



Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 04/01/2021

February 10, 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
DALE R. FOLWELL, CPA

Role 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, PharmD
- 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 04/01/2021

CVS Caremark's Quarterly Formulary Update:

- Formulary Additions (New molecule entries, line extensions)
- New Utilization Management Criteria
- 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
BRUKINSA (zanubrutinib)	A kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy	SGM; Specialty QL	6
EVRYSDI (risdiplam)	A SMN2 splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older	SGM; Specialty 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
ZOKINVY (lonafarnib)	A farnesyltransferase inhibitor indicated in patients 12 months of age and older (with a BSA of 0.39 m ² and above) to reduce risk of mortality in specific types of progeria.	SGM; Specialty QL	6

Formulary Updates – New Molecular Entities

QUESTIONS?

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
BPM-PSE-DM SYP 2-30-10	1	RETACRIT INJ 20000UNI	4
DIFICID SUS	2	EPCLUSA TAB 200-50MG	5
TRELEGY AER ELLIPTA	2	HIZENTRA INJ 1GM/5ML	5
XERAIVA INJ 100MG	3	HIZENTRA INJ 2GM/10ML	5
CLINIMIX INJ 8/14	3	HIZENTRA SOL 20%	5
CLINIMIX E INJ 8/10	3	NPLATE INJ 125MCG	6
INVEGA SUSTENNA	3	FENSOLVI INJ 45MG	6

Formulary Updates – Other Formulary Additions

QUESTIONS?

Utilization Management Policy Review

Sivextro Initial Prior Authorization

Affected Medications:

- Sivextro (tedizolid)

Coverage Criteria:

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is being converted from IV (intravenous) Sivextro (tedizolid) as prescribed by or in consultation with an Infectious Disease specialist

OR

- The patient has an acute bacterial skin or skin structure infection (ABSSSI) proven or strongly suspected to be caused by susceptible isolates of the following Gram-positive microorganisms: A) Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), B) Streptococcus pyogenes, C) Streptococcus agalactiae, D) Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), E) Enterococcus faecalis

AND

- The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies or the bacteria are not susceptible to any other antibiotics

Utilization Management Policy Review

Nuzyra Initial Prior Authorization

Affected Medications:

- Nuzyra (omadacycline)

Coverage Criteria:

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is being converted from intravenous (IV) omadacycline (Nuzyra) as prescribed by or in consultation with an Infectious Disease specialist

OR

- The requested drug is being prescribed for the treatment of an adult patient with community-acquired bacterial pneumonia (CABP) caused by any of the following susceptible microorganisms: A) *Streptococcus pneumoniae*, B) *Staphylococcus aureus* (methicillin-susceptible isolates), C) *Haemophilus influenzae*, D) *Haemophilus parainfluenzae*, E) *Klebsiella pneumoniae*, F) *Legionella pneumophila*, G) *Mycoplasma pneumoniae*, H) *Chlamydophila pneumoniae*

OR

- The requested drug is being prescribed for the treatment of an adult patient with an acute bacterial skin and skin structure infection (ABSSSI) caused by any of the following susceptible microorganisms: A) *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), B) *Staphylococcus lugdunensis*, C) *Streptococcus pyogenes*, D) *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), E) *Enterococcus faecalis*, F) *Enterobacter cloacae*, G) *Klebsiella pneumoniae*

AND

- The infection is proven or strongly suspected to be caused by susceptible bacteria

AND

- The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies or the bacteria are not susceptible to any other antibiotics

Utilization Management Policy Review

Flector, Licart (Brand & Generic) Quantity Limits

Affected Medications:

- Flector, Licart, diclofenac epolamine topical system

Quantity Limits:

LIMIT CRITERIA

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

Drug	1 Month Limit*	3 Months Limit*
Flector 1.3% topical systems (patches)	30 patches (1 box) / 25 days	Does not apply*
Licart 1.3% topical systems (patches)	15 patches (1 box) / 25 days	Does not apply*

* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

* These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.

Formulary Updates – Utilization Management Policy Review

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
Endocrine and Metabolic/ Contraceptives/ Progestin only	SLYND	282	norethindrone
Gastrointestinal/ Antispasmodics	HYOSCYAMINE ER TAB	203	dicyclomine
Central Nervous System/ Psychotherapeutic-Miscellaneous/ Vasomotor Symptom Agents	PAROXETINE CAP 7.5MG	150	paroxetine HCl
Central Nervous System/ Fibromyalgia	LYRICA	133	duloxetine, pregabalin
Central Nervous System/ Anticonvulsants	TOPIRAMATE ER CAP (generics for Qudexy XR only)	85	carbamazepine, clobazam, divalproex sodium, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenobarbital, phenytoin, phenytoin sodium extended, primidone, rufinamide, tiagabine, topiramate, valproic acid, zonisamide, FYCOMPA, OXTELLAR XR, TROKENDI XR, VIMPAT, XCOPRI

