Medicare Part D – 2016

Prior Authorization Group Description
SOVALDI

Covered Uses:
All FDA-approved indications not otherwise excluded from Part D. For the treatment of hepatitis C virus genotypes 5 and 6.

Exclusion Criteria:

Required Medical Information:
Diagnosis of chronic hepatitis C (CHC) and genotype 1, 2, 3, 4, 5 or 6 confirmed by detectable serum hepatitis C virus RNA by quantitative assay OR For treatment of CHC in patients with hepatocellular carcinoma (HCC) meeting Milan criteria (awaiting liver transplantation): Milan criteria is defined as the presence of a tumor 5 cm or less in diameter in patients with single hepatocellular carcinomas and no more than three tumor nodules, each 3 cm or less in diameter in patients with multiple tumors and no extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor.

Age Restrictions:

Prescriber Restrictions:
Gastroenterologist, hepatologist or infectious disease physician

Coverage Duration:
CHC GT 1,2,3,4,5 or 6: 12 to 24 weeks or HCC with CHC: up to 48 weeks or until liver transplantation

Other Criteria:
Sovaldi, Olysio for 12 weeks: Liver transplant patients with genotype 1 in allograft with or without compensated cirrhosis. Sovaldi, Daklinza for 12 weeks: For genotype 1 only: Failure or clinically significant adverse effects to Harvoni (sofosbuvir/ledipasvir), Genotype 1 or 4 with decompensated cirrhosis (including those with hepatocellular carcinoma), Genotype 1, 2, 3 or 4 infection in the allograft including those with compensated cirrhosis, Genotype 1 treatment naive or treatment experienced with Peg-IFN/RBV with or without protease inhibitor and without cirrhosis, Genotype 2 treatment naive without cirrhosis AND unable to tolerate RBV, Genotype 3 treatment naive or treatment experienced with Peg IFN/RBV without cirrhosis. Sovaldi, Daklinza for 24 weeks: For genotype 2 only: Failure or clinically significant adverse effects to sofosbuvir/ribavirin, Genotype 1 or 4 with decompensated cirrhosis (including those with hepatocellular carcinoma) and intolerant of RBV, Genotype 1, 2, 3 or 4 infection in the allograft including those with compensated cirrhosis and intolerant of RBV, Genotype 1 treatment naive or treatment experienced with Peg-IFN/RBV with or without protease inhibitor and with cirrhosis, Genotype 2 who are not eligible to receive IFN in whom previous treatment with Sovaldi/RBV has failed, Genotype 3 who are not eligible to receive IFN in whom previous treatment with Sovaldi/RBV has failed, Genotype 3 treatment naive or treatment experienced with Peg IFN/RBV with cirrhosis. Sovaldi, RBV for 12 weeks: Genotype 2 treatment naive without cirrhosis. Sovaldi, RBV for 16 weeks: Genotype 2 treatment naive with cirrhosis. Sovaldi, RBV for 24 weeks: Genotype 3 treatment naive, Genotype 4 treatment naive or experienced, Liver transplant patient with genotype 2 in the allograft including compensated cirrhosis, Liver transplant patient with genotype 3 in the allograft including compensated cirrhosis, Liver transplant patient with genotype 3 treatment-naive and -experienced liver transplant recipients with infection in the allograft with decompensated cirrhosis (Child Turcotte Pugh class B or C). Sovaldi, RBV for 48 weeks or until liver transplantation, whichever occurs first: Hepatocellular carcinoma patients awaiting liver transplantation. Sovaldi, RBV up to 48 weeks: Genotype 2 or 3 with decompensated cirrhosis (moderate or severe hepatic impairment: CTP class B or C) who may or may not be candidates for liver transplantation including those with hepatocellular carcinoma). Sovaldi, RBV, PEG-IFN 12 weeks: Genotype 4, 5, or 6 treatment experienced or treatment naive.