



# Louisiana

## Pegylated Interferons (Pegasys<sup>®</sup>, PegIntron<sup>®</sup>) for Other (Non-Hepatitis C) Uses

**Policy #** 00375

Original Effective Date: 11/01/2013

Current Effective Date: 10/17/2018

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Returned to Active Status: 10/17/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Treatment of Hepatitis C with Dual Therapy (Ribavirin Plus Pegylated Interferon Alfa) is addressed separately in medical policy 00374.*

*Note: Treatment of Hepatitis C with a sofosbuvir (Sovaldi<sup>®</sup>) Based Regimen is addressed separately in medical policy 00397.*

### When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

### Chronic Hepatitis B

Based on review of available data, the Company may consider use of pegylated interferon alfa-2a (Pegasys<sup>®</sup>)<sup>‡</sup> or pegylated interferon alfa-2b (PegIntron<sup>®</sup>)<sup>‡</sup> to be **eligible for coverage** for the treatment of chronic hepatitis B.

#### Patient Selection Criteria

Coverage eligibility for the treatment of chronic hepatitis B with pegylated interferon alfa-2a (Pegasys) or pegylated interferon alfa-2b (PegIntron) for 48 weeks will be considered when all of the following criteria are met:

- Patient is ≥ 18 years of age; and
- Patient has a confirmed diagnosis of compensated chronic hepatitis B; and
- Patient has not received previous treatment with pegylated interferon therapy.

### Other Indications

Based on review of available data, the Company may consider the use of pegylated interferon alfa-2a (Pegasys) or pegylated interferon alfa-2b (PegIntron) for certain other off-label indications to be **eligible for coverage** based on the below patient selection criteria.

#### Patient Selection Criteria

Coverage eligibility for the treatment of certain other off-label indications with pegylated interferon alfa-2a (Pegasys) or pegylated interferon alfa-2b (PegIntron) will be considered when one of the following criteria is met:

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- Patient has a diagnosis of chronic myeloid leukemia (CML); or
- Patient has a diagnosis of essential thrombocythemia

### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of pegylated interferon alfa-2a (Pegasys) or pegylated interferon alfa-2b (PegIntron) when patient selection criteria are not met or for indications not listed in the patient selection criteria to be **investigational**.\*

### **Background/Overview**

Pegylated interferons (Pegasys and PegIntron) are used as one of the main components for the treatment of chronic hepatitis C virus. They are often paired with ribavirin in dual therapy. In triple therapy for chronic hepatitis C, they are often paired with ribavirin and a protease inhibitor, such as Incivek or Victrelis. There are however, other uses for the pegylated interferons. Pegasys (pegylated interferon alfa-2a) is indicated for use in chronic hepatitis C as well as for use as monotherapy in patients with chronic hepatitis B virus. PegIntron (pegylated interferon alfa-2b) is currently only indicated for the treatment of chronic hepatitis C virus.

### **Hepatitis B**

There are an estimated 1.25 million hepatitis B carriers in the United States. Carriers of Hepatitis B are at an increased risk of developing cirrhosis, hepatic decompensation, and hepatocellular carcinoma. It is estimated that 15-40% of carriers of hepatitis B will develop some sort of serious sequelae during their lifetime. Hepatitis B is often transmitted parenterally (by either contaminated blood or blood products) but can also be spread through sex partners and in closed institutions.

### **Other Uses**

There is literature on the usage of pegylated interferons for the treatment of patients with CML. There is also literature on its usage in patients with essential thrombocythemia.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Pegasys (pegylated interferon alfa-2a) was approved by the FDA in 2002. It carries indications for both Hepatitis C and Hepatitis B Virus. Peg-Intron (pegylated interferon alfa-2b) was approved by the FDA in 2001. It carries an indication for the treatment of hepatitis C.

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### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Pegylated interferon alfa-2a (Pegasys) 180mcg weekly was studied in a Phase III trial as monotherapy vs. pegylated interferon alfa-2a 180mcg weekly plus lamivudine 100mg daily vs. lamivudine 100mg daily as monotherapy for 48 weeks. HBeAg seroconversion was similar in the three groups at the end of treatment: 27%, 24%, and 20%, respectively, but the HBeAg seroconversion was significantly higher in the two groups that received pegylated interferon alfa-2a therapy when assessed 24 weeks after therapy was stopped (32%, 27%, and 19%, respectively). The data indicated that the pegylated interferon alfa-2a monotherapy was superior to lamivudine monotherapy and comparable to pegylated interferon alfa-2a plus lamivudine combination therapy in sustaining HBeAg seroconversion. There have also been studies looking at the efficacy of pegylated interferon alfa-2b for the treatment of patients with hepatitis B that have somewhat similar results as pegylated interferon alfa-2a.

There is also evidence of using pegylated interferon alfa in patients with CML. In CML, the interferon class has typically shown evidence of cytogenetic response and improved survival. This has been test in pegylated interferon alfa as well. A number of studies also exist for the use of pegylated interferon alfa in the treatment of essential thrombocythemia. Data shows that pegylated interferon alfa decreased the platelet count in patients with essential thrombocythemia and maintained the lower platelet count throughout treatment. Length of therapy depends on the patient's tolerance to the pegylated interferon alfa since it can typically cause unpleasant adverse events.

### **References**

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5. Samuelsson J, Hasselbalch H, Bruserud O, et al. A Phase II Trial of Pegylated Interferon alfa 2b Therapy for Polycythemia Vera and Essential Thrombocythemia. *Cancer*. 2006;106: 2397-2405.
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09/05/2013 Medical Policy Committee review  
 09/18/2013 Medical Policy Implementation Committee approval. New policy. One of three policies that replace medical policies 00171 Treatment of Hepatitis C and B with Pegylated Interferon and/or Ribavirin and 00310 Treatment of Hepatitis C with Pegylated Interferon, Ribavirin and/or Telaprevir (Incivek) and Boceprevir (Victrelis).  
 09/04/2014 Medical Policy Committee review  
 09/17/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
 01/06/2015 Policy reposted with corrections to clerical error.  
 09/03/2015 Medical Policy Committee review  
 09/23/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
 09/08/2016 Medical Policy Committee review  
 09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
 09/07/2017 Medical Policy Committee review. Recommend archiving policy.  
 09/20/2017 Medical Policy Implementation Committee approval. Archived.  
 10/04/2018 Medical Policy Committee review.  
 10/17/2018 Medical Policy Implementation Committee approval. Returned to active status with coverage eligibility unchanged.

Next Scheduled Review Date: 10/2019

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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