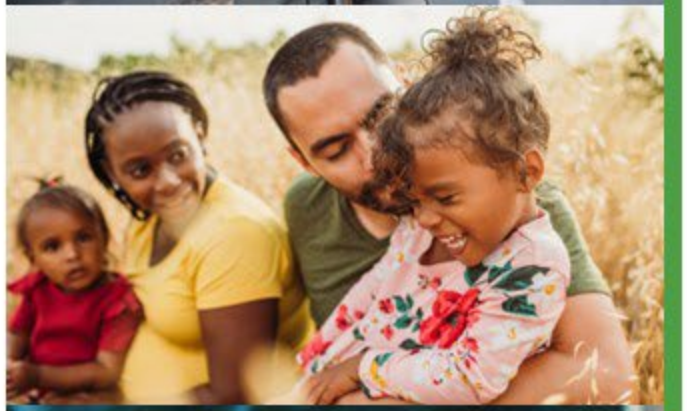


January 28, 2026

6:30PM-8PM

# Pharmacy & Therapeutics Committee Meeting

## Formulary and Program Updates Effective 4/1/2026

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

# Roll Call

## P&T COMMITTEE MEMBERS

David Konanc, MD

Jennifer Burch, PharmD, CDE

Ghassan Al-Sabbagh, MD

W. Russell Laundon, PharmD, MS, BCPS

Timothy Ashley, MD, MPH

Garland Moeller, MD

Stephen Hsieh, MD

## PLAN STAFF & VENDORS

### State Health Plan

- Tom Friedman, Executive Director
- Caroline Smart, Deputy Executive Administrator
- Jenny Vogel, PharmD, Sr. Clinical Pharmacist
- Joel Heimbach, Assistant General Counsel
- Emma Turner, Director of Economics, Finance, & Analysis
- Bryan Allard, Financial Analyst
- Justin Wylie, Web Designer

### CVS Caremark

- Renée Jarnigan, RPh, Clinical Advisor

# 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?
- If not, the minutes will stand approved as is.

# Agenda

- CVS Proposed Formulary Changes*
- State Health Plan Proposed Formulary Change*
- Formulary Evaluation Framework and Examples
- Closed Session
- Voting of Proposed Changes

*requires a recommendation from the P&T Committee

# CVS Proposed Formulary Updates – Effective 4/1/2026

## CVS Caremark's Quarterly Formulary Update:

- Formulary Additions (including new molecular entities, biosimilar additions, add backs, and line extensions)
- Utilization Management
- Product Exclusions
- Tier Changes (Uptiers/Brand-over-Generic Strategy Reversal)

## Presented by:

- Renée Jarnigan, RPh, Clinical Advisor, CVS Health
- Jenny Vogel, PharmD, Sr. Clinical Pharmacist, North Carolina 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 | Projected Annual Utilizers | Tier |
|---|---|---|---|---|
| **Blujepa** (gepotidacin) oral tablet | • Uncomplicated urinary tract infections (uUTI) in female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg).<br>• Uncomplicated urogenital gonorrhea in adult and pediatric patients 12 years of age and older weighing at least 45 kilograms who have limited or no alternative treatment options.*Approval of this indication is based on limited clinical safety data.* | Custom PA | < 400 | 3 |
| **Zevtera** (ceftobiprole) Powder for Injection | • Adult patients with Staphylococcus aureus bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis,<br>• Adult patients with acute bacterial skin and skin structure infections (ABSSSI), and<br>• Adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP). | n/a | Minimal | 3 |

# Formulary Update- Biosimilar 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).

| Therapeutic Category | Biosimilar Drug | Reference Product | Current Utilizers | Projected Annual Utilizers | Tier |
|---|---|---|---|---|---|
| Hematologic/ Hematopoietic Growth Factors | **Fulphila** (pegfilgrastim-jmdb) subcutaneous injection | Neulasta (pegfilgratstim) | 0 | < 25 | 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).

