Centers for Medicare & Medicaid Services
Center for Medicare Management
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Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2022

Note: The information provided on this tracking form will be made publicly available.

1. Technology Name: Veklury (remdesivir)

2. Manufacturer Name: Gilead Sciences, Inc.

3. Trade Brand of Technology: Veklury®

4. A) Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)?

   No, Veklury is a drug and therefore does not qualify for Breakthrough Device designation.

   B) Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)? If yes, specify if QIDP or LPAD.

   No, Veklury has not been designated by the FDA as a QIDP or LPAD.

5. Brief Description of Service, Device or Drug:

   Veklury is an investigational nucleotide analog with broad-spectrum antiviral properties, demonstrating activity countering viral pathogens such as MERS, SARS, and SARS-CoV-2, the virus responsible for COVID-19.

   The FDA has recently authorized the emergency use of Gilead's Veklury to treat hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19. Gilead submitted a new drug application (NDA) on August 7, 2020 for Veklury for treatment of COVID-19 and has received Fast Track designation and Priority Review.

   Veklury has been tested in randomized, double blind, placebo controlled clinical trial for its efficacy in treating COVID-19 with a primary outcome of reduced time to recovery including in severe and critical disease. Veklury shortened the time to recovery for patients with COVID-19 by a median of 5 days compared to placebo.