Formulary Update

At A Glance

Formulary Additions

- Dabigatran (Pradaxa) 75 mg, 110 mg, 150 mg tablets
- Tiotropium/Olodaterol (Stiolto Respimat) 2.5 mcg/2.5 mcg inhalation spray
- Clindamycin 1%/Benzoyl Peroxide 5% (generic DUAC) gel
- Tofacitinib (Xeljanz 5 mg, Xeljanz XR 11 mg) tablets
- Mometasone/Formoterol (Dulera), 100 mcg/5 mcg, 200 mcg/5 mcg inhalation aerosol
- Mechlorethamine Compound 0.02%, 0.04% Ointment
- Emtricitabine/tenofovir (Descovy) tablets; Elvitegravir/cobicistat, emtricitabine/tenofovir (Genvoya); Emtricitabine/rilpivirine/tenofovir (Odefsey)

Criteria Restricted Medication Additions

- Sofosbuvir/velpatasvir (Epclusa) tablet
- Ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira XR) tablet

Formulary Additions

Tiotropium/olodaterol 2.5/2.5 mcg (Stiolto Respimat) was added to the Commercial Formulary effective September 7, 2016. Stiolto Respimat is a fixed-dose orally inhaled combination of the long-acting muscarinic antagonist (LAMA), tiotropium and the long-acting beta-agonist (LABA), olodaterol for the long-term once-daily maintenance treatment of airflow obstruction in chronic COPD. Potential advantages of Stiolto Respimat include once-daily administration and the convenience of two drugs in a single inhaler. Stiolto can be considered in patients with COPD whose symptoms are not improved with single agents. Since Stiolto Respimat is not indicated to reduce COPD exacerbations, it may not take the place of an inhaled corticosteroid (ICS)/LABA combination for patients with severe COPD who experience frequent exacerbations that are not controlled by long-acting bronchodilators.
Formulary Additions, Continued

Dabigatran (Pradaxa) 75 mg, 110 mg, and 150 mg was added to the Commercial Formulary effective September 7, 2016. Dabigatran is a target specific oral anticoagulant (TSOA) used for the prevention of stroke in patients with non-valvular atrial fibrillation (NVAF) and for the treatment and prevention of venous thrombosis. Other TSOAs remain non-formulary. Warfarin remains the most cost-effective formulary oral anticoagulant treatment option, particularly for those patients unable to tolerate, afford, or who are not eligible to receive TSOAs. Trials evaluating the efficacy of dabigatran for the supported indications demonstrate non-inferiority of dabigatran compared to warfarin. The ARR for intracranial hemorrhage (ICH) with dabigatran compared to warfarin was 0.44% (0.30% vs. 0.74%/yr; p < 0.001). A FDA Drug Safety Communication has reported the results of two Mini-Sentinel investigations which found lower rates of stroke or death, similar bleeding rates, but more GI bleeding with dabigatran compared to warfarin (1.51% vs 1.02%/yr; p < 0.001). Dabigatran should not be used in patients with CrCl ≤30 ml/min or on dialysis for VTE and <15 ml/min or on dialysis for NVAF. Dabigatran should be swallowed whole. Do not crush, chew or break the capsules open. Dabigatran should remain in the original container, not a pill box, and expires 120 days after opening. A reversal agent for dabigatran, idarucizumab (Praxbind) was recently approved by the FDA.

Clindamycin 1% / Benzoyl Peroxide 5% (Generic DUAC) was added to the Commercial Formulary effective September 7, 2016. Generic DUAC is a fixed combination medication used for the treatment of acne and is a once-daily treatment. The addition of a once-daily treatment has the potential to improve adherence in our teenage members with acne who are unlikely to comply with a twice daily topical regimen or complex regimen applications.

Tofacitinib (Xeljanz, Xeljanz XR) will be added to the Commercial Formulary effective September 28, 2016. Tofacitinib is a first-in-class Janus Kinase inhibitor as well as the first orally available disease-modifying antirheumatic drug (DMARD) to be FDA approved in over a decade. It is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. The American College of Rheumatology (ACR) Guidelines for the treatment of RA include tofacitinib as an option after conventional non-biologic DMARD therapies. The cost of therapy is considerably lower than the KP-preferred outpatient TNF inhibitors. The cost of the extended release and immediate release version are the same. The addition of tofacitinib to the Commercial Formulary will allow an additional therapy option to spare or delay the use of the biologic DMARDS.

