EXPRESS SCRIPTS®

Express Scripts Holding Company
Pharmacy and Therapeutics Committee
Proceedings
July 15, 2017

New Drug Evaluations

The Committee reviewed the following new drugs.

A. **Bevyxxa™ (betrixaban capsules)** Portola Pharmaceuticals
B. **Brineura™ (cerliponase alfa injection for intraventricular use)** BioMarin
C. **Haegarda® (C1 esterase inhibitor [human] for subcutaneous injection)** CSL Behring
D. **Imfinzi™ (durvalumab intravenous infusion)** AstraZeneca
E. **Kevzara™ (sarilumab subcutaneous injection)** Sanofi-Aventis/ Regeneron
F. **Noctiva™ (desmopressin acetate nasal spray for intranasal use [0.83 mcg/0.1 mL and 1.66 mcg/0.1 mL])** Serenity
G. **Odactra™ (house dust mite allergen extract tablet for sublingual use)** Merck/ALK-Abello
H. **Radicava™ (edaravone intravenous infusion)** Mitsubishi Tanabe Pharma
I. **Rituxan Hycela™ (rituximab and hyaluronidase human injection for subcutaneous use)** Biogen and Genentech/Roche
J. **Symproic® (naldemedine tablets)** Shionogi/Purdue
K. **Tremfya™ (guselkumab for subcutaneous injection)** Janssen Biotech/Johnson & Johnson

New Clinical Line Extensions

The Committee reviewed the following new clinical line extensions.

A. **Cotempla XR-ODT™ (methylphenidate extended-release orally disintegrating tablets)** Neos Therapeutics
B. **Isentress® HD (raltegravir 600 mg tablets)** Merck
C. **Jadenu® Sprinkles (deferasirox oral granules)** Novartis
D. **Mydayis™ (mixed salts of a single-entity amphetamine product extended-release capsules)** Shire
E. **Norvir® (ritonavir oral powder)** AbbVie
F. **Symjepi™ (epinephrine injection, for intramuscular or SC use)** Adamis

New Indications for Existing Products

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

A. **Actemra® (tocilizumab subcutaneous injection)** Genentech – New indication for the treatment of giant cell arteritis in adult patients.
B. **Aerospan® (flunisolide inhalation aerosol)** Meda – Removed indication for asthma patients requiring oral corticosteroid therapy, where adding Aerospan inhalation aerosol may reduce or eliminate the need for oral corticosteroids.
C. **Darzalex® (daratumumab injection)** Janssen – New indication in combination with Pomalyst® (pomalidomide capsules) and dexamethasone for the treatment of patients with

multiple myeloma who have received at least two prior therapies including Revlimid® (lenalidomide capsules) and a proteasome inhibitor.

D. **Dysport® (abobotulinumtoxinA injection)** Ipsen – Expanded indication for the treatment of spasticity in adult patients.
E. **Kalydeco® (ivacaftor tablets)** 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 gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.
F. **Kalydeco® (ivacaftor 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 gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.
G. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication for use in combination with Alimta® (pemetrexed injection) and carboplatin, as first-line treatment of patients with metastatic nonsquamous NSCLC.
H. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.
I. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
J. **Keytruda® (pembrolizumab injection for intravenous use)** Merck – New indication for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
K. **Mekinist® (trametinib tablets)** Novartis – New indication in combination with Tafinlar, for the treatment of patients with metastatic NSCLC with BRAF V600E mutation as detected by an Food and Drug Administration (FDA)-approved test. A new limitation of use is that Mekinist is not indicated for treatment of patients with melanoma who have progressed on prior BRAF-inhibitor therapy.
L. **Mirena® (levonorgestrel-releasing intrauterine system)** Bayer – Change to the indication to remove the recommendation, "for use in women who have had at least one child". Mirena is indicated for intrauterine contraception for up to 5 years and for the treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception.
M. **Orencia® (abatacept subcutaneous injection)** Bristol-Myers Squibb – New indication for the treatment of adult patients with active psoriatic arthritis with or without non-biologic disease-modifying antirheumatic drug.
N. **Orencia® (abatacept intravenous injection)** Bristol-Myers Squibb – New indication for the treatment of adult patients with active psoriatic arthritis with or without non-biologic disease-modifying antirheumatic drugs.
O. **Tafinlar® (dabrafenib capsules) Novartis** – New indication in combination with Mekinist, for the treatment of patients with metastatic nonsmall cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. A new limitation of use is that Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF NSCLC.
P. **Vectibix® (panitumumab injection for intravenous use)** Amgen – Expanded indication for the treatment of patients with wild-type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC) as first-line therapy in combination with FOLFOX (5-fluorouracil, leucovorin, oxaliplatin) or as

monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy. Vectibix is not indicated for the treatment of patients with RAS-mutant mCRC or for whom RAS mutation status is unknown.

Q. **Zykadia® (ceritinib capsules)** Novartis – Expanded indication for the treatment of patients with metastatic NSCLC whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.