| Therapeutic Category | Drug | Current Utilizers | Projected Utilizers | Tier |
|---|---|---|---|---|
| Antineoplastic Agents/ Kinase Inhibitors | **Jakafi** (ruxolitinib) oral tablet | 43 | 50 | 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).

| Therapeutic Category | Drug | Tier |
|---|---|---|
| Antineoplastic Agents/ Kinase Inhibitors | **BRUKINSA TAB 160MG** | 5 |
| Anti-Infectives/ Antivirals | **PAXLOVID PAK** | 5 |
| Anti-Infectives/ Antiretroviral Combination Agents | **KALETRA SOL** | 3 |
| Anti-Infectives/ Antiretroviral Combination Agents | **PREZCOBIX TAB 675/150** | 3 |
| Endocrine and Metabolic/ Antiobesity | **EGRIFTA WR KIT 11.6MG** | 6 |
| Endocrine and Metabolic/ Antiobesity | **Iomaira TAB 8MG** | 1 |
| Hematologic/ Anticoagulants | **ELIQUIS CAP 0.15MG, TAB 0.5MG,1.5MG, 2MG** | 2 |
| Hematologic/ Bleeding Disorders Agents | **FIBRYGA INJ 2GM** | 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/ Migraine-Triptans and Combinations | **Onzetra Xsail** (sumatriptan) nasal inhalation powder | 4 | eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, Imitrex (sumatriptan), Nurtec ODT (rimegepant), Relpax (eletriptan), Ubrelvy (ubrogepant), and Zembrace Symtouch (sumatriptan succinate). |
| Central Nervous System/ Movement Disorders | **Austedo XR** (deutetrabenazine ext-rel) oral extended-release tablet | 22 | tetrabenazine, Austedo (deutetrabenazine), and Ingrezza (valbenazine). |
| Hematologic/ Hematopoietic Growth Factors | **Fylnetra** (pegfilgrastim-pbbk) subcutaneous injection | 8 | Fulphila (pegfilgratim-jmdb), Nyvepria (pegfilgratim-apgf) |

# Formulary Updates – Product Exclusions

| Therapeutic Category | Drug | # Utilizers (6 mo.) | Formulary Preferred Alternatives |
|---|---|---|---|
| Antineoplastic Agents/ Biologic Response Modifiers | **Revlimid** (lenalidomide) oral capsule | 56 | lenalidomide or consult physician depending on diagnosis |
| Antineoplastic Agents/ Kinase Inhibitors | **Zydelig*** (idelalisib) oral tablet | 0 | BRUKINSA, CALQUENCE |
| Antineoplastic Agents/ Kinase Inhibitors | **Copiktra*** (duvelisib) oral capsule | 0 | BRUKINSA, CALQUENCE |

*Prior use exemption will be provided to current utilizers.

# 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.

| Therapeutic Category | Drug | Current Utilizers | Tier Change |
|---|---|---|---|
| Ophthalmic/ Retinal Disorders | **Cimerli** (ranibizumab-eqrn) intravitreal injection | 0 | 5 → 6 |
| Immunologic Agents/ Disease-Modifying Anti-Rheumatic Drugs (DMARDs) | **Otrexup** (methotrexate) subcutaneous injection | 8 | 5 → 6 |
| Endocrine and Metabolic/ Polyneuropathy | **Tegsedi** (inotersen) subcutaneous injection | 0 | 5 → 6 |

# Brand-Over-Generic Strategy Reversal

- Claims for the brand adjudicate at the generic cost share for members, which is typically the tier that includes low-cost generic alternatives.
- The strategy maintains the generic member copay/coinsurance for the brand product.
- Supports the lowest net cost formulary principle and extends savings to members.

| Drug | Change Type | Tier | # Utilizers (6 mo.) |
|---|---|---|---|
| colchicine oral capsules | Addition | NC → Tier 1 | 0 |
| Mitigare (colchicine) oral capsules | Exclusion | Tier 1 → NC | 127 |

