



Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 4/1/2024

February 21, 2024
6:30PM – 8PM



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

Formulary Updates – Effective 4/1/2024

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	Therapeutic Category	Tier
VITLIPID N INJ (ADULT and INFANT)	Nutritional/ Supplements/ Vitamins	3
APRETUDE (cabotegravir)	Anti-infectives/ Antiretroviral Agents/ Integrase Inhibitors	6
FYARRO (sirolimus)	Immunologic Agents/ Immunosuppressants	6
IMJUDO INJ 25/1.25; IMJUDO INJ 300/15ML	Antineoplastic Agents/ Miscellaneous	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
BREO ELLIPTA INH 50-25MCG	2
ZENPEP CAP 60000 UNT	2
ZORYVE MIS 0.3%	3
BOSULIF CAP 50MG and 100MG	5

Drug	Tier
COSENTYX INJ 300/2ML	5
ROZLYTREK PAK 50MG	5
ZEMAIRA INJ 4000MG and 5000MG	5
KALYDECO GRA 5.8MG	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
BIMZELX (bimekizumab)	○ Treatment of moderate to severe plaque psoriasis (PsO) in adult patients who are candidates for systemic therapy or phototherapy.	SGM QL	5
SPEVIGO (spesolimab)	○ Treatment of generalized pustular psoriasis (GPP) flares in adults.	SGM QL	6
IWILFIN (eflornithine)	○ To reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.	SGM QL	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
KIMMTRAK (tebentafusp-tebn)	<ul style="list-style-type: none"> ○ Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. 	SGM QL	6
ELAHERE (mirvetuximab soravtansine-gynx)	<ul style="list-style-type: none"> ○ Treatment of adult patients with folate receptor-alpha positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. 	SGM	6
PADCEV (enfortumab vedotin-ejfv)	<ul style="list-style-type: none"> ○ As a single agent: Treatment of adults with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy or are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy. ○ In combination with pembrolizumab: Treatment of adults with locally advanced or metastatic urothelial cancer (mUC) who are not eligible for cisplatin-containing chemotherapy. 	SGM QL	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
Antineoplastic Agents/ Kinase Inhibitors	IMBRUVICA*	28	BRUKINSA, CALQUENCE
Endocrine and Metabolic/ Phosphate Binder Agents	VELPHORO	47	calcium acetate, sevelamer carbonate, AURYXIA
Immunologic Agents/ Autoimmune Agents (Self-Administered)	HUMIRA	1600	Consult Physician

*Prior Use Exemption will be applied for the 28 current utilizers

Review of Autoimmune Indication-Based Management

- Autoimmune therapy class is dynamic
 - High-cost launch pricing
 - Year-over-year inflation
 - Supplemental indications
- Indication based management of this class was a strategy launched by CVS in 2017
- Manages utilization for specific drugs used to treat specific indications rather than managing formulary placement at a therapy class level
- Delivers value in the class and allows providers numerous preferred options for their patients
- Strategy was reviewed by the P&T Committee in November 2017 and implemented by the Plan on 1/1/2018

Autoimmune Class Preferred Products by Indication

Indication	Primary Preferred Product*	Secondary Preferred Product*
Plaque psoriasis	<ul style="list-style-type: none"> • adalimumab-adaz • Hyrimoz (adalimumab-adaz) • Otezla (apremilast) • Skyrizi (SC) (risankizumab-rzaa) • Sotyktu(deucravacitinib) • Stelara (SC) (ustekinumab) • Taltz (ixekizumab) • Tremfya (guselkumab) 	<ul style="list-style-type: none"> • Bimzelx (bimekizumab-bkzx) (after 2 primary preferred products) • Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)
Ankylosing spondylitis	<ul style="list-style-type: none"> • adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hyrimoz (adalimumab-adaz) • Rinvoq (upadacitinib) 	<ul style="list-style-type: none"> • Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)
Psoriatic arthritis	<ul style="list-style-type: none"> • adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hyrimoz (adalimumab-adaz) • Otezla (apremilast) • Rinvoq (upadacitinib) • Skyrizi (SC) (risankizumab-rzaa) • Stelara (SC) (ustekinumab) • Tremfya (guselkumab) 	<ul style="list-style-type: none"> • Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)

