Supplemental Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
February 28, 2018	
Tezacaftor/ivacaftor and ivacaftor ***(Symdeko—Vertex Pharmaceuticals)*** **Agent treats cystic fibrosis in some patients aged 12 years and older**	FDA approved tezacaftor/ivacaftor and ivacaftor for treating the underlying cause of cystic fibrosis (CF) in people aged 12 and older who have two copies of the *F508del* mutation in the CF transmembrane conductance regulator (CFTR) gene or who have at least one mutation that is responsive to tezacaftor/ivacaftor. The most common adverse effects of tezacaftor/ivacaftor and ivacaftor include headache, nausea, sinus congestion, and dizziness. The agent can cause serious adverse effects, including high liver enzymes in the blood, which have been reported in people treated with tezacaftor/ivacaftor and ivacaftor or treated with ivacaftor alone. Patients will need blood tests to check their liver before they start tezacaftor/ivacaftor and ivacaftor, every 3 months during the first year of taking the agent, and every year thereafter while taking it. Patients should call their doctor right away if they have any of the following symptoms of liver problems: pain or discomfort in the upper right abdominal area; yellowing of the skin or the white of the eyes; loss of appetite; nausea or vomiting; or dark, amber-colored urine. Cataracts have occurred in some children and adolescents treated with tezacaftor/ivacaftor and ivacaftor or with ivacaftor alone. Patients should avoid food or drink that contains grapefruit or Seville oranges while taking the agent. Vertex offers copay assistance program for patients with insurance coverage and a free medicine program for qualifying patients who are uninsured and meet certain income and other eligibility criteria. More information is available by visiting www.VertexGPS.com or by calling 877-752-5933.

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