Pharmacy & Therapeutics Committee Meeting

Formulary and Program Updates Effective 1/1/19

October 23, 2018
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
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 August’s meeting went into effect 10/1/2018 and include the following:
  - Removed the following products from the formulary:
    - LAZANDA, ZOLPIMIST, levorphanol, fluocinonide 0.1% cream hydrocortisone 1% in Absorbase, & benzonatate 150 mg capsules.
  - Moved the following branded products to non-preferred status:
    - BENZAACLIN, MIRAPREX, MINASTRIN 24 FE chewables, APTENSIO XR, & QUILLIVANT XR.
  - Adopted the following new utilization management criteria:
    - Nuedexta Initial Prior Authorization
    - Topical NSAIDs Initial Prior Authorization with Quantity Limit
    - Chenodal Initial Prior Authorization
    - Naprelan Initial Prior Authorization
    - Thiola Initial Prior Authorization
Minutes from Previous Committee Meeting

• Instead of having the Secretary read the minutes, copies have been distributed for your review.

• They are located just after the conflict of interest statement in the P&T Booklet that was attached to your meeting invite.

• Are there any additions or corrections to the minutes?

• If not, the minutes will stand approved as is.
# 2019 Formulary Strategy

## Standard Control Formulary Removals

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Removed Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiemetic</td>
<td>Zuplenz</td>
</tr>
<tr>
<td>Anti-Infective</td>
<td>Acticlute, Targadox</td>
</tr>
<tr>
<td>Anti-Obesity Oral</td>
<td>Contravo</td>
</tr>
<tr>
<td>Antipsoriatricis</td>
<td>Sorilux</td>
</tr>
<tr>
<td>CNS</td>
<td>Vanatol LQ/Vanatol S</td>
</tr>
<tr>
<td>DPP4 and biguanide combinations</td>
<td>Jentadueto/XR, Tradjenta</td>
</tr>
<tr>
<td>Growth Hormone</td>
<td>Norditropin</td>
</tr>
<tr>
<td>Hemophilia VIII</td>
<td>Elocate</td>
</tr>
<tr>
<td>Hemophilia IX</td>
<td>Alprolix</td>
</tr>
<tr>
<td>Migraine NSAID</td>
<td>Cambia</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Avenova</td>
</tr>
<tr>
<td>Pulmonary Enzyme Deficiency</td>
<td>Prolastin C, Zemaira</td>
</tr>
<tr>
<td>Severe Asthma</td>
<td>Fasenra</td>
</tr>
<tr>
<td>SGLT2 and biguanide combinations</td>
<td>Invokana and Invokamet/XR</td>
</tr>
<tr>
<td>Thyroid Agents</td>
<td>Tirosint</td>
</tr>
<tr>
<td>Topical Derm Acne</td>
<td>Acanya, Benzaclin, Onexton, Veltin, Ziana</td>
</tr>
</tbody>
</table>

## Standard Control Formulary Add Backs

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Added Back Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoimmune</td>
<td>Xelijanz/XR</td>
</tr>
<tr>
<td>Growth Hormone</td>
<td>Genotropin</td>
</tr>
<tr>
<td>SGLT2 and biguanide combinations</td>
<td>Jordiance, Synjardy/XR</td>
</tr>
</tbody>
</table>
Formulary Updates – Effective 1/1/2019

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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Therapeutic Category/ Subcategory</th>
<th>Rationale/Alternatives</th>
<th>Change Type</th>
<th>Proposed NC Status/Tier</th>
<th>Utilizers (6 mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTRAVE (naltrexone/bupropion)</td>
<td>Endocrine and Metabolic/ Antiobesity/ Oral</td>
<td>Availability of additional adjunctive options for weight management.</td>
<td>Exclude</td>
<td>2→ Not Covered</td>
<td>1226</td>
</tr>
<tr>
<td>JENTADUETO (linagliptin/metformin)</td>
<td>Endocrine and Metabolic/ Dipeptidyl Peptidase-4 (DPP-4) Inhibitor/Biguanide Combinations</td>
<td>Availability of additional options for the treatment of type 2 diabetes mellitus. Preferred options include Janumet (sitagliptin-metformin) and Janumet XR (sitagliptin-metformin ext-rel).</td>
<td>Exclude</td>
<td>2→ Not Covered</td>
<td>78</td>
</tr>
<tr>
<td>JENTADUETO XR (linagliptin/metformin ext-rel)</td>
<td>Endocrine and Metabolic/ Dipeptidyl Peptidase-4 (DPP-4) Inhibitor/Biguanide Combinations</td>
<td>Availability of additional options for the treatment of type 2 diabetes mellitus. Preferred options include Janumet (sitagliptin-metformin) and Janumet XR (sitagliptin-metformin ext-rel).</td>
<td>Exclude</td>
<td>2→ Not Covered</td>
<td>102</td>
</tr>
<tr>
<td>TRADJENTA (linagliptin)</td>
<td>Endocrine and Metabolic/ Dipeptidyl Peptidase-4 (DPP-4) Inhibitors</td>
<td>Availability of additional options for the treatment of type 2 diabetes mellitus. The preferred option is Januvia (sitagliptin).</td>
<td>Exclude</td>
<td>2→ Not Covered</td>
<td>679</td>
</tr>
<tr>
<td>ACANYA GEL (benzoyl peroxide 2.5% and clindamycin 1.2%)</td>
<td>Topical/ Dermatology/ Acne/ Topical</td>
<td>Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).</td>
<td>Exclude</td>
<td>2→ Not Covered</td>
<td>18</td>
</tr>
<tr>
<td>BENZAACLIN GEL (benzoyl peroxide 5% and clindamycin 1%)</td>
<td>Topical/ Dermatology/ Acne/ Topical</td>
<td>Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>12</td>
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</table>
## Formulary Updates – Product Exclusions

