Formulary Update

At A Glance

Formulary Additions

- Augmented betamethasone 0.5% gel and ointment
- Theophylline 600 mg Extended Release tablets
- Sofosbuvir/Velpatasvir (Epclusa) tablets

Criteria Restricted Medication Additions

- Sofosbuvir/velpatasvir (Epclusa) tablets
- Reslizumab (Cinqair) injection
- Daclizumab (Zinbryta) injection

Formulary Removals

- Neomycin-polymixin B-hydrocortisone (Cortisporin) otic suspension and solution
- Neomycin-polymixin B-hydrocortisone-thonzonium bromide otic (Coly-Mycin S and Cortisporin-TC)

Formulary Additions

Augmented Betamethasone 0.5% gel and ointment added to the Commercial Formulary effective November 30, 2016. Augmented Betamethasone 0.5% gel and ointment are included in the ultra-high potency (I) topical steroid category and offer a lower cost alternative to clobetasol 0.5% ointment and gel. Systemic absorption of high and ultra-high topical steroids can produce a reversible suppression of the hypothalamic-pituitary-adrenal axis, and therefore the use of these medications in these categories should be limited to 2 weeks.
Formulary Additions, Continued

Theophylline 600 mg ER tablets added to the Commercial Formulary effective November 30, 2016. Theophylline extended release 100, 200, 300 mg tablets are on the commercial formulary. Currently, there is a shortage of theophylline 300 mg ER tablets, with an estimated availability of 2nd Quarter 2017. Because of this shortage, the cost of the 300 mg ER tablets has increased significantly. The 600 mg ER tablets are scored and therefore may be split in half for patients on the 300 mg dose.

Sofosbuvir/Velpatasvir (Epclusa) added to the Commercial Formulary effective December 28, 2016. Epclusa is a two-drug combination for the treatment of Hepatitis C. It is indicated for adult patients with genotypes 1, 2, 3, 4, 5, and 6 infection without cirrhosis or with compensated cirrhosis. It is also indicated in patients with decompensated cirrhosis for use in combination with ribavirin. This is the first approved antiviral treatment for chronic Hepatitis C infection that has activity against all genotypes. Epclusa has been incorporated into QRM criteria restrictions, as other Hepatitis C agents requiring prior authorization review.

Formulary Additions, Continued

The following medications will be added to the list of Criteria Restricted Medications (QRM):

- sofosbuvir/velpatasvir (Epclusa)
- reslizumab (Cinqair)
- daclizumab (Zinbryta)

Changes to Criteria Restricted Medications

Diabetes Medications: DPP-4 Inhibitors, SGLT-2 Inhibitors, GLP-1 Agonists

- QRM Criteria NO longer requires prescribing by Endocrinology
- Any Provider may prescribe one of these agents after confirming the patient meets criteria, including HgbA1c 7-8.5%, and preferred medications
- Prescriber submits the prescription which initiates QRM review (not necessary to call QRM, as long as criteria documented in Encounter note)
- Prescriber advises patient specific criteria are to be met before this medication may be prescribed at a copay. The patient will be notified quickly, within 14 days, with the coverage decision.
If you have any questions or concerns, please contact any of the following P&T Committee members and designated alternates:

**P&T Chair:**
Carole Gardner, MD

**P&T Committee Members:**
- Debbi Baker, PharmD, BCPS
  Clinical Pharmacy
- Gary Beals, RPh
  Director of Pharmacy
- Karen Bolden, RN, BSN
  Clinical Services
- Alyssa Dayton, MD
  Obstetrics and Gynecology
- Carole Gardner, MD
  Elder Care
- Patrice Gaspard, MD
  Pediatrics
- David Jones, MD
  Pediatrics
- Craig Kaplan, MD
  Ambulatory Medicine
- Felecia Martin, PharmD
  Pharmacy/Geriatrics
- Shayne Mixon, PharmD
  Pharmacy Operations
- Rachel Robins, MD
  Hospitalist
- Jennifer Rodriguez, MD
  Behavioral Health
- Ivorique Turner, MD
  Ambulatory Medicine

