North Carolina State Health Plan
FOR TEACHERS AND STATE EMPLOYEES
A Division of the Department of State Treasurer

STATE TREASURER OF NORTH CAROLINA
DALE R. FOLWELL, CPA

Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 4/1/19

February 13, 2019
6:30 – 8:00 PM

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

- Carl Antolick III, PharmD
- Tracy Linton, MPH
- Dee Jones

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.

Recent Plan Formulary Decisions

All approved negative formulary changes from October's meeting went into effect 1/1/2019 and include the following:

Removed the following products from the formulary:

- ACANYA, BENZACLIN, ONEXTON, VELTIN, ZIANA, JENTADUETO, JENTADUETO XR, TRADJENTA, CAMBIA, CONTRAVE, SORILUX, ACTICLATE, TARGADOX, ZUPLENZ, VANATOL LQ, TIROSINT, AVENOVA, ZEMAIRA, ELOCTATE, LUPRON DEPOT, FASENRA, ALPROLIX, & CIMZIA.

Moved the following branded products to non-preferred status:

- LUPRON DEPOT KIT 3.75MG AND 11.25MG, ZOLADEX, FENTORA, WELCHOL PAK 3.75GM, & PYRIDIUM tablet 100MG.

Adopted the following new utilization management criteria:

- Corticosteroid-Pulmicort 1mg Post Limit Policy
- Select Medical Devices Initial Prior Authorization

Minutes from Previous Committee Meeting

Instead of having the Secretary read the minutes, copies found in the P&T Booklet 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 4/1/2019

CVS Caremark's Quarterly Formulary Update:

- Product Exclusions
- Tier Changes
- New Drug Additions
- Utilization Management Criteria

Presented by:

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

Formulary Updates – Product Exclusions

Advanced Control Specialty Formulary

- Removals of certain high-cost drugs to maximize utilization of preferred products, biosimilars and generic alternatives.
- The following exclusions are only for branded products

ZYTIGA® (abiraterone)

- Availability of other options for the treatment of metastatic castration-resistant or high-risk castration-sensitive prostate cancer.
- Preferred options are generic abiraterone and Xtandi (enzalutamide).

EPOGEN® & PROCRIT® (epoetin alfa)

- Availability of other erythropoiesis-stimulating agents for the treatment on anemia and reduction of allogeneic RBC transfusions in specific conditions.
- Preferred options include Aranesp (darbepoetin alfa) and the biosimilar Retacrit (epoetin alfa-epbx).

Formulary Updates – Product Exclusions

Hyperinflation

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

BUTAL/APAP CAP 50-300MG (only NDC 69499034230)

- Generic barbiturate for the relief of tension headaches
- Manufactured by *Solubiomix*
- Average Wholesale Price (AWP): $66 per tablet
  - Plan's Average Net Cost per Prescription: >$1,900
- Number of current NCSHP utilizers: 0
- Formulary alternatives include:
  - Other NDC's
  - Diclofenac sodium, naproxen & other NSAIDs
- No clinical advantage over the other alternatives

Formulary Updates – Product Exclusions

Hyperinflation

- Targets drugs with >100% year-over-year price inflation that have readily available, clinically appropriate and more cost-effective formulary alternatives

DICLOFENAC GEL 1% (Only NDC 69499031866)

- Topical generic NSAID for the treatment of joint pain
- Manufactured by *Solubiomix*
- Average Wholesale Price (AWP): $486 per tube
  - Plan's Average Net Cost per Prescription: >$1,000
- Number of current NCSHP utilizers: 0
- Formulary alternatives include:
  - Other NDC's
  - Diclofenac sodium, meloxicam, naproxen & other NSAIDs
- No clinical advantage over the other alternatives

Formulary Updates – Uptiers

Movement to Non-preferred Status

- Typically branded medications that have readily available generic alternatives 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)

ATRALIN® GEL 0.05% (tretinoin)

- Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).

COREG® CR (carvedilol controlled-release)

- Preferred options include atenolol, carvedilol, carvedilol phosphate ext-rel, metoprolol succinate ext-rel, metoprolol tartrate, nadolol, pindolol, propranolol, propranolol ext-rel, and Bystolic (nebivolol).

Formulary Updates – Uptiers

Movement to Non-preferred Status

ESTRACE® VAGINAL CREAM (estradiol)

- Preferred options include estradiol, Estring (estradiol), and Premarin Cream (conjugated estrogens).

LUZU® CREAM 1% (luliconazole)

- Preferred options include ciclopirox, clotrimazole, econazole, ketoconazole, luliconazole, and Naftin (naftifine).

