



Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 10/01/2021

**August 11, 2021
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
- John Engemann, MD
- Joseph Shanahan, MD
- Peter Robie, MD
- Phil Seats, RPh
- Sheel Desai Solomon, MD
- Sundhar Ramalingam, 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
- Stephanie Morrison, PharmD, BCPS

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

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?

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.

Old Business- CGM

As requested, the proposal to add Continuous Glucose Monitors (CGMs) to the pharmacy formulary was presented to the Board in July 2021.

- Pending additional cost analysis, a proposal will be brought for a vote later this month.

Formulary Updates – Effective 10/01/2021

CVS Caremark's Quarterly Formulary Update:

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

Presented by:

- Renée Jarnigan, RPh, Clinical Advisor, CVS Health
- Stephanie Morrison, PharmD, BCPS, 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
LUMAKRAS TAB 120MG	Treatment of adult patients with <i>Kirsten rat sarcoma viral oncogene homologue (KRAS) G12C</i> -mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.	SGM	6
BREXAFEMME TAB 150MG	Treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis.	ST, QL	3

Formulary Updates – New Molecular Entities

QUESTIONS?

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	Drug	Tier
INGREZZA CAP 60MG	5	COSENTYX INJ 75MG/0.5	5
XCOPRI PAK 100-150	2	VANCOMYCIN INJ 100GM	3
SKYRIZI INJ 150MG/ML	5	AMINOCAPROIC SOL 0.25/ML	2
TRIKAFTA TAB	5	RIASTAP	6
WEGOVY INJ	3		

Formulary Updates – Other Formulary Additions

QUESTIONS?

Utilization Management – Wegovy PA

Coverage Criteria

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has completed at least 3 months of therapy with the requested drug at a stable maintenance dose

AND

- The patient lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. Documentation is required for approval.

OR

- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management in an adult

AND

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

AND

- The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter

OR

- The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)

Utilization Management – Wegovy PA

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
Analgesics/ NSAIDs	meloxicam capsule	1	diclofenac sodium, ibuprofen, meloxicam tablet, naproxen (except naproxen CR or naproxen suspension)
Anti-Infectives/ Antibacterials/ Tetracyclines	doxycycline hyclate 100 mg delayed-release tablet	87	doxycycline hyclate 20 mg, doxycycline hyclate capsule, minocycline, tetracycline
Central Nervous System/ Antidepressants/ Selective Serotonin Reuptake Inhibitors (SSRIs)	paroxetine 37.5MG ext-rel tab (NDC 60505367503 only)	0	citalopram, escitalopram, fluoxetine (except fluoxetine tablet 60 mg, fluoxetine tablet [generics for SARAFEM]), paroxetine HCl, paroxetine HCl ext-rel (except NDC 60505367503), sertraline, TRINTELLIX
Endocrine and Metabolic/ Glucocorticoids	BETAMETHASONE ACETATE- BETAMETHASONE SODIUM PHOSPHATE (Brands and generic NDC 7123062002 only)	0	dexamethasone, hydrocortisone, methylprednisolone, prednisolone solution, prednisone
Endocrine and Metabolic/ Antiobesity	XENICAL	3	QSYMIA, SAXENDA, WEGOVY (pending addition)

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Hematologic/ Anticoagulants/ Injectable	HEPARIN SODIUM in D5W IV Solution (brands and generics)	0	Consult doctor
Topical/ Dermatology/ Antipsoriatics/ Topical	calcipotriene foam	14	calcipotriene ointment, calcipotriene solution
Topical/ Dermatology/ Corticosteroids/ High Potency	HALOG SOLUTION 0.1%	5	desoximetasone (except desoximetasone ointment 0.05%), fluocinonide (except fluocinonide cream 0.1%), BRYHALI
Topical/ Dermatology/ Corticosteroids/ High Potency	HALOG CREAM 0.1%	1	desoximetasone (except desoximetasone ointment 0.05%), fluocinonide (except fluocinonide cream 0.1%), BRYHALI
Topical/ Dermatology/ Corticosteroids/ High Potency	HALOG OINTMENT 0.1%	1	desoximetasone (except desoximetasone ointment 0.05%), fluocinonide (except fluocinonide cream 0.1%), BRYHALI

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Topical/ Dermatology/ Corticosteroids/ Low Potency	CORDRAN LOTION 0.05%	0	desonide, hydrocortisone
Topical/ Dermatology/ Corticosteroids/ Very High Potency	ULTRAVATE LOTION 0.05%	10	clobetasol cream, clobetasol foam, clobetasol gel, clobetasol lotion, clobetasol ointment
Topical/ Dermatology/ Corticosteroids/ Very High Potency	CORDRAN TAPE	8	clobetasol cream, clobetasol foam, clobetasol gel, clobetasol lotion, clobetasol ointment
Topical/ Dermatology/ Corticosteroids/ Low Potency	CORDRAN CREAM	0	desonide, hydrocortisone