Mometasone/Formoterol (Dulera) will be added to the Commercial Formulary effective September 28, 2016. Dulera is a combination inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA) indicated for the treatment of asthma, and used off label for COPD. ICSs are the preferred treatment option for initiating long-term control therapy. The KP preferred ICS is QVAR. For patients with moderate to severe persistent asthma uncontrolled on medium-dose QVAR, the addition of a LABA to an ICS (DULERA) is recommended to improve asthma control.

Descovy, Genvoya, Odefsey will be added to the Commercial Formulary effective September 28, 2016. Several combination HIV drugs containing the new prodrg of the nucleotide analog reverse transcriptase inhibitor (NRTI) tenofovir (TFV), tenofovir alafenamide (TAF), have been approved. TAF is considered the successor to tenofovir disoproxil fumarate (TDF). TAF offers more potent antiviral activity compared to TDF with a lower risk for renal toxicity and bone mineral density changes. The acquisition costs of the combination drugs containing TAF under the National KP contract are lower than the TDF containing products.

Mechlorethamine Compound 0.02%, 0.04% Ointment will be added to the Commercial Formulary effective September 28, 2016. Mechlorethamine ointment is used for the treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma. KPGA has a contracted price on compounded 0.02% and 0.04% from Leiter’s Compounding. The cost of compounded mechlorethamine ointment is significantly lower than commercially available Valchlor topical gel which is currently not included on the KPGA Commercial Formulary.
Questions and Concerns?

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  
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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

New Criteria Restricted Medications

Criteria restricted medications require review by Quality Resource Management (QRM) prior to coverage. The prior authorization process and criteria apply to all formularies except the Medicare Part D Formulary. Providers must call QRM to request authorization consideration at 404-364-7320. A complete listing of prior authorization medications and their corresponding criteria is available on the intranet under Healthcare Delivery/Guides & References/Formularies/Criteria Restricted (QRM) Medications.

The following medications will be added to the list of Criteria Restricted Medications (QRM):
- sofosbuvir/velpatasvir (Epclusa)
- ombitasvir/paritaprevir/ritonavir/dasabuvir (Vekira XR)

Medical Office Floorstock Additions

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

<table>
<thead>
<tr>
<th>Department Name</th>
<th>Medication Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology</td>
<td>Heparin-D5W 25,000/250 ml IV pre-mix bags</td>
</tr>
<tr>
<td>Ophthalmology &amp; Urgent Care</td>
<td>Proparacaine</td>
</tr>
</tbody>
</table>

Medications Reviewed, but Not Added to the Formulary

- Patiromer (Veltassa) powder for suspension was not added to the Commercial Formulary, Non-Preferred Tier 4 for National MPD formulary
- Sacubitril/Valsartan (Entresto) tablets were not added to the Commercial Formulary, decision pending for National MPD formulary
- Ivrabadine (Corlanor) tablets were not added to the Commercial Formulary, decision pending for National MPD formulary.

National Medicare Part D Formulary

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.

National MPD Formulary 2016 tier changes are listed below with the corresponding effective date.

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Tier</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftin suspension 125mg/ 5ml</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Stiolto Respimat 2.5-2.5 mcg</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Docetaxel Inj 80 mg/4 ml</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Flebogamma Inj 20mg/400 ml</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Flebogamma Inj DIF 5%, 10%</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Flebogamma DIF Soln (5 gm/100 ml, 10 gm/100ml)</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Fleogamma DIF Soln (10 gm/200 ml, 20 gm/200 ml)</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Descovy tabs 200-25 mg</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Odefsey tabs 200-25-25 mg</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
<tr>
<td>Genvoya tabs 150-150-200-10 mg</td>
<td>Tier 3</td>
<td>09/06/2016</td>
</tr>
</tbody>
</table>

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

Kaiser Permanente Georgia 3
National Medicare Part D Formulary, Cont.

Medication Name | Tier | Effective Date
--- | --- | ---
Epiduo Forte Topical Gel 0.3%/2.5% | Tier 3 | 09/06/2016
ZenPep (25,000, 40,000 lipase Units | Tier 3 | 09/06/2016
Varenicline (Chantix) | Tier 3 | 09/06/2016

National Medicare Part D Formulary initial tier placements are listed below with the corresponding effective date.