UCERIS® (budesonide)

- Preferred options include balsalazide, budesonide ext-rel, sulfasalazine, sulfasalazine delayed-rel, Apriso (mesalamine ext-rel), Lialda (mesalamine delayed-rel), and Pentasa (mesalamine ext-rel).

Formulary Updates – Uptiers

Movement to Non-preferred Status

MESTINON® TIMESPAN (pyridostigmine bromide ER)

- Preferred option includes pyridostigmine ext-release.

TOPICORT® (desoximetasone)

- Preferred options include betamethasone valerate cream, lotion, ointment 0.1%; clocortolone cream 0.1%; desoximetasone cream, ointment 0.05%; fluocinolone acetonide cream, ointment 0.025%; fluticasone propionate cream, lotion 0.05%, ointment 0.005%; hydrocortisone butyrate cream, ointment, solution 0.1%; hydrocortisone valerate cream, ointment 0.2%; mometasone cream, lotion, ointment 0.1%, triamcinolone acetonide cream, lotion 0.025%; triamcinolone acetonide cream, lotion, ointment 0.1%; Cutivate (fluticasone propionate cream, lotion 0.05%, ointment 0.005%), and Elocon (mometasone cream, lotion, ointment 0.1%).

Formulary Updates – Downtiers

Movement to Preferred Status

- Typically branded medications that are added as preferred products to provide additional treatment options.
- Non-specialty drugs will move from tier 3 (non-preferred brand) to tier 2 (preferred brand) while specialty drugs will move from tier 6 (non-preferred specialty) to tier 5 (preferred specialty).

COPAXONE® 20MG/ML (glatiramer acetate)

- To provide an additional option for the treatment of multiple sclerosis.
- Specialty medication moving from tier 6 to tier 5

MULPLETA® CR (lusutrombopag)

- To provide an option for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
- Specialty medication moving from tier 6 to tier 5

Formulary Updates – Downtiers

Movement to Preferred Status

DUPIXENT® 200MG/1.14ML (dupilumab)

- To provide an additional option for the treatment of moderate-to-severe asthma.
- Specialty medication moving from tier 6 to tier 5

ARISTADA® INITIO (aripiprazole lauroxil)

- To provide an option for the loading dose initiation of Aristada when used for the treatment of schizophrenia in adults.
- Non-specialty medication moving from tier 3 to tier 2

Formulary Updates – New Drug Additions

New-to-Market Block Removals

- CVS Health program that initially blocks new drugs from being added to the formulary and evaluates:
  - Drug's place in therapy
  - Potential market share
  - Cost
  - Appropriate utilization management
- CVS adds new drugs to their formulary throughout the year, however the Plan only adds these medications on a quarterly basis

Add-Backs

- Medications that were previously removed from the formulary but are now being added back
- Only occurs once a year
  - Xeljanz, & Xeljanz XR were added back this year beginning 1/1/2019

New Molecular Entities

- Are also initially placed on CVS's New-to-Market Block
- These medications are reviewed by the members of the Plan's P&T Committee to determine:
  - Satisfactory tier position
  - Appropriate utilization management

