Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 01/01/2022

October 13, 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

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.

Formulary Updates – Effective 01/01/2022

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:

- 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
RUKOBIA (fostemsavir ER)	Indicated in combination with other antiretrovirals for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations	N/A- no UM currently on HIV products	3
INQOVI (decitabine/cedazuridine)	Treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British (FAB) subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia (CMML) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System (IPSS) groups	SGM, QL	6

Formulary Updates – New Molecular Entities

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Drug	Indication	Criteria for Approval	Tier
WAKIX (pitolisant)	Treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy	SGM, QL	5
ENSPRYNG (saltralizumab-mwge)	Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.	SGM, QL	5

Formulary Updates – New Molecular Entities

Formulary Additions

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Drug	Indication	Criteria for Approval	Tier
VERQUVO (vericiguat)	To reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for HF or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%	PA Option	2
QELBREE (viloxazine ER)	Treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients 6 years of age to 17 years of age	PA Option	2

Formulary Updates – New Molecular Entities

Formulary Additions

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Drug	Indication	Criteria for Approval	Tier
KERENDIA (finerenone)	To reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-state kidney disease, cardiovascular (CV) disease, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes	PA Option	2
MYFEMBREE (relugolix/estradiol/norethindrone)	Management of heavy menstrual bleeding associated with uterine leiomyomas (i.e., fibroids) in premenopausal women	PA Option	2

Formulary Updates – Other Formulary 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	Drug	Tier
bepotastine drop 1.5%	1	LUPR DEP-PED	5
calcitonin inj 200/ML	1	ORLADEYO	5
pregabalin er	1	PLEGRIDY	6
AUVI-Q	2	SEVENFACT	5
MYRBETRIQ SUS 8MG/ML	2	TAVALISSE	5
NATAZIA	2	UPTRAVI INJ 1800MCG	5
AVONEX	5	XYWAV	5

Formulary Updates – Indication-Based

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	Indication Requirements for Coverage
CIMZIA	5	•Non-radiographic axial spondylarthritis •Ankylosing spondylitis (after failure of two preferred agents) •Crohn's disease (after failure of two preferred agents) •Psoriasis (after failure of two preferred agents) •Psoriatic arthritis (after failure of two preferred agents) •Rheumatoid arthritis (after failure of two preferred agents)

Formulary Updates – Additions

QUESTIONS?

Coverage Addition- CGM

As requested by the P&T Committee, the proposal to add Continuous Glucose Monitors (CGMs) to the pharmacy formulary was presented to the Plan's Board of Directors.

- The Board approved coverage under the pharmacy benefit
- Dexcom CGM will be preferred on the Plan's formulary
- Prior Authorization for use is pending the Plan's evaluation
- All other CGM brands will be considered a formulary exclusion and require a medical necessity exception approval for coverage

Utilization Management – Dexcom PA

Coverage Criteria

The requested continuous glucose meter will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of diabetes mellitus

  AND

- The patient is using an intensive insulin regimen [Note: An intensive insulin regimen is defined as multiple daily injections (i.e., 3 or more injections per day) or insulin pump therapy]

  AND

  - The request is for a continuation of therapy and the patient has experienced improved glycemic control or decreased hypoglycemia episodes while using a continuous glucose meter (CGM)

  OR

  - The request is for a continuation of therapy and the patient is being assessed every six months by the prescriber for adherence to their continuous glucose meter (CGM) regimen and diabetes treatment plan

  OR

  - The patient is less than 18 years of age

  OR

  - The patient is not meeting glycemic targets OR the patient is experiencing hypoglycemia (including hypoglycemia unawareness)

