Formulary Additions

At A Glance

Formulary Additions

- Zejula (Niraparib) capsules
- Zydelig (idelalisib) tablets

Prior Authorization Medication Additions (QRM)

- Mavyret (Glecaprevir/Pibrentasvir) tablets
- Hizentra (Subcutaneous Immune Globulin)
- Saxenda (Liraglutide) injection

Tier Changes

- Pentasa (Mesalamine) tablets
- Canasa (Mesalamine) suppositories

Formulary Additions

The following medications will be added to the Commercial Formulary effective April 25, 2018:

- **Zejula (Niraparib):** Third-in-class FDA approved poly ADP-ribose polymerase (PARP) inhibitor. Zejula is indicated for the treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy. This is the first PARP inhibitor approved for maintenance treatment of patients regardless of BRCA mutation status. Similar to other PARP inhibitors, Zejula has a warning for myelodysplastic syndrome, acute myeloid leukemia, and embryo-fetal toxicity. In addition, Zejula also has warnings for bone marrow suppression and cardiovascular effects.
Formulary Additions, Con’t

- **Zydelig (I delalisib):** First-in-class Phosphatidylinositol-3 Kinase delta inhibitor indicated for treating relapsed chronic lymphocytic leukemia (CLL) in combination with Rituximab, relapsed follicular B-Cell non-Hodgkin lymphoma (FL), and relapsed small lymphocytic lymphoma (SLL). Zydelig offers another treatment option for relapsed or refractory CLL and should be reserved for patients being considered for rituximab monotherapy, with poor prognostic markers, or intolerant to ibrutinib. Zydelig carries several Black Box Warnings, including Fatal/Serious infections, intestinal perforation, hepatotoxicity, pneumonitis, and diarrhea/colitis.

Medications added to Prior Authorization (QRM)

**Mavyret (Glecaprevir/Pibrentasvir):** Treatment of adult patients with chronic hepatitis C genotypes 1,2,3,4,5, and 6 infections without cirrhosis and with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult patients with HCV genotype 1 infection who previously have been treated with a regimen containing an HCV NSSA inhibitor or an NS3/4A protease inhibitor. Mavyret is the first pan-genotypic therapy for patients with severe renal insufficiency (CrCl < 30 ml/min) or end stage renal disease. It is an alternative option for chronic hepatitis C that should be reserved for patients with severe renal insufficiency or those receiving hemodialysis.

**Hizentra (Subcutaneous Immune Globulin):** Treatment of primary immunodeficiency or inflammatory demyelinating polyneuropathy in adults. Hizentra should be reserved for patients with a documented systemic adverse reaction or intolerance to intravenous immune globulin or those with limited venous access.

**Saxenda (Liraglutide) - effective July 25, 2018:** Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, dyslipidemia). A documented failure, intolerance, or contraindication to both phentermine and two other weight management therapies is required for benefit coverage. The criteria only apply to members WITH an obesity rider.

Interregional Practice Recommendations

The Emerging Therapeutics Strategy (ETS) Program is a centralized effort that applies our evidence-based model to develop interregional practice recommendations with KP physician specialists, coordinates KP HeathConnect clinical content for decision support, and monitors outcomes to measure uptake of the clinical and strategy recommendations. Through the collaboration of Pharmacy, Permanente physicians, and Federation partners, the ETS Program offers a unified approach in the provision and management of specialty drugs, to help ensure that our members derive the greatest value from these products.

New Interregional Practice Recommendations have been approved for the following ETS Program Medications:

- **Luxturna (voretifene neparvovec-rzyl)** is indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Luxturna is a one-time sub-retinal injection that can only be administered at certified centers. Currently, none of the KP facilities are certified.

Medications not added to the Formulary

- **Xepi (Oxenoxacin)** - A non-fluorinated quinolone antibacterial cream for the treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older. Generic Bactroban ointment (mupirocin) will remain our preferred topical therapy for the treatment of impetigo. Step therapy restriction will be added to the QHP 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
  Geriatric Medicine
Jay Polokoff, MD
  Pediatrics
Craig Kaplan, MD
  Adult Primary Care
George Kawamura, MD
  Adult Primary Care
Amy Levine, MD
  Pediatrics
Felecia Martin, PharmD
  Pharmacy/Geriatrics
Shayne Mixon, PharmD
  Pharmacy Operations
Rachel Robins, MD
  Hospitalist
Jennifer Rodriguez, MD
  Behavioral Health

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

Formulary Tier Changes

Pentasa (mesalamine) 250 mg, 500 mg oral tablets will move from the Specialty Tier to Preferred Brand Tier.

