



Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 01/01/2023

October 12, 2022
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
- Dee Jones

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.

Tier 1 (Brand-over-generic) Strategy

- Claims for the brand adjudicate at the Tier 1 cost share for members, which is typically the tier that includes low-cost generic alternatives.
- The Tier 1 Strategy maintains the generic member copay/coinsurance for the brand product.
- The interchange from generic to Brand is made at the pharmacy, does not require a new prescription or create disruption to members or providers.
- Supports the lowest net cost formulary principle and extends savings to members.

Tier 1 (Brand-over-generic) Strategy UPDATE

- In August, this committee approved 12 branded products to be placed at Tier 1, with their generics excluded
- Since then, we learned that the Tier 1 strategy will be adding-back generics for the ADHD products (Adderall XR and Concerta) to the formulary, as well as the generic for Asacol HD, effective 1/1/2023.
- Therefore, the Plan delayed implementation of the Tier 1 Strategy in order to avoid unnecessary member disruption between October and January.
- With your approval, we are now only proposing 9 branded products to be placed at Tier 1, with their generics excluded, effective 1/1/2023.

Tier 1 (Brand-over-generic) Strategy- UPDATE

Drug	Change Type	Tier	# Utilizers (6 mo.)
ADDERALL XR	Add-Back	NC→1	68
amphetamine/dextroamphetamine-ER cap	Exclude	1→NC	6095
ADVAIR DISKUS	Downtier	2→1	138
fluticasone propionate/salmeterol; Wixela	Exclude	2→NC	579
ASACOL HD	Add-Back	NC→1	0
mesalamine-ER*	Exclude*	2→NC*	46
CONCERTA	Downtier	3→1	90
methylphenidate-ER tab	Exclude	1→NC	3128
MITIGARE	Downtier	3→1	15
colchicine cap	Exclude	2→NC	234
ORACEA	Downtier	3→1	8
doxycycline mono 40mg DR cap	Exclude	2→NC	211

Tier 1 (Brand-over-generic) Strategy- UPDATE

Drug	Change Type	Tier	# Utilizers (6 mo.)
VAGIFEM	Downtier	3→1	9
estradiol; Yuvaferm TAB 10MCG	Exclude	1→NC	1184
VASCEPA CAPSULE 1GM and 0.5 GM	Downtier	2→1	477
icosapent capsule 1GM and 0.5 GM	Exclude	2→NC	457
SOOLANTRA CREAM 1%	Downtier	2→1	103
ivermectin cream 1%	Exclude	2→NC	148
UCERIS	Downtier	3→1	3
budesonide ER	Exclude	2→NC	0
NUVARING	Add-Back	NC→1	3
EluRyng; etonogestrel/ethinyl estradiol vaginal ring	Exclude	1→NC	1727
RESTASIS SINGLE DOSE	Downtier	2→1	644
cyclosporine (30) ophthalmic emulsion 0.05%	No Change	NC→NC	

Tier 1 (Brand-over-generic) Strategy

QUESTIONS?

Formulary Updates – Effective 01/01/2023

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:

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

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
GAVRETO (pralsetinib)	For the treatment of: (1.) adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC); (2.) adult and pediatric patients (12 and older) with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy; (3.) adult and pediatric patients (12 and older) with advanced or metastatic RET fusion-positive thyroid cancer who are radioactive iodine refractory.	SGM: Specialty QL	5
RETEVMO (selpercatinib)	For the treatment of: (1.) adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC); (2.) adult and pediatric patients (12 and older) with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy; (3.) adult and pediatric patients (12 and older) with advanced or metastatic RET fusion-positive thyroid cancer who are radioactive iodine refractory.	SGM: Specialty QL	5
TIVDAK (tisotumab vedotin)	For the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.	SGM: Specialty QL	6

Formulary Updates – New Molecular Entities

Formulary Additions

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Drug	Indication	Criteria for Approval	Tier
DAYVIGO (lemborexant)	Indicated for the topical treatment of adults with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	PA/QL in Place for insomnia products	2
BESREMI (ropeginterferon alfa 2b)	For the treatment of adults with polycythemia vera.	SGM: Specialty QL	6
TEZSPIRE (tezepelumab)	For add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. <u>Limitations of use:</u> Not for relief of acute bronchospasm or status asthmaticus.	SGM: Specialty QL	5