Utilization Management – Dexcom 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
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral	TRUVADA	70	abacavir-lamivudine, emtricitabine-tenofovir disoproxil fumarate, lamivudine-zidovudine, CIMDUO, DESCOVY, TEMIXYS
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	ATRIPLA	14	efavirenz-emtricitabine-tenofovir disoproxil fumarate, efavirenz-lamivudine-tenofovir disoproxil fumarate, BIKTARVY, DOVATO, GENVOYA, ODEFSEY, SYMTUZA, TRIUMEQ
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	LEUKINE	1	NIVESTYM
Antineoplastic Agents/ Kinase Inhibitors	ICLUSIG	2	imatinib mesylate, BOLSULIF, SPRYCEL
Central Nervous System/ Botulinum Toxins	BOTOX	117	Consult doctor

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Central Nervous System/ Migraine/ Preventive Migraine Agents/ Monoclonal Antibodies	AIMOVIG	1013	AJOVY, EMGALITY
Endocrine and Metabolic/ Contraceptives/ Monophasic	BALCOLTRA	94	ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-levonorgestrel, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron, ethinyl estradiol-norgestimate, LO LOESTRIN FE, NATAZIA
Hematologic/ Anticoagulants/ Oral	ELIQUIS	5113	warfarin, XARELTO
Hematologic/ Hematopoietic Growth Factors	ARANESP	2	RETACRIT
Hematologic/ Hematopoietic Growth Factors	FEIBA	0	NOVOSEVEN RT, SEVENFACT

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Hematologic/ Hematopoietic Growth Factors	CINRYZE	1	ORLADEYO, TAKHZYRO
Hematologic/ Miscellaneous Bleeding Disorders Agents	HAEGARDA	7	ORLADEYO, TAKHZYRO
Hematologic/ Thrombocytopenia Agents	MULPLETA	0	Consult doctor
Hematologic/ Thrombocytopenia Agents	NPLATE	1	PROMACTA, TAVALISSE
Immunologic Agents/ Hereditary Angioedema	XALKORI	1	ALECENSA, ALUNBRIG, ZYKADIA
Immunologic Agents/ Hereditary Angioedema	AFINITOR	15	everolimus, AFINITOR DISPERZ
Respiratory/ Anaphylaxis Treatment Agents	SYMJEPI	18	epinephrine auto-injector, AUVI-Q, EPIPEN, EPIPEN JR
Respiratory/ Anaphylaxis Treatment Agents	ADRENALIN	0	epinephrine auto-injector, AUVI-Q, EPIPEN, EPIPEN JR

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)	Tier Change
REYVOW	43	2→3
DDAVP TABLET	0	2→3
DDAVP NASAL SPRAY	0	2→3
DOPTELET	3	5→6
DIPROLENE OINT	0	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	Drug	# Utilizers (6 mo)	Tier Change
BRUKINSA	n/a	6→5	VITRAKVI	n/a	6→5
IMBRUVICA	n/a	6→5	WEGOVY	n/a	3→2
ZYKADIA	n/a	6→5	NOVOSEVEN RT	n/a	6→5
ROZLYTREK	n/a	6→5	PROMACTA	n/a	6→5

Formulary Updates – Downtiers

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
ABRAXANE	0	3→6
LYSODREN	2	2→5
PROVENGE	0	3→6

Formulary Updates – Specialty Product Movement

QUESTIONS?

Summary of Formulary Changes Effective 01/01/22

NEW MOLECULAR ENTITIES

- 8 new drug products were added to the formulary

OTHER FORMULARY ADDITIONS

- 14 products were added to the formulary including formulary add backs and line extensions
- 1 indication-based criteria update- Cimzia

UTILIZATION MANAGEMENT

- 5 Prior Authorizations – Verquvo, Qelbree, Kerendia, Myfembree, and CGMs

PRODUCT EXCLUSIONS

- 18 products were excluded impacting 6469 members

UPTIERS/DOWNTIERS

- 16 products had tier movements, including 3 products moving from non-specialty to specialty status

Next meeting: TBD 2022

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Proposed Meeting Dates for 2022

- Wednesday, February 9, 2022
- Wednesday, May 11, 2022
- Wednesday, August 10, 2022
- Wednesday, October 12, 2022