Formulary Updates – New Drug Additions

Therapeutic Category/ Subcategory	Brand Name	Generic Name	Specialty Flag	GPI	CVS Block Removal Date	Proposed NCSHP Tier	Comments	UM Status	UM Criteria	New Molecular Entity
Analgesics/ Opioid Analgesics	DVORAH TAB	Acetaminophen/Caffeine/ Dihydrocodeine Bitartrate Oral	N	65991303050320	1/2/2019	1	Acet-Caff-Dihydrocodeine 325-30-16 mg combination Tab	Opioid UM	Active	N
Anti-Infectives/ Antibacterials/ Miscellaneous	VANCOMYCIN INJ 750MG/7.5ML, 1000MG/10ML, 1250MG/12.5ML, 1500MG/15ML, 1750MG/17.5ML, 2000MG/20ML		N	16280080102050, 16280080102055, 16280080102060, 16280080102065, 16280080102070, 16280080102075	10/31/2018	3	New SSB	No UM	n/a	N
Anti-Infectives/ Antibacterials/ Miscellaneous	VANCOMYCIN SOL 1.5GM, 1.25GM		N	16280080102122, 16280080102121	1/2/2019	3	New SSB	No UM	n/a	N
Anti-Infectives/ Antibacterials/ Miscellaneous	VANCOMYC/D5W INJ 1.5/300		N	16280080122062	1/2/2019	3	New SSB	No UM	n/a	N
Antineoplastic Agents/ Kinase Inhibitors	KISQALI TAB 400DOSE, 600DOSE	Ribociclib Oral	Y	21531070500320, 21531070500320	1/24/19	5	Additional NDCs based on packaging	SGM	Active	N
Antineoplastic Agents/ Miscellaneou	SIKLOS TAB 1000MG	Hydroxyurea Oral	N	82803030000340	11/21/2018	3	New strength	No UM	n/a	N
Cardiovascular/ Calcium Channel Blockers	DILTIAZEM INJ 25MG/5ML		N	3400001010E520	12/26/2018	3	SSB - Prefilled Syringe Form	No UM	n/a	N
Central Nervous System/ Migraine/ Monoclonal Antibodies	EMGALITY INJ 120MG/ML	Galcanezumab-gnlm Injection	N	6770203530E520	1/24/19	2	Prefilled syringe; Pen formulation already on formulary	ST	Active	N
Endocrine and Metabolic/ Antidiabetics/ Insulins	TRESIBA INJ 100UNIT	Insulin Degludec Injection	N	27104007002020	1/18/19	2	Vial formulation; Flex Pen forms are already on formulary at Tier 2			N
Endocrine and Metabolic/ Antidiabetics/ Insulins	DIVIGEL GEL 0.75MG	Estradiol Transdermal	N	24000035004042	1/18/19	2	New strength (estradiol transdermal)		n/a	N
Hematologic/ Hematopoietic Agents	PROMACTA POW 12.5MG	Eltrombopag Olamine Oral	Y	82405030103030	1/24/19	6	Additional NDCs	SGM	Active	N
Hematologic/Anticoagulants	XARELTO TAB 2.5MG	Rivaroxaban Oral	N	83370060000310	11/8/2018	2	New strength	No UM	n/a	N
Immunologic Agents/ Immune Globulins	HIZENTRA INJ 1GM/5ML, 2GM/10ML, 4GM/20ML, 10/50ML	Immune Globulin Injection	Y	19100020202050, 19100020202054, 19100020202058, 19100020202065	12/19/2018	5	Formulations already on formulary at Tier 5 per NCSHP request of initial formulary customizations	SGM	Active	N
Immunologic Agents/ Immune Globulins	CYTOGAM INJ	Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-IGIV) Injection	Y	19100005002200	12/19/2018	6	Immune globulin indicated for cytomegalovirus prophylaxis.	No UM	n/a	N

Formulary Updates – New Drug Additions

Therapeutic Category/ Subcategory	Brand Name	Generic Name	Specialty Flag	GPI	CVS Block Removal Date	Proposed NCSHP Tier	Comments	UM Status	UM Criteria	New Molecular Entity
Immunologic Agents/ Immunosuppressants	ZORTRESS TAB 1MG	Everolimus Oral	Y	99404035000335	11/14/2018	2	New strength	No UM	n/a	N
Immunologic Agents/ Miscellaneous	ANAVIP INJ	Crotalidae Immune F(ab')2, Equine Origin Injection	N	19200022002120	12/19/2018	6	Antivenin mgmt indic for rattlesnake bites	No UM	n/a	N
Nutritional/Supplements/ Dietary Management Products	TYLACTIN POW BLD 20PE	formulation of glycomacropeptide and essential amino acids without added tyrosine and phenylalanine	N	81200000003000		3	Supplement for tx of tyrosinemia – whole protein (glycomacropeptide or GMP); modified formulation of Glytactin (for tx of PKU).	No UM	n/a	N
Nutritional/Supplements/ Nutritional Therapy	AMINO ACID INJ 48MG/ML		N	80302010102010	11/21/2018	3	SSB Amino acid 5% infusion	No UM	n/a	N
Nutritional/Supplements/Electrolytes	SODIUM BICARBONATE SOL 8.4%		N	79050020002026	11/8/2018	3	SSB Sodium Bicarb Inj	No UM	n/a	N
Respiratory/ Severe Asthma Agents	XOLAIR INJ 75MG/0.5ML, 150MG/ML	Omalizumab Injection	Y	4460306000E510, 4460306000E520	11/21/2018	6	Line extension	SGM	Active	N
Respiratory/ Severe Asthma Agents	DUPIXENT SOL	Dupilumab Injection	Y	4460352000E530	1/2/2019	5	New strength for asthma indication	SGM	Active	N
Hematologic/ Hematopoietic Growth Factors	RETACRIT INJ 2000UNIT, 3000UNIT, 4000UNIT, 10000UNT, 40000UNT	Epoetin Alfa Recombinant (Erythropoietin; EPO) Injection	Y	82401020042010, 82401020042015, 82401020042020, 82401020042040, 82401020042060	4/1/2019	4	Biosimilar - Epogen/Procrit	No UM	n/a	N