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<tr>
<th>Drug</th>
<th>Therapeutic Category/Subcategory</th>
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<tr>
<td>ONEXTON GEL</td>
<td>Topical/ Dermatology/ Acne/ Topical</td>
<td>Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>60</td>
</tr>
<tr>
<td>VELTIN GEL</td>
<td>Topical/ Dermatology/ Acne/ Topical</td>
<td>Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>54</td>
</tr>
<tr>
<td>ZIANA GEL</td>
<td>Topical/ Dermatology/ Acne/ Topical</td>
<td>Availability of additional options for the topical treatment of acne. Preferred options include adapalene, benzoyl peroxide, clindamycin solution, clindamycin-benzoyl peroxide, erythromycin solution, erythromycin-benzoyl peroxide, tretinoin, Atralin (tretinoin), Differin (adapalene), Epiduo (adapalene-benzoyl peroxide), Retin-A Micro (tretinoin gel microsphere), and Tazorac (tazarotene).</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>15</td>
</tr>
<tr>
<td>CAMBIA (diclofenac)</td>
<td>Analgesics/ NSAIDs</td>
<td>Availability of generic nonsteroidal anti-inflammatory agents (NSAIDs) for treating migraines. Preferred options include diclofenac sodium, meloxicam, and naproxen.</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>154</td>
</tr>
<tr>
<td>SORILUX (calcipotriene)</td>
<td>Topical/ Dermatology/ Antipsoriatics</td>
<td>Availability of a generic option for the treatment of plaque psoriasis. The preferred option is calcipotriene.</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>15</td>
</tr>
<tr>
<td>ACTICLATE (doxycycline)</td>
<td>Anti-Infectives/ Antibacterials/ Tetracyclines</td>
<td>Availability of a generic antibiotic option for the treatment of infections. The preferred option is generic doxycycline hyclate.</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>44</td>
</tr>
<tr>
<td>TARGADOX (doxycycline)</td>
<td>Anti-Infectives/ Antibacterials/ Tetracyclines</td>
<td>Availability of a generic antibiotic option for the treatment of infections. The preferred option is generic doxycycline hyclate.</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>55</td>
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# Formulary Updates – Product Exclusions

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<tr>
<th>Drug</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Zuplenz (ondansetron)</td>
<td>Gastrointestinal/ Antiemetics</td>
<td>Availability of additional options for the prevention of nausea and vomiting. Preferred options include granisetron, ondansetron, and Sancuso (granisetron transdermal).</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>7</td>
</tr>
<tr>
<td>Vanatol LQ</td>
<td>Analgesics/ Non-Opioid Analgesics</td>
<td>Availability of generic options for the relief of tension headache. Preferred options include diclofenac sodium and naproxen.</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>1</td>
</tr>
<tr>
<td>Tirosint (levothyroxine)</td>
<td>Endocrine and Metabolic/ Thyroid Supplements</td>
<td>Availability of additional options for the treatment of hypothyroidism. Preferred options include levothyroxine and Synthroid (levothyroxine).</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>247</td>
</tr>
<tr>
<td>Avonova Sol Neutrox (pure hypochlorous acid, 0.01%)</td>
<td>Topical/ Ophthalmic/ Miscellaneous</td>
<td>Availability of additional options for eyelid cleansing and removal of microorganism and debris. Consult doctor for preferred options.</td>
<td>Exclude</td>
<td>3→ Not Covered</td>
<td>113</td>
</tr>
<tr>
<td>Cimzia Kit (certolizumab pegol)</td>
<td>Immunologic Agents/ Autoimmune Agents</td>
<td>Availability of additional options for the treatment of ankylosing spondylitis (AS), Crohn’s Disease (CD), psoriasis (Ps), psoriatic arthritis (PsA), and rheumatoid arthritis (RA). Preferred options include: • Ankylosing spondylitis (AS): Cosentyx (secukinumab), Enbrel (etanercept), and Humira (adalimumab) • Crohn’s Disease (CD): Humira (adalimumab) and Stelara Subcutaneous (ustekinumab) • Psoriasis (Ps): Humira (adalimumab), Otezla (apremilast), Stelara Subcutaneous (ustekinumab), and Taltz (ixekizumab) • Psoriatic Arthritis (PsA): Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast) • Rheumatoid Arthritis (RA): Enbrel (etanercept), Humira (adalimumab), Kevzara (sarilumab), Orencia ClickJect (abatacept), Orencia Subcutaneous (abatacept), Xeljanz (tocafitinib), and Xeljanz XR (tocafitinib)</td>
<td>Exclude (ACSF)</td>
<td>Tier 2/ Excluded</td>
<td>81</td>
</tr>
</tbody>
</table>
# Formulary Updates – Product Exclusions

<table>
<thead>
<tr>
<th>Drug</th>
<th>Therapeutic Category/Subcategory</th>
<th>Rationale/Alternatives</th>
<th>Change Type</th>
<th>Proposed NC Status/Tier</th>
<th>Utilizers (6 mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPRON DEPOT KIT 7.5MG; 22.5MG; 30MG &amp; 45MG (leuprolide acetate for depot suspension)</td>
<td>Antineoplastic Agents/Hormonal Antineoplastic Agents/Luteinizing Hormone-Releasing Hormone (LHRH) Agonists</td>
<td>Availability of an additional option for the treatment of advanced prostatic cancer. The preferred option is Eligard (leuprolide acetate).</td>
<td>Exclude (ACSF)</td>
<td>Tier 2/ ACSF Excluded</td>
<td>0</td>
</tr>
<tr>
<td>ELOCTATE [Antihemophilic Factor (Recombinant), Fc Fusion Protein]</td>
<td>Hematologic/ Hemophilia A Agents</td>
<td>Availability of additional management options for adults and children with hemophilia A. Preferred options include Adynovate (antihemophilic factor [recombinant] pegylated), Jivi (antihemophilic factor [recombinant] pegylated-aucl), Kogenate FS (antihemophilic factor [recombinant]), Kovaltry (antihemophilic factor [recombinant]), Novoeight (antihemophilic factor [recombinant]), and Nuwiq (antihemophilic factor [recombinant]).</td>
<td>Exclude (ACSF)</td>
<td>Blocked-&gt; Not Covered/ ACSF</td>
<td>2</td>
</tr>
<tr>
<td>ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein]</td>
<td>Hematologic/ Hemophilia B Agents</td>
<td>Availability of additional options for adults and children with hemophilia B. Consult doctor for preferred options.</td>
<td>Exclude (ACSF)</td>
<td>Tier 3-&gt; Not Covered/ ACSF</td>
<td>0</td>
</tr>
<tr>
<td>ZEMAIRA (Alpha -Proteinase Inhibitor [Human])</td>
<td>Respiratory/ Pulmonary Enzyme Deficiency Agents</td>
<td>Availability of additional options for the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency. Preferred options include Aralast NP (alpha1-proteinase inhibitor) and Glassia (alpha1-proteinase inhibitor), Prolastin-C (alpha1-proteinase inhibitor).</td>
<td>Exclude (ACSF)</td>
<td>Tier 3-&gt; Not Covered/ ACSF</td>
<td>0</td>
</tr>
<tr>
<td>FASENRA (benralizumab)</td>
<td>Respiratory/ Severe Asthma Agents</td>
<td>Availability of an additional maintenance option for severe asthma with an eosinophilic phenotype. The preferred option is Nucala (mepolizumab).</td>
<td>Exclude (ACSF)</td>
<td>Tier 3-&gt; Not Covered/ ACSF</td>
<td>28</td>
</tr>
</tbody>
</table>
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