Formulary Updates – New Molecular Entities

Formulary Additions

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Drug	Indication	Criteria for Approval	Tier
WINLEVI (clascoterone)	Indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.	ST/QL	2
ADBRY (tralokinumab)	For the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.	SGM; Specialty QL	5
CIBINQO (abrocitinib)	For the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.	SGM; Specialty QL	5

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	Tier
AIMOVIG	2
ALPROLIX	5
ILUMYA	5
MULPLETA	6
ZYDELIG	5

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	Tier
epinephrine INJ 0.15 MG	1
pemetrexed INJ 750 MG and 1000 MG	1
quetiapine TAB 150 MG	1
CAPLYTA CAP 10.5 MG and 21 MG	2
DESCOVY TAB 120-15 MG	2
INJECTAFER INJ 100/2 ML	3

Drug	Tier
PHEBURANE MIS 483/GM	3
ZTILIDO PAD 1.8%	3
IMBRUVICA SUS 70MG/ML	5
CALQUENCE TAB 100 MG	6
RYLAZE INJ 10/0.5 ML	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
Central Nervous System/ Attention Deficit Hyperactivity Disorder	CONCERTA TAB	147	amphetamine-dextroamphetamine mixed salts ext-rel, dexamethylphenidate ext-rel, methylphenidate ext-rel, AZSTARYS, JORNAY PM, MYDAYIS, VYVANSE
Analgesics/ Interleukin-1 Blockers	ARCALYST	1	Ilaris
Analgesics/ Opioid Analgesics	NUCYNTA, NUCYNTA ER	285	hydromorphone, morphine, oxycodone
Analgesics/ Opioid Analgesics	SUBSYS	0	fentanyl transmucosal lozenge
Antineoplastic Agents/ Antimetabolites	ALIMTA	0	pemetrexed
Antineoplastic Agents/ Kinase Inhibitors	SUTENT	3	sunitinib, CABOMETYX, INLYTA, LENVIMA, NEXAVAR
Antineoplastic Agents/ Kinase Inhibitors	VOTRIENT	7	sunitinib, CABOMETYX, INLYTA, LENVIMA, NEXAVAR
Antineoplastic Agents/ Miscellaneous	RUBRACA	5	LYNPARZA, ZEJULA

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Cardiovascular/ Antiarrhythmics	MULTAQ	144	amiodarone
Cardiovascular/ Antiarrhythmics	NEXTERONE	0	amiodarone
Central Nervous System/ Hypnotics/ Nonbenzodiazepines	EDLUAR	1	doxepin, eszopiclone, ramelteon, zolpidem, zolpidem ext-rel, BELSOMRA, DAYVIGO
Endocrine and Metabolic/ Metabolic Modifiers	NITYR	0	ORFADIN
Genitourinary/ Urinary Antispasmodics	TOVIAZ	270	darifenacin ext-rel, oxybutynin ext-rel, solifenacin, tolterodine, tolterodine ext-rel, trospium, trospium ext-rel, GEMTESA
Hematologic/ Hemophilia Agents	BENEFIX	2	ALPROLIX, REBINYN
Hematologic/ Hemophilia Agents	IXINITY	0	ALPROLIX, REBINYN
Hematologic/ Hemophilia Agents	RIXUBIS	0	ALPROLIX, REBINYN
Immunologic Agents/ Hereditary Angioedema	FIRAZYR	6	Icatibant, RUCONEST
Respiratory/ Pulmonary Fibrosis Agents	ESBRIET	5	pirfenidone, OFEV

