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Drug Information Updates

Reblozyl Approved for Second Indication **04/04/2020**

Bristol Myers Squibb and Acceleron Pharma's Reblozyl® (luspatercept-aamt) gained approval for a second indication from the FDA. Reblozyl, an erythroid maturation agent (EMA), was first approved on Nov. 8, 2019, to treat anemia for adult patients who have beta thalassemia and who need regular transfusions of red blood cells (RBCs). The new approval is to treat anemia for adults who have tried an erythropoiesis stimulating agent (ESA), such as Epogen® but who still require two or more units of RBCs over eight weeks. Reblozyl is given as subcutaneous (SC) injection once every three weeks at a starting dose of 1mg/kg.

Formulary Status: Reblozyl is not covered under the pharmacy benefit as it is administered in a healthcare setting

New Indication for Braftovi **04/08/2020**

Braftovi® (encorafenib), an oral small-molecule kinase inhibitor from Pfizer, was given a new FDA indication, in combination with Erbitux® (cetuximab – Eli Lilly) solution for injection, for previously treated patients who have metastatic colorectal cancer (CRC) that tests positive for $BRAF^{V600E}$ mutations. In combination with Mektovi® (binimetinib - Pfizer), Braftovi also is approved to treat BRAF-mutated metastatic or inoperable melanoma. The FDA expedited approval for the new indication under its Priority Review and Breakthrough Therapy programs.

Formulary Status: Braftovi is not covered under the pharmacy benefit as it is administered in a healthcare setting.

Controlled Substance Designation Removed for Epidiolex **04/06/2020**

GW Pharmaceuticals disclosed that the DEA has removed Epidiolex® (cannabinol) oral solution from the federal schedule of controlled substances. Approved in June 2018, Epidiolex, a marijuana derivative sold in the U.S by GW's subsidiary, Greenwich Biosciences, Epidiolex is used to treat children two years of age and older with Lennox-Gastaut syndrome or Dravet syndrome, which are rare forms of epilepsy.

Formulary Status: Epidiolex is a non-preferred brand specialty product only approved for LGS and DS.

Koselugo Approved for Neurofibromatosis **04/10/2020**

The FDA approved Koselugo® (selumetinib) capsules to treat neurofibromatosis type 1 (NF1), a rare genetic condition caused by mutations in specific genes that control cell formation in the nervous system. NF1 results in small, slow-growing, non-cancerous tumors around nerves, on the skin or just underneath the skin which often cannot be removed by surgery. Koselugo inhibits mitogen-activated protein kinase (MEK), an enzyme that promotes the growth and spread of tumor cells. Koselugo is the first drug approved to treat any form of NF1, and will be launched during April at a cost of approximately $130,000 per year.

Formulary Status: Koselugo will be reviewed at the next P&T Committee meeting in June.

Additional Notices

04/09/2020 – First generic approved for Proventil HFA

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

04/24/2020 – MenQuadfi™ (meningococcal (groups A, C, Y, W) polysaccharide tetanus toxoid conjugate vaccine – Sanofi): Vaccine to help prevent meningococcal meningitis; IM injection

04/26/2020 – Ongentys® (opicapone - Neurocrine): Once-daily, highly-selective catechol-o-methyltransferase (COMT) inhibitor for use as an adjunctive treatment to levodopa/carbidopa to treat adult patients who have Parkinson's disease and motor fluctuations; oral therapy

GENERAL INFORMATION:

For more information, please either visit FDA.gov or contact your account manager.