• CHLORZOXAZONE 250 MG (generic only)
  • Skeletal Muscle Relaxant
  • Manufactured by Solubiomix
  • Average Wholesale Price (AWP): $25.00 per tablet
    • Plan’s Average Net Cost per Prescription: >$2,300
  • Number of current NCSHP utilizers: 102
  • Formulary alternatives include:
    • Chlorzoxazone 500 MG scored tablet
    • Other muscle relaxants
  • No clinical advantage over the other alternatives
Formulary Updates – Product Exclusions

Summary

• 23 drugs are being removed from the formulary
• 3093 members will have to change therapies or obtain an exception
  • 0.5% of the Plan’s population
  • The removal of Tradjenta and Contrave account for 61% of the members affected
• Removing one generic hyperinflated product at this time
  • Chlorzoxazone
# Formulary Updates – Uptiers

<table>
<thead>
<tr>
<th>Drug</th>
<th>Therapeutic Category/Subcategory</th>
<th>Rationale/Alternatives</th>
<th>Change Type</th>
<th>Proposed NC Status/Tier</th>
<th>Utilizers (6 mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FENTORA (fentanyl buccal tablet)</td>
<td>Analgesics/Opioid Analgesics</td>
<td>Availability of additional options for managing breakthrough pain in adults with cancer. Preferred options include fentanyl transmucosal lozenge, Abstral (fentanyl citrate sublingual), and Subsys (fentanyl sublingual spray).</td>
<td>Uptier</td>
<td>2→3</td>
<td>4</td>
</tr>
<tr>
<td>WELCHOL PAK 3.75GM (colesevelam)</td>
<td>Cardiovascular/Antilipemics/Bile Acid Resins</td>
<td>Availability of generic options for the treatment of high cholesterol. The preferred options include cholestyramine and colesevelam.</td>
<td>Uptier</td>
<td>2→3</td>
<td>421</td>
</tr>
<tr>
<td>PYRIDIUM TAB 100MG (phenazopyridine)</td>
<td>Genitourinary/Miscellaneous</td>
<td>Availability of additional options for managing symptoms of pain, burning, urgency, frequency and other discomforts associated with irritation of the urinary tract mucosa. The preferred option is OTC phenazopyridine.</td>
<td>Uptier</td>
<td>2→3</td>
<td>1</td>
</tr>
<tr>
<td>ZOLADEX (goserelin acetate)</td>
<td>Antineoplastic Agents/Hormonal Antineoplastic Agents/Luteinizing Hormone-Releasing (LHRH) Agonists</td>
<td>Availability of additional options for the treatment of prostate cancer, endometriosis, endometrial-thinning prior to endometrial ablation, or advanced breast cancer. Preferred options include Eligard (leuprolide acetate) for prostate cancer. Consult doctor for preferred options for endometriosis and advanced breast cancer.</td>
<td>Uptier</td>
<td>Tier 5→ Tier 6/ACSF</td>
<td>0</td>
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</tbody>
</table>
## Formulary Updates – Downtiers

<table>
<thead>
<tr>
<th>Drug</th>
<th>Therapeutic Category/ Subcategory</th>
<th>Rationale/Alternatives</th>
<th>Change Type</th>
<th>Proposed NC Status/Tier</th>
<th>Utilizers (6 mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARNUITY ELLIPTA</td>
<td>Respiratory/ Steroid Inhalants</td>
<td>To provide an additional prophylactic option for the treatment of asthma.</td>
<td>Downtier</td>
<td>3 → 2</td>
<td>173</td>
</tr>
<tr>
<td>(fluticasone furoate)</td>
<td></td>
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<tr>
<td>ABSTRAL</td>
<td>Analgesics/ OPIOID Analgesics</td>
<td>To provide an additional option for managing breakthrough pain in adults with cancer.</td>
<td>Downtier</td>
<td>3 → 2</td>
<td>0</td>
</tr>
<tr>
<td>(fentanyl/ sublingual)</td>
<td></td>
<td></td>
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<tr>
<td>EUCRISA</td>
<td>Topical/ Dermatology/ Atopic Dermatitis/ Topical</td>
<td>To provide an additional option for the treatment of atopic dermatitis.</td>
<td>Downtier</td>
<td>3 → 2</td>
<td>471</td>
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<tr>
<td>(crisaborole)</td>
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<tr>
<td>ZEJULA</td>
<td>Antineoplastic Agents/ Miscellaneous</td>
<td>To provide an option for the maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.</td>
<td>Downtier</td>
<td>Tier 6 → Tier 5/ ACSF</td>
<td>7</td>
</tr>
<tr>
<td>(miraparib)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>ARALAST NP</td>
<td>Respiratory/ Pulmonary Enzyme Deficiency Agents</td>
<td>To provide an option the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency.</td>
<td>Downtier</td>
<td>Tier 6 → Tier 5/ ACSF</td>
<td>0</td>
</tr>
<tr>
<td>(alpha1-proteinase inhibitor [human])</td>
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<td></td>
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<tr>
<td>GLASSIA</td>
<td>Respiratory/ Pulmonary Enzyme Deficiency Agents</td>
<td>To provide an option the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency.</td>
<td>Downtier</td>
<td>Tier 6 → Tier 5/ ACSF</td>
<td>0</td>
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<tr>
<td>(alpha1-proteinase inhibitor [human])</td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>NUCALA</td>
<td>Respiratory/ Severe Asthma Agents</td>
<td>To provide an option for the treatment of severe asthma or eosinophilic granulomatosis with polyangiitis (EGPA).</td>
<td>Downtier</td>
<td>Tier 6 → Tier 5/ ACSF</td>
<td>50</td>
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<tr>
<td>(mepolizumab)</td>
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<tr>
<td>PROLASTIN-C</td>
<td>Respiratory/ Pulmonary Enzyme Deficiency Agents</td>
<td>To provide an option the treatment of emphysema due to an inherited disorder known as alpha1-antitrypsin deficiency.</td>
<td>Downtier</td>
<td>Tier 6 → Tier 5/ ACSF</td>
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</tr>
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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 are being added back this year