# Formulary Updates –
# Uptiers / Brand-Over-Generic Reversal

# Questions?

# State Health Plan Proposed Formulary Change

## Brand exclusions in favor of FDA approved generic equivalent.

### SHP expects $5-10 million/year in savings from the accumulation of these exclusions

| SHP Proposed Formulary Exclusion | Utilizers | SHP Proposed addition/downtier |
|---|---|---|
| **Vagifem**<br>Tier 1 → NC | 2379 | **yuvafem**<br>NC→ Tier 1 |
| **Nuvaring**<br>Tier 0 → NC | 1797 | **etonogestrel-ethinyl estradiol vaginal ring***<br>NC → Tier 0 |
| **Entresto tablets**<br>Tier 2 → NC | 1238 | **sacubitril/valsartan tablets**<br>Tier 2 → Tier 1 |
| **Wellbutrin SR 12**<br>Tier 3 → NC | 10 | **bupropion ER 12**<br>Tier 1 |

*etonorgestrel-ethinyl estradiol vaginal ring is an ACA preventive medication and will be available for members in Tier 0 ($0 copay)

# SHP Proposed Formulary Change

# Questions?

# *Understanding the Plan's* Formulary Evaluation Framework

MEMBER IMPACT,
OPERATIONAL VIABILITY,
ADMINISTRATIVE REVIEW

CLINICAL EVALUATION

UM REVIEW,
UTILIZATION ANALYSIS

ECONOMIC IMPACT
STRATEGIC FIT
MARKET ANALYSIS

Decisions are evidence-based,
BALANCING clinical, economic, operational,
and strategic factors WHILE PRIORITIZING
member needs.

# SHP Proposed Change: Stelara Exclusion/Yesintek Addition

| | |
|---|---|
| **Strategic Fit** | Generics/**biosimilars** first |
| **Economic Impact** | Reduces net pharmacy costs by ~$12 million/year |
| **UM Review** | Created custom UM to allow pathway to exceptions in case of intolerance, disease regression, or shortage |
| **Operational Viability** | Provided custom member outreach, supply concerns addressed with manufacturer, confirmed availability with specialty pharmacy |
| **Clinical Evaluation** | FDA approved, clinically equivalent, and interchangeable* biosimilar |
| **Member Impact** | NCGS 90-85.28 interchangeable biosimilars may be substituted at the pharmacy without requiring a new prescription, lower copay |

*An *interchangeable* biosimilar is the FDA's designation for a biosimilar that has additional evidence demonstrating that it can be safely substituted for the original biologic medicine with the same clinical result expected in any given patient.

# Formulary Evaluation Framework

**Member Impact**

-Quality of life, access to care, member out-of-pocket costs, member experience

**Operational Viability**

- Speed of implementation, system integration, scalability

**Administrative Review**

- Formulary maintenance: simple line extension, medication discontinuation, projected medical benefits utilization

# Formulary Evaluation Framework
# Clinical Evaluation

## Value Addition

Safety

Efficacy

Comparative Effectiveness

Treating an unmet need

Novel MOA

## Sources of Clinical Information

Clinical Trial Data

Professional society guidelines

FDA labeling

Drug Monographs

# Formulary Evaluation Framework
# UM Review

**Evaluate CVS Proposed UM**

Prior authorization, Step-Therapy, Quantity Limits

**Alignment with FDA approved indications**

**Determine if customization is necessary**

# Formulary Evaluation Framework Utilization Analysis

**Projected Impact of Additions**

- Expected utilization based on prevalence of clinical indications
- Availability of therapeutic alternatives and shifting
- Clinician prescribing behavior insights

**Disruption Impact of Exclusions**

- Current utilization
- PUE (Prior Use Exemption) Eligible

# Formulary Evaluation Framework

## Economic Impact

-Short term/long term budget impact

-Cost-effectiveness

## Strategic Fit

- Alignment with strategic priorities

-Stakeholder support

-Long-term sustainability

# Formulary Evaluation Framework
# Market Analysis

## Market Analysis

- **Drug pricing** – inflation, discounts, regulatory impacts
- **Net Cost** – UM impact, rebates
- **Market share** – utilization trends, marketing, prescriber and patient behavior, UM impact

