



Dale R. Folwell, CPA
STATE TREASURER OF NORTH CAROLINA
DALE R. FOLWELL, CPA



Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 10/1/2020

August 12, 2020
6:30 – 8:00 PM

A Division of the Department of State Treasurer

Role Call

P&T COMMITTEE MEMBERS

- David Konanc, MD
- Matthew K. Flynn, MD
- Jennifer Burch, PharmD
- Peter Robie, MD
- Tony Gurley, RPh, JD
- John B. Anderson, MD, MPH
- John Engemann, MD
- Joseph Shanahan, MD
- Sundhar Ramalingam, MD

PLAN STAFF & VENDORS

State Health Plan

- Natasha Davis
- Caroline Smart
- Dee Jones

Segal Consulting

- Kautook Vyas, PharmD

CVS Caremark

- Renee Jarnigan, RPh
- Stephanie Morrison, PharmD

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

Formulary Updates – Effective 10/1/2020

CVS Caremark's Quarterly Formulary Update:

- Product Exclusions
- Tier Changes (Uptier/Downtier)
- Formulary Additions (New molecule entries, line extensions)
- New Utilization Management Criteria

Presented by:

- Renée Jarnigan, RPh, Clinical Advisor, CVS Health
- Stephanie Morrison, PharmD, BCPS, Clinical Advisor, CVS Health

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

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.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Gastrointestinal/ Miscellaneous	SUCRALFATE SUSPENSION 1GM/10ML	Availability of a generic option for the short-term treatment of active duodenal ulcers. The preferred option is sucralfate tablet.	504
Central Nervous System/ Antidepressants/ Selective Serotonin Reuptake Inhibitors (SSRIs)	FLUOXETIN(S) and FLUOXETINE TAB 10MG and 20 MG	Availability of generic options for the treatment of Premenstrual Dysphoric Disorder (PMDD). Preferred options include fluoxetine (except fluoxetine tablet 60 mg, fluoxetine tablet [generics for SARAFEM]), paroxetine HCl ext-rel, and sertraline.	90
Analgesics/ Non-Opioid Analgesics	BUPAP TAB and BUTALB/ACETA 50-300MG	Availability of generic options for the relief of tension headache. Preferred options include diclofenac sodium, ibuprofen, and naproxen (except naproxen CR or naproxen suspension).	52

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.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Dermatology/ Antifungals	OXICONAZOLE CREAM and OXICONAZOLE NITRATE CREAM 1%	Availability of generic topical antifungal options. Preferred options include ciclopirox, clotrimazole, econazole, ketoconazole cream 2%, and luliconazole.	26
Cardiovascular/ Pulmonary Arterial Hypertension/ Endothelin Receptor Antagonists	LETAIRIS TAB	Availability of additional options for the treatment of pulmonary arterial hypertension. Preferred options include ambrisentan, bosentan, and Opsumit (macitentan).	12
Central Nervous System/ Hypnotics/ Benzodiazepines	QUAZEPAM TAB	Availability of additional options for the treatment of insomnia. Preferred options include doxepin, eszopiclone, ramelteon, zolpidem, zolpidem ext-rel, zolpidem sublingual, and Belsomra (suvorexant).	5

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.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Analgesics/ Opioid Analgesics	TRAMADOL HCL TAB 100MG (NDC 52817019610)	Availability of additional generic options for the management of mild to moderate pain. Preferred options include tramadol (except NDC 52817019610) and tramadol ext-rel.	4
Cardiovascular/ Antilipemics/ Niacins	NIACOR and NIACIN TAB 500MG	Availability of a generic niacin option for the treatment of high cholesterol and triglycerides. The preferred option is niacin ext-rel.	2
Antineoplastic Agents/ Kinase Inhibitors	ZYDELIG TAB	Availability of an additional option for the treatment of relapsed chronic lymphocytic leukemia, follicular lymphoma, or small lymphocytic lymphoma. The preferred option is Copiktra (duvelisib).	1

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.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Cardiovascular/ Beta-Blockers	INDERAL LA CAP; INDERAL XL CAP; INNOPRAN XL CAP	Availability of additional beta-blockers. Preferred options include atenolol, carvedilol, carvedilol phosphate ext-rel, metoprolol succinate ext-rel, metoprolol tartrate, nadolol, pindolol, propranolol, propranolol ext-rel, and Bystolic (nebivolol).	1
Antineoplastic Agents/ Kinase Inhibitors	ALIQOPA VIA 60MG	Availability of an additional option for the treatment of relapsed follicular lymphoma. The preferred option is Copiktra (duvelisib).	0
Analgesics/ NSAIDs	FENOPROFEN TAB 600MG	Availability of additional generic NSAIDs for pain management. Preferred options include diclofenac sodium, ibuprofen, meloxicam, and naproxen (except naproxen CR or naproxen suspension).	0

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.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Gastrointestinal/ Antidiarrheals	MYTESI TAB 125MG	Availability of additional options for managing non-infectious diarrhea. Consult doctor.	0
Respiratory/ Antihistamines, Sedating	DIPHEN ELX 12.5/5ML	Availability of a generic antihistamine option. The preferred option is levocetirizine.	0

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 are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand).