Canasa (mesalamine) 1000 mg rectal suppositories will move from the Specialty Tier to Non-preferred Brand Tier.

Changes to 2018 QHP Formulary

• Fiasp (insulin aspart): Step therapy Restriction added. Currently on Specialty Tier 5.

Departmental Floorstock Additions

<table>
<thead>
<tr>
<th>Medication</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium Oxide 400 mg tablets</td>
<td>Cardiology</td>
</tr>
<tr>
<td>Chlorothiazide 250 mg tablets</td>
<td></td>
</tr>
<tr>
<td>Metolazone 2.5 mg tablets</td>
<td></td>
</tr>
<tr>
<td>Potassium 20 meq tablets</td>
<td></td>
</tr>
<tr>
<td>Oxytocin vials</td>
<td>Procedure Suite (Emergency Box)</td>
</tr>
<tr>
<td>Ceftriaxone 1 gm vials</td>
<td>Urogynecology</td>
</tr>
<tr>
<td>Shingrix (Herpes Zoster)</td>
<td>Infectious Disease</td>
</tr>
<tr>
<td>Saline Flushes</td>
<td>All Departments</td>
</tr>
</tbody>
</table>

Medicare Part D

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.

The following medications were reviewed at the April P&T Meeting for Medicare Part D coverage:

1. Rituxan Hyclea (rituximab and hyaluronidase) subcutaneous injection: Specialty Tier 5
2. Vyxeos (Daunorubicin and cytarabine liposome) injection: Specialty Tier 5

2019 Medicare Part D Tier Changes

<table>
<thead>
<tr>
<th>Product</th>
<th>2018 Formulary Tier</th>
<th>2019 Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisoprolol 5 mg, 10 mg tabs</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Pioglitazone 15 mg, 30 mg, 45 mg tabs</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Buspirone 5 mg, 10 mg tabs</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Verapamil 80 mg, 120 mg tabs</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Montelukast 4 mg, 5 mg chew</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Montelukast 10 mg tabs</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Rosuvastatin 5 mg, 10 mg, 20 mg, 40 mg</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Ezetimibe 10 mg</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
### Medicare Part D, Con’t

**Initial Tier Placements—Recently launched and approved medications**

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Tier</th>
<th>Implementation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>apalutamide 60 mg tablets (Erleada)**</td>
<td>Specialty Tier 5</td>
<td>2/16/2018</td>
</tr>
<tr>
<td>glycopyrrolate 25 mcg/ml solution (Lonhala)</td>
<td>Specialty Tier 5</td>
<td>2/16/2018</td>
</tr>
<tr>
<td>tezacaftor-ivacaftor 100-150 mg tablet therapy pack (Symdeko)</td>
<td>Specialty Tier 5</td>
<td>2/16/2018</td>
</tr>
<tr>
<td>hydroxyprogesterone 275 mg/1.1 ml injection (Makena)</td>
<td>Specialty Tier 5</td>
<td>2/27/2018</td>
</tr>
<tr>
<td>ibrutinib 70 mg capsules (Imbruvica)**</td>
<td>Specialty Tier 5</td>
<td>2/27/2018</td>
</tr>
<tr>
<td>ibrutinib 140 mg, 280 mg, 420 mg, 560 mg tablets (Imbruvica)**</td>
<td>Specialty Tier 5</td>
<td>2/27/2018</td>
</tr>
<tr>
<td>trasluzumab-dkst 420 mg injection (Ogivri)**</td>
<td>Specialty Tier 5</td>
<td>pending</td>
</tr>
<tr>
<td>vestronidase alfa-vjbk 10 mg/5 ml injection (Mepsevii)</td>
<td>Specialty Tier 5</td>
<td>pending</td>
</tr>
<tr>
<td>ibalizumab-uiyk 150 mg/ml injection (Trogarzo)**</td>
<td>Specialty Tier 5</td>
<td>pending</td>
</tr>
<tr>
<td>secnidazole 2 gm oral granule (Solosec)</td>
<td>Non-preferred Tier 4</td>
<td>pending</td>
</tr>
<tr>
<td>netarsudil dimesylate 0.02% ophthalmic solution (Rhopressa)</td>
<td>Non-preferred Tier 4</td>
<td>pending</td>
</tr>
<tr>
<td>angiotensin II 25 mg/ml injection (Giapreza)</td>
<td>Non-Preferred Tier 4</td>
<td>pending</td>
</tr>
<tr>
<td>ertugliflozin and metformin 2.5-500 mg, 2.5-1000 mg, 7.5-500 mg, 7.5-1000 mg tablets (Segluromet)</td>
<td>Non-Preferred Tier 4</td>
<td>pending</td>
</tr>
<tr>
<td>ertugliflozin and sitagliptin 5-100 mg, 15-100 mg tablets (Stelujan)</td>
<td>Non-Preferred Tier 4</td>
<td>pending</td>
</tr>
<tr>
<td>ertugliflozin 5 mg, 15 mg tablets (Steglatro)</td>
<td>Non-Preferred Tier 4</td>
<td>pending</td>
</tr>
<tr>
<td>macimorelin 0.5 mg solution (Macrilen) <em>(Launch Pending)</em></td>
<td>Non-Preferred Tier 4</td>
<td>pending</td>
</tr>
<tr>
<td>bictegravir-emtricitabine-tenofovir alagenamide 50mg/200mg/25 mg tablets (Biktarvy)**</td>
<td>Non-Preferred Tier 4</td>
<td>pending</td>
</tr>
</tbody>
</table>

