





Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 04/01/2022

February 9, 2022 6:30 – 8:00 PM





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

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?



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



Charter and By-Law Proposals

Copies were distributed prior to the meeting for your review.

• Are there any additions or corrections to the Charter or By-Laws?



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Coronavirus Updates: At-Home Rapid tests

- Per the President's Executive Order, At-Home Rapid COVID-19 tests will be covered 100% effective January 15, 2022 via the pharmacy benefit. There is a limit of 8 At-Home Rapid tests per 30 days (based in the number of tests not kits).
- Plan members will have two options for coverage of At-Home Rapid COVID-19 tests:
 - Purchase your At-Home Rapid COVID-19 test at a local pharmacy using your State Health Plan ID card. When purchased at the pharmacy with your ID card, there should be no cost to the member, or
 - Purchase an At-Home Rapid COVID-19 test online or in a store and submit a receipt and claims form for reimbursement
 - Members electing to purchase the test and submit a claim should use the <u>Prescription</u> <u>Reimbursement Claim form(link is external)</u> located on the Plan's website. Members should submit a receipt, that clearly indicates the test purchased, along with the claims form. Expect the claims reimbursement process to take between 30 and 90 days.



Coronavirus Updates: Treatment Summary

Drug	Authorized Use			
bamlanivumab/ etesevimab	NOT currently authorized in any U.S. region.			
RegenCOV (casirivimab/ imdevimab)	NOT currently authorized in any U.S. region.			
sotrovimab	Mild-to-mod COVID-19 in pts (\geq 12 yrs old weighing \geq 40 kg) with positive results of direct SARS-CoV-2 viral testing, and at high risk for progression to severe COVID-19, including hospitalization or death.			
ACTEMRA (tocilizumab)	COVID-19 in hospitalized pts (≥2 yrs) receiving systemic corticosteroids who require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).			
OLUMIANT (baricitinib)	Suspected or lab- confirmed COVID-19 in certain hospitalized pts requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).			



Coronavirus Updates: Treatment Summary

Drug	Authorized Use
EVUSHELD (tixagevimab/ cilgavimab)	 Pre-exposure prophylaxis for prevention of COVID-19 in individuals ≥12 years of age weighing ≥40 kg: Who are not currently infected and who have not had a known recent exposure to an individual infected with SARS-CoV-2 AND o Who have mod-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination OR o For whom vaccination with any available COVID-19 vaccine is not recommended
VEKLURY (remdesivir)	FDA Approved : pts \geq 12 years of age weighing \geq 40 kg for treatment of COVID-19 requiring hospitalization EUA Revision 1/21/2022 : COVID-19 treatment in non-hospitalized pts age \geq 12 weighing \geq 40 kg with positive results of direct SARS- CoV-2 viral testing, with mild-to-mod COVID-19, at high risk for progression to severe COVID-19, including hospitalization or death



Coronavirus Updates: Treatment Summary

Drug	Authorized Use
PAXLOVID TAB (nirmatrelvir/ ritonivir)	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
MOLNUPIRAVIR CAP 200MG	Treatment of mild-to-moderate coronavirus disease 2019 (COVID- 19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.



Formulary Updates – Effective 04/01/2022

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
EMPAVELI	Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).	SGM/Spec QL	5
	Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.	SGM/Spec QL	6
RYPLAZIM	Treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia).	SGM	6



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	Comments	UM
GEMTESA	2	New addition for treatment of overactive bladder	n/a
HAEGARDA	6	Formulary Add-Back	n/a



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	Comments	UM
ONUREG	6	Oral azacitidine approved for AML. Brand Vidaza is inj form of azacitidine approved for myelodysplastic syndromes.	SGM/Spec QL
EPCLUSA PAK 200-50MG	5	New GPI for existing strength	SGM/Spec QL in place
EPCLUSA PAK 150-37.5	5	New Strength	SGM/Spec QL in place
BIKTARVY 30 TAB 120-15	2	New Strength	Spec QL in place



