PRIOR AUTHORIZATION POLICY

POLICY: Pegylated Interferons Prior Authorization Policy
- Pegasys® (peginterferon alfa-2a injection for subcutaneous use – Hoffman-La Roche/Genentech)
- PegIntron® (peginterferon alfa-2b injection for subcutaneous use – Schering)

REVIEW DATE: 10/14/2020

OVERVIEW

Pegasys and PegIntron are pegylated interferons (peginterferons) indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults and children.[1-2] Pegasys (alone or in combination with ribavirin) and PegIntron (in combination with ribavirin) are indicated for the treatment of chronic HCV in patients ≥ 5 years of age and ≥ 3 years of age, respectively, with compensated liver disease previously untreated with interferon alfa. In the past, the standard of care for patients with HCV consisted of peginterferon and ribavirin generally administered for 24 to 48 weeks depending on patient factors and genotype. However, with the approval of direct-acting antivirals, pegylated interferons no longer have a role in the management of HCV for adults or pediatric patients.

Guidelines

Peginterferons are no longer addressed by the American Association for the Study of Liver Diseases recommendations for testing, managing, and treating HCV.[3] Further, direct-acting antiviral treatment with an approved regimen is recommended for all children and adolescents with HCV infection ≥ 3 years of age as they will benefit from antiviral therapy, regardless of disease severity.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Pegasys and PegIntron (collectively referred to as "peginterferons" in these criteria) for HCV infection. The intent of this policy is to provide recommendations for use in **hepatitis C *only***. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with the peginterferons as well as the monitoring required for adverse events AEs and efficacy, approval requires peginterferons to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pegasys and PegIntron (peginterferon[s]) is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6.** Approve for up to 48 weeks in patients who meet all of the following criteria (A, B, and C):
   A) Patient is ≥ 2 years of age; AND
   B) The medication is prescribed in combination with ribavirin; AND

C) The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or liver transplant physician.

Other Uses with Supportive Evidence (in the Treatment of Hepatitis C)

2. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Pediatric and Adolescent (≥ 2 Years and ≤ 17 Years of Age)**. Approve for 48 weeks in patients who meet all of the following criteria (A, B, and C):
   A) Patient is ≥ 2 years of age and < 17 years of age; AND
   B) The medication is prescribed in combination with ribavirin unless there is a contraindication or intolerance to ribavirin according to the prescriber; AND
   C) The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: a gastroenterologist, hepatologist, infectious diseases physician, or liver transplant physician.

3. **Chronic Hepatitis C Virus (HCV) – Awaiting Liver Transplantation, Any Viral Genotype - Pediatric and Adolescents (≥ 2 years and ≤ 17 years of age).** Approve for 12 months in patients who meet all of the following criteria (A, B, and C):
   A) Patient is ≥ 2 years of age and ≤ 17 years of age; AND
   B) The medication is prescribed in combination with ribavirin unless there is a contraindication or intolerance to ribavirin according to the prescriber; AND
   C) The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a liver transplant center: a gastroenterologist, hepatologist, infectious diseases physician, or liver transplant physician.

4. **Patient has Been Started on Pegasys.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications or Other Uses with Supportive Evidence). Authorization duration will vary based on the indication but should not exceed a total duration of 12 months.

5. **Patient has Been Started on PegIntron.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications or Other Uses with Supportive Evidence). Authorization duration will vary based on the indication but should not exceed a total duration of 12 months.

6. **Indications Other Than Hepatitis C.** Approve for 12 months. Pegasys and PegIntron have been used for many off-label indications in adults and for few indications in children.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Pegasys and PegIntron (peginterferon[s]) is not recommended in the following situations:

1. **Hepatitis C Virus (HCV), Maintenance Therapy.** Evidence does not support use. Major published trials have failed to demonstrate a consistent benefit of maintenance therapy in the prevention of hepatocellular carcinoma (HCC).[3-7]

2. **Life Expectancy < 12 Months Due to Non-Liver Related Co-Morbidities.** Patients with a limited life expectancy that cannot be remediated by HCV treatment, liver transplantation, or another directed therapy do not require antiviral treatment.[3] Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert. Little evidence exists to support initiation of HCV treatment in patients with a limited life expectancy (< 12 months) owing to non-liver-related comorbid

conditions. For these patients, the benefits of HCV treatment are unlikely to be realized and palliative care strategies should take precedence.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Pegasys® injection [package insert]. Nutley, NJ: Hoffman-La Roche Pharmaceuticals; October 2017.
2. PegIntron® powder for injection [package insert]. Kenilworth, NJ: Schering Corporation; August 2019.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Updated November 6, 2019. Available at: http://www.hcvguidelines.org. Accessed on: August 20, 2020.
4. Mack CL, Gonzalez-Peralta RP, Gupta N, et al. North American Society for Pediatric Gastroenterology, Hepatology and Nutrition Practice Guidelines: Diagnosis and Management of Hepatitis C Infection in Infants, Children and Adolescents. *J Pediatr Gastroenterol Nutr*. 2012;54(6):838-55.
5. Sherman KE, Anderson JW, Butt A, et al for the AIDS Clinical Trials Group A5178 Study Team. Sustained long-term antiviral maintenance therapy in HCV/HIV co-infected patients (SLAM-C). *J Aquir Immune Defic Syndr*. 2010;55(5):597-605
6. Lok AS, Everhart JE, Wright EC, et al; HALT-C Trial Group. Maintenance peginterferon therapy and other factors associated with hepatocellular carcinoma in patients with advanced hepatitis C. *Gastroenterology*. 2011;140(3):840-849.
7. Di Bisceglie AM, Stoddard AM, Dienstag JL, et al; and The HALT-C Trial group. Excess mortality in patients with advanced chronic hepatitis C treated with long-term peginterferon. *Hepatology*. 2011;53(4):1100-1108.