**Protected Class**
## 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>
| Insulin Aspart | Novolog 100 U/ml solution  
Novolog Flexpen 100 U/ml  
Fiasp 100 U/ml Solution  
Fiasp FlexTouch 100 U/ml Pen-injector | • Humulin R Vial  
• Humalog Vial NF  
• Humalog Kwikpen NF (for patients who meet the criteria for insulin pens)  
*Note: Humalog NF preferred in the following circumstances: DM1, documented adequate therapeutic trial or intolerance (persistent hypoglycemia) to Humulin R | NovoLog/Fiasp to Humulin R or Humalog is a 1:1 Conversion  
Fiasp is insulin aspart with 2 added excipients:  
• Vitamin B3 which increases the speed of initial absorption  
• L-arginine which aids in stabilizing the formulation.  
Fiasp/Novolog 10 ml vial is ~13X the cost of Humulin R vial  
Fiasp/Novolog pens are ~7X the cost of Humalog Kwikpen |

| Insulin Lispro | Humalog 100U/ml solution  
Humalog Kwikpen 100 U/ml  
Humalog Kwikpen 200 U/ml (Concentrated Insulin)*  
Admelog 100 U/ml solution  
Admelog 100 U/ml Solostar prefilled pens | • Humulin R Vial  
• Humalog Vial NF  
*When converting from Humalog U-200 to Humulin R or Humalog U-100, no dose conversion is needed | Humalog/Admelog to Humulin R is a 1:1 Conversion  
Humalog 10 ml vial is ~2X the cost of Humulin R vial  
Admelog Solostar pen is ~6X the cost of Humalog Kwikpen |

### In the News. . .

Evidence from traditional randomised controlled trials (RCTs) may be declining as smaller patient populations make it harder to design studies, and the costs of conducting RCTs are rising. Interest in pragmatic clinical trials (PCTs) that combine randomisation with more real world circumstances has grown with the potential use of routine data sources to record patient events and outcomes, transforming the costs, size and feasibility of such trials. This changing landscape is creating new opportunities for the use of real world evidence.

The Institute for Clinical and Economic Review (ICER), in collaboration with the Office of Health Economics (OHE), has released two new white papers to provide guidance to payers and manufacturers on the development and use of real world evidence for drug coverage and formulary decisions. These papers were developed as part of the annual ICER Policy Summit, where life science and payer organizations meet to develop collaborative approaches to addressing key policy issues related to the generation and application of evidence to improve value in the US health care system.

The first paper, entitled *Real World Evidence for Coverage Decisions: Opportunities and Challenges*, highlights the challenges associated with wider use of real world evidence, including increased potential for bias, the risks of incomplete data, and the lack of universally accepted methodological standards.

A companion paper, *Understanding the context, Selecting the Standards: A Framework to Guide the Optimal Development and Use of Real World Evidence for Coverage and Formulary Decisions*, provides specific steps to help both manufacturers and payers meet the challenge of developing observational real world evidence through a transparent process that can be considered credible by all stakeholders.