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Respiratory/ Severe Asthma Agents	NUCALA lyophilized (Clinician Administered)	18	DUPIXENT, FASRENA, NUCALA (except lyophilized powder), TEZSPIRE, XOLAIR
Respiratory/ Steroid Inhalants	FLOVENT DISKUS	192	FLOVENT HFA, PULMICORT FLEXHALER
Respiratory/ Steroid Inhalants	ARNUITY ELLIPTA	231	FLOVENT HFA, PULMICORT FLEXHALER
Respiratory/ Steroid Inhalants	QVAR REDHALER	640	FLOVENT HFA, PULMICORT FLEXHALER

Hyperinflation Exclusion

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Analgesics/ NSAIDs/ Topical	diclofenac solution 2%	24	diclofenac sodium, diclofenac sodium gel 1%, diclofenac sodium solution 1.5%, ibuprofen, meloxicam tablet, naproxen (except naproxen CR or naproxen suspension)

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
VELCADE	0	bortezomib, NINLARO	5→6
NARCAN	54	naloxone	2→3

Formulary Updates – Uptiers

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	Tier Change
AKLIEF	3→2
ARAZLO	3→2
QULIPTA	3→2
RHOFADE	3→2
RYTARY	3→2

Drug	Tier Change
SIKLOS	3→2
TWYNEO	3→2
DOPTELET	6→5
ENDARI	6→5
FENSOLVI	6→5

Drug	Tier Change
ILARIS	6→5
INLYTA	6→5
LENVIMA	6→5
MENOPUR	6→5
NEXAVAR	6→5

Formulary Updates – Downtiers

QUESTIONS?

Summary of Formulary Changes Effective 01/01/23

TIER 1 (BRAND-OVER-GENERIC) STRATEGY

- Paused until 1/1/2023 to accommodate updates
- 9 branded products to be placed at Tier 1, with their generics excluded

NEW MOLECULAR ENTITIES

- 9 new drug products were added to the formulary

OTHER FORMULARY ADDITIONS

- 5 products were added to the formulary that were add-backs
- 11 products that are line extensions were added to the formulary

UTILIZATION MANAGEMENT

- PA/QL for Dayvigo
- ST/QL for Winlevi
- SGM/Specialty QL for Adbry, Cibinco, Tezspire, Gavreto, Retevmo, Tivdak, Besremi

PRODUCT EXCLUSIONS

- 23 products were excluded impacting 2035 members

UPTIERS/DOWNTIERS

- 17 products had tier movements (2 uptiers, 15 downtiers)

COVID-19 Update

Vaccine	FDA Approved
COMIRNATY INJ 30/0.3ML	Yes
SPIKEVAX INJ COVID-19	Yes
AZ VACCINE INJ COVID-19	NO
JANSSEN VACC INJ COVID-19	EUA
MODERNA VACC INJ 6M-5Y	EUA
MODERNA VACC INJ 6-11Y	EUA
MODERNA VAC INJ 50/0.5ML	EUA
MODERNA VAC INJ COVID-19	EUA
MODERNA INJ BIVALENT	EUA
MODERNA BIVA INJ BA4/BA5	EUA
NOVAVAX VAC INJ COVID-19	EUA

Vaccine	FDA Approved
PFIZER VACC INJ COVID-19	EUA
PFIZER VACC INJ ADLT RTU	EUA
PFIZER VACC INJ 5-11Y	EUA
PFIZER VACC INJ 6M-4Y	EUA
PFIZER BIVAL INJ BA4/BA5	EUA
PFIZER BIVAL INJ 5-11Y	Pending EUA
SANOFI VACC EMU 5/0.5ML	NO

Antiviral	FDA Approved
LAGEVRIO CAP	EUA
PAXLOVID TAB	EUA
REMDESIVIR INJ	EUA
VEKLURY SOL	Yes

Smallpox and Monkeypox

Vaccine	FDA Approved Smallpox	FDA Approved - Monkeypox
JYNNEOS INJ	Yes (2019)	Yes (2019) *EUA (2022) for fraction dose administered intradermally
ACAM2000 INJ	Yes	EUA

Antiviral	FDA Approved Smallpox	FDA Approved – Monkeypox
TPOXX CAPSULE; TPOXX INJ for IV infusion	Yes (2018)	NO

Meeting Dates for 2023

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