



MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	09/26/2017	10/19/2016
Policy Name		Policy Number
Pegylated and Non-Pegylated Interferon		SRx-0037
Policy Type		
<input checked="" type="checkbox"/> Pharmacy	<input type="checkbox"/> Administrative	<input type="checkbox"/> Payment

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
 - Peginterferon alfa-2a (Pegasys)
 - Peginterferon alfa-2b (PegIntron)
 - Peginterferon beta-1a (Plegridy)
- Non-Pegylated Interferon
 - Interferon alfa-2b (Intron A)
 - Interferon beta-1a (Avonex, Rebif)
 - Interferon beta-1b (Betaseron, Extavia)
 - Interferon gamma-1b (Actimmune)

B. BACKGROUND

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

C. DEFINITIONS

N/A

D. POLICY



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

A. Chronic Hepatitis C

1. Documented diagnosis of chronic Hepatitis C compensated liver disease with detectable HCV RNA levels higher than 50 IU/mL and evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest- ActiTest panel or Fibroscan only. *Include lab results and documentation.*
2. Patient is 5 years of age or older.
3. Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist.
4. Negative pregnancy test for female of child bearing potential. *Include laboratory documentation.*
5. Not currently enrolled in hospice.
6. No current use of alcohol or illicit substances confirmed by a negative urine drug and alcohol screen within the last 60 days. *Include laboratory documentation.*
7. If patient has a history of alcohol or illicit substance abuse, must meet ALL of 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. Negative urine drug and alcohol screen for three consecutive months. *Include laboratory documentation.*
8. If request is for monotherapy with peginterferon alfa-2a (Pegasys), patient must have contraindications or significant tolerance to other HCV antiviral drug. *Include chart documentation.*
9. Patient does not have any contraindications to the use of peginterferon alfa-2a (Pegasys).

B. Chronic Hepatitis B

1. *Documented diagnosis of chronic hepatitis B with Hep B surface antigen positive for at least six months OR Hep B viral DNA level greater than (20,000 IU/ml, 100,000 copies/ml)* who have compensated liver disease and evidence of viral replication and liver inflammation.
2. Patient is 18 years or older.
3. Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist.
4. No current use of alcohol or illicit substances confirmed by a negative urine drug and alcohol screen within the last 60 days. *Include laboratory documentation.*
5. If patient has a history of alcohol or illicit substance abuse, must meet ALL of 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. Negative urine drug and alcohol screen for three consecutive months. *Include laboratory documentation.*
6. No history of failure with pegylated interferon therapy.
7. Patient does not have any contraindications to the use of peginterferon alfa-2a (Pegasys).

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

A. Chronic Hepatitis C



1. Documented diagnosis of chronic Hepatitis C compensated liver disease with detectable HCV RNA levels higher than 50 IU/mL and evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest- ActiTest panel or Fibroscan only. *Include lab results and documentation.*
 2. Patient is 3 years of age or older.
 3. Prescribed by a hepatologist, gastroenterologist or infectious disease specialist
 4. Negative pregnancy test for female of child bearing potential. *Include laboratory documentation.*
 5. Not currently enrolled in hospice.
 6. No current use of alcohol or illicit substances confirmed by a negative urine drug and alcohol screen within the last 60 days. *Include laboratory documentation.*
 7. If patient has a history of alcohol or illicit substance abuse, must meet ALL of 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. Negative urine drug and alcohol screen for three consecutive months. *Include laboratory documentation.*
 8. If request is for monotherapy with peginterferon alfa-2b (PegIntron), patient must have contraindications or significant tolerance to ribavirin and only if previously untreated. *Include chart documentation.*
 9. Patient does not have any contraindications to the use of peginterferon alfa-2b (PegIntron).
- III. CareSource will approve the use of **peginterferon beta-1a (Plegridy)**, and consider its use as **medically necessary** when **ALL** of the following criteria have been met:
- A. Multiple Sclerosis
 1. See Multiple Sclerosis Therapy Class policy SRx-0022.
- IV. 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 specific to diagnosis as listed below:
- A. AIDS-related Kaposi's Sarcoma
 1. Documented diagnosis of AIDS-related Kaposi's Sarcoma. *Include lab results and/or chart documentation.*
 2. *Patient is 18 years of age or older.*
 3. Prescribed by an oncologist or infectious disease specialist.
 4. Patient does not have any contraindications to the use of interferon alfa-2b (Intron A).
 - B. Condyloma Acuminata
 1. Documented diagnosis of Condyloma Acuminata with involvement of external surfaces of the genital and perianal areas. *Include lab results and/or chart documentation.*
 2. *Patient is 18 years of age or older.*
 3. Prescribed by a dermatologist or infectious disease specialist.
 4. Patient has a history of trial and failure to two or more of the following:
 - a. Imiquimod 3.75% or 5% cream
 - b. Podofilox 0.5% solution or gel
 - c. sinecatechins 15% ointment
 - d. Trichloroacetic acid or bichloroacetic acid
 - e. Cryotherapy
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- f. Surgery
 - 5. Patient does not have any contraindications to the use of interferon alfa-2b (Intron A).
 - C. Hairy Cell Leukemia
 - 1. Documented diagnosis of Hairy Cell Leukemia. *Include lab results and/or chart documentation.*
 - 2. Patient is 18 years of age or older.
 - 3. Prescribed by/or in conjunction with an oncologist.
 - 4. Patients who have relapsed or who have had a less than complete response to first-line therapy with a purine analogue OR cannot take purine analogues due to pregnancy and severe neutropenia.
 - 5. Patient does not have any contraindications to the use of interferon alfa-2b (Intron A).
 - D. Malignant Melanoma
 - 1. Documented diagnosis of malignant melanoma as an adjuvant to surgical treatment in a patient free of disease but at high risk for systemic recurrence. *Include lab results and/or chart documentation.*
 - 2. Patient is 18 years of age or older.
 - 3. Prescribed by/or in conjunction with an oncologist.
 - 4. Treatment must be within 56 days of surgery. *Include chart documentation.*
 - 5. Patient does not have any contraindications to the use of interferon alfa-2b (Intron A).
 - E. Follicular Lymphoma
 - 1. Documented diagnosis of follicular Non-Hodgkin's Lymphoma stage 3 or 4 with interferon alfa-2b (IntronA) used in combination with anthracycline-containing chemotherapy. *Include chart documentation.*
 - 2. Patient is 18 years of age or older.
 - 3. Prescribed by/or in conjunction with an oncologist.
 - 4. Treatment must be within 56 days of surgery. *Include chart documentation.*
 - 5. Patient does not have any contraindications to the use of interferon alfa-2b (Intron A).
 - F. Chronic hepatitis B
 - 1. Documented diagnosis of chronic hepatitis B with Hep B surface antigen positive for at least six months OR Hep B viral DNA level greater than (20,000 IU/ml, 100,000 copies/ml) who have compensated liver disease and evidence of viral replication and liver inflammation.
 - 2. Patient is 18 years or older.
 - 3. Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist
 - 4. No current use of alcohol or illicit substances confirmed by a negative urine drug and alcohol screen within the last 60 days. *Include laboratory documentation.*
 - 5. If patient has a history of alcohol or illicit substance abuse, must meet ALL of 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. Negative urine drug and alcohol screen for three consecutive months. *Include laboratory documentation.*
 - 6. Patient does not have any contraindications to the use of interferon alfa-2b (Intron A).
 - F. Chronic hepatitis C
 - 1. Documented diagnosis of chronic Hepatitis C compensated liver disease with detectable HCV RNA levels higher than 50 IU/mL and evidence of stage 3 or 4
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liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest- ActiTest panel or Fibroscan only. *Include lab results and documentation.*

