Infergen
(interferon alfacon-1)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Hepatitis C is a viral disease caused by the hepatitis C virus (HCV) that leads to inflammation of the liver. Most people who were recently infected with hepatitis C do not have symptoms, but most people infected with hepatitis C develop a chronic infection. Untreated, chronic infection can lead to liver cirrhosis and/or liver cancer. Six genotypes of the hepatitis C virus exist and genotyping is essential to effective treatment. Hepatitis C infection may be detected in the blood by the HCV RNA assay. Disease status may be monitored by assays of biochemical liver tests or liver biopsy.

The goals of HCV treatment are to remove the virus from the blood and reduce the risk of cirrhosis and liver cancer that can result from long-term HCV infection. The most common treatment regimens are based on combinations of pegylated interferon alfa, ribavirin, and the protease inhibitors, telaprevir and boceprevir. In some cases, treatment with a single agent or two agents is most appropriate.

Regulatory Status
FDA-approved indication: Infergen (interferon alfacon-1) is indicated for treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease. This indication is based on clinical trials conducted using Infergen alone at a time before combination treatment of chronic hepatitis C became the standard of care, and on a single trial evaluating Infergen in combination with ribavirin in patients who failed to respond to previous treatment with a pegylated interferon and ribavirin. Use of monotherapy with an interferon such as Infergen for the treatment of hepatitis C is not recommended unless a patient is unable to take ribavirin (1).

Limitation of use: The safety and efficacy of the combination of Infergen /ribavirin in treatment-naïve patients or in patients co-infected with HBV or HIV-1 have not been evaluated. Patients with the following characteristics are less likely to benefit from retreatment with Infergen /ribavirin combination therapy: response of <1 log_{10} drop HCV RNA on previous treatment, Genotype 1, high viral load (≥850,000 IU/mL), African American race, and/or presence of cirrhosis (1).

Copegus is a nucleoside analogue indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with Pegasys in patients 5 years of age and older with compensated liver disease.
Infergen
(interferon alfacon-1)
disease not previously treated with interferon alpha, and in adult CHC patients coinfectected with HIV (6).

Ribasphere (ribavirin, USP) is a nucleoside analogue indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with peginterferon alfa-2a in adults with compensated liver disease not previously treated with interferon alpha, and in CHC patients coinfectected with HIV (7).

Summary
Hepatitis C is a viral disease caused by the hepatitis C virus (HCV) that leads to inflammation of the liver. Untreated, chronic infection can lead to liver cirrhosis and/or liver cancer. The most common treatment regimens are based on combinations of pegylated interferon alfa, ribavirin, and the protease inhibitors, telaprevir and boceprevir. In some cases, treatment with a single agent or two agents is most appropriate.

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Infergen and ribavirin while maintaining optimal therapeutic outcomes.

References