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Ophthalmic/ Prostaglandins	TRAVATAN Z	Availability of additional options for reducing elevated intraocular pressure. Preferred options include latanoprost, travoprost, and Lumigan (bimatoprost).	119
Endocrine and Metabolic/ Thyroid Supplements	CYTOMEL TAB	Availability of generic liothyronine.	61
Central Nervous System/ Hypnotics/ Tricyclics	SILENOR TAB	Availability of additional options for the management of insomnia. Preferred options include doxepin, eszopiclone, ramelteon, zolpidem, zolpidem ext-rel, zolpidem sublingual, and Belsomra (suvorexant).	31

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 are non-specialty and will be moving from tier 2 (preferred brand) to tier 3 (non-preferred brand).

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Topical/ Ophthalmic/ Anti- Infectives	MOXEZA SOL 0.5% OP	Availability of additional topical anti-infective ophthalmic agents. Preferred options include ciprofloxacin, erythromycin, gentamicin, levofloxacin, moxifloxacin, ofloxacin, sulfacetamide, tobramycin, Besivance (besifloxacin), and Ciloxan Ointment (ciprofloxacin).	8
Topical/ Dermatology/ Corticosteroids/ Low Potency	SYNALAR SOL 0.01%	Availability of generic fluocinolone.	0

Formulary Updates – Uptiers

QUESTIONS?

Formulary Updates – Formulary Additions

Formulary Additions

- All Drugs, including add backs, that are not new to market but medications that were previously blocked by the plan and are now added to the formulary.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Anti-Infectives/ Antiretroviral Agents/ Antiretroviral Combinations	DOVATO TAB	Addition of a preferred treatment for HIV.	0
Antineoplastic Agents/ Kinase Inhibitors	COPIKTRA CAP	To provide an option for the treatment of relapsed or refractory chronic lymphocytic leukemia, small lymphocytic lymphoma, and follicular lymphoma.	0
Analgesics/ Opioid Analgesics	HYDROCODONE CAP ER	Addition generic ext-rel hydrocodone to the formulary; brand Zohydro remains not covered.	0

Formulary Updates – Formulary Additions

Formulary Additions

- All Drugs, including add backs, that are not new to market but medications that were previously blocked by the plan and are now added to the formulary.

Therapeutic Category/ Subcategory	Drug	Rationale/Alternatives	# Utilizers (6 mo)
Endocrine and Metabolic/ Antidiabetics/ Sodium- Glucose Co-Transporter 2 (SGLT2) Inhibitor/Dipeptidyl Peptidase-4 (DPP-4) Inhibitor/Biguanide Combinations	TRIJARDY XR TAB	Trijardy XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	0
Respiratory/ Anticholinergic / Beta Agonist Combinations/ Short Acting	COMBIVENT INH RESPIMAT	Availability of other anticholinergic-beta agonist option for the treatment of chronic obstructive pulmonary disease (COPD).	0

Formulary Updates – Formulary Additions

QUESTIONS?

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
TUKYSA	Indicated in combination with Herceptin and Xeloda for tx of adults with unresectable or metastatic HER2-positive breast cancer.	Authorization of 12 months may be granted for treatment of recurrent or advanced unresectable or metastatic HER2-positive breast cancer in combination with trastuzumab and capecitabine when the member has received one or more prior anti-HER2-based regimens in the metastatic setting.	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
TRODELVY	Indicated for tx of adults with triple negative breast cancer (TNBC) who have received at least two prior therapies for metastatic dz.	<p>Authorization of 12 months may be granted for treatment of recurrent or metastatic triple-negative breast cancer (mTNBC) when all of the following criteria are met:</p> <ol style="list-style-type: none"> 1. The diagnosis of triple-negative breast cancer : <ol style="list-style-type: none"> i. Human epidermal growth factor receptor 2 (HER2) ii. Estrogen iii. Progesterone 2. The member has received at least two prior therapies for metastatic disease 	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
TEPEZZA	Indicated for the tx of thyroid eye disease.	<p>Thyroid eye disease (TED)</p> <p>Authorization of 6 months may be granted for treatment of TED when all of the following criteria are met:</p> <p>A. Member is 18 years of age or older</p> <p>B. Member has active disease with a CAS greater than or equal to 4 (see Appendix A)</p> <p>C. Member has moderate-to-severe disease (see Appendix B)</p>	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
VYNDAMAX	Indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults.	A. Amyloid deposits B. Cardiac involvement confirmed C. Hereditary ATTR-CM, presence of a mutation of the TTR gene confirmed. D. Presence of transthyretin precursor proteins confirmed. E. The member exhibits clinical symptoms of cardiomyopathy and heart failure F. The member is not a liver transplant recipient. G. Contraindicated with inotersen (Tegsedi) or patisiran (Onpattro).	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
FINTEPLA	Indicated for the treatment of seizures associated with Dravet syndrome	Pending	6
XCOPRI	Indicated for the treatment of partial-onset seizures as either monotherapy or adjunctive therapy.	Pending	3

Formulary Updates – New Molecular Entities

QUESTIONS?