**Designated Alternates:**
- Jacqueline Anglade, MD
  Obstetrics and Gynecology
- Lesia Jackson, RN
  Clinical Services

### Changes to Criteria Restricted Medications, Continued

#### Hepatitis C Medications
- Sofosbuvir (Solvadi) no longer a preferred agent for Hepatitis C

#### Mepolizumab (Nucala)
- Alignment with National Guidelines
- Nucala designated as the preferred agent over Reslizumab (Cinqair) due to safety profile, route of administration, and cost

### Medications Reviewed, but Not Added to the Formulary
- Insulin glargine (Basaglar) was not added to the Commercial Formulary, decision pending for National MPD formulary.
- Lifitgrast (Xiidra) ophthalmic solution was not added to the Commercial Formulary, decision pending for National MPD formulary. This medication will have a 30-day QTY limit: 1 box of 60 single use containers

### New Standing Order for Carafate Suspension to Sucralfate tablets

<table>
<thead>
<tr>
<th>Medication</th>
<th>Equivalent Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucralfate 10 ml (1 gm) suspension</td>
<td>Sucralfate 1 g tablet dissolved in 20 ml of water</td>
</tr>
</tbody>
</table>

### New Standing Order for Combivent Respimat to Stiolto Respimat

<table>
<thead>
<tr>
<th>Medication</th>
<th>Equivalent to</th>
<th>Stiolto Respimat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combivent Respimat</td>
<td>4 to 6 puffs daily</td>
<td>2 puffs once daily</td>
</tr>
</tbody>
</table>

*Exclusion: Patients with active orders for any other inhaled or nebulized therapies for respiratory diseases (except albuterol).
- Stiolto is a LAMA plus LABA. Same device as Combivent and Spiriva
- LAMA and/or LABAs now considered the best therapy for most patients with COPD
- Once daily (2 puffs) = higher adherence than twice daily meds.

### OTC Pyrantel Pamoate now available in KP Pharmacies

OTC treatment for pinworm is preferred over albendazole (Albenza) due to cost and availability

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole 200 mg tablets</td>
<td>$335.45 (2 tabs)</td>
</tr>
<tr>
<td>Pyrantel Pamoate 50 mg/ml (Pinworm Suspension)</td>
<td>Retail Price = $8.45 (30 ml)</td>
</tr>
</tbody>
</table>
Kaiser Permanente has a National Medicare Part D (MPD) Formulary. Each regional P&T Committee reviews drugs and decides on tier status. The National Medicare Part D Pharmacy and Therapeutics Committee is charged with reconciling regional differences in MPD Formulary recommendations through consensus building in order to maintain one National MPD Formulary for Kaiser Permanente.

MPD Formulary initial tier placements are listed below with the corresponding effective date.

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Tier</th>
<th>Implementation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>lifitegrast 5% ophthalmic drops (Xiidra)</td>
<td>4</td>
<td>10/5/2016</td>
</tr>
<tr>
<td>eteplisosen 100 mg/2 ml; 500 mg/10 ml injection (Exondys 51)</td>
<td>5</td>
<td>10/5/2016</td>
</tr>
<tr>
<td>infliximab-dyyb 100 mg injection (Inflectra)</td>
<td>5</td>
<td>10/25/2016</td>
</tr>
<tr>
<td>olaratumb 10 mg/ml injection (Lartuvo)</td>
<td>5</td>
<td>10/28/2016</td>
</tr>
<tr>
<td>lixisenatide 0.05 mg/mL, 0.1 mg/mL injection (Adlyxin)</td>
<td>4</td>
<td>Pending</td>
</tr>
<tr>
<td>tenofovir alafenamide 25 mg tablets (Vemridy)</td>
<td>5</td>
<td>11/18/2016</td>
</tr>
<tr>
<td>calciediol 30 mcg capsules (Rayaldee)</td>
<td>5</td>
<td>11/18/2016</td>
</tr>
<tr>
<td>etanercept SZZS 25 mg/0.5 ml and 50 mg/ml injection</td>
<td>5</td>
<td>Pending</td>
</tr>
<tr>
<td>lesinurad 200 mg tablet (Zurampic)</td>
<td>4</td>
<td>Pending</td>
</tr>
<tr>
<td>bezlotoxumab 1000 mg/40 ml (25 mg/ml) injection (Zinplava)</td>
<td>5</td>
<td>Pending</td>
</tr>
<tr>
<td>adalimumab/atoo 40 mg/0.8 ml, 20 mg/0.4 ml injection (Amjevita)</td>
<td>5</td>
<td>Pending</td>
</tr>
</tbody>
</table>