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
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<tr>
<th>Drug</th>
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<tbody>
<tr>
<td>ADYNOVATE (anhemophilic factor [recombinant], Pegylated)</td>
<td>Hematologic/ Hemophilia A Agents</td>
<td>To provide an additional option for the treatment of hemophilia A. Twice-weekly dosing compared to Advate.</td>
<td>Add</td>
<td>Blocked→ Tier 5/ ACSF</td>
<td>No, pegylated version of Advate which is a preferred formulary option.</td>
</tr>
<tr>
<td>AJOYY (frenamizzumab-vfm)</td>
<td>Central Nervous System/ Migraine/ Monoclonal Antibody</td>
<td>To provide an additional option for the prevention of migraines.</td>
<td>Add</td>
<td>Blocked→ 2</td>
<td>Yes.</td>
</tr>
<tr>
<td>ALIQOPA (copanlisib)</td>
<td>Antineoplastic Agents/ Kinase Inhibitors</td>
<td>To provide an additional option for the treatment of relapsed follicular lymphoma.</td>
<td>Add</td>
<td>Blocked→ Tier 6/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>ALLINERIG (brigatinib)</td>
<td>Antineoplastic Agents/ Kinase Inhibitors</td>
<td>To provide an additional option for the treatment of ALK+ metastatic NSCLC.</td>
<td>Add</td>
<td>Blocked→ Tier 6/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>AZEORA (iobenguane I 131)</td>
<td>Antineoplastic Agents/ Miscellaneous</td>
<td>Provides the first FDA-approved drug for the treatment of cancers known as pheochromocytoma and paraganglioma that are positive for the noradrenochrome transporter (as determined by an iobenguane scan), and who require systemic anticancer therapy.</td>
<td>Add</td>
<td>Blocked→ Tier 6/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>BORTEZOMIB (bortezomib)</td>
<td>Antineoplastic Agents/ Miscellaneous</td>
<td>Provides an additional option to Velcade.</td>
<td>Add</td>
<td>Blocked→ Tier 6/ ACSF</td>
<td>No, same active ingredient as Velcade (came to market in May 2003); Bortezomib is a single source brand available from a different manufacturer available 12/2017.</td>
</tr>
<tr>
<td>BRAFTOFI (encorafenib)</td>
<td>Antineoplastic Agents/ Kinase Inhibitors</td>
<td>Provides an additional option for the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutation w/Mektovi</td>
<td>Add</td>
<td>Blocked→ Tier 0/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>BROMSITE (bromfenac ophthalmic solution)</td>
<td>Topical/ Ophthalmic/ Anti-Inflammatory/ Nonsteroidal</td>
<td>First and only topical ophthalmic nonsteroidal anti-inflammatory drug (NSAID) indicated to prevent ocular pain after cataract surgery</td>
<td>Add</td>
<td>Blocked → 3</td>
<td>No, Brand product of Bromfenac ophthalmic solution - a NSAID; not a new molecular entity but new GPI that was available 10/31/18.</td>
</tr>
<tr>
<td>BUPIVACAINIE INJ 312.5/10 (bupivacaine)</td>
<td>Central Nervous System/ Local Anesthetics</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → 3</td>
<td>No, new Single Sourced Brand of bupivacaine; not a new drug entity</td>
</tr>
<tr>
<td>BUTAL/APAP CAP 50-300MG (butabital/asetaminophen)</td>
<td>Central Nervous System/ Migraine</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → 3</td>
<td>No, new Generic Product Identifier (GPI) but not a new drug entity</td>
</tr>
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<tr>
<td>DUROLANE (hyaluronic acid)</td>
<td>Analgesics/ Viscosupplements</td>
<td>To provide an additional option for the treatment of knee pain due to osteoarthritis (OA).</td>
<td>Add</td>
<td>Blocked --&gt; 2</td>
<td>No, another Single Sourced Brand formulation of sodium hyaluronate.</td>
</tr>
<tr>
<td>EMBEDA (morphine/naltrexone)</td>
<td>Analgesics/ Opioid Analgesics</td>
<td>To provide an additional option for the treatment of severe pain.</td>
<td>Add</td>
<td>Blocked --&gt; 2</td>
<td>No, another abuse-deterrent opioid formulation</td>
</tr>
<tr>
<td>EMGALITY (galcanezumab-gnlm) (galcanezumab)</td>
<td>Central Nervous System/ Migraine/ Monoclonal Antibody</td>
<td>To provide an additional option for the prevention of migraines.</td>
<td>Add</td>
<td>Blocked --&gt; 2</td>
<td>Yes.</td>
</tr>
<tr>
<td>EPINEPHRINE INJ 1MG/10ML (epinephrine)</td>
<td>Cardiovascular/ Vasopressors</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked --&gt; 3</td>
<td>No, new Generic Product Identifier (GPI) but not a new drug entity</td>
</tr>
<tr>
<td>ERLLEADA (apalutamide)</td>
<td>Antineoplastic Agents/ Hormonal Antineoplastic Agents/ Antiandrogens</td>
<td>To provide a new option for the treatment of non-metastatic, castration-resistant prostate cancer.</td>
<td>Add</td>
<td>Blocked --&gt; Tier 5/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>GLYXAMBI (empagliflozin/linagliptin)</td>
<td>Endocrine and Metabolic/ Antidiabetics/ Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor / Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Combinations</td>
<td>To provide an additional option to improve glycemic control in adults with type 2 diabetes mellitus.</td>
<td>Add</td>
<td>Blocked --&gt; 2</td>
<td>No, combination product of Jardiance &amp; Tradjenta</td>
</tr>
<tr>
<td>IDELVION (coagulation factor IX [recombinant], albumin fusion protein)</td>
<td>Hematologic/ Hemophilia B Agents</td>
<td>To provide an additional option for the treatment of hemophilia B.</td>
<td>Add</td>
<td>Blocked --&gt; Tier 6/ ACSF</td>
<td>No, another Factor IX product - not a new molecular entity</td>
</tr>
<tr>
<td>JIVI (antihemophilic factor [recombinant PEGylated-aul])</td>
<td>Hematologic/ Hemophilia A Agents</td>
<td>To provide an additional option for the treatment of hemophilia A.</td>
<td>Add</td>
<td>Blocked --&gt; Tier 5/ ACSF</td>
<td>No, antihemophilic Factor VIII - not a new molecular entity</td>
</tr>
<tr>
<td>KCL/D5W INJ 20/250ML (potassium chloride in 5% dextrose)</td>
<td>Nutritional/Supplements/ Electrolytes</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked --&gt; 3</td>
<td>No, new Single Sourced Brand of KCL/D5W; not a new drug entity</td>
</tr>
<tr>
<td>KYPROLIS (carfilzomib)</td>
<td>Antineoplastic Agents/ Proteasome Inhibitor</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked --&gt; Tier 6/ ACSF</td>
<td>No, new 10mg strength; 30 mg and 60 mg strengths already on formulary at tier 6</td>
</tr>
</tbody>
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# Formulary Updates – New Drug Additions

