Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 07/01/2023

August 9, 2023
6:30 – 8:00 PM

North Carolina State Health Plan
FOR TEACHERS AND STATE EMPLOYEES
A Division of the Department of State Treasurer

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
- 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

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?

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.

Bylaw Amendment Proposal

Copies were distributed prior to the meeting for your review.

Formulary Updates – Effective 10/01/2023

CVS Caremark's Quarterly Formulary Update:

- Formulary Additions (including new molecular entities, line extensions, and add-backs)
- 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- 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
QUVIVIQ	2
FYLNETRA	5
NYVEPRIA	5
OBIZUR	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	Tier
methylphenidate tab er (18mg, 27mg, 36mg, and 54mg)	1
levofloxacin sol 1.5%	2
GRALISE TAB (450mg, 750mg and 900mg)	2
NAMZARIC CAP PACK	2
AKYNZEO INJ 235-0.25	3
PERTZYE CAP 24000U	3
PODIAPN CAP	3
PRECEDEX INJ 1000/250	3

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
TEMBEXA TAB 100MG; SUS 10MG/ML	3
ZEJULA TAB (100 MG, 200 MG and 300 MG)	5
ZEPOSIA CAP STR KIT	5
AMJEVITA INJ 10/0.2ML	6
KALYDECO GRA 13.4 MG	6
TRIKAFTA PAK (59.5 MG and 75 MG)	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
VOWST (fecal microbiota spores live-brpk)	Indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).	SGM; Specialty QL	6
REZZAYO (rezafungin)	Treatment of candidemia and invasive candidiasis in patients 18 and older who have limited or no alternative treatment options.		3
MOUNJARO (tirzepatide)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	PA, QL	2

Formulary Updates – New Molecular Entities

Formulary Additions

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Drug	Indication	Criteria for Approval	Tier
POLIVY (polatuzumab vedotin-piiq)	1) In combination with bendamustine and a rituximab for treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, after at least two prior therapies; 2) In combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.	SGM	6
KRAZATI (adagrasib)	Treatment of adult patients with Kirsten rat sarcoma (KRAS) G12C-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; Specialty QL	6
SOTYKTU (deucravacitinib)	Treatment of adult patients with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.	SGM: Specialty QL	5

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
VTAMA (tapinarof)	Topical treatment of plaque psoriasis in adults	PA QL	2
ZORYVE (roflumilast)	Topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older	PA QL	2

Formulary Updates – Additions

QUESTIONS?

Utilization Management – Dermatological Strategy

- A package of standard Utilization Management (UM) criteria designed to help ensure appropriate utilization of new and existing dermatological products.
- Implemented by the Plan 10/1/2017
- Updates to the strategy include addition of PAs for the following:
  - Vtama (tapinarof)
  - Zoryve (roflumilast)
  - Topical Vitamin D Analogs:
    - (calcipotriene topical scalp solution)
    - Calcitrene (calcipotriene ointment)
    - Dovonex (calcipotriene cream)
    - Enstilar (calcipotriene/betamethasone dipropionate foam)
    - Sorilux (calcipotriene foam)
    - Taclonex (calcipotriene/betamethasone dipropionate ointment, suspension)
    - Vectical (calcitriol ointment)
    - Wynzora (calcipotriene/betamethasone dipropionate cream)

Utilization Management – Vtama Prior Authorization

COVERAGE CRITERIA

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

- The requested drug is being prescribed for the treatment of plaque psoriasis
  AND
  - The patient has experienced an inadequate treatment response, intolerance or the patient has a contraindication to a topical steroid
    OR
  - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)
    AND
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

Quantity Limit: 60 grams per 25 days or 180 grams per 75 days.
For greater body surface area: 120 grams per 25 days OR 360 grams per 75 days

Utilization Management – Zoryve Prior Authorization

COVERAGE CRITERIA

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

- The requested drug is being prescribed for topical treatment of plaque psoriasis
  AND
- The patient is 12 years of age or older
  AND
  - The patient has experienced an inadequate treatment response, intolerance or has a contraindication to a topical steroid
    OR
  - The requested drug will be used on sensitive skin areas (e.g., face, genitals or skin folds)
    AND
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

Quantity Limit: 60 grams per 25 days or 180 grams per 75 days.
For greater body surface area: 120 grams per 25 days OR 360 grams per 75 days

Utilization Management – Topical Vitamin D Analogs

COVERAGE CRITERIA

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

- The requested drug is being prescribed for the treatment of psoriasis
  AND
- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to a topical steroid

