ACTIMMUNE

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Interferon gamma-1b (e.g., Actimmune) meets member benefit certificate Primary Coverage Criteria that there be scientific evidence of effectiveness in improving health outcomes:

FDA Labeled Indications:
The use of this drug is covered if an FDA-approved oncologic indication exists

INITIAL APPROVAL:
1. Individual has one of the following:
    a. Chronic granulomatous disease of childhood; **OR**
    b. Delaying time to disease progression in individuals with severe, malignant osteopetrosis; **AND**
2. Individual does not have idiopathic pulmonary fibrosis; **AND**

CONTINUATION OF THERAPY:
1. Individual continues to meet the initial approval criteria; **AND**
2. Individual experiences objective benefit from continued treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Off-label Indications:

The use of this drug for off-label indications not listed below is subject to policy 2000030.

INITIAL APPROVAL:

The following indications are covered when the individual meets the related NCCN category 1 or 2A recommendations specific to the indications below (e.g., histology, cancer staging, surgical status, mono- or combination therapy):

1. **Primary Cutaneous Lymphomas:**
    a. Mycosis Fungoides/Sezary Syndrome
        i. System therapy as primary treatment for
            1. Stage IA mycosis fungoides (MF) in combination with skin-directed therapy in selected cases* (NCCN 2A); **OR**
            2. Stage IB-IIA MF, in combination with skin-directed therapy in selected cases** (NCCN 2A); **OR**
            3. Stage IIB MF with limited tumor lesions, with or without local radiation therapy (NCCN 2A); **OR**
            4. Stage IIB MF with generalized tumor lesions, with or without skin-directed therapy (NCCN 2A); **OR**
            5. Stage III MF, with or without skin-directed therapy (NCCN 2A); **OR**
            6. Stage IVA1 or IVA2 Sezary syndrome (NCCN 2A); **OR**
        ii. Systemic therapy as subsequent treatment for:

1. Relapsed or persistent stage IA MF with T1 skin disease, in combination with skin-directed therapy in selected cases* (NCCN 2A); **OR**
2. Stage IA MF that is refractory to multiple previous therapies, with or without skin-directed therapy** (NCCN 2A); **OR**
3. Relapsed or persistent stage IB-IIA MF with a lower skin disease burden (eg, predominantly patch disease), in combination with skin-directed therapy in selected cases** (NCCN 2A); **OR**
4. Stage IB-IIA MF with a higher skin disease burden (eg, predominantly plaque disease) that is relapsed or persistent with T1-T2 disease, in combination with skin-directed therapy in selected cases**; **OR**
5. Stage IB-IIA MF that is refractory to multiple previous therapies, in combination with skin-directed therapy (NCCN 2A); **OR**
6. Relapsed stage IIB T1-2 MF with limited tumor lesions, in combination with skin-directed therapy in selected cases** (NCCN 2A); **OR**
7. Relapsed stage IIB MF with T3 limited tumor lesions, with or without local radiation therapy and with or without skin-directed therapy (NCCN 2A); **OR**
8. Persistent stage IIB MF with T1-3 limited tumor lesions, with or without local radiation therapy and with or without skin-directed therapy (NCCN 2A); **OR**
9. Stage IIB MF with limited tumor lesions that is refractory to multiple previous therapies, in combination with skin-directed therapy (NCCN 2A); **OR**
10. Relapsed stage IIB T1-2 MF with generalized tumor lesions, in combination with skin-directed therapy in selected cases** (NCCN 2A); **OR**
11. Relapsed stage IIB MF with T3 generalized tumor lesions, in combination with skin-directed therapy (NCCN 2A); **OR**
12. Persistent stage IIB MF with T1-3 generalized tumor lesions, in combination with skin-directed therapy (NCCN 2A); **OR**
13. Relapsed or persistent stage III MF, in combination with skin-directed therapy (NCCN 2A); **OR**
14. Relapsed or persistent stage IVA1 or IVA2 Sezary syndrome in combination with skin-directing therapy (NCCN 2A).

*Systemic therapies should be reserved for individuals with blood involvement or for whom skin-directed therapies do not provide sufficient disease control or who have disease that is not amenable to skin-directe (eg, in regions where topical therapies are difficult to apply regularly).

**Systemic therapies should be considered for individuals with extensive skin involvement, higher skin disease burden, predominantly plaque disease, blood involvement, and/or inadequate response to skin-direct

CONTINUATION OF THERAPY:

1. Individual continues to meet the initial approval criteria; **AND**

2. Individual experiences objective benefit from continued treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

Please see the NCCN Drugs and Biologics Compendium for a complete list of NCCN 1 & 2A indications. To view the most recent and complete version of the guideline or Compendium, go online to NCCN.org. Please note, N kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Dosage and Administration

For FDA labeled indications, Interferon gamma-1b (e.g., Actimmune) must be dosed in accordance with the indication specific recommended dose per FDA label unless otherwise specified below.

For off-label indications, authorizations will not exceed the maximum FDA labeled dose and frequency across all the FDA labeled indications unless higher dose is allowed for the specific indication below.

The recommended dose of interferon gamma 1b is 50 mcg/square meters for individuals whose body surface area is greater than 0.5 square meters and 1.5 mcg/kg/dose for individuals whose body surface area is equal to or less than 0.5 s
Interferon gamma 1b is available as 100 mcg (2 million International Units) in 0.5 mL solution in a single use vial.

Please refer to a separate policy on Site of Care or Site of Service Review (policy #2018030) for pharmacologic/biologic medications.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

Interferon gamma-1b (e.g., Actimmune), for any indication or circumstance not described, does not meet Primary Coverage Criteria that there be scientific evidence of effectiveness in improving health outcomes.

For members with contracts without Primary Coverage Criteria, interferon gamma-1b (e.g., Actimmune), for any indication or circumstance not described, is considered **investigational**. **Investigational** services are specific contract exclusions in most member benefit certificates of coverage.