ACTIMMUNE

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

Interferon gamma-1b meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes:

Non-oncologic:

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**
3. Must be dosed in accordance with the FDA label.

Oncologic:

1. **Primary Cutaneous Lymphomas:**
    a. Mycosis Fungoides/Sezary Syndrome
        i. Preferred systemic therapy as primary treatment for:
            1. Stage IIB MF with limited tumor lesions, with or without local radiation therapy (NCCN 2A)
            2. Stage IIB MF with generalized tumor lesions, with or without skin-directed therapy (NCCN 2A)
            3. Stage III MF, with or without skin-directed therapy (NCCN 2A)
            4. Stage IVA1 or IVA2 Sezary syndrome (NCCN 2A)
        ii. Preferred systemic therapy as subsequent treatment for:
            1. Stage IA MF that is refractory to multiple previous therapies, with or without skin-directed therapy (NCCN 2A)
            2. Relapsed stage IIB MF with T3 limited tumor lesions, with or without local radiation therapy (NCCN 2A)
            3. Persistent stage IIB MF with T1-3 limited tumor lesions, with or without local radiation therapy (NCCN 2A)
            4. Relapsed stage IIB MF with T3 generalized tumor lesions, with or without skin-directed therapy (NCCN 2A)
            5. Persistent stage IIB MF with T1-3 generalized tumor lesions, with or without skin-directed therapy (NCCN 2A)
            6. Relapsed or persistent stage III MF, with or without skin-directed therapy (NCCN 2A)
            7. Stage III MF that is refractory to multiple previous therapies (NCCN 2A)
            8. Relapsed or persistent stage IVA1 or IVA2 Sezary syndrome (NCCN 2A)
        iii. Skin-directed/systemic combination therapy (phototherapy + interferon) or systemic/systemic combination therapy (photopheresis + interferon, photopheresis + retinoid + interferon, or retinoid + interferon) as primary treatment for:

1. Stage IB-IIA MF with a higher skin disease burden (e.g., predominantly plaque disease), with or without skin-directed therapy (NCCN 2A)
2. Stage IIB MF with generalized tumor lesions, with or without skin-directed therapy (NCCN 2A)
3. Stage III MF (preferred) (NCCN 2A)
4. Stage IVA1 or IVA2 Sezary syndrome (preferred) (NCCN 2A)

iv. Skin-directed/systemic combination therapy (phototherapy + interferon or systemic/systemic combination therapy (photopheresis + interferon, photopheresis + retinoid + interferon, or retinoid + interferon) as subsequent treatment for:
1. Stage IB-IIA MF with a higher skin disease burden (e.g., predominantly plaque disease) that is relapsed or persistent with T1-T2 disease, with or without skin-directed therapy (NCCN 2A)
2. Stage IB-IIA MF with a higher skin disease burden (e.g., predominantly plaque disease) that is refractory to multiple previous therapies, with or without skin-directed therapy (NCCN 2A)
3. Relapsed stage IIB MF with T3 generalized tumor lesions, with or without skin-directed therapy (NCCN 2A)

The use of this drug is covered if a FDA-approved oncologic indication exists (not listed as an indication above) with the member meeting all of the additional requirements of the prescribing information (package insert listed in the "Indications and Usage") AND/OR a NCCN category 1 or 2A recommendation is recognized in the NCCN Drugs and Biologics Compendium with the member meeting specified criteria (See policy #2000030).

Dosage and Administration

Dosing per FDA Guidelines

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 square meters three times weekly.

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, 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 for any indication or circumstance not described, is considered **investigational**.

Investigational services are specific contract exclusions in most member benefit certificates of coverage.