FOR HEALTHCARE PROVIDER OFFICE STAFF USE ONLY. DO NOT DISTRIBUTE.

Dear Healthcare Provider,

There are times when a prior authorization request may be denied by your patient's health plan. If that happens, an appeal can be submitted to the plan requesting that the decision be reconsidered. Appeal requirements may vary according to the health plan.

To use the sample letter provided as a separate Word document, modify the content as needed based on your medical judgment and discretion when providing a diagnosis and characterization of your patient's medical condition. For additional guidance, tips and a checklist have been included below and on page 2.

Use of the information in this document does not guarantee that the health plan will provide coverage for ACTIMMUNE® (Interferon gamma-1b), and it is not intended to be a substitute for, or an influence on, your independent medical judgment.

Before sending the appeal letter to the health plan, please ensure all variable text (as indicated by pink brackets and open text fields) is filled in or deleted as required.

APPEAL CHECKLIST

Documents for Filing a Response to Treatment Denial

Each appeal may require different information based on the plan's requirements. Below is a list of materials that you may need to include in an appeal package. Review each denial and the insurer's requirements to determine what to include in a patient's appeal package.

Commonly Required Documents Include:

- ☐ Letter of appeal
- ☐ Letter of medical necessity
- ☐ Patient authorization and notice of release of information
- ☐ Copy of the patient's health plan and/or prescription card (front and back)
- ☐ Denial information, including the patient's denial letter and/or explanation of benefits
- ☐ Supporting documentation:
  - ☐ ACTIMMUNE® Prescribing Information
  - ☐ ACTIMMUNE® clinical studies
  - ☐ Clinical documentation of:
    - ☐ Test results supporting the diagnosis (eg, DHR assay, genetic test, x-ray)
    - ☐ Lifestyle modifications
    - ☐ Infections, hospitalizations, and any relevant clinical notes
    - ☐ Treatment history, including name, dosage, and dates and duration of treatment (include all prophylactic antibiotic and antifungal medications)

DHR, dihydrorhodamine.

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 Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

APPEAL TIPS

Tips for Filing an Appeal of Treatment Denial

This document provides information that may be useful when creating an appeal letter. Some plans have specific coverage authorization forms that must be used. It is important to determine the plan's requirements and follow them when requesting an appeal for ACTIMMUNE® (Interferon gamma-1b) to avoid further treatment delays. Horizon By Your Side is a patient support program that provides education to healthcare providers and appropriate office staff to answer nonmedical logistical questions as well as information about insurance processes and accessing treatment. Please contact health plans directly for specific information about their current coverage policies.

Identify the Reason for Denial

Find out in writing why the authorization request has been denied. The denial letter from the patient's health plan or the explanation of benefits should outline the reason(s) for denial. These can be obtained from the health plan if you did not receive them. The denial is also summarized in the health plan's online portal or should be available where you submitted the prior authorization.

Determine the Appeal Guidelines

Some health plans have short appeal periods, so it is important to contact the health plan to find out its deadline for submitting an appeal. Be sure to inquire about the number of appeals permitted (some plans allow only one) and the mailing address or fax number to which the appeal should be sent. You may also need to schedule a peer-to-peer consultation.

Contact the Review Department

The denial letter may include a telephone number for the review department. If so, the prescribing physician should call for further clarification about the denial. The reviewer may agree with the rationale and approve treatment during the call. If so, the appeal process is complete.

Compose the Appeal and Schedule a Consultation

The health plan will tell you what supporting documentation is needed. You may also need to schedule a peer-to-peer consultation.

Provide Additional Supporting Documentation

It is important to determine each health plan's appeal requirements, as they may vary according to payor. The appeal package should include all relevant medical documentation, including clinical notes and related test results, as well as any newly available information related to the patient's condition. The Horizon By Your Side team works directly with patients to answer nonmedical logistical questions and to provide information about insurance processes and accessing treatment.

Follow Up as Needed

Contact the health plan to learn about the appeal review timeline. Though some plans may respond within 7 days, most health plans respond within 30 to 60 days of receipt of the appeal package.

Maintain Complete Records

Retain a copy of all documentation submitted with the patient's appeal and record all subsequent communications made to the patient's health plan, including the date and the name of the person contacted.

NOTE: As a reminder, do not send patient medical records to Horizon Therapeutics.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ACTIMMUNE is contraindicated 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 Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

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 Full Prescribing Information.

HORIZON

ACTIMMUNE® (Interferon gamma-1b)