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<tr>
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<tbody>
<tr>
<td>LENVIMA CAP 12MG &amp; 4MG (lenvatinib)</td>
<td>Antineoplastic Agents/ Kinase Inhibitors</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>No, new strength. Lenvima already on formulary at tier 6</td>
</tr>
<tr>
<td>MEKTOVI (binimetinib)</td>
<td>Antineoplastic Agents/ Kinase Inhibitors</td>
<td>Provides an additional option for the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutation w/Brafv600</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>NERLYNX (neratinib)</td>
<td>Antineoplastic Agents/ Kinase Inhibitors</td>
<td>To provide an additional option for the treatment of early-stage HER2-positive breast cancer</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>NOVAREL INJ 5000UNIT (chorionic gonadotropin)</td>
<td>Endocrine and Metabolic/ Fertility Regulators/ Ovulation Stimulants, Gonadotropins</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>No, new strength - Novarel 10000 unit already on formulary at tier 6</td>
</tr>
<tr>
<td>NUPZID 34MG &amp; 10MG (pimavanserin)</td>
<td>Central Nervous System/ Antipsychotics/ Atypicals</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>No, new strength</td>
</tr>
<tr>
<td>ORKESI 100-125 &amp; 150-180 (lucifacor/vinacor)</td>
<td>Respiratory/ Cystic Fibrosis</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>No, new granules packet dosage form; Orkambi Tabs on formulary at T6</td>
</tr>
<tr>
<td>PANCREAZE (pancrelase)</td>
<td>Gastrointestinal/ Pancreatic Enzymes</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → 3</td>
<td>No, new formulation of pancreatic enzymes</td>
</tr>
<tr>
<td>PHENYLEPHRINE INJ 0.8/10ML (phenylephrine)</td>
<td>Cardiovascular/ Vasopressors</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → 3</td>
<td>No, new Generic Product Identifier (GPI) but not a new drug entity</td>
</tr>
<tr>
<td>POTELIGEO (mogamulizumab-kpck)</td>
<td>Immunologic Agents/ Monoclonal Antibodies</td>
<td>To provide a new option for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>REBINYN (coagulation factor IX [recombinant], glycoPEGylated)</td>
<td>Hematologic/ Hemophilia Agents</td>
<td>To provide an option for the treatment of hemophilia B</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>No, another Factor IX product - not a new molecular entity</td>
</tr>
<tr>
<td>RHOPRESSA (nontasudil ophthalmic solution)</td>
<td>Topical/ Ophthalmic/ Miscellaneous</td>
<td>First ROCK inhibitor. Alternatives are latanoprost, Lumigan, Travatan Z</td>
<td>Add</td>
<td>Blocked → 2</td>
<td>Yes.</td>
</tr>
<tr>
<td>SERNIVO (betamethasone dipropionate)</td>
<td>Topical/ Dermatology/ Corticosteroids/ High Potency</td>
<td>Alternatives include generics desoximetasone, fluocinonide.</td>
<td>Add</td>
<td>Blocked → 3</td>
<td>No, new formulation of betamethasone - not a new molecular entity</td>
</tr>
<tr>
<td>SIGNIFOR LAR INJ 10MG &amp; 30MG (pasireotide)</td>
<td>Endocrine and Metabolic/ Acromegaly</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → Tier 6/ ACSF</td>
<td>No, new strength of entity already on formulary at tier 6</td>
</tr>
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<tbody>
<tr>
<td>SIKLOS (hydroxyurea)</td>
<td>Antineoplastic Agents/Miscellaneous</td>
<td>The first and only hydroxyurea-based treatment for pediatric patients with sickle cell anemia</td>
<td>Add</td>
<td>Blocked→ Tier 6/ ACSF</td>
<td>No, Single Sourced Brand formulation of Hydroxyurea tablet 100mg - not a new molecular entity</td>
</tr>
<tr>
<td>TIBSOVO (ivosidenib)</td>
<td>Antineoplastic Agents/Kinase Inhibitors</td>
<td>First IDH1 inhibitor for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) who have that specific genetic mutation.</td>
<td>Add</td>
<td>Blocked→ Tier 6/ ACSF</td>
<td>Yes.</td>
</tr>
<tr>
<td>ULTRAVATE LOTION 0.05% (halobetasol propionate)</td>
<td>Topical/Dermatology/Corticosteroids/Very High Potency</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked → 3</td>
<td>No, another formulation of halobetasol (lotion).</td>
</tr>
<tr>
<td>VANCOMYCIN INJ 250MG (vancomycin)</td>
<td>Anti-Infectives/Miscellaneous</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked→ 3</td>
<td>No, new Single Sourced Brand of 250 mg inj of vancomycin; not a new drug entity</td>
</tr>
<tr>
<td>FYXEOS (daunorubicin/cytarabine)</td>
<td>Antineoplastic Agents/Antimetabolites</td>
<td>Provides additional drug coverage.</td>
<td>Add</td>
<td>Blocked→ Tier 6/ ACSF</td>
<td>No, combo of existing drugs Daunoruobin/Cytarabine - not a new molecular entity</td>
</tr>
<tr>
<td>VYZULTA (latanoprostene bunod)</td>
<td>Topical/Ophthalmic/Prostaglandins</td>
<td>Alternatives available in preferred brands Lumigan, Travatan Z.</td>
<td>Add</td>
<td>Blocked → 3</td>
<td>Yes.</td>
</tr>
<tr>
<td>XELJANZ (tofacitinib)</td>
<td>Immunologic Agents/Autoimmune Agents</td>
<td>To provide an additional option for the treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ulcerative colitis (UC).</td>
<td>Add</td>
<td>Not Covered/ACSF→ Tier 5/ ACSF</td>
<td>No, approved in 2012, additional Janus-associated kinase inhibitor</td>
</tr>
<tr>
<td>XELJANZ XR (tofacitinib ext-rel)</td>
<td>Immunologic Agents/Autoimmune Agents</td>
<td>To provide an additional option for the treatment of rheumatoid arthritis (RA).</td>
<td>Add</td>
<td>Not Covered/ACSF→ Tier 5/ ACSF</td>
<td>No, approved in 2012, additional Janus-associated kinase inhibitor</td>
</tr>
<tr>
<td>ZEMDRI (plazomicin)</td>
<td>Anti-Infectives/Antibacterials/Aminoglycosides</td>
<td>To provide an additional option for the treatment of complicated UTI.</td>
<td>Add</td>
<td>Blocked→ 3</td>
<td>Yes.</td>
</tr>
</tbody>
</table>
AJOVY (fremanezumab-vfrm)

- **Indication:**
  - Preventive treatment of migraine in adults

- **Mechanism of Action:**
  - Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist
  - Human monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor

