



EXPRESS SCRIPTS®

**Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings**

September 1, 2017 Ballot Vote and September 14, 2017 Meeting

New Drug Evaluations

The Committee reviewed the following new drugs.

- A. **Baxdela™ (delafloxacin tablets for oral use)** Melinta Therapeutics
- B. **Benlysta® (belimumab injection for subcutaneous [SC] use)** Human Genome Sciences, Inc./GlaxoSmithKline
- C. **Besponsa™ (inotuzumab ozogamicin injection for IV use)** Wyeth/Pfizer
- D. **Endari™ (L-glutamine oral powder)** Emmaus Medical, Inc.
- E. **Idhifa® (enasidenib tablets)** Celgene/Agios
- F. **Mavyret™ (glecaprevir/pibrentasvir tablets)** AbbVie
- G. **Nerlynx™ (neratinib tablets)** Puma Biotechnology, Inc.
- H. **Triptodur™ (triptorelin for extended-release injectable suspension)** Arbor Pharmaceuticals
- I. **Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir tablets)** Gilead

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

- A. **CaroSpir® (spironolactone oral suspension)** CMP Pharma
- B. **Duzallo® (lesinurad and allopurinol tablets)** Ironwood
- C. **Flolipid® (simvastatin oral suspension)** Salerno
- D. **Gocovri™ (amantadine extended release capsules)** Adamas
- E. **Kedrab™ (rabies immune globulin [human] injection)** Kedrion Biopharma/Kamada
- F. **Lynparza® (olaparib tablets)** AstraZeneca/Merck
- G. **Nityr™ (nitisinone tablets)** Cycle Pharmaceuticals
- H. **Qvar® RediHaler™ (beclomethasone dipropionate HFA inhalation aerosol)** Teva
- I. **Vyxeos™ (daunorubicin and cytarabine liposome for IV injection)** Jazz Pharmaceuticals

New Indications for Existing Products

The Committee reviewed the following new indications for existing products: See product inserts for specific wording.

- A. **Abilify Maintena® (aripiprazole for extended-release injectable suspension)** Otsuka/Lundbeck – New indication for the maintenance monotherapy treatment of bipolar I disorder in adults.
- B. **Amitiza® (lubiprostone capsules)** Takeda/ Sucampo – Clarification of the opioid-induced constipation (OIC) indication to state that these medications are indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.



Public Information

- C. **Blincyto[®] (blinatumomab injection, for intravenous [IV] use)** Amgen – Expanded indication for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia in adults and children.
- D. **Epclusa[®] (sofosbuvir 400mg/velpatasvir 100mg tablets)** Gilead – Expanded patient population to include treatment of chronic hepatitis C virus infection in patient coinfecting with human immunodeficiency virus type 1 (HIV-1).
- E. **Faslodex[®] (fulvestrant injection)** AstraZeneca – New indication for use as monotherapy in women with hormone-receptor positive, human epidermal growth factor receptor 2 negative advanced breast cancer, who have gone through menopause and have not received previous endocrine therapy.
- F. **Flovent[®] Diskus[®] (fluticasone propionate inhalation powder)** GlaxoSmithKline – Removed indication for patients requiring oral corticosteroid therapy for asthma, and also the statement that many of these patients may be able to reduce or eliminate their requirement for oral corticosteroids over time.
- G. **Flovent[®] HFA (fluticasone propionate Inhalation aerosol)** GlaxoSmithKline – Removed indication for patients requiring oral corticosteroid therapy for asthma, and also the statement that many of these patients may be able to reduce or eliminate their requirement for oral corticosteroids over time.
- H. **Fycompa[®] (perampanel tablets and oral suspension)** Eisai – New indication as monotherapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged ≥ 12 years.
- I. **Imbruvica[®] (ibrutinib capsules)** Pharmacyclics/ Janssen – New indication for the treatment of adult patients with chronic graft-versus-host disease after failure of one or more lines of systemic therapy.
- J. **Kalydeco[®] (ivacaftor tablets and oral granules)** Vertex – Expanded indication for the treatment of cystic fibrosis in patients ≥ 2 years of age who have one mutation in the cystic fibrosis transmembrane regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.
- K. **Liletta[®] (levonorgestrel-releasing intrauterine system)** Medicines360 – Expanded duration of use for prevention of pregnancy for up to 4 years. The system should be replaced after 4 years if continued use is desired.
- L. **Movantik[®] (naloxegol tablets)** AstraZeneca – Clarification of the opioid-induced constipation (OIC) indication to state that these medications are indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
- M. **Opdivo[®] (nivolumab injection)** Bristol-Myers Squibb – New indication for the treatment of adult and pediatric patients ≥ 12 years of age with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
- N. **Relistor[®] (methylnaltrexone bromide tablets and subcutaneous injection)** Salix Pharmaceuticals – Clarification of the opioid-induced constipation (OIC) indication to state that these medications are indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
- O. **Symproic[®] (naldemedine tablets)** Shionogi – Clarification of the opioid-induced constipation (OIC) indication to state that these medications are indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
- P. **Victoza[®] (liraglutide subcutaneous injection)** Novo Nordisk – New indication to reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or

non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

- Q. Vimovo® (naproxen and esomeprazole magnesium delayed-release tablets)** Horizon Pharma – Expanded age indication for use in adult and adolescent patients ≥ 12 years of age weighing at least 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers.
- R. Yervoy® (ipilimumab injection) Bristol-Myers Squibb** – Expanded age indication for the treatment of unresectable or metastatic melanoma in adults and pediatric patients (≥ 12 years of age).

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