Formulary Updates – New Molecular Entities

XERAVA (eravacycline)

Indication:

- Treatment of complicated intra-abdominal infections in patients 18 years of age and older

Mechanism of Action:

- Tetracycline class antibacterial

Drug Facts:

- 1 mg/kg every 12 hours by IV infusion over 60 minutes for 4 to 14 days
- Adverse reactions include: infusion site reactions (7.7%), nausea (6.5%) and vomiting (3.7%)

Place in Therapy:

- 2- to 4-fold more potent than tigecycline in vitro against Gram-positive and Gram-negative bacteria, and 2- to 8-fold more potent against most anaerobes
- Proven as effective as carbapenems in complicated intra-abdominal infections

Proposed Tier Placement:

- Tier 3 – Non-preferred Brand

Formulary Updates – New Molecular Entities

ARIKAYCE (amikacin)

Indication:

- Treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy

Mechanism of Action:

- Aminoglycoside antibacterial

Drug Facts:

- Once daily oral inhalation of the contents of one vial
- Adverse reactions (≥10%) include: dysphonia, cough, bronchospasm, hemoptysis, ototoxicity, upper airway irritation, musculoskeletal pain, fatigue/asthenia and exacerbation of underlying pulmonary disease, diarrhea, and nausea

Place in Therapy:

- First and only FDA-approved treatment for patients who have limited or no alterative treatment options for MAC

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

LUMOXITI (moxetumomab pasudotox-tdfk)

Indication:

- Treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)

Mechanism of Action:

- CD22-directed cytotoxin

Drug Facts:

- 0.04 mg/kg as an intravenous infusion over 30 minutes on days 1, 3, and 5 of each 28-day cycle
- Adverse reactions (≥20%) include: infusion related reactions, edema, nausea, fatigue, headache, pyrexia, constipation, anemia, and diarrhea

Place in Therapy:

- 75% response rate, with 30% having a complete response that lasted more than 180 days

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

LUMOXITI (moxetumomab pasudotox-tdfk)

Specialty Guideline Management:

Hairy Cell Leukemia

Authorization of 6 months may be granted for treatment of relapsed or refractory hairy cell leukemia when all of the following criteria are met:

A. The patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog.

B. The patient has not previously received 6 or more cycles of treatment with Lumoxiti.

Formulary Updates – New Molecular Entities

LIBTAYO (cemiplimab-rwlc)

Indication:

- Treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation

Mechanism of Action:

- Programmed death receptor-1 (PD-1) blocking antibody

Drug Facts:

- 350 mg as an intravenous infusion over 30 minutes every 3 weeks
- Adverse reactions (≥20%) include: fatigue, rash, and diarrhea

Place in Therapy:

- Provides an additional treatment option for CSCC

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

LIBTAYO (cemiplimab-rwlc)

Specialty Guideline Management:

Cutaneous squamous cell carcinoma

Authorization of 12 months may be granted for treatment of cutaneous squamous cell carcinoma when all of the following criteria are met:

A. The disease is metastatic or locally advanced
B. The patient is not a candidate for curative surgery or curative radiation

Formulary Updates – New Molecular Entities

ONPATTRO (patisiran)

Indication:

- Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

Mechanism of Action:

- Transthyretin-directed small interfering RNA

Drug Facts:

- For patients weighing less than 100 kg, the recommended dosage is 0.3 mg/kg every 3 weeks by intravenous infusion. For patients weighing 100 kg or more, the recommended dosage is 30 mg
- Adverse reactions (>10%) include: upper respiratory tract infections and infusion-related reactions

Place in Therapy:

- The first and only FDA-approved RNAi treatment for the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

ONPATTRO (patisiran)

Specialty Guideline Management:

Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis

Authorization of 12 months may be granted for treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (also called transthyretin-type familial amyloid polyneuropathy [ATTR-FAP]) when all of the following criteria are met:

A. The diagnosis is confirmed by detection of a mutation of the TTR gene.

B. Patient exhibits clinical manifestations of ATTR-FAP (e.g., amyloid deposition in biopsy specimens, TTR protein variants in serum, progressive peripheral sensory-motor polyneuropathy).