2. Patient is 3 years of age and older if previously untreated with interferon alfa therapy **OR** 18 years of age or older if relapsed following interferon alfa therapy.
 3. Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist.
 4. Negative pregnancy test for female of child bearing potential. *Include laboratory documentation.*
 5. Not currently enrolled in hospice.
 6. No current use of alcohol or illicit substances confirmed by a negative urine drug and alcohol screen within the last 60 days. *Include laboratory documentation.*
 7. If patient has a history of alcohol or illicit substance abuse, must meet ALL of 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. Negative urine drug and alcohol screen for three consecutive months. *Include laboratory documentation.*
 8. Patient does not have any contraindications to the use of interferon alfa-2b (Intron A).
- V. CareSource will approve the use of **interferon beta-1a (Avonex, Rebif)**, and consider its use as **medically necessary** when **ALL** of the following criteria have been met:
- A. Multiple Sclerosis
 2. See Multiple Sclerosis Therapy Class policy SRx-0022.
- VI. CareSource will approve the use of **interferon beta-1b (Betaseron, Extavia)**, and consider its use as **medically necessary** when **ALL** of the following criteria have been met:
- A. Multiple Sclerosis
 3. See Multiple Sclerosis Therapy Class policy SRx-0022.
- VI. CareSource will approve the use of **interferon gamma-1b (Actimmune)**, and consider its use as **medically necessary** when **ALL** of the following criteria have been met specific to diagnosis as listed below:
- A. Chronic Granulomatous Disease (CGD)
 1. Documented diagnosis of chronic granulomatous disease. *Include lab results and/or chart documentation.*
 2. Patient does not have any contraindications to the use of interferon gamma-1b (Actimmune).
 - B. Malignant osteopetrosis
 1. Documented diagnosis of malignant osteoporosis. *Include lab results and/or chart documentation.*
 2. Patient does not have any contraindications to the use of interferon gamma-1b (Actimmune).

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.



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	Peginterferon alfa-2a (Pegasys)– J3490 *Must provide NDC#*
	Peginterferon alfa-2b (PegIntron) – J3490 *Must provide NDC#*
	Peginterferon beta-1a (Plegridy) – Q3028
	Interferon alfa-2b (Intron A) – J9214
	Interferon beta-1a (Avonex, Rebin) – J1826
	Interferon beta-1b (Betaseron, Extavia) – J1830
	Interferon gamma-1b (Actimmune) – J9216

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 vary according to diagnosis. 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

Multiple Sclerosis Therapy Class policy SRx-0022.

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
9/29/2016- Updated criteria. Added Plegridy, Avonex, Rebin, Betaseron, Extavia, and Actimmune. Updated references.

G. REFERENCES

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 3. Plegridy (peginterferon beta-1a) [prescribing information]. Cambridge, MA: Biogen Idec Inc.; October 2015.
 4. Intron A (interferon alfa-2b) [prescribing information]. Whitehouse Station, NJ: Merck & Co, Inc.; February 2016.
 5. Actimmune (interferon gamma-1b) [prescribing information]. Roswell, GA: HZNP USA Inc.;
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 24. Betaseron (interferon beta-1b) [prescribing information]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc.; April 2016.
 25. Extavia (interferon beta-1b) [prescribing information]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc.; May 2016.

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