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Tier</th>
<th>Effective Date</th>
</tr>
</thead>
</table>
daclizumab 150 mg/ml injection (Zinbyta) | 5 | 8/2/2016 |
dolutegravir 10 mg, 25 mg tablets (Tivicay) | 4 | 8/2/2016 |
Nitisinone 20 mg capsules (Orfadin) | 5 | 8/19/2016 |
Izekizumab 80 mg/ml (Taltz) | 5 | 9/6/2016 |
Lixisenatide 0.05 mg/mL, 0.1 mg/mL injection (Adlyxin) | 4 | Pending |
infliximab-dyyb 100 mg injection (Inflectra) | 5 | Pending |
Lesinurad 200 mg tablet (Zurampic) | 4 | Pending |

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

New Standing Order for Asmanex Twihsthaler to Asmanex HFA

<table>
<thead>
<tr>
<th>Dosing Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asmanex Twihsthaler 220 mcg</td>
</tr>
<tr>
<td>2 puffs (440 mcg) twice daily</td>
</tr>
<tr>
<td>2 puffs (440 mcg) once daily OR 1 puff (220mcg) twice daily</td>
</tr>
<tr>
<td>1 puff (220 mcg) once daily</td>
</tr>
</tbody>
</table>

*Note: Asmanex Twihsthaler 220 mcg delivers 200 mcg of mometasone per inhalation*

December 2016:

**Medication Class Reviews**
- Vaccines
- Antihistamines
- Nasal Agents-systemic & topical
- Cough/cold/allergy
- Respiratory Agents--Misc
- Antianginal
- Beta Blockers
- Calcium Channel Blockers
- Antiarrhythmics
- Diuretics
- Vasopressors
- Antihyperlipidemics
- Cardiovascular Agents-- Misc

Please start recommending Reese’s Pinworm over Albenza

**Available October 3rd in KP Pharmacies**

Pyrantel Pamoate is available without prescription. The dose for adults and children > 2 years of age for pinworms is 11 mg/kg administered as a single dose.
# 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>
<tbody>
<tr>
<td>ICS/LABA</td>
<td>• Fluticasone/Salmeterol (Advair)</td>
<td>• Mometasone/Formoterol (Dulera)*</td>
<td>• For the cost of every 1 patient treated with Advair approximately 2 patients can be treated with Dulera.</td>
</tr>
<tr>
<td></td>
<td>• Budesonide/Formoterol (Symbicort)</td>
<td>*Recommended if uncontrolled on medium dose QVAR</td>
<td>• For the cost of every 1 patient treated with Symbicort approximately 2 patients can be treated with Dulera.</td>
</tr>
<tr>
<td>LAMA/LABA</td>
<td>• Umeclidinium/vilanterol (Anoro Ellipta)</td>
<td>• Tiotropium/Oldaterol (Stiolto)</td>
<td></td>
</tr>
<tr>
<td>Respiratory Agents</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>• The cost of Stiolto is lower than the cost of Anoro Ellipta and Combivent Respimat.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The cost of Stiolto is lower than giving two separate inhalers of the mono-components</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Clinical Updates

**FDA panel votes to remove serious warning from Pfizer’s smoking cessation pill, varenicline (Chantix).** The recommendation followed a two-year effort by Pfizer to remove the Black Box Warning—the most serious type of health alert—that indicated Chantix could cause patients to experience such side effects as suicidal thoughts and hostility. An earlier attempt in 2014 failed when an FDA panel recommended that the warning should remain.

In making its recommendation, A US Food and Drug Administration advisory panel reviewed the results from a study published in the Lancet that was published earlier this year. The study found that Chantix does not appear to increase the risk of suicidal behavior.

The study involved 8,144 adults between the ages of 18 and 75, who, on average, smoked more than 10 cigarettes a day. Eighty-two percent had previously made at least one attempt to quit smoking. Of these, about half or 4116 participants had a history of a previous or currently stable psychiatric condition, of whom about half were taking a psychotropic medicine.

Among patients already diagnosed with a psychiatric disorder, 6.5 percent of those on Chantix had a neuropsychiatric side effect, compared to 4.9 percent on placebo. Of those not diagnosed with a psychiatric disorder, 1.3 percent of those on Chantix experienced such a side effect, compared to 2.4 percent on placebo. This study also examined patients given Zyban, which is sold by GlaxoSmithKline.

The FDA staff raised concerns about the methodology of this study in a report released ahead of the FDA advisory committee meeting. The FDA staff said the trial was “designed in a well-intentioned attempt to capture somewhat ill-defined and complex neuropsychiatric phenomena.” They found “many problems in the implementation were apparent upon review of the collected data.” But when the FDA conducted its own analysis, excluding data they deemed unreliable, the results appeared to be consistent with Pfizer’s conclusion that Chantix does not significantly increase the incidence of such side effects. The FDA is not obligated to follow the recommendation of the advisory committee, but typically does so.