Formulary Updates – New Molecular Entities

EPIDIOLEX (cannabidiol)

Indication:

- Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older

Mechanism of Action:

- Active ingredient is a highly purified form of cannabidiol (CBD)

Drug Facts:

- Starting dosage is 2.5 mg/kg twice daily orally up to 10 mg/kg twice daily
- Adverse reactions (>10%) include: somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder, and poor-quality sleep; and infections

Place in Therapy:

- The First and Only FDA-Approved Prescription Cannabidiol (CBD) for Dravet and LGS

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

EPIDIOLEX (cannabidiol)

Specialty Guideline Management:

Seizures associated with Lennox-Gastaut syndrome or Dravet syndrome

Authorization of 12 months may be granted for treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome.

Formulary Updates – New Molecular Entities

OXERVATE (cenegermin-bkbj)

Indication:

- Treatment of neurotrophic keratitis

Mechanism of Action:

- Recombinant human nerve growth factor

Drug Facts:

- One drop in the affected eye(s), 6 times per day at 2-hour intervals, for eight weeks.
- Adverse reactions (>5%) include: eye pain, ocular hyperemia, eye inflammation and increased lacrimation

Place in Therapy:

- Provides a novel topical treatment that offers potential complete corneal healing versus palliative surgical interventions

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

JULUCA (dolutegravir sodium/rilpivirine hydrochloride)

Indication:

- A complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of JULUCA

Mechanism of Action:

- Integrase strand transfer inhibitor (INSTI) & non-nucleoside reverse transcriptase inhibitor (NNRTI)

Drug Facts:

- One tablet taken orally once daily with a meal
- Adverse reactions (>2%) include: diarrhea and headache

Place in Therapy:

- The only single-pill, 2-drug regimen for the treatment of HIV-1

Proposed Tier Placement:

- Tier 3 – Non-preferred Brand

Formulary Updates – New Molecular Entities

LORBRENA (lorlatinib)

Indication:

- Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or alectinib as the first ALK inhibitor therapy for metastatic disease; or ceritinib as the first ALK inhibitor therapy for metastatic disease.

Mechanism of Action:

- Kinase inhibitor

Drug Facts:

- 100 mg orally once daily
- Adverse reactions (≥20%) include: edema, peripheral neuropathy, cognitive effects, dyspnea, fatigue, weight gain, arthralgia, mood effects, and diarrhea.

Place in Therapy:

- Provides an additional treatment option for NSCLC after it has progressed on other treatments

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Drug Additions

LORBRENA (lorlatinib)

Specialty Guideline Management:

Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of metastatic NSCLC when all of the following criteria are met:

A. The disease is anaplastic lymphoma kinase (ALK)-positive

B. The disease has progressed on any of the following therapies for metastatic disease:

1. Crizotinib and at least one other ALK inhibitor
2. Alectinib as the first ALK inhibitor therapy
3. Ceritinib as the first ALK inhibitor therapy

Formulary Updates – New Molecular Entities

GALAFOLD (migalastat)

Indication:

- Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

Mechanism of Action:

- alpha-galactosidase A (alpha-Gal A) pharmacological chaperone

Drug Facts:

- 123 mg orally once every other day at the same time of day
- Adverse reactions (>10%) include: headache, nasopharyngitis, urinary tract infection, nausea, and pyrexia.

Place in Therapy:

- First precision and first oral medicine for Fabry disease approved for 348 amenable GLA variants
- First new treatment option for Fabry disease in the U.S. in 15+ years

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

GALAFOLD (migalastat)

Specialty Guideline Management:

Fabry disease with an amenable galactosidase alpha gene (GLA) variant

Indefinite authorization may be granted for treatment of Fabry disease with an amenable galactosidase alpha gene (GLA) variant when all of the following criteria are met:

A. The diagnosis of Fabry disease was confirmed by enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity or by genetic testing, or the member is a symptomatic obligate carrier.

