Prior Authorization Protocol

Medicare Part D – 2016

Prior Authorization Group Description:

DAKLINZA

Covered Uses:

All FDA-approved indications not otherwise excluded from Part D. For the treatment of hepatitis C virus genotype 2 and recurrent HCV infection post-liver transplantation in Genotypes 1, 2, 3, 4. Criteria will be applied consistent with current AASLD-IDSA guidance.

Exclusion Criteria:

Required Medical Information:

Refer to the document, "Recommendations for Testing, Managing, and Treating Hepatitis C," by AASLD-IDSA available at http://www.hcvguidelines.org for drug regimen and duration of treatment based on genotype, treatment status, previous drug regimens used, past medical history and comorbidities.

Age Restrictions:

Prescriber Restrictions:

Gastroenterologist, Hepatologist or Infectious Disease physician

Coverage Duration:

12 to 24 weeks based on genotype, prior treatment, or cirrhosis status.

Other Criteria:

Must be used in combination with Sovaldi. Genotype 1: Failure or clinically significant adverse effects to Harvoni (sofosbuvir/ledipasvir). Genotype 2: Failure or clinically significant adverse effects to sofosbuvir/ribavirin.