- **Drug Facts:**
  - 225 mg sub-q monthly or 675 mg every 3 months
  - Very well tolerated, besides pain at injection site & possible hypersensitivity reactions

- **Place in Therapy:**
  - Second approved anti-CGRP behind AIMOVIG
  - Groundbreaking treatment for migraine patients

- **Proposed Tier Placement:**
  - Tier 2 – Preferred Brand
ALIQOPA (copanlisib)

- **Indication:**
  - Treatment of relapsed follicular lymphoma in adults who have received at least 2 prior systemic therapies

- **Mechanism of Action:**
  - Phosphatidylinositol 3-Kinase Inhibitor (PI3K)
  - Copanlisib inhibits phosphatidylinositol 3-kinase (PI3K), primarily the P13K-alpha and P13K-delta isoforms which are expressed in malignant B-cells. Copanlisib induces tumor cell death through apoptosis and inhibition of proliferation of primary malignant B cell lines. In addition, copanlisib inhibits several signaling pathways, including B-cell receptor signaling, CXCR12 mediated chemotaxis of malignant B cells, and NFkB signaling in lymphoma cell lines

- **Drug Facts:**
  - 60 mg IV on days 1, 8, and 15 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity
  - Avoid concomitant use of strong CYP3A inhibitors, reduce dose to 45 mg
  - **Warnings:** Infection, Hyperglycemia, Hypertension, Pulmonary toxicity, Bone marrow suppression, Dermatologic toxicity, GI toxicity

- **Place in Therapy:**
  - Provides an additional choice for treatment with relapsed follicular lymphoma
  - Achieved a 59% overall response rate as the first intravenous PI3K inhibitor

- **Proposed Tier Placement:**
  - Tier 6 – Non-Preferred Specialty
Formulary Updates – New Drug Additions

ALIQOPA Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Follicular lymphoma
Authorization of 12 months may be granted for treatment of relapsed follicular lymphoma (FL) when the member has received at least two prior systemic therapies.
ALUNBRIG (brigatinib)

- **Indication:**
  - Treatment of anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer (NSCLC) in patients who have progressed on or are intolerant to crizotinib

- **Mechanism of Action:**
  - Anaplastic Lymphoma Kinase Inhibitor; Tyrosine Kinase Inhibitor
  - Brigatinib is a tyrosine kinase inhibitor (TKI) designed to target and inhibit the ALK mutation in NSCLC

- **Drug Facts:**
  - 90 mg once daily for 7 days; if tolerated, increase dose to 180 mg once daily
  - Many possible drug-drug interactions
  - **Warnings:** Pulmonary toxicity, Cardiac effects, Ocular toxicity, Creatine phosphokinase elevation, GI toxicity, Hyperglycemia, Anaplastic lymphoma kinase testing

- **Place in Therapy:**
  - The ALTA trial has established ALUNBRIG as a potential second-line treatment option for ALK+ NSCLC, by demonstrating significant efficacy with a manageable safety profile

- **Proposed Tier Placement:**
  - Tier 6 – Non-Preferred Specialty
ALUNBRIG Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Non-small cell lung cancer (NSCLC)
Authorization of 12 months may be granted for the treatment of recurrent or metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC for members who have progressed on or are intolerant to crizotinib.

Brain metastases from NSCLC
Authorization of 12 months may be granted for the treatment of brain metastases from ALK-positive NSCLC.
AZEDRA (iobenguane I 131)

- **Indication:**
  - Treatment of adults and adolescents age 12 and older with rare tumors of the adrenal gland (pheochromocytoma or paraganglioma) that cannot be surgically removed (unresectable), have spread beyond the original tumor site and require systemic anticancer therapy

- **Mechanism of Action:**
  - Radioactive I 131 labeled iobenguane, similar in structure to the neurotransmitter norepinephrine
  - AZEDRA is taken up and accumulates within pheochromocytoma and paraganglioma cells, and radiation resulting from radioactive decay of I 131 causes cell death and tumor necrosis

- **Drug Facts:**
  - Administer intravenously as a dosimetric dose followed by two therapeutic doses administered 90 days apart
  - **Warnings:** Risk from radiation exposure, Myelosuppression, Secondary myelodysplastic syndrome, leukemia and other malignancies, Hypothyroidism, Elevations in blood pressure, Renal toxicity, Pneumonitis, Embryo-Fetal toxicity, Risk of infertility

- **Place in Therapy:**
  - This is the first FDA-approved drug for this use

- **Proposed Tier Placement:**
  - Tier 6 – Non-Preferred Specialty
BRAFTOVI (encorafenib)

- **Indication:**
  - Treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with binimetinib, as detected by an FDA-approved test
  - Encorafenib is not indicated for treatment of wild-type BRAF melanoma

- **Mechanism of Action:**
  - BRAF Kinase Inhibitor, which stops tumor cell growth

- **Drug Facts:**
  - 450 mg once daily (in combination with binimetinib) until disease progression or unacceptable toxicity

- **Warnings:** Malignancy, Hemorrhage, Ocular toxicity, QT prolongation, Dermatologic toxicity, Many drug-drug interactions

- **Place in Therapy:**
  - Possibly a new standard of care for BRAF-mutant melanoma patients based on median overall survival in a Phase 3 trial (COLUMBUS)

- **Proposed Tier Placement:**
  - Tier 6 – Non-Preferred Specialty
MEKTOVI (binimetinib)

- **Indication:**
  - Treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with encorafenib, as detected by an FDA-approved test

- **Mechanism of Action:**
  - Mitogen-activated extracellular kinase (MEK) inhibitor

- **Drug Facts:**
  - 45 mg twice daily, ~12 hours apart (in combination with encorafenib) until disease progression or unacceptable toxicity

- **Warnings:** Cardiotoxicity, Thromboembolism, Ocular toxicity, Pulmonary toxicity, Hepatotoxicity, Rhabdomyolysis, Hemorrhage

- **Place in Therapy:**
  - Possibly a new standard of care for BRAF-mutant melanoma patients based on median overall survival in a Phase 3 trial (COLUMBUS)

- **Proposed Tier Placement:**
  - Tier 6 – Non-Preferred Specialty
BRAFTOVI Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Melanoma
Authorization of 12 months may be granted for treatment of unresectable or metastatic melanoma when all of the following criteria are met:
A. Braftovi is used in combination with binimetinib
B. Tumor is positive for BRAF V600E or V600K mutation
MEKTOVI Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Melanoma
Authorization of 12 months may be granted for treatment of unresectable or metastatic melanoma when all of the following criteria are met:
A. Mektovi is used in combination with encorafenib
B. Tumor is positive for BRAF V600E or V600K mutation
EMGALITY (galcanezumab-gnlm)