B. Member has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

Formulary Updates – New Molecular Entities

MULPLETA (lusutrombopag)

Indication:

- Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure

Mechanism of Action:

- Thrombopoietin receptor agonist

Drug Facts:

- 3 mg orally once daily with or without food for 7 days
- Adverse reactions (≥3%) include: headache

Place in Therapy:

- Will provide another treatment option other than platelet transfusions

Proposed Tier Placement:

- Tier 5 – Preferred Specialty

Formulary Updates – New Molecular Entities

MULPLETA (lusutrombopag)

Specialty Quantity Limit:

Medication	Standard Limit	FDA-recommended dosing
Mulpleta (lusutrombopag) 3 mg tablets	7 per 14 days	3 mg orally once daily with or without food for 7 days

Formulary Updates – New Molecular Entities

VITRAKVI (larotrectinib)

Indication:

- Treatment of adult and pediatric patients with solid tumors that: have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory alternative treatments or that have progressed following treatment

Mechanism of Action:

- Kinase inhibitor

Drug Facts:

- 100 mg orally twice daily; pediatric with body surface area of less than 1.0 meter-squared: 100 mg/m^2 orally twice daily
- Adverse reactions (>20%) include: fatigue, nausea, dizziness, vomiting, increased AST, cough, increased ALT, constipation, and diarrhea.

Place in Therapy:

- Second time a cancer therapy was approved on a common biomarker across different types of tumors rather than the location in the body where the tumor originated

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

VITRAKVI (larotrectinib)

Specialty Guideline Management:

Solid tumors with a NTRK gene fusion

Authorization of 12 months may be granted for treatment of solid tumors when all of the following criteria are met:

A. The tumors have a NTRK gene fusion without a known acquired resistance mutation, as demonstrated by laboratory testing (e.g., next-generation sequencing [NGS] or fluorescence in situ hybridization [FISH]).

B. The disease is metastatic or surgical resection is likely to result in severe morbidity.

C. No satisfactory alternative treatments are available or disease has progressed following standard systemic treatment for the disease.

Formulary Updates – New Molecular Entities

NUZYRA (omadacycline)

Indication:

- Treatment of adult patients with the following infections caused by susceptible microorganisms (1): Community-acquired bacterial pneumonia (CABP); Acute bacterial skin and skin structure infections (ABSSSI)

Mechanism of Action:

- Tetracycline class antibacterial

Drug Facts:

- CABP treatment is intravenous infusion while ABSSSI can be treated orally
- Adverse reactions (>2%) include: nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation

Place in Therapy:

- First and only once-daily IV and oral antibiotic approved to treat both CABP and ABSSSI patients in nearly 20 Years

Proposed Tier Placement:

- Tier 3 – Non-preferred Brand

Formulary Updates – New Molecular Entities

REVCOVI (elapegademase)

Indication:

- Treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients

Mechanism of Action:

- Recombinant adenosine deaminase

Drug Facts:

- Patients transitioning from Adagen to REVCOVI: The starting dose of REVCOVI is 0.2 mg/kg weekly, intramuscularly. Adagen-naïve patients: The starting dose of REVCOVI is 0.4 mg/kg weekly based on ideal body weight, divided into two doses (0.2 mg/kg twice a week), intramuscularly
- Adverse reactions (>30%) include: cough and vomiting

Place in Therapy:

- Can reduce patients' risk of potentially serious, life-threatening infections and their debilitating complications by providing specific and direct replacement of the adenosine deaminase enzyme

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

AEMCOLO (rifamycin)

Indication:

- Treatment of adult patients with travelers' diarrhea caused by noninvasive strains of Escherichia coli (E. coli), not complicated by fever or blood in the stool.

Mechanism of Action:

- Minimally-absorbed rifamycin antibacterial

Drug Facts:

- 388 mg orally twice daily for three days, with a full glass of water, with or without food
- Adverse reactions include: headache and constipation

Place in Therapy:

- Provides an additional treatment option for travelers' diarrhea

Proposed Tier Placement:

- Tier 3 – Non-preferred Brand

Formulary Updates – New Molecular Entities

GAMIFANT (emapalumab-lzsg)

Indication:

- Treatment of pediatric (newborn and older) and adult patients with primary haemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance to conventional HLH therapy.

Mechanism of Action:

- Monoclonal antibody

Drug Facts:

- 1 mg/kg as an intravenous infusion over 1 hour twice per week
- Adverse reactions (>20%) include: infections, hypertension, infusion-related reactions, and pyrexia

Place in Therapy:

- Provides a new therapeutic option for blocking the hyperinflammation typical of HLH without the need for high-dose steroids

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

FIRDAPSE (amifampridine)

Indication:

- Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults

Mechanism of Action:

- Potassium channel blocker

Drug Facts:

- 15 mg to 30 mg daily taken orally in divided doses (3 to 4 times daily)
- Adverse reactions (>10%) include: paresthesia, upper respiratory tract infection, abdominal pain, nausea, diarrhea, headache, elevated liver enzymes, back pain, hypertension, and muscle spasms

