PRIOR AUTHORIZATION (PA) CHECKLIST FOR ACTIMMUNE® (Interferon gamma-1b)

This checklist is for informational purposes only. For health plan–specific criteria, please contact a **Horizon By Your Side** representative. Initiate your patient's enrollment in Horizon By Your Side, a patient support program, by submitting the Patient Enrollment Form. Your patient must complete enrollment to access these patient-focused services and resources.

Although requirements vary by plan, below are the common criteria that may be requested for ACTIMMUNE®. Case Managers can provide education about navigating insurance processes and accessing treatment during your patient's access journey.

1 BENEFITS INVESTIGATION

- ☐ PA requirements vary between plans. Contact the health plan to understand the process, step therapy requirements, duration or approval, and other relevant information

2 PA REQUIREMENTS

Patient/Provider Information

- ☐ Name
- ☐ Date of birth
- ☐ Health plan
- ☐ Provider name
- ☐ Provider identification number

Some plans may require documentation of specific information, while some may require physician attestation.

Diagnosis Information

- ☐ Diagnosis/ICD-10-CM code
  - — Chronic granulomatous disease D71
  - — Severe malignant osteopetrosis (SMO) Q78.2
  - — Injection, interferon, gamma-1b, 3 million units J9216
- ☐ Diagnosis confirmed by one or more of the following methods:
  - — Dihydrorhodamine (DHR) assay
  - — Genetic testing results
  - — Nitroblue tetrazolium test
  - — X-ray (SMO only)

Be sure to provide relevant clinical support, such as clinical notes, laboratory results, etc.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

INDICATIONS AND USAGE

ACTIMMUNE® (Interferon gamma-1b) is indicated:

- For reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease
- For delaying time to disease progression in patients with severe, malignant osteopetrosis

Please see Important Safety Information on page 3 and see accompanying Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

PA CHECKLIST FOR ACTIMMUNE® (Interferon gamma-1b) (CONT'D)

2 PA REQUIREMENTS (CONT'D)

Treatment Information

- ☐ Note lifestyle modifications
- ☐ Note any and all previous medications, including name, dosage, and dates and duration of treatment (include all prophylactic antibiotic and antifungal medications)
- ☐ Documentation of infections, hospital admissions, and any additional clinical notes
- ☐ Include a letter of medical necessity
- ☐ Note reauthorization criteria
- ☐ Note any consultations with a specialist (eg, immunologist, infectious disease physician, or hematologist)

Step therapy requirements may vary between plans.

3 PA SUBMISSION

- ☐ Submit the PA directly to the health plan or by using an an electronic PA submission service such as CoverMyMeds®
- ☐ Verify that the PA (including the number of pages) was received
- ☐ Check with the patient's plan to see how long it typically takes for a PA to be reviewed
- ☐ Communicate with the team at Horizon By Your Side to follow up on status and to see if any additional information is required

PA, prior authorization.

HORIZON BY your side

Available Monday through Friday, 9 AM to 8 PM ET

1-844-4MY-HBYS (1-844-469-4297)

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- In patients who develop or have known hypersensitivity to interferon-gamma, *E coli*-derived products, or any component of the product

Please see additional Important Safety Information on page 3 and see accompanying Full Prescribing Information.

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INDICATIONS and IMPORTANT SAFETY INFORMATION

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WARNINGS AND PRECAUTIONS

- **ACTIMMUNE should be used with caution in patients with:**
  - Pre-existing cardiac conditions, including ischemia, congestive heart failure, or arrhythmia
  - Seizure disorders or compromised central nervous system function; reduce dose or discontinue
  - Myelosuppression, or receiving other potentially myelosuppressive agents; consider dose reduction or discontinuation of therapy
  - Severe renal insufficiency
  - Age <1 year
- **Monitoring:**
  - Patients begun on ACTIMMUNE before age 1 year should receive monthly assessments of liver function. If severe hepatic enzyme elevations develop, ACTIMMUNE dosage should be modified
  - Monitor renal function regularly when administering ACTIMMUNE in patients with severe renal insufficiency; accumulation of interferon gamma-1b may occur with repeated administration. Renal toxicity has been reported in patients receiving ACTIMMUNE
- **Pregnancy, Lactation, and Fertility:**
  - ACTIMMUNE should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus
  - Use of ACTIMMUNE by lactating mothers is not recommended. ACTIMMUNE or nursing should be discontinued dependent on the importance of the drug to the mother
  - Long-term effects of ACTIMMUNE on fertility are not known

DRUG INTERACTIONS

- Concomitant use of drugs with neurotoxic, hematotoxic, or cardiotoxic effects may increase the toxicity of interferons
- Avoid simultaneous administration of ACTIMMUNE with other heterologous serum protein or immunological preparations (eg, vaccines)

ADVERSE REACTIONS

- The most common adverse experiences occurring with ACTIMMUNE therapy are “flu-like” symptoms such as fever, headache, chills, myalgia, or fatigue, which may decrease in severity as treatment continues, and may be minimized by bedtime administration of ACTIMMUNE. Acetaminophen may be used to prevent or partially alleviate the fever and headache
- Isolated cases of acute serious hypersensitivity reactions have been observed in patients receiving ACTIMMUNE
- Reversible neutropenia, thrombocytopenia, and elevations of AST and/or ALT have been observed during ACTIMMUNE therapy
- At doses 10 times greater than the weekly recommended dose, ACTIMMUNE may exacerbate pre-existing cardiac conditions, or may cause reversible neurological effects such as decreased mental status, gait disturbance, and dizziness

Please see accompanying Full Prescribing Information.

HORIZON

ACTIMMUNE® (Interferon gamma-1b)