aetna™

Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.

Policies submitted without this form will not be considered for review.

<table>
<tr><td>Plan: Aetna Better Health</td><td>Submission Date: 8/1/2021</td></tr>
<tr><td>Policy Number:</td><td>Effective Date: 8/1/2020
Revision Date: 5/2021</td></tr>
<tr><td colspan="2">Policy Name: Interferons</td></tr>
<tr><td colspan="2">Type of Submission – Check all that apply:

☐ New Policy
X Revised Policy
☐ Annual Review – No Revisions</td></tr>
<tr><td colspan="2">*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:</td></tr>
<tr><td>Name of Authorized Individual (Please type or print):

Natalie Nkurunziza, Pharm.D.</td><td>Signature of Authorized Individual:

[signature]</td></tr>
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Last Review: 5/2021
Previous PARP Approval: 12/2019
Current PARP Approval: 8/2021

AETNA BETTER HEALTH®

Prior Authorization guideline for Interferons (non-Hepatitis C uses) Non-PDL

Drugs Covered

α-Interferon

- Alferon N
- Intron A

β-Interferon

See Multiple Sclerosis Agents

γ-Interferon

- Actimmune

Authorization guidelines

Chronic Hepatitis B Infection (Intron A)

A. Prescribed by, or in consultation with, an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician
B. Diagnosis of Chronic Hepatitis B (CHB) with current lab results to support the following:
    a. Alanine Aminotransferase (ALT) greater than 2 times the Upper Limit of Normal (ULN)
    b. Detectable Hepatitis B Virus Deoxyribonucleic Acid (HBV DNA) level
    c. Hepatitis B e-antigen (HBe-Ag) (positive or negative)
C. Compensated liver disease
D. Age restriction: Must be at least 1 year old

Follicular Non-Hodgkin's Lymphoma (Stage III/IV) (Intron A)

A. Member is 18 years of age or older
B. Prescribed by, or in consultation with a hematologist/oncologist
C. Given in conjunction with anthracycline-containing combination chemotherapy

Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi's sarcoma (Intron A [powder for solution ONLY)

A. Prescribed by, or in consultation with an infectious disease physician or HIV specialist
B. Member is 18 years of age or older

Hairy-cell Leukemia (Intron A)

A. Member is 18 years of age or older
B. Prescribed by, or in consultation with Hematologist/Oncologist
C. Member meets one of the following:
    - Demonstrated less than a complete response to cladribine or pentostatin
    - Relapsed after less than 2 years of demonstrating a complete response to cladribine or pentostatin

Chronic Granulomatous Disease (Actimmune)

A. Prescribed by, or in consultation with an immunologist
B. Member is one year of age or older

Malignant Osteopetrosis (Actimmune)

A. Prescribed by, or in consultation with a hematologist/oncologist or endocrinologist
B. Prescribed for the treatment of severe, malignant osteopetrosis

Condylomata acuminata (genital or venereal warts) (Intron A, Alferon N)

A. Member is 18 years of age or older
B. For intralesional use
C. Lesions are small and limited in number
D. Trial and failure of topical treatments or surgical technique (i.e. imiquimod cream, Condylox, cryotherapy, laser surgery, electrodessication, surgical excision)

Additional Information:

Interferons are NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

Approval Duration:

Initial Approval:

Hepatitis B

- Intron A –16 weeks for adults; 24 weeks for children

Kaposi's sarcoma: 16 weeks

Hairy cell leukemia: 6 months

Condylomata acuminate: 3 weeks

All other indications: 1 year

<u>Renewal:</u>

Hepatitis B:

- Intron A: additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive
- Intron A: indefinite for Hepatitis B e-antigen (HBe-Ag)-negative patients

Osteopetrosis: 1 year if no evidence of disease progression

Chronic Granulomatous Disease *(CGD)*: 1 year if number and/or severity of infections has decreased

Condylomata acuminate:

- Intron A: 16 weeks
- Alferon N: 8 weeks; there must be at least 3 months between treatments unless there are signs of disease progression

All others: 1 year

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those

functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:

1. Intron A (interferon alfa-2b) [package insert]. August 2019. Kenilworth, NJ; Merck Sharp & Dohme Corp. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=30789790-8317-49f9-b97b-8c5ba17b53d2&type=display Accessed May 21, 2021
2. Actimmune (interferon gamma-1b) [package insertRevised March 2021. Roswell, GA; HZNP USA, Inc. https://www.hzndocs.com/ACTIMMUNE-Prescribing-Information.pdf Accessed May 21, 2021.
3. National Comprehensive Cancer Network. Hairy Cell Leukemia version 2.2021 - March 11, 2021. NCCN. https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf. Accessed May 21, 2021.
4. National Comprehensive Cancer Network. Cutaneous Melanoma version 2.2021 - February 19, 2021. NCCN. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed May 21, 2021.
5. National Comprehensive Cancer Network. T-cell Lymphomas version 1.2021 - October 5, 2020. NCCN. https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed May 21, 2021.
6. Terrault, N. A., Bzowej, N. H., Chang, K.-M., Hwang, J. P., Jonas, M. M. and Murad, M. H. (2018), Update on Preventon, Diagnosis and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. https://www.aasld.org/sites/default/files/2019-06/HBVGuidance_Terrault_et_al-2018-Hepatology.pdf Hepatology, 67: 261–283. Accessed May 21, 2021.