Formulary Updates – Line Extensions

Line Extensions

- These are new formulations or strengths of existing formulary medications being added to the formulary.

Drug	Tier	Drug	Tier
NYMALIZE SOL	3	HARVONI TAB 45-200MG	5
BIJUVA CAP 1-100MG	3	JYNARQUE TAB 15MG	6
DOVATO TAB 50-300MG	5	JYNARQUE PAK 30-15MG	6
SOVALDI PAK 150MG	6	HYDROCODONE CAP ER	1
SOVALDI PAK 200MG	6	AKYNZEO INJ	3
SOVALDI TAB 200MG	6	GVOKE HYPO INJ and PFS	2
HARVONI PAK 45-200MG	5	DUPIXENT INJ 300/2ML	5
HARVONI PAK	5	TRIJARDY XR TAB	2

Formulary Updates – Line Extensions

Line Extensions

- These are new formulations or strengths of existing formulary medications being added to the formulary.

Drug	Tier	Drug	Tier
FERPRX 2-DAY TAB 1000MG	6	METHADO/NACL INJ 1MG/ML	3
FINTEPLA SOL 2.2MG/ML	6	ENBREL INJ 25MG	5
PHENYLEPHRIN INJ 0.8MG/10	3	ZERVIATE DRO 0.24%	3
EPINEPHRINE INJ 0.1MG/10	3	NAYZILAM SPRAY	3
BUPIVACAINE INJ 0.125%	3	VALTOCO SPRAY	3
SIRTURO TAB 20MG	3		

Formulary Updates – Line Extensions

QUESTIONS?

Formulary Updates – New Utilization Management

New Utilization Management – Proton Pump Inhibitors (PPI)

- Background
 - Plan moved from an Open Formulary to a Closed Custom Formulary with the transition to CVS in 2017
 - PPIs were all covered, difference between Generic and Brand was the member's cost share
 - Transition to CVS, most Brands became Non-Covered and Generics remained Preferred
 - Plan currently has Generic Step Therapy for certain classes
 - PPIs are additional opportunity

Formulary Updates – New Utilization Management

New Utilization Management – Proton Pump Inhibitors (PPI)

- Coverage Criteria
 - The requested branded proton pump inhibitor (PPI) will be covered with post step therapy prior authorization when the following criteria are met:
 - The patient has experienced an inadequate treatment response after at least a 30 day trial of at least one generic proton pump inhibitor (PPI) drug. OR
 - The patient has a documented contraindication or potential drug interaction that would prohibit a trial of at least one generic proton pump inhibitor (PPI) drug. OR
 - The patient has experienced an intolerance to at least one generic proton pump inhibitor (PPI) drug. OR
 - The patient requires use of a specific dosage form (e.g., suspension, solution) that is not available as a generic proton pump inhibitor (PPI) drug.
 - Current criteria applies to the following PPI brands: Aciphex Sprinkles, Dexilant, Prilosec Packets and Protonix Packets
- CVS estimates on member disruption
 - Members with a rejected claim- 10,669
 - Estimated walkaways- 60%

Formulary Updates – New Utilization Management

Open Discussion

Formulary Updates – New Utilization Management

New Utilization Management – Exclusion of Anti-Obesity Medications

- The plan currently covers anti-obesity medications with PA criteria for medications such as Saxenda.
- Given these medications can be prescribed without much medical scrutiny, plan is considering exclusion of these therapies.
- Members retain access to formulary excluded process via the medical necessity/exceptions process.
- The plan with the guidance and recommendations from the Committee retain the flexibility of determining requirements within the medical necessity criteria.
 - Restrict prescribing ability to certain specialists
 - Apply shorter duration of approval to allow providers to re-evaluate benefit/adherence to therapy
- Effective 01/01/2021

Formulary Updates – New Utilization Management

Open Discussion

Summary of Formulary Changes Effective 10/01/20

PRODUCT EXCLUSIONS

- 13 products were excluded impacting 693 members

UPTIERS

- 5 products had movement to a higher tier impacting 219 members

FORMULARY ADDITIONS

- 5 products were added to the formulary including formulary add backs.

NEW MOLECULAR ENTITIES

- 6 new drug products were added to the formulary.

LINE EXTENSIONS

- 27 products had additional strengths and formulations added to the formulary.

Discussion Points

- PPIs and Anti-Obesity medication utilization management was discussed



Next meeting: **October 14, 2020**



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
DALE R. FOLWELL, CPA

www.shpnc.org

www.nctreasurer.com