## Contract Terms / Plan Design

- **PBM contract** – minimum rebate guarantees, discount guarantees, brand/generic/specialty
- **Member cost** – access and incentives, cost-sharing

# Examples of Requirements for Abbreviated and Full Evaluations

| Abbreviated Evaluation* | Full Evaluation Required |
| --- | --- |
| • Formulary maintenance<br>  • new generics<br>  • new doses of existing medications on the formulary<br>  • low cost/low utilization | • High utilization<br>• High cost<br>• High member impact<br>• New molecular entities |

*Abbreviated reviews are reserved for less material changes with minimal member disruption, clinical impact, or financial consequences for SHP.

# CVS Proposed Addition: Tosymra (sumatriptan) nasal spray

| | |
|---|---|
| **Clinical Evaluation** | Approved via the 505(b)(2) pathway using sumatriptan injection as the reference product. |
| **Economic Impact** | >3x more expensive than generic sumatriptan nasal spray |
| **Strategic Fit** | Does **NOT** fit with generic first strategy. Does **NOT** provide an unmet need. |
| **Member Impact** | Members have access on the formulary to generic sumatriptan nasal spray, subcutaneous injection, and tablets. |
| **Operational Viability** | Generic sumatriptan nasal spray, subcutaneous injection, and tablets are widely available without FDA drug shortage concerns |
| **UM Review** | Recommended in Tier 2 with standard UM (ST, PA, QL) |

# Formulary Evaluation Framework

# Questions?


# Closed Session

# Vote on Formulary Changes Effective 4/1/2026

- CVS PROPOSED FORMULARY CHANGES
  - FORMULARY ADDITIONS
  - UTILIZATION MANAGEMENT
    - Custom PA for BLUJEPA
  - PRODUCT EXCLUSIONS
  - BRAND-OVER-GENERIC REVERSAL
    - 1 generic product was placed in Tier 1, with the branded product excluded
  - UPTIERS
- PLAN PROPOSED FORMULARY CHANGE

# Summary of Formulary Changes Effective 4/1/2026

NEW MOLECULAR ENTITIES

- 2 new drug products were added to the formulary

OTHER FORMULARY ADDITIONS

- 10 additional products were added to the formulary

UTILIZATION MANAGEMENT

- Custom PA for BLUJEPA

PRODUCT EXCLUSIONS

- 6 products were excluded

BRAND-OVER-GENERIC REVERSAL

- 1 generic product was placed in Tier 1, with the branded product excluded

UPTIERS

- 3 products had tier movement

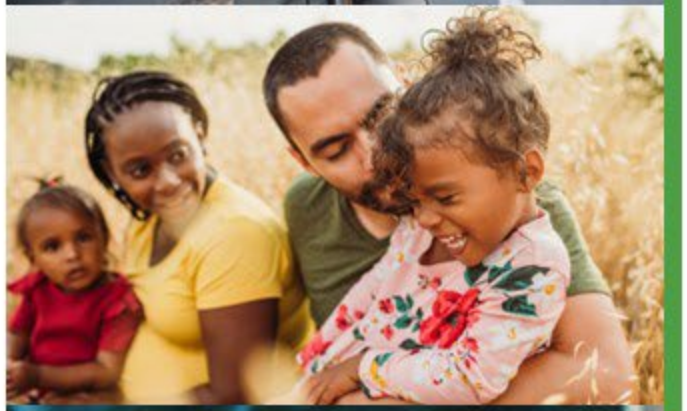
PLAN PROPOSED FORMULARY CHANGE

- 4 branded products were excluded from the formulary, with the corresponding FDA approved generic placed in Tier 0 or Tier 1

# New Business?

# Upcoming Meeting Dates for 2026

- Wednesday, April 29, 2026
- Wednesday, July 29, 2026
- Wednesday, September 30, 2026



# Thank You.

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