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo)	Formulary Preferred Alternatives
Topical/ Ophthalmic/ Prostaglandins	TRAVATAN Z	84	latanoprost, travoprost, LUMIGAN, ZIOPTAN
Endocrine and Metabolic/ Thyroid Agents/ Thyroid Supplements	CYTOMEL	58	levothyroxine, liothyronine, SYNTHROID
Topical/ Dermatology/ Corticosteroids/ Medium Potency	TRIAMCINOLONE OINT 0.05% (including Trianex generic)	53	hydrocortisone butyrate cream, hydrocortisone butyrate ointment, hydrocortisone butyrate solution, mometasone, triamcinolone cream, triamcinolone lotion, triamcinolone ointment (except triamcinolone ointment 0.05%)
Central Nervous System/ Attention Deficit Hyperactivity Disorder	FOCALIN XR	52	amphetamine-dextroamphetamine mixed salts ext-rel (excluding certain NDCs), dexamethylphenidate ext-rel, methylphenidate ext-rel (excluding certain NDCs), MYDAYIS, VYVANSE

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo)	Formulary Preferred Alternatives
Topical/ Dermatology/ Corticosteroids/ Medium Potency	CLOCORTOLONE TOPICAL CRM	46	hydrocortisone butyrate cream, hydrocortisone butyrate ointment, hydrocortisone butyrate solution, mometasone, triamcinolone cream, triamcinolone lotion, triamcinolone ointment (except triamcinolone ointment 0.05%)
Central Nervous System/ Antidepressants/ Selective Serotonin Reuptake Inhibitors (SSRIs)	ZOLOFT	33	citalopram, escitalopram, fluoxetine (except fluoxetine tablet 60 mg, fluoxetine tablet [generics for SARAFEM]), paroxetine HCl, paroxetine HCl ext-rel, sertraline, TRINTELLIX
Anti-infectives/ Miscellaneous	NITROFURANTN SUSP (NDC 70408023932 only)	28	nitrofurantoin (except NDC 70408023932)
Topical/ Dermatology/ Corticosteroids/ Medium Potency	DESOXIMETASONE OIN 0.05%	25	hydrocortisone butyrate cream, hydrocortisone butyrate ointment, hydrocortisone butyrate solution, mometasone, triamcinolone cream, triamcinolone lotion, triamcinolone ointment (except triamcinolone ointment 0.05%)

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo)	Formulary Preferred Alternatives
Endocrine and Metabolic/ Contraceptives/ Monophasic	YASMIN	23	ethinyl estradiol-drospirenone, ethinyl estradiol-drospirenone-levomefolate, ethinyl estradiol-norethindrone acetate, ethinyl estradiol-norethindrone acetate-iron
Respiratory/ Leukotriene Modulators	ZILEUTON ER	16	montelukast, zafirlukast
Central Nervous System/ Attention Deficit Hyperactivity Disorder	ADDERALL	14	amphetamine-dextroamphetamine mixed salts, methylphenidate
Analgesics/ Gout	ULORIC	13	febuxostat, allopurinol
Cardiovascular/ Angiotensin II Receptor Antagonist/Calcium Channel Blocker Combinations	AZOR	13	amlodipine-olmesartan, amlodipine-telmisartan, amlodipine-valsartan
Cardiovascular/ Antilipemics/ Fibrates	FENOFIBRATE CAPSULE 50MG and 130 mg	13	fenofibrate (except fenofibrate capsule 50 mg, 130 mg; fenofibrate tablet 40 mg, 120 mg), fenofibric acid delayed-rel

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo)	Formulary Preferred Alternatives
Cardiovascular/ Angiotensin II Receptor Antagonists/Diuretic Combinations	COZAAR	12	candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan
Central Nervous System/ Hypnotics	SILENOR	12	doxepin, eszopiclone, ramelteon, zolpidem, zolpidem ext-rel, zolpidem sublingual, BELSOMRA
Cardiovascular/ Beta-Blockers	COREG CR	11	atenolol, carvedilol, carvedilol phosphate ext-rel, metoprolol succinate ext-rel, metoprolol tartrate, nadolol, pindolol, propranolol, propranolol ext-rel, BYSTOLIC
Topical/ Dermatology/ Atopic Dermatitis/ Topical	ELIDEL	11	pimecrolimus, tacrolimus, EUCRISA
Topical/ Dermatology/ Corticosteroids/ Medium Potency	HYDROCORTISONE BUTYRATE LOTION	10	hydrocortisone butyrate cream, hydrocortisone butyrate ointment, hydrocortisone butyrate solution, mometasone, triamcinolone cream, triamcinolone lotion, triamcinolone ointment (except triamcinolone ointment 0.05%)

