No	Yes, only 100 mg/mL	
Pending Approval	<u>AVT02</u> (adalimumab)	<u>Alvotech</u> /Teva	July 1, 2023	High (Pending approval)	Pending approval	Yes	
	<u>Yuflyma</u> (adalimumab)	Celltrion	July 1, 2023	High (Pending approval)	Pending approval	Yes	TBD

\*Concentration: Low=50 mg/mL, High=100 mg/mL

**Reference brand Humira indications:** Rheumatoid arthritis, juvenile idiopathic arthritis (JIA) age 2 years and older, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, pediatric Crohn's disease age 6 years and older, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, uveitis (10 indications).

**\*\*These 3 pediatric indications still have exclusivity and will not be covered by the biosimilars. Proposed biosimilar indications:** Rheumatoid arthritis, juvenile idiopathic arthritis (JIA) age 2 years and older, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, pediatric Crohn's disease age 6 years and older, ulcerative colitis, plaque psoriasis (8 indications).

Source: CVS Caremark Pipeline Services, as of 01/06/2023

# 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
Anti-Infectives/Antiretroviral Agents/ Fusion inhibitors	SELZENTRY	4	maraviroc
Antineoplastic agents/ Miscellaneous	TARGRETIN	0	bexarotene
Cardiovascular/ Beta-Blockers	BYSTOLIC	86	atenolol, carvedilol, carvedilol phosphate ext-rel, metoprolol succinate ext-rel, metoprolol tartrate, nadolol, nebivolol, pindolol, propranolol, propranolol ext-rel
Cardiovascular/ Pulmonary Arterial Hypertension/ Prostaglandin Vasodilators	TYVASO DPI	3	Consult physician

## Hyperinflation Exclusion

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Cardiovascular/ Antilipemics/ Fibrates	fenofibrate micronized 30mg, 90mg	2	fenofibrate (except fenofibrate capsule 30 mg, 50 mg, 90 mg, 130 mg; fenofibrate tablet 40 mg, 120 mg), fenofibric acid delayed-rel

# Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Central Nervous System/ Antiseizure Agents	DEPAKOTE; DEPAKOTE ER; DEPAKOTE SPRINKLE	37	carbamazepine, carbamazepine ext-rel, clonazepam, divalproex sodium, divalproex sodium ext-rel, ethosuximide, gabapentin, lamotrigine, lamotrigine ext-rel, levetiracetam, levetiracetam ext-rel, oxcarbazepine, phenobarbital, phenytoin, phenytoin sodium extended, primidone, tiagabine, topiramate, valproic acid, zonisamide, APTIOM, FYCOMPA, OXTELLAR XR, TROKENDI XR, VIMPAT, XCOPRI
Central Nervous System/ Antiseizure Agents	DILANTIN (CAP, CHW TAB, SUSP)	40	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, APTIOM, FYCOMPA, OXTELLAR XR, TROKENDI XR, VIMPAT, XCOPRI
Central Nervous System/ Antiseizure Agents	TEGRETOL (TAB, SUSP); TEGRETOL XR	25	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, APTIOM, FYCOMPA, OXTELLAR XR, TROKENDI XR, VIMPAT, XCOPRI
Central Nervous System/ Antiseizure Agents	TRILEPTAL	4	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, APTIOM, FYCOMPA, OXTELLAR XR, TROKENDI XR, VIMPAT, XCOPRI

**NOTE: Prior use exemptions will be provided for members currently utilizing branded seizure treatments so they do not have to change or go through exception PA process.**

# Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Central Nervous System/ Multiple Sclerosis Agents	GILENYA	113	dimethyl fumarate delayed-rel, fingolimod, glatiramer, AUBAGIO, AVONEX, BETASERON, COPAXONE, KESIMPTA, MAYZENT, OCREVUS, REBIF, TYSABRI, VUMERITY, ZEPOSIA.
Endocrine and Metabolic/ Menopausal Symptom Agents/ Transdermal	CLIMARA	12	estradiol, DIVIGEL, EVAMIST
Endocrine and Metabolic/ Miscellaneous	CARBAGLU	0	carglumic acid
Endocrine and Metabolic/ Miscellaneous	CYSTADANE	0	betaine
Respiratory/ Phosphodiesterase-4 inhibitors	DALIRESP	57	roflumilast
Topical / Dermatolog/ Acne/ Topical	ACZONE	1	adapalene (except adapalene pad), benzoyl peroxide, clindamycin gel (except NDC 68682046275), clindamycin solution, clindamycin-benzoyl peroxide, dapsone, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, AKLIEF, ARAZLO, EPIDUO, ONEXTON, TWYNEO, WINLEVI
Topical/ Ophthalmic/ Sympathomimetic / Beta- Blocker Combinations	COMBIGAN	144	brimonidine-timolol



# Formulary Updates – Product Exclusions

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

Drug	# Utilizers (6 mo)	Alternatives	Tier Change
ZOMIG NASAL SPRAY	0	eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, NURTEC ODT, ONZETRA XSAIL, UBRELVY, ZEMBRACE SYMTOUCH	2→3
PERFOROMIST	5	formoterol inhalation solution	2→3

# Formulary Updates – Uptiers

QUESTIONS?

# Summary of Formulary Changes Effective 04/01/23

## NEW MOLECULAR ENTITIES

- 5 new drug products were added to the formulary

## OTHER FORMULARY ADDITIONS

- 13 additional products were added to the formulary

## UTILIZATION MANAGEMENT

- SGM/Specialty QL for CAMZYOS, ULTOMIRIS, VOXZOGO
- SGM only for ENHERTU
- Specialty QL only for LIVTENCITY

## PRODUCT EXCLUSIONS

- 16 products were excluded impacting 526 members

## UPTIERS/DOWNTIERS

- 2 products had tier movements

# New Business?

# Targeted Therapy – MEK/BRAF/RET Inhibitors

Drug	Formulary Status	Utilization Jan-June 2022	Utilization July 2022-Jan 2023
<b>GAVRETO</b> (pralsetinib)	<b>RET Inhibitor – Added PREFERRED</b> 1/1/2023	0	0
<b>RETEVMO</b> (selpercatinib)	<b>RET Inhibitor – Added PREFERRED</b> 1/1/2023	2	3
<b>MEKINIST</b> (trametinib)	MEK Inhibitor – Excluded 7/1/2022	9	10
<b>TABRECTA</b> (capmatinib)	MEK Inhibitor – Excluded 7/1/2022	0	2
<b>TEPMETKO</b> (tepotinib)	MEK Inhibitor – Excluded 7/1/2022	0	0
<b>COTELLIC</b> (cobimetinib)	<b>MEK Inhibitor – PREFERRED</b> as of 7/1/2022	0	0
<b>MEKTOVI</b> (binimetinib)	<b>MEK Inhibitor – PREFERRED</b> as of 7/1/2022	8	7
<b>TAFINLAR</b> (dabrafenib)	BRAF Inhibitor – Excluded 7/1/2022	4	6
<b>BRAFTOVI</b> (encorafenib)	<b>BRAF Inhibitor - PREFERRED</b> as of 7/1/2022	12	10
<b>ZELBORAF</b> (vemurafenib)	<b>BRAF Inhibitor - PREFERRED</b> as of 7/1/2022	2	1

# Meeting Dates for 2023

- Wednesday, February 8, 2023
- Wednesday, May 10, 2023
- Wednesday, August 9, 2023
- Wednesday, October 11, 2023