Formulary Updates – Product Exclusions- LUPRON

Therapeutic Category	Drug	# Utilizers (6 mo.)	Proposed 7/1/2021 Formulary Status Change	Notes
Endocrine and Metabolic/ Central Precocious Puberty	LUPR DEP-PED INJ 7.5MG, LUPR DEP-PED INJ 11.25MG, LUPR DEP-PED INJ 15MG, LUPR DEP-PED INJ 3M 30MG	7	6→NC	P&T approved change for 7/1/2021
Endocrine and Metabolic/ Endometriosis	LUPRON DEPOT INJ 3.75MG	15	6→NC	P&T did not approve change for 7/1/2021
Endocrine and Metabolic/ Endometriosis	LUPRON DEPOT INJ 11.25MG	6	6→NC	P&T did not approve change for 7/1/2021
Antineoplastic Agents/ Prostate Cancer	LUPRON DEPOT INJ 7.5MG, LUPRON DEPOT INJ 22.5MG, LUPRON DEPOT INJ 30MG, LUPRON DEPOT INJ 45MG	0	NC→NC	Formulary exclusion from P&T approval back in 10/2018 effective 1/1/2019. Utilization: Lupron - 0; Eligard - 1; Firmagon - 0

Formulary Updates – Product Exclusions

QUESTIONS?

Formulary Updates – Specialty Product Movement

Products Adding to the Specialty Drug List

- CVS' Pharmaceutical Technology Evaluation Committee reviews products to determine if they meet the criteria to be designated as Specialty Pharmaceuticals
- Rationale for the specialty designation for the following products includes:
 - Treats rare/chronic condition
 - High cost therapy
 - Limited Distribution

Drug	# Utilizers (6 mo)	Tier Change
CHENODAL	1	3→6
FASLODEX	0	3→6
FULVESTRANT	0	1→4

Formulary Updates – Specialty Product Movement

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)	Tier Change
TRUVADA	80	2→3
BACTRIM	0	2→3
BACTRIM DS	1	2→3
DYMISTA	111	2→3
AZOPT	89	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	# Utilizers (6 mo)	Tier Change
TAGRISSO	29	6→5

Formulary Updates – Downtiers

QUESTIONS?

Management of Select Unapproved Products

- Under the Federal Food, Drug, and Cosmetic Act (FFDCA), certain drugs may be legally marketed despite lacking approval from the U.S. Food and Drug Administration (FDA).
- FDA does not publicly identify which unapproved drugs are legally marketed.
- Universal exclusion of unapproved drugs is not clinically appropriate and may risk disrupting therapy for plan members using legally marketed drugs.
- CVS Caremark developed coverage recommendations for unapproved drugs utilizing the information in the CMS data file, along with detailed clinical reviews.

Management of Select Unapproved Products

Covered Product Examples:

Drug Class	Product Example
Antispasmodics	Hyoscyamine Sub
Barbiturate Hypnotics	Phenobarbital
Fluorides	Fluoride Chewable
Prenatal Vitamins	PNV Prenatal Plus Tab
Renal Agents	K/Na Citrate
Thyroid	NP Thyroid

Management of Select Unapproved Products

Non-Covered Product Examples:

Drug Class	Product Examples	Alternatives	SHP Utilization
Anorectal Agents	Anucort-HC; HC Pramoxine 2.5-1% Cream	FDA-approved Rx and/or OTC anorectal hydrocortisone, phenylephrine, pramoxine	972
Topical Acne Agents	AVAR Cleanser; Benzepro Cloths; Sodium sulfacetamide/sulfur; salicylic acid	FDA-approved Rx and/or OTC topical acne products	510
Estrogens	Esterified estrogens/methyltestosterone	FDA-approved Rx estradiol; conjugated estrogens and estrogen/progesterone combination products for HRT	245
Hematopoietic Agents	Ferrex; Chromagen; Integra Plus; Niferex	OTC iron products	29
Urinary Analgesics	Phenazopyridine; Hyophen; Uribel; Uro-MP	OTC products	1877

*3845 is the total number of members with utilization of non-covered products with the above classes representing the majority

Management of Select Unapproved Products

Strategy Summary:

- Coverage not allowed for certain unapproved drugs that have suitable clinical alternatives
- Coverage continues for of select unapproved drugs that are legally marketed or deemed clinically necessary
- Advanced notification will be provided to both impacted members and their providers
- Quarterly updates are made based on review of CMS and Medispan files for any potential changes to legacy unapproved products
- Strategy is widely implemented by commercial plans
- Proposed implementation for the State Health Plan is **1/1/2022**

Management of Select Unapproved Products

QUESTIONS?

Summary of Formulary Changes Effective 10/01/21

NEW MOLECULAR ENTITIES

- 2 new drug products were added to the formulary

OTHER FORMULARY ADDITIONS

- 9 products were added to the formulary including formulary add backs and line extensions

UTILIZATION MANAGEMENT

- 1 Step Therapy with Quantity Limits - Brexafemme
- 1 Prior Authorization - Wegovy

PRODUCT EXCLUSIONS

- 14 products were excluded impacting 127 members

UPTIERS/DOWNTIERS

- 8 products had tier movements

NEW STRATEGY – Management of Select Unapproved Products

- Implementation Effective Date: 01/01/2022

Next meeting: **October 13, 2021**