Tier 1 = Value Generic  Tier 3 = Brand  Tier 5 = Specialty
Tier 2 = Generic  Tier 4 = Non-Preferred Brand  Tier 6 = Injectable Part D Vaccine

Medical Office Floorstock Additions

Approved medications will be added to the electronic floorstock ordering forms on the intranet.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone liquid 1 mg/ml</td>
<td>Pediatrics</td>
</tr>
<tr>
<td>Ceftriaxone 500 mg, 1 gm</td>
<td>Dermatology</td>
</tr>
<tr>
<td>Ethyl chloride</td>
<td>Dermatology</td>
</tr>
<tr>
<td>Candin</td>
<td>Dermatology</td>
</tr>
<tr>
<td>MS Contin 15 mg</td>
<td>ACC/CDU</td>
</tr>
<tr>
<td>Metoprolol 25 mg tablets</td>
<td>Internal Medicine</td>
</tr>
<tr>
<td>Invega Trinza</td>
<td>Behavioral Health</td>
</tr>
<tr>
<td>Keppra IV + vial2bag adapter</td>
<td>ACC/CDU</td>
</tr>
</tbody>
</table>
### Non-Formulary Cost Considerations

<table>
<thead>
<tr>
<th>Class</th>
<th>Non-formulary Medications</th>
<th>Formulary Alternatives</th>
<th>Clinical/Cost Pearls</th>
</tr>
</thead>
</table>
| Agents for Dry Eye Disease (DED) | • Restasis (Cyclosporine) 0.05% Ophthalmic Emulsion  
• Lifitegrast (Xiidra) 5% ophthalmic solution | • Fluorometholone 0.1%  
• OTC Refresh P.M Ointment  
• OTC Refresh Tears Solution | • There are no comparative trials with cyclosporine ophthalmic emulsion and lifitegrast  
• These agents are 100 times more expensive than first-line OTC artificial tears and lubricating drops |
| Long-acting Insulin Analogs | • Insulin glargine (Basaglar Kwikpen)  
• Insulin glargine U-100 (Lantus, Lantus Solostar)  
• Insulin glargine U-300 (Toujeo Solostar)  
• Insulin Degludec U-100, U-200 (Tresiba Flextouch)  
• Insulin Detemir U-100 (Levemir, Levemir Flextouch) | • NPH Insulin (Humulin N) | • NPH is the preferred first-line basal insulin as it is a more cost-effective option  
• The cost of Lantus is approximately 6 times more expensive than NPH  
• The cost of Levemir is approximately 15 times more expensive than NPH |

### Clinical Updates

**FDA approves Jardiance to reduce cardiovascular death in adults with type 2 diabetes.** The FDA approved a new indication (empagliflozin) to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and cardiovascular disease. Cardiovascular disease is the leading cause of death in adults with type 2 diabetes mellitus. According to the CDC, the risk of death from heart disease is 70 percent higher in diabetics compared to those without diabetes.

The decision was based on a postmarketing study required by the FDA when Jardiance was approved in 2014. Jardiance was studied in a postmarketing clinical trial (EMPA-REG) of more than 7,000 patients with type 2 diabetes and cardiovascular disease. In the trial, Jardiance was shown to reduce the risk of cardiovascular death compared to placebo when added to standard therapies for diabetes and atherosclerotic cardiovascular disease. This is the first trial to show a reduction in the risk of cardiovascular death with a medication for diabetes mellitus.

Empagliflozin is an inhibitor of the sodium glucose co-transporter 2 (SGLT2) pathway, reducing blood glucose by causing it to be excreted in urine. Jardiance can cause dehydration and hypotension. Jardiance can also cause ketoacidosis, serious urinary tract infection, acute kidney injury and impairment in renal function, hypoglycemia (when used with insulin or insulin secretagogues), vaginal yeast infections and genital mycotic infections, and increased cholesterol.

**FDA Drug Safety Communication:** Updated FDA review concludes that use of type 2 diabetes medicine pioglitazone may be linked to an increased risk of bladder cancer.

**FDA Drug Safety Communication:** FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women.
http://www.fda.gov/Drugs/DrugSafety/ucm532356.htm