MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	09/26/2016	09/22/2015

Policy Name	Policy Number
Pegylated and Non-Pegylated Interferon (alfa-2a: Pegasys, alfa-2b: PegIntron, interferon alfa-2b: Intron A)	**SRx-0037**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

- Pegylated Interferon
  - **alfa-2a (Pegasys)**
  - **alfa-2b (PegIntron)**
- Non-Pegylated Interferon
  - **Interferon alfa-2b (Intron A)**

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the interferon medication (PA) Program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

CareSource will approve the use of peginterferon alfa-2a (Pegasys) and peginterferon alfa-2b (PegIntron) and consider its use as **medically necessary** when **ALL** of the following criteria have been met for:

I. **Chronic Hepatitis C**

Prior Authorization Criteria:

A. Documented diagnosis of Hepatitis C
B. Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
C. Negative pregnancy test for female of child bearing potential
D. Not currently enrolled in hospice
E. Not currently participating in alcohol abuse or illicit substance abuse:
    1. One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
    2. Previous abusers must meet **ALL** the following:
        a. Enrolled for at least 6 months in counseling services or receiving therapy from an addiction specialist prior to starting hepatitis treatment – Documentation must be provided
        b. Confirmed current monthly negative urine drug and alcohol screen for **3 (three)** consecutive months
F. Provided detectable HCV RNA levels are higher than 50 IU/ml
G. Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest-ActiTest panel or Fibroscan only
H. Must be in combination with ribavirin and a DAA (Direct Acting Agent)

II. **Chronic Hepatitis B**

Prior Authorization Criteria:

A. Documented diagnosis of compensated chronic hepatitis B (Hep B surface antigen positive for at least **6 (six)** months or Hep B viral DNA level greater than (20,000 IU/ml,100,000 copies/ml)
B. Prescribed by a gastroenterologist, infectious disease specialist or hepatologist
C. Not currently participating in alcohol abuse or illicit substance abuse:
    1. One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
    2. Previous abusers must meet **ALL** the following:
        c. Enrolled for at least **6 (six)** months in counseling services or receiving therapy from an addiction specialist prior to starting hepatitis treatment – Documentation must be provided
        d. Confirmed current monthly negative urine drug and alcohol screen for **3 (three)** consecutive months
C. Not a previous non-responder
D. Patient has compensated liver disease

CareSource will approve the use of interferon alfa-2b (Intron A), and consider its use as medically necessary when **ALL** of the following criteria have been met:

III. **AIDS-related Kaposi Sarcoma**

IV. **Condyloma Acuminata**

A. Involvement of external surfaces of genital and/or perianal areas
B. Unsatisfactory response to **1 (one) or more** of the following:

1. Cryotherapy
2. Laser therapy
3. Podophyllin resin
4. Surgery

V. **Hairy Cell Leukemia**
   A. Patients who have relapsed or who have had a less than complete response to first-line therapy with a purine analogue

VI. **Malignant Melanoma**
   A. High risk for systemic recurrence, as indicated by **1 (one) or more** of the following:
      1. Stage IIB or IIC (ie, Breslow thickness greater than 4mm)
      2. Stage III (ie, primary or recurrent nodal involvement)

VII. **Renal Cancer**
   A. Predominant clear cell histology
   B. Relapsed or unresectable stage IV disease
   C. Used concurrently with bevacizumab

VIII. **Symptomatic Systemic Mastocytosis**

Note: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but are not limited to, test reports, chart notes from provider's office or hospital admission notes.

For Medicare Plan members, reference the Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD).

CONDITIONS OF COVERAGE
PLACE OF SERVICE
**Preferred place of service is in the home/self-administered
Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

HCPCS Intron A – J9214
Pegasys – J3490 *Must provide NDC#*
PegIntron – J3490 *Must provide NDC#*

CPT

Step Therapy
Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

AUTHORIZATION PERIOD
Approved initial authorizations are valid for **3 (three)** months. Continued treatment may be considered when the member has shown biological response to treatment. **ALL** authorizations are subject to continued eligibility.

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued:	06/15/2011
Date Reviewed:	06/15/2011, 07/15/2014, 09/26/2014
Date Revised:	07/15/2014 – Added non-pegylated interferon to policy 09/22/2015 – Revised Hepatitis C to align with oral Hep C policy, Hep B update substance abuse section, revised Diagnosis for Intron A

G. REFERENCES

1. Pegasys® [Package Insert]. Nutley, NJ: Hoffman-La Roche Inc.; March 2015.
2. PegIntron® [Package Insert], Whitehouse Station, NJ: Merck and Co., Inc; 2015.
3. Intron A® [Package Insert], Whitehouse Station, NJ: Merck and Co., Inc; 2015..
4. NIH guidelines on Chronic Hepatitis C. at http://consensus.nih.gov/2002/2002Hepatitisc2002116html.htm. (April 22, 2011)
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6. Lok ASF, McMahon BJ. AASLD practice guidelines: Chronic hepatitis B: Update 2009. Hepatology 2009;50:661–662. Zeuzem S et al. "Peginterferon alfa-2a in patients with chronic hepatitis C." *NEJM* 2000;343:1666-72
7. Manns MP et al. "Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomized trial." *Lancet* 2001;358:958-65
8. Fried MW et al. "Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection." *NEJM* 2002;347:975-82
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10. American Gastroenterological Association Medical Position Statement on the Management of Hepatitis C. *Gastroenterology* 2006;130:225-230.
11. American Gastroenterological Association Technical Review on the Management of Hepatitis C. *Gastroenterology* 2006;130:231–24.
12. AASLD/IDSA HCV Guidance Panel (2015), Hepatitis C guidance: AASLD-IDSA recommendations for testing, managing, and treating adults infected with hepatitis C virus. Hepatology. doi: 10.1002/hep.27950.
13. Carter MC, Metcalfe DD, Komarow HD. Mastocytosis. *Immunol. Allergy Clin. North Am*. 2014;34(1):181-196.

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.