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo)	Formulary Preferred Alternatives
Endocrine and Metabolic/ Androgens	ANDROGEL 1.62% GEL	9	testosterone gel (except authorized generics for TESTIM and VOGELXO), testosterone solution, ANDRODERM
Respiratory/ Steroid/Beta Agonist Combinations	ADVAIR HFA (Only NDCs 00173071522; 00173071622; 00173071722)	9	alternate ADVAIR HFA NDC (except NDCs 00173071522, 00173071622, and 00173071722).
Respiratory/ Steroid/Beta Agonist Combinations	BREO ELLIPTA (Only institutional NDCs 00173085914; 00173088214)	8	alternate BREO ELLIPTA NDC (except NDCs 00173085914 and 00173088214)
Cardiovascular/ Angiotensin II Receptor Antagonists/Diuretic Combinations	MICARDIS	7	candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan
Central Nervous System/ Anticonvulsants	BANZEL SUSP	7	clobazam, clonazepam, lamotrigine, rufinamide, topiramate, TROKENDI XR
Gastrointestinal/ Irritable Bowel Syndrome	ZELNORM TAB 6MG	7	LINZESS, VIBERZI

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo)	Formulary Preferred Alternatives
Cardiovascular/ Antilipemics/ Fibrates	FENOFIBRATE TAB 40MG	6	fenofibrate (except fenofibrate capsule 50 mg, 130 mg; fenofibrate tablet 40 mg, 120 mg), fenofibric acid delayed-rel
Central Nervous System/ Migraine/ Acute Migraine Agents/ Triptans	MAXALT/MAXALT MLT	6	eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, NURTEC ODT, ONZETRA XSAIL, REYVOW, UBRELVY, ZEMBRACE SYMTOUCH, ZOMIG NASAL SPRAY
Cardiovascular/ Angiotensin II Receptor Antagonists/Diuretic Combinations	HYZAAR	4	candesartan-hydrochlorothiazide, irbesartan-hydrochlorothiazide, losartan-hydrochlorothiazide, olmesartan-hydrochlorothiazide, telmisartan-hydrochlorothiazide, valsartan-hydrochlorothiazide
Cardiovascular/ Pulmonary Arterial Hypertension/ Prostaglandin Vasodilators	REMODULIN	4	treprostinil
Cardiovascular/ Angiotensin II Receptor Antagonists/Diuretic Combinations	MICARDIS HCT	2	candesartan-hydrochlorothiazide, irbesartan-hydrochlorothiazide, losartan-hydrochlorothiazide, olmesartan-hydrochlorothiazide, telmisartan-hydrochlorothiazide, valsartan-hydrochlorothiazide

Formulary Updates – Product Exclusions

Therapeutic Category	Drug	# Utilizers (6 mo)	Formulary Preferred Alternatives
Antineoplastic Agents/ Alkylating Agents	BELRAPZO	0	bendamustine; BENDEKA
Cardiovascular/ ACE Inhibitor/Diuretic Combinations	ZESTORETIC	0	fosinopril-hydrochlorothiazide, lisinopril-hydrochlorothiazide, quinapril-hydrochlorothiazide
Gastrointestinal/ Antispasmodics	OSCIMIN SR	0	dicyclomine
Gastrointestinal/ Antispasmodics	SYMAX-SR	0	dicyclomine
Gastrointestinal/ Proton Pump Inhibitors	PANTOPRAZOLE DR SUSP	0	esomeprazole delayed-rel, lansoprazole delayed-rel, omeprazole delayed-rel, pantoprazole delayed-rel tablet, DEXILANT

Formulary Updates – Product Exclusions

QUESTIONS?

Formulary Updates – Tier Changes

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
ATRIPLA	43	2-->3
SYMFI	0	2-->3
SYMFI LO	0	2-->3
TYKERB	2	5-->6
ORAPRED ODT	1	2-->3
LEVBIID	0	2-->3
DRISDOL	0	2-->3

Formulary Updates – Tier Changes

QUESTIONS?

Summary of Formulary Changes Effective 04/01/21

NEW MOLECULAR ENTITIES

- 3 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

NEW UTILIZATION MANAGEMENT

- 2 Initial Prior Authorization Policies and 1 Quantity Limit Policy

PRODUCT EXCLUSIONS

- 40 products were excluded impacting 1,449 members

UPTIERS/DOWNTIERS

- 7 products had tier movements

Next meeting: **May 12, 2021**

