Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 4/1/19

February 13, 2019
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
- Carl Antolick III, PharmD
- Tracy Linton, MPH
- Dee Jones

### CVS Caremark
- Renee Jarnigan, RPh
- Stephanie Morrison, PharmD

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North Carolina State Health Plan for Teachers and State Employees  
A Division of the Department of State Treasurer
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).
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).
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   | 65961300550300 | 1/3/2019 | 1          | Acet-Coff-Dihydrocodeine 320-30-18 mg combination Tab | Optimal UM | Active | N               |
| Anti-Infective/ Antibacterial/ Miscellaneous | VANCOMYCIN INJ 1.5GM, 2.5GM, 5GM/10ML, 15GM/25ML, 20GM/40ML | 16260860102260, 16260860102250, 16260860102260, 16260860102260, 16260860102270 | N   | 10/31/2018 | 3          | New SSB | No UM | n/a | N               |
| Anti-Infective/ Antibacterial/ Miscellaneous | VANCOMYCIN SOL 1.0GM, 1.25GM | 16260860102121, 16260860102121 | N   | 1/3/2019 | 3          | New SSB | No UM | n/a | N               |
| Anti-Infective/ Antibacterial/ Miscellaneous | VANCOMYCIN SOL 1.0GM, 1.25GM | 16260860102121, 16260860102121 | N   | 1/3/2019 | 3          | New SSB | No UM | n/a | N               |
| Antineoplastic Agents/ Kinase Inhibitors | KISERLIG TAB 400DOSE, 800DOSE | Riboside Oral | Y   | 21561970500320, 21561970500320 | 1/4/19 | 6          | Additional NDCs based on packaging | SGM | Active | N               |
| Antineoplastic Agents/ Miscellaneous | SILOS TAB 1000MG | Hydroxyurea Oral | N   | 62303020000340 | 11/21/2018 | 3          | New strength | No UM | n/a | N               |
| Cardiovascular/ Calcium Channel Blockers | DILTIAZEM INJ 25MG/1ML | 240000010100050 | N   | 12/20/2018 | 3          | SGB - Prefilled Syringe Form | No UM | n/a | N               |
| Central nervous system/ Migraine/ Monoclonal Antibodies | EMGALY INJ 120MG/4ML | Galantansumab-gate Injection | N   | 67702030100320 | 1/4/19 | 2          | Prefilled syringe; Pen formulation already on formulary | ST | Active | N               |
| Endocrine and Metabolic/ Antidiabetic/ Insulins | TRESBA INJ 100UNIT | Insulin Degludec Injection | N   | 27104000000200 | 1/18/19 | 2          | Vial formulation; Flex Pen forms are already on formulary at Tier 2 | N | - | N               |
| Endocrine and Metabolic/ Antidiabetic/ Insulins | DIVGEL GEL 0.75MG | Estradiol Transdermal | N   | 24000000000402 | 11/18/19 | 2          | New strength (estradiol transdermal) | No UM | n/a | N               |
| Hematologic/ Hematopoietic Agents | PROMACTA POW 12.5MG | Enoxaparin Gammex Oral | N   | 62405000100000 | 1/24/19 | 6          | Additional NDCs | SGM | Active | N               |
| Hematologic/Anticoagulants | XARELTO TAB 2.5MG | Rivaroxaban Oral | N   | 63370000000310 | 11/8/18 | 2          | New strength | No UM | n/a | N               |
| Immunologic Agents/ Immune Globulins | HIZENTRA INJ 10MG/ML, 50MG/10ML, 100MG/20ML | 16100000100000, 16100000100000, 16100000100000 | N   | 12/16/2018 | 5          | Formulations already on formulary | SGM | Active | N               |
| Immunologic Agents/ Immune Globulins | CYTOO3AM INJ | Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-100iV) Injection | Y   | 19100000000320 | 12/16/2018 | 6          | Immune globulin indicated for cytomegalovirus prophylaxis | No UM | n/a | N               |
# Formulary Updates – New Drug Additions