Utilization Management – Insomnia Agents Limit Customization for Temazepam

COVERAGE CRITERIA

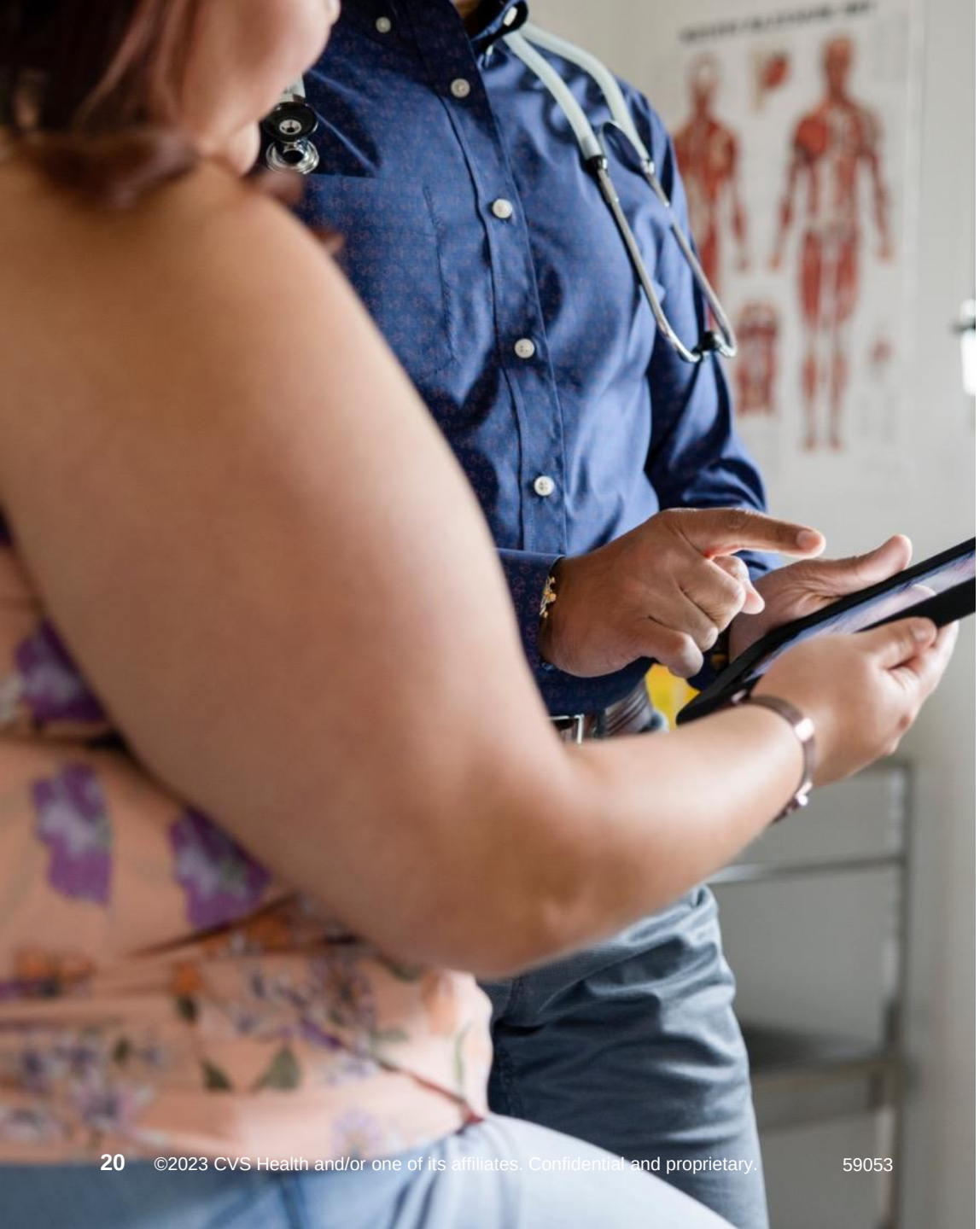
Current Quantity Limits applied to temazepam when used for insomnia are 15 capsules per 25 days and 45 capsules per 75 days with no exception

New customization allows for ongoing use of temazepam and a quantity limit of 60 capsules per 25 days or 180 capsules per 75 days.

This additional quantity is covered when:

- The requested drug is being prescribed for narcolepsy (confirmed by a sleep lab evaluation)
    - **OR** a diagnosis of REM sleep behavior disorder

  AND
- The member has had an inadequate treatment response OR contraindication to clonazepam



Weight Management UM Bundle

Manage utilization to control rising trend

The UM bundle relies on **the latest non-specialty UM criteria** available for weight management medications to help ensure coverage is **clinically appropriate and cost-effective**

UM criteria included for:

Select weight management medications*

Contrave

Qsymia

Saxenda

Wegovy

Xenical

Auto-updates for the bundle allow for day-one management
of pipeline weight management drugs by applying new UM criteria as soon as they become available

*Target drugs: benzphetamine, diethylpropion, phendimetrazine, phentermine.

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Utilization Management – 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 – Hyperinflation Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Analgesics/NSAIDs	diclofenac powder	44	diclofenac sodium, ibuprofen, naproxen (except naproxen CR or naproxen suspension)

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Hematopoetic Agents/Growth Factors	ZIEXTENZO	37	FYLNETRA, NYVEPRIA

Formulary Updates – 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
VYVANSE	8431	amphetamine-dextroamphetamine mixed salts ext-rel, dexmethylphenidate ext-rel, **lisdexamfetamine*,** methylphenidate ext-rel, AZSTARYS	2→3

***generic launch projected in late August**

Formulary Updates – Uptiers

QUESTIONS?

Summary of Formulary Changes Effective 10/01/23

NEW MOLECULAR ENTITIES

- 8 new drug products were added to the formulary

OTHER FORMULARY ADDITIONS

- 18 additional products were added to the formulary

UTILIZATION MANAGEMENT

- SGM/Specialty QL for VOWST, KRAZATI, and SOTYKTU
- SGM for POLIVY
- PA and QL for MOUNJARO, VTAMA and ZORYVE;
- PA for Topical Vitamin D Analogs;
- Revised QL for temazepam
- Adoption of the Weight Management UM Bundle

PRODUCT EXCLUSIONS

- 2 products were excluded impacting 81 members

UPTIERS/DOWNTIERS

- 1 product had tier movements

New Business?

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Upcoming Meeting Dates for 2023

- Wednesday, October 11, 2023

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