- **Indication:**
  - Preventive treatment of migraine in adults

- **Mechanism of Action:**
  - Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist
  - Human monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor

- **Drug Facts:**
  - 240 mg subcutaneously as loading dose, then 120 mg once monthly
  - Very well tolerated, besides pain at injection site & possible hypersensitivity reactions

- **Place in Therapy:**
  - Third approved anti-CGRP behind AIMOVIG & AJOVY
  - Groundbreaking treatment for migraine patients

- **Proposed Tier Placement:**
  - Tier 2 – Preferred Brand
ERLEADA (apalutamide)

- **Indication:**
  - Treatment of non-metastatic, castration-resistant prostate cancer

- **Mechanism of Action:**
  - Nonsteroidal androgen receptor inhibitor
  - Apalutamide binds directly to the androgen receptor ligand-binding domain to prevent androgen-receptor translocation, DNA binding, and receptor-mediated transcription. Androgen receptor inhibition results in decreased proliferation of tumor cells and increased apoptosis, leading to a decrease in tumor volume.

- **Drug Facts:**
  - 240 mg once daily (in combination with a gonadotropin-releasing hormone analog agonist or antagonist) until disease progression or unacceptable toxicity
  - **Warnings:** Falls/fractures, Seizures, Dermatologic toxicity, Thyroid dysfunction, Cardiovascular disease, Many drug-drug interactions, QT prolongation

- **Place in Therapy:**
  - First FDA-approved therapy to treat patients with non-metastatic castration-resistant prostate cancer

- **Proposed Tier Placement:**
  - Tier 5 – Preferred Specialty
ERLEADA Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Non-metastatic castration-resistant prostate cancer
Authorization of 24 months may be granted for treatment of non-metastatic castration-resistant prostate cancer when Erleada will be administered with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.
NERLYNX (neratinib)

- **Indication:**
  - Extended adjuvant treatment of early stage human epidermal growth receptor type 2 (HER2) overexpressed/amplified breast cancer (following adjuvant trastuzumab-based therapy)

- **Mechanism of Action:**
  - Anti-HER2, Epidermal Growth Factor Receptor (EGFR) inhibitor, Tyrosine kinase inhibitor
  - Targeted therapy that blocks several enzymes that promote cell growth

- **Drug Facts:**
  - 240 mg once daily for 1 year
  - **Warnings:** GI toxicity, Hepatotoxicity, Many drug-drug interactions,

- **Place in Therapy:**
  - First extended adjuvant therapy for early-stage, HER2-positive breast cancer

- **Proposed Tier Placement:**
  - Tier 6 – Non-Preferred Specialty
NERLYNX Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Breast cancer
Authorization of up to 12 months total may be granted for the treatment of early stage HER2-positive breast cancer when Nerlynx is initiated within two years after completing adjuvant trastuzumab based therapy.
POTELIGEO (mogamulizumab-kpkc)

- **Indication:**
  - Treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy

- **Mechanism of Action:**
  - Monoclonal anti-CC Chemokine Receptor Antibody
  - Binding to CCR4 targets a cell for antibody-dependent cellular cytotoxicity (ADCC), resulting in target cell depletion

- **Drug Facts:**
  - 1 mg/kg IV on days 1, 8, 15, and 22 of cycle 1, followed by 1 mg/kg IV on days 1 and 15 of each subsequent cycle; continue until disease progression or unacceptable toxicity
  - **Warnings:** Dermatologic toxicity, Infusion reactions, Infections, Autoimmune toxicity, Hematopoietic stem cell transplant, Bone marrow suppression, Polysorbate 80, Many drug-drug interactions

- **Place in Therapy:**
  - First-in-class defucosylated, humanized IgG1 kappa monoclonal antibody

- **Proposed Tier Placement:**
  - Tier 6 – Non-Preferred Specialty
POTELIGEO Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

**Mycosis fungoides (MF) or Sézary syndrome (SS)**
Authorization of 12 months may be granted for treatment of mycosis fungoides (MF) or Sézary syndrome (SS).

**Adult T-cell leukemia/lymphoma**
Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma.
RHOPRESSA (netarsudil ophthalmic)

- **Indication:**
  - Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension

- **Mechanism of Action:**
  - Rho Kinase Inhibitor
  - Although the exact mechanism of action of netarsudil, a rho kinase inhibitor, is unknown, it may reduce IOP by increasing the outflow of aqueous humor through the trabecular meshwork route.

- **Drug Facts:**
  - 1 drop in affected eye(s) once daily in the evening
  - **Warnings:** Bacterial keratitis, Remove contact lens

- **Place in Therapy:**
  - First Rho Kinase inhibitor on the market
  - Provides an additional treatment for patients with open-angle glaucoma and ocular hypertension to lower eye pressure

- **Proposed Tier Placement:**
  - Tier 2 – Preferred Brand
VYZULTA (latanoprostene bunod)

- **Indication:**
  - Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma and ocular hypertension

- **Mechanism of Action:**
  - Antiglaucoma ophthalmic prostaglandin
  - Latanoprost acid is thought to lower intraocular pressure by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes.

- **Drug Facts:**
  - Instill 1 drop into affected eye(s) once daily in the evening
  - *Warnings:* Ocular effects, Ocular inflammation, Ocular disease, Bacterial keratitis, Contact lens wearers

- **Place in Therapy:**
  - A new prostaglandin that provides an additional treatment for patients with open-angle glaucoma and ocular hypertension to lower eye pressure

- **Proposed Tier Placement:**
  - Tier 3 – Non-Preferred Brand
TIBSOVO (ivosidenib)

- **Indication:**
  - Treatment of relapsed or refractory acute myeloid leukemia (AML) in adult patients with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an approved test

- **Mechanism of Action:**
  - Isocitrate dehydrogenase 1 (IDH1) enzyme inhibitor
  - Susceptible IDH1 mutations can lead to increased levels of 2-hydroxyglutarate (2-HG) in leukemia cells. 2-HG inhibits alpha-ketoglutarate-dependent enzymes, resulting in impaired hematopoietic differentiation.

- **Drug Facts:**
  - 500 mg once daily; continue for a minimum of 6 months and then until disease progression or unacceptable toxicity
  - **Warnings:** Differentiation syndrome, QT prolongation, Guillain-Barré syndrome, GI toxicity, Tumor lysis syndrome, Many drug-drug interactions

- **Place in Therapy:**
  - First Oral, Targeted Therapy for Adult Patients with Relapsed/Refractory Acute Myeloid Leukemia and an IDH1 Mutation

- **Proposed Tier Placement:**
  - Tier 6 – Non-Preferred Specialty
TIBSOVO Specialty Guideline Management:

CRITERIA FOR INITIAL APPROVAL

Acute Myeloid Leukemia

Authorization of 12 months may be granted for treatment of relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation.
Formulary Updates – New Drug Additions

ZEMDRI (plazomicin)

• **Indication:**
  - Treatment of complicated UTI, including pyelonephritis caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Enterobacter cloacae* in patients ≥18 years of age. Note: Reserve for use in complicated UTI patients who have limited or no alternative treatment options.