<table>
<thead>
<tr>
<th>Therapeutic Category/ Subcategory</th>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Specialty Flag</th>
<th>GPI</th>
<th>CVS Block Removal Date</th>
<th>Proposed NCSHP Tier</th>
<th>Comments</th>
<th>UM Status</th>
<th>UM Criteria</th>
<th>New Molecular Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunologic Agents/ Immunosuppressants</td>
<td>ZORTRESS  TAB 1MG</td>
<td>Everolimus Oral</td>
<td>Y</td>
<td>064040000000335</td>
<td>11/14/2018</td>
<td>2</td>
<td>New strength</td>
<td>No UM</td>
<td>n/a</td>
<td>N</td>
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<tr>
<td>Immunologic Agents/ Miscellaneous</td>
<td>ANAVIP  INJ</td>
<td>Crotalidae immunes F(aze)2, Equine Origin Injection</td>
<td>N</td>
<td>16200020012030</td>
<td>12/19/2016</td>
<td>6</td>
<td>Antivenin mg/ml indigo for rattlesnake bites</td>
<td>No UM</td>
<td>n/a</td>
<td>N</td>
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<tr>
<td>Nutritional/Supplements/ Dietary Management Products</td>
<td>TVLACTIN  POW BLD 20PE</td>
<td>formulation of glycosyls and essential amino acids without added tyrosine and phenylalanine</td>
<td>N</td>
<td>8120000000003000</td>
<td>11/19/2016</td>
<td>3</td>
<td>Supplement for tx of tyrosinemia – whole protein (glycosyls and 5% infusion)</td>
<td>No UM</td>
<td>n/a</td>
<td>N</td>
</tr>
<tr>
<td>Nutritional/Supplements/ Nutritional Therapy</td>
<td>AMINO ACID  INJ 48MG/ML</td>
<td>SODIUM BI CARBONATE SOL 8.4%</td>
<td>N</td>
<td>803001010203010</td>
<td>11/29/2016</td>
<td>3</td>
<td>SSB Amino acid 5% infusion</td>
<td>No UM</td>
<td>n/a</td>
<td>N</td>
</tr>
<tr>
<td>Nutritional/Supplements/Electrolytes</td>
<td>N</td>
<td>SODIUM BI CARBONATE SOL 150MG/ML</td>
<td>N</td>
<td>7065000000002028</td>
<td>11/9/2016</td>
<td>3</td>
<td>SSB Sodium Bicarb Inj</td>
<td>No UM</td>
<td>n/a</td>
<td>N</td>
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<tr>
<td>Respiratory/ Severe Asthma Agents</td>
<td>XOLAR  INJ 75MG/5ML, 150MG/ML</td>
<td>Omnizumab Injection</td>
<td>Y</td>
<td>4460300000002010, 4460300000002020</td>
<td>11/21/2018</td>
<td>5</td>
<td>Line extension</td>
<td>SGM</td>
<td>Active</td>
<td>N</td>
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<tr>
<td>Respiratory/ Severe Asthma Agents</td>
<td>DUPINENT  SOL</td>
<td>Dupilumab Injection</td>
<td>Y</td>
<td>4460300000002030</td>
<td>1/2/2016</td>
<td>5</td>
<td>New strength for asthma indication</td>
<td>SGM</td>
<td>Active</td>
<td>N</td>
</tr>
<tr>
<td>Hematologic/ Hematopoietic Growth Factors</td>
<td>RETACRIT INJ 2000UNIT, 3000UNIT, 4000UNIT, 10000UNIT, 40000UNIT</td>
<td>Epoetin Alfa Recombinant (Erythropoetin, EPO) Injection</td>
<td>Y</td>
<td>624010000402010, 624010000402015, 624010000402030, 624010000402030, 624010000402040, 624010000402080</td>
<td>4/1/2018</td>
<td>4</td>
<td>Biosimilar - Epogen/Procrit</td>
<td>No UM</td>
<td>n/a</td>
<td>N</td>
</tr>
</tbody>
</table>
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
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 alternative treatment options for MAC

**Proposed Tier Placement:**
- Tier 6 – Non-Preferred Specialty
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
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.
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
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


**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).
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
EPILODEX (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.
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
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
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
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
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
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.
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:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Standard Limit</th>
<th>FDA-recommended dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mulpleta (lusutrombopag)</td>
<td>7 per 14 days</td>
<td>3 mg orally once daily with or without food for 7 days</td>
</tr>
<tr>
<td>3 mg tablets</td>
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</tbody>
</table>
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/m² 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
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.
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
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
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
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
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
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
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
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
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 to 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
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:

<table>
<thead>
<tr>
<th>LIMIT CRITERIA</th>
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</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>1 Month Limit*</th>
<th>3 Month Limit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>butalbital, acetaminophen, and caffeine solution</td>
<td>720 mL / 25 days</td>
<td>2160 mL / 75 days</td>
</tr>
<tr>
<td>butalbital 25 mg and acetaminophen 325 mg</td>
<td>96 units / 25 days</td>
<td>288 units / 75 days</td>
</tr>
<tr>
<td>butalbital and acetaminophen</td>
<td>48 units / 25 days</td>
<td>144 units / 75 days</td>
</tr>
<tr>
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<td>48 units / 25 days</td>
<td>144 units / 75 days</td>
</tr>
<tr>
<td>butalbital, acetaminophen, caffeine, and codeine</td>
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<td>144 units / 75 days</td>
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</tbody>
</table>

*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.
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
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
DMARD Combination for the Treatment of Rheumatoid Arthritis

Affected Medications

- Actemra, Cimzia, Enbrel, Humira, Inflectra, Kevzara, Kineret, Olumiant, Orenica, 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)
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