Autoimmune Class Preferred Products by Indication

Indication	Primary Preferred Product*	Secondary Preferred Product*
Rheumatoid Arthritis	<ul style="list-style-type: none"> adalimumab-adaz Enbrel (etanercept) Hyrimoz (adalimumab-adaz) Kevzara (sarilumab) Orencia (SC)/Orencia ClickJect (abatacept) Rinvoq (upadacitinib) Xeljanz/Xeljanz XR (tofacitinib) 	<ul style="list-style-type: none"> Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)
Non-Radiographic Axial Spondyloarthritis	<ul style="list-style-type: none"> Cimzia syringe (certolizumab pegol) Cosentyx (secukinumab) Rinvoq (upadacitinib) 	None
Crohn's disease	<ul style="list-style-type: none"> adalimumab-adaz Hyrimoz (adalimumab-adaz) Rinvoq (upadacitinib) Skyrizi (SC) (risankizumab-rzaa) Stelara (SC) (ustekinumab) 	<ul style="list-style-type: none"> Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)
Ulcerative colitis	<ul style="list-style-type: none"> adalimumab-adaz Hyrimoz (adalimumab-adaz) Rinvoq (upadacitinib) Stelara (SC) (ustekinumab) Xeljanz/Xeljanz XR (tofacitinib) Zeposia (ozanimod) 	None

We engage with prescribers across multiple touchpoints

to help enhance efficiency, lower costs and create better experiences

In the office



Engagement in advance of formulary changes creates transparency to cost, benefit design and medication history*

- Real-time benefits

In the pharmacy



EHR connectivity eases administrative burden and simplifies patient onboarding

- EHR connectivity

Behind the scenes



Driving cost savings for payors and their members using PBM capabilities*

- Prescriber messaging for formulary changes

Ongoing basis



Delivering ongoing clinical support and connects patients with financial assistance programs

- Prescriber messaging for lower-cost covered options
- Copay assistance



We anticipate that over 90% of patients will smoothly transition to a covered product by utilizing CVS Specialty pharmacy in conjunction with our EMR connectivity.

Prescriber outreach enabled with RxChange

For Providers



Messages sent to provider's EHR with a clear ask for a change and/or additional information – **reducing the need for additional faxes and phone calls**

Allows them to quickly and easily respond with an 'approve' or 'deny' message from their EHR resulting in **higher and faster response rates vs. faxes**

For Pharmacies



Response is systematically sent back to the requesting pharmacy

Client case study
Frictionless experience for members and prescribers

95%

adoption of preferred biosimilar over a 45-day period



Functionality available at Specialty, Mail Order, and CVS retail pharmacies
Source: CVS Specialty Operations, 2023

 **CVS Health**

Illustrative example

RxChange

collaboration that lends itself to better patient outcomes

HUMIRA PEN (2/BOX) 40MG/0.4ML

Inject 40 mg (0.4ML) subcutaneous every other week

Qty: 2 pens

Refills: 6

Substitutions: Y

Date Written 7/31/2023

Last Filled: N/A

Note:

Prescriber's view

RxChange Request: Therapeutic Interchange Request :

From: CVS Specialty
Sent: August 1, 2023
To: Test Prescriber

Select Suggested Medication

HYRIMOZ PEN ~ 40MG/0.4ML

Original Medication

HUMIRA PEN (2/BOX) ~ 40MG/0.4ML

[View full Rx Details](#)

Notes From Pharmacy

Humira no longer covered on patients' insurance. Please switch to a covered alternative medication

Approve

Deny

Replace

Test Patient (F)

DOB: 2/14/1982 (41 years)
(123) 555-1234 (c)
1234 Sunshine Rd
Walnut Creek, CA 94565

Provider:

Test Prescriber
1234 Hummingbird Way
Walnut Creek, CA 94565
(925)555-4567 (p)
DEA: AP8642490

Pharmacy:

CVS Specialty
1127 Bryn Mawr Ave Ste A
Redlands, CA 92374

Example above does not represent actual EHR screens.
Formulary selections are plan specific and determined by payor selections.

Formulary Updates – Exclusions

Humira/Biosimilar Discussion

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
BIDIL	5	isosorbide dinitrate-hydralazine	2 → 3
EVAMIST	35	estradiol, DIVIGEL	2 → 3
PYLERA	2	bismuth-metronidazole-tetracycline, TALICIA	2 → 3
ZYCLARA	0	fluorouracil cream 5%, fluorouracil solution, imiquimod	2 → 3

Formulary Updates – Uptiers Questions?

Summary of Formulary Changes Effective 4/1/24

NEW MOLECULAR ENTITIES

- 6 new drug products were added to the formulary

OTHER FORMULARY ADDITIONS

- 4 additional products were added to the formulary

UTILIZATION MANAGEMENT

- SGM/Specialty QL for BIMZELX, IWILFIN, KIMMTRAK, PADCEV, and SPEVIGO
- SGM for ELAHERE

PRODUCT EXCLUSIONS

- 3 products were excluded impacting 1,675 members

UPTIERS/DOWNTIERS

- 4 products had tier movements

New Business?

Upcoming Meeting Dates for 2024

- Wednesday, May 8, 2024
- Wednesday, August 14, 2024
- Wednesday, October 9, 2024