• **Mechanism of Action:**
  - Aminoglycoside antibiotic
  - Interferes with bacterial protein synthesis by binding to 30S ribosomal subunit resulting in a defective bacterial cell membrane.

• **Drug Facts:**
  - 15 mg/kg IV once daily for 4 to 7 days
  - **Warnings:** Nephrotoxicity, Ototoxicity, Hearing impairment, Neuromuscular blockade, Neuromuscular disorders, Pregnancy, Many drug-drug interactions

• **Place in Therapy:**
  - The structure of plazomicin protects it from most aminoglycoside-modifying enzymes, which typically inactivate existing aminoglycosides
  - Provides an additional treatment for patients with cUTI who have limited or no alternative treatment options

• **Proposed Tier Placement:**
  - Tier 3 – Non-Preferred Brand
Utilization Management Policy Review

New Policies Under Consideration

- Corticosteroid-Pulmicort 1mg Post Limit Policy

- Select Prescription Only Medical Devices
  - 510(k) products
Corticosteroid-Pulmicort 1mg Post Limit Policy:

**AFFECTED MEDICATIONS**
- PULMICORT RESPULES 1MG ONLY

**CRITERIA FOR INITIAL APPROVAL**
The requested drug will be covered with prior authorization when the following criteria are met:
- The patient has the diagnosis of eosinophilic esophagitis (EoE)
  **AND**
- The request is for continuation of therapy with Budesonide (Pulmicort) Respules at a dose of 1mg twice daily (2mg daily), and the patient has been evaluated for improvement or relapse in symptoms or inflammation
  **OR**
- The patient had all of the following: A) Eosinophil-predominant inflammation on biopsy, B) Trial of a proton pump inhibitor (PPI), C) Secondary causes of esophageal eosinophilia were ruled out

The quantity for approval will be 2 packages/60 respules of Budesonide 1 mg (Pulmicort) Respules per month.
Select Medical Devices Initial Prior Authorization:

RATIONALE
The intent of the criteria is to ensure that patients follow selection elements noted in labeling in order to decrease the potential for inappropriate utilization and to confirm the appropriate coverage of select medical devices. A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or
- intended to affect the structure or any function of the body, and which does not achieve any of its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.\(^1\)

This policy is intended to ensure that select medical devices are utilized in accordance with indications or uses within the manufacturer’s guidelines and to foster cost-effective, first-line use of available FDA-approved medications and over-the-counter (OTC) products.

In addition, if the patient has experienced an inadequate treatment response, intolerance, or contraindication to all available FDA-approved drugs and over-the-counter (OTC) products for the patient’s medical condition, the prior authorization will be approved. If criteria for coverage are met, the requested medical device will be approved for 3 months.
## Utilization Management Policy Review

### Select Medical Devices Initial Prior Authorization:

**AFFECTED MEDICATIONS**

<table>
<thead>
<tr>
<th>CLASS</th>
<th>DRUG NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dermatological Products</strong></td>
<td>Loyon, Nuvail 16%, Kamdoy, Emulsion, Epiceram, Entty, Ceracade, Phlag,</td>
</tr>
<tr>
<td></td>
<td>Eletone, Xeralux, Tetrax, Hylatopic, Neosalus, Neocera, Pruclair, Prumyx,</td>
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<tr>
<td></td>
<td>Nivatopic, Dexeryl, Atopiclair, Mb Hydrogel, PR Cream, Alevicyn, Presera,</td>
</tr>
<tr>
<td></td>
<td>HPR, Tropazone</td>
</tr>
<tr>
<td><strong>Antiseborrheic Products</strong></td>
<td>Loutrex, Promiseb</td>
</tr>
<tr>
<td><strong>Artificial Saliva</strong></td>
<td>Bocasal, Aqoral, Caphosol, Numoisyn, Aquoral</td>
</tr>
<tr>
<td><strong>Wound Dressing</strong></td>
<td>Biafine, Avo Cream, Prutect, Sonafine, Noxifine, Ca Alginate Mis 12&quot; Rope,</td>
</tr>
<tr>
<td></td>
<td>Curity Hyper Mis 1/2&quot;x15' (Curity Hypertonic Sodium Chloride Packing Strip),</td>
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<tr>
<td></td>
<td>Sil-k Pad (Aka Blaine Scarcare Patch)</td>
</tr>
<tr>
<td><strong>Oral Wound Care Products</strong></td>
<td>Salicept, Oramagicrx, Mucotrol, Gelx, Mugard</td>
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<tr>
<td><strong>Hyaluronate Products</strong></td>
<td>Bionect, Gelclair</td>
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<tr>
<td><strong>Scar Treatment Products</strong></td>
<td>Celacyn, Recedo, Beau, Restizan, Scar Manage</td>
</tr>
<tr>
<td><strong>Eyelid Cleansers</strong></td>
<td>Acuicyn, Ocusoft</td>
</tr>
</tbody>
</table>
Select Medical Devices Initial Prior Authorization:

CRITERIA FOR INITIAL APPROVAL

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

- The medical device is being used according to the manufacturer’s indication
- The patient experienced an inadequate treatment response, intolerance, or contraindication to all available FDA-approved drugs and over-the-counter (OTC) products for their medical condition
If approved, the following formulary changes will go into effect 1/1/2019 and include the following:

- **DRUG EXCLUSIONS**
  - Acanya, Jentadueto, Jentadueto XR, Tradjenta, Contrave, Benzaclin, Onexton, Veltin, Ziana, Cambia, Sorilux, Acticlate, Targadox, Zuplenz, Vanatol LQ, Tirosint, Avenova, Cimzia, Lupron Depot 7.5/22.5/30/45 mg, Eloctate, Alprolix, Zemaira, & Fasenra

- **UPTIERS**
  - Fentora, Welchol, Pyridium, Lupron Depot 3.75/11.25 mg, & Zoladex

- **DOWNTIERS**
  - Arnuity Ellipta, Abstral, Eucrisa, Zejula, Aralast Np, Glassia, Nucala, & Prolastin-C

- **NEW DRUG ADDITIONS**

- **UTILIZATION MANAGEMENT**
  - Select Medical Devices, Corticosteroid-Pulmicort 1mg,
Next meeting:  
February 19, 2019