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	Comments	UM
XEPI CREAM	3	New NDCs	n/a
TRANDOLAPRIL/VERAPAMIL TAB 2-240 ER	3	Line ext - SSB sharing GPI with Preferred Brand Tarka and its generic	n/a
CYCLOPHOSPHAMIDE INJ 2GM/10ML	3	Line ext - IV formulation	n/a
GVOKE KIT INJ 1MG/0.2	2	Line ext - Kit containing single dose vial and syringe	n/a
XARELTO SUS 1MG/ML	2	Line ext - suspension dosage form	n/a



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
Cardiovascular/ ACE Inhibitors	EPANED	9	enalapril, fosinopril, lisinopril, quinapril, ramipril
Genitourinary/ Urinary Antispasmodics	MYRBETRIQ	1836	darifenacin ext-rel, oxybutynin ext-rel, solifenacin, tolterodine, tolterodine ext- rel, trospium, trospium ext-rel, GEMTESA, TOVIAZ
Respiratory/ Nasal Steroids/Combinations	DYMISTA	85	azelastine-fluticasone, flunisolide, fluticasone, mometasone



Formulary Updates – Hyperinflation Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo.)	Formulary Preferred Alternatives
Analgesics/ Non-Opioid Analgesics	butalbital-acetaminophen capsule; butalbital-acetaminophen tablet 25 mg-325 mg; Vtol LQ	4	diclofenac sodium, ibuprofen, naproxen (except naproxen CR or naproxen suspension)
Anti-Infectives/ Antibacterials/ Tetracyclines	doxycycline hyclate delayed- release tablet (75 mg, 80 mg and 150 mg)	16	doxycycline hyclate 20 mg, doxycycline hyclate capsule, minocycline, tetracycline
Endocrine and Metabolic/ Glucocorticoids	prednisolone solution (10 mg/5 ml and 20 mg/5 ml)	17	dexamethasone, hydrocortisone, methylprednisolone, prednisolone solution (except prednisolone solution 10 mg/5 mL, 20 mg/5 mL), prednisone
Gastrointestinal/ Laxatives	peg 3350 electrolytes (generics for MoviPrep only)	0	peg 3350-electrolytes (except generics for MoviPrep) and Clenpiq (sodium picosulfate-magnesium oxide-citric acid)
Topical/ Dermatology/ Acne/ Topical	adapalene pad	0	adapalene (except adapalene pad), benzoyl peroxide, clindamycin gel (except NDC 68682046275), clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Epiduo (adapalene-benzoyl peroxide), and Onexton (clindamycin- benzoyl peroxide).
Topical/ Dermatology/ Atopic Dermatitis	desonide gel, DesRx	2	desonide (except desonide gel) and hydrocortisone.
Topical/ Otic/ Anti- infective/ Anti-inflamm Combinations	ciprofloxacin/fluocinolone otic	0	ciprofloxacin-dexamethasone and ofloxacin otic.

Formulary Updates – Product Exclusions

QUESTIONS?



<u>Formulary Updates – Uptiers</u>

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
SUTENT	3	everolimus, sunitinib, Cabometyx (cabozantinib), and Votrient (pazopanib)	5→6
BYSTOLIC	1366	atenolol, carvedilol, carvedilol phosphate ext-rel, metoprolol succinate ext-rel, metoprolol tartrate, nadolol, nebivolol, pindolol, propranolol, propranolol ext-rel	2→3
DUREZOL	288	dexamethasone, difluprednate, loteprednol, prednisolone acetate 1%	2→3



Formulary Updates – Uptiers

QUESTIONS?



Summary of Formulary Changes Effective 04/01/22

NEW MOLECULAR ENTITIES

• 3 new drug products were added to the formulary

OTHER FORMULARY ADDITIONS

 11 products were added to the formulary including 1 formulary add-back and 9 line extensions

UTILIZATION MANAGEMENT

- Specialty Guidelines Management (SGM) for EMPAVELI, LIVMARLI, RYPLAZIM, and ONUREG
- Specialty QL for EMPAVELI, LIVMARLI, and ONUREG

PRODUCT EXCLUSIONS

• 10 products were excluded impacting 1969 members

UPTIERS/DOWNTIERS

• 3 products had tier movements



Meeting Dates for 2022

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