Place in Therapy:

- The only FDA-approved, evidence-based therapy for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults

Proposed Tier Placement:

- Tier 6 – Non-Preferred Specialty

Formulary Updates – New Molecular Entities

FIRDAPSE (amifampridine)

Specialty Guideline Management:

Solid Lambert-Eaton Myasthenic Syndrome (LEMS)

Authorization of 6 months may be granted for treatment of Lambert-Eaton myasthenic syndrome (LEMS) when the diagnosis is confirmed by either of the following:

A. Neurophysiology studies (e.g., electromyography)
B. A positive anti- P/Q type voltage-gated calcium channel antibody test

Formulary Updates – New Molecular Entities

ANDEXXA (coagulation factor Xa [recombinant], inactivated-zhzo)

Indication:

- Indicated for patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding

Mechanism of Action:

- Recombinant modified human Factor Xa (FXa) protein

Drug Facts:

- IV infusion of 400 to 800 mg at a target rate of 30 mg/min with a follow-up infusion of 4 to 8 mg/min for up to 120 minutes
- Adverse reactions (>3%) include: urinary tract infections, pneumonia and infusion-related reactions

Place in Therapy:

- The first and only antidote indicated for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding

Proposed Tier Placement:

- Tier 3 – Non-preferred Brand

Formulary Updates – New Molecular Entities

LOKELMA (sodium zirconium cyclosilicate)

Indication:

- Treatment of adults with hyperkalaemia

Mechanism of Action:

- Highly-selective, oral potassium-binder

Drug Facts:

- Starting dose of 10 g three times daily for up to 48 hours with a maintenance dose of 10 g once daily
- Adverse reactions include: mild to moderate edema

Place in Therapy:

- A new treatment that provides rapid and sustained treatment for adults with hyperkalaemia

Proposed Tier Placement:

- Tier 2 – Preferred Brand

Formulary Updates – New Molecular Entities

ORILISSA (elagolix)

Indication:

- Indicated for the management of moderate to severe pain associated with endometriosis

Mechanism of Action:

- Gonadotropin-releasing hormone (GnRH) receptor antagonist

Drug Facts:

- 150 mg once daily for up 6 months if hepatic impairment or up to 24 months with normal function or 200 mg twice daily for up to 6 months
- Adverse reactions (>5%) include: hot flushes and night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions and mood changes

Place in Therapy:

- First FDA-approved oral pill specifically developed for women with moderate to severe endometriosis pain in over a decade

Proposed Tier Placement:

- Tier 2 – Preferred Brand

Formulary Updates – New Molecular Entities

INTRAROSA (prasterone)

Indication:

- Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause

Mechanism of Action:

- Steroid

Drug Facts:

- One tablet intravaginally once daily at bedtime, using applicator
- Adverse reactions (>2%) include: vaginal discharge and abnormal Pap smear

Place in Therapy:

- A vaginal non-estrogen-based therapy with no FDA boxed warning and no restrictions on duration of use

Proposed Tier Placement:

- Tier 3 – Non-preferred Brand

Utilization Management Policy Review

New Policies Under Consideration

- Butalbital Containing Analgesics (Brand & Generic)
- Fortamet, Glumetza Policy
- Onfi Policy
- Orilissa Policy
- Rheumatoid Arthritis Enhanced SGM

Utilization Management Policy Review

Butalbital Containing Analgesics (Brand & Generic) Quantity Limits

Affected Medications:

- Butalbital containing products (e.g., Allzital, Esgic, Fioricet, Fioricet with Codeine, Fiorinal, Fiorinal with Codeine, Vanatol)

Quantity Limits:

LIMIT CRITERIA

This quantity limit 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 Month Limit*
butalbital, acetaminophen, and caffeine solution	720 mL / 25 days	2160 mL / 75 days
butalbital 25 mg and acetaminophen 325 mg	96 units / 25 days	288 units / 75 days
butalbital and acetaminophen	48 units / 25 days	144 units / 75 days
butalbital, acetaminophen, and caffeine	48 units / 25 days	144 units / 75 days
butalbital, acetaminophen, caffeine, and codeine	48 units / 25 days	144 units / 75 days
butalbital, aspirin, and caffeine	48 units/ 25 days	144 units / 75 days
butalbital, aspirin, caffeine, and codeine	48 units / 25 days	144 units / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*
**The limit criteria apply to both brand and generic, if available.*

Utilization Management Policy Review

Fortamet, Glumetza Initial Prior Authorization

Affected Medications:

- FORTAMET & GLUMETZA

Coverage Criteria:

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

- The patient has experienced an intolerance to generic Glucophage XR

Utilization Management Policy Review

Onfi Initial Prior Authorization

Affected Medications:

- Onfi

Coverage Criteria:

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

- The requested drug is being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in a patient 2 years of age or older

Utilization Management Policy Review

Orilissa Initial Prior Authorization

Affected Medications:

- Orilissa

Coverage Criteria:

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

- The patient has the diagnosis of moderate to severe pain associated with endometriosis

AND

- The patient has not received the maximum recommended treatment course of 12 months of Lupron Depot or Lupaneta Pack or 6 months of Synarel or Zoladex

AND

- The patient will receive 150 mg once daily of the requested drug

  AND

  - The patient has not already received greater than or equal to 24 months of therapy of the requested drug

OR

- The patient will receive 200 mg twice daily of the requested drug

  AND

  - The patient has not already received greater than or equal to 6 months of therapy of the requested drug

Utilization Management Policy Review

DMARD Combination for the Treatment of Rheumatoid Arthritis

Affected Medications

- Actemra, Cimzia, Enbrel, Humira, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Remicade, Renflexis, Simponi, Simponi Aria, Xeljanz, Xeljanz XR

Specialty Guideline Management:

Coverage for a requested branded biologic disease modifying antirheumatic drugs (DMARDs) is provided when the member meets one of the following (criteria set A or B):

A. Member has previously received a branded biologic or targeted synthetic DMARD for rheumatoid arthritis (RA)

B. Member has not previously received a branded biologic or targeted synthetic DMARD for RA and meets one of the following (criteria set 1 or 2):

1. Member has failed to achieve a low disease activity after a 3-month trial of a treatment regimen of methotrexate (MTX) at a maximum titrated dose of 20 mg per week and meets any of the following conditions:
   a. Member has failed treatment with at least one other non-biologic DMARD (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose
   b. Member has experienced an intolerable adverse event or has a contraindication to leflunomide, hydroxychloroquine, and/or sulfasalazine (see Appendix B)
   c. Member has a moderate to high disease activity with poor prognostic feature(s) (see Appendix C)
2. Member has experienced an intolerable adverse event or has a contraindication to MTX (see Appendix A) and meets any of the following conditions:
   a. Member has failed treatment with another non-biologic DMARD (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s)
   b. Member has experienced an intolerable adverse event or has a contraindication to leflunomide, hydroxychloroquine, and/or sulfasalazine (see Appendix B)
   c. Member has a moderate to high disease activity with poor prognostic feature(s) (see Appendix C)

Summary of Formaulary Changes Effective 4/1/19

DRUG EXCLUSIONS

- ZYTIGA, EPOGEN, PROCRIT, & *Solubiomix's* BUTALBITAL/ACETAMINOPHEN 50-300 MG capsules, & DICLOFENAC GEL 1%.

UPTIERS

- ATRALIN GEL 0.05%, COREG CR, ESTRACE VAGINAL CREAM 0.01%, LUZUCREAM 1%, UCERIS, MESTINON TIMESPAN, & TOPICORT

DOWNTIERS

- COPAXONE SYRINGES 20MG/ML, MULPLETA TABLETS 3MG, DUPIXENT 200MG/1.14ML, & ARISTADA INITIO.

NEW DRUG ADDITIONS

- XERAVA, ARIKAYCE, LUMOXITI, LIBTAYO, ONPATTRO, EPIDIOLEX,OXERVATE, JULUCA, LORBRENA, GALAFOLD, MULPLETA, VITRAKVI,NUZYRA, REVCOVI, AEMCOLO, GAMIFANT, FIRDAPSE, ANDEXXA,LOKELMA, ORILISSA, INTRAROSA, DVORAH, VANCOMYCIN, KISQALI, SIKLOS, DILTIAZEM, EMGALITY,TRESIBA, DIVIGEL, PROMACTA, XARELTO, HIZENTRA, CYTOGAM, ZORTRESS, ANAVIP, TYLACTIN, AMINO ACID, SODIUM BICARBONATE,XOLAIR, DUPIXENT, & RETACRIT

UTILIZATION MANAGEMENT

- Butalbital Containing Analgesics (Brand/Generics) Policy, Fortamet, Glumetza Policy (Proposed Revisions), Onfi Policy, Orilissa Policy, & Rheumatoid Arthritis Enhanced SGM

Next meeting: **May 15, 2019**

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A Division of the Department of State Treasurer

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

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