

# **ACTIMMUNE® (INTERFERON GAMMA-1B) PRESCRIPTION ENROLLMENT FORM INSTRUCTIONS**

The Prescription Enrollment Form is required to initiate treatment with Horizon Therapeutics' prescription medicine, ACTIMMUNE®.

**Instructions:**

1. Complete the following enrollment form in its entirety, including
  - a. Patient information
  - b. Insurance information with picture of insurance card
  - c. Diagnosis and prescription information
  - d. Prescriber information
2. A signature is required from the patient's healthcare provider.
3. Fax the completed form to Horizon Patient Services™ at 1 (877) 305-7706.
4. Check with your patient to ensure he or she has printed, signed, and dated the required Patient Authorization Form providing HIPAA authorization for Horizon Patient Services and initiation of patient support.
5. If you have any questions or comments, please contact Horizon Patient Services at 1 (877) 305-7704.

**Please see Important Safety Information inside and the ACTIMMUNE® Full Prescribing Information available at [ACTIMMUNEhcp.com](http://ACTIMMUNEhcp.com).**

Please fax completed form to 1 (877) 305-7706, or email it to HPSACT@horizontherapeutics.com.

**1. PATIENT INFORMATION**

First Name \_\_\_\_\_ MI \_\_\_\_\_ Last Name \_\_\_\_\_  
Address \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
Home Phone \_\_\_\_\_ Mobile Phone \_\_\_\_\_  
Date of Birth \_\_\_\_\_ Gender  M  F Height \_\_\_\_\_ Weight \_\_\_\_\_  
Email \_\_\_\_\_ Preferred Method of Contact  Home  Mobile  Email  Mail

**ALTERNATIVE CONTACT AND/OR CAREGIVER**

Best Time to Contact \_\_\_\_\_  
First Name \_\_\_\_\_ MI \_\_\_\_\_ Last Name \_\_\_\_\_  
Home Phone \_\_\_\_\_ Mobile Phone \_\_\_\_\_  
Email \_\_\_\_\_ Preferred Method of Contact  Home  Mobile  Email  Mail

Is your patient currently on ACTIMMUNE®?  Yes  No If Yes, provide last date of use: \_\_\_\_\_

**2. PRESCRIBER INFORMATION**

Prescriber First Name \_\_\_\_\_ MI \_\_\_\_\_ Last Name \_\_\_\_\_ Prescriber NPI# \_\_\_\_\_  
Address \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
Phone \_\_\_\_\_ Fax \_\_\_\_\_ Physician Specialty \_\_\_\_\_  
Office Contact Name \_\_\_\_\_ Email \_\_\_\_\_ Phone \_\_\_\_\_

**3. INSURANCE INFORMATION — Please attach a copy of both sides of the patient's insurance card(s).**

**No Insurance**

**PRIMARY INSURANCE**

Insurance Carrier \_\_\_\_\_  
Customer Service Phone \_\_\_\_\_  
Subscriber Name \_\_\_\_\_  
Patient's Relationship to Subscriber \_\_\_\_\_  
Subscriber Date of Birth \_\_\_\_\_  
Subscriber ID Number \_\_\_\_\_  
Policy/Employer/Group Number \_\_\_\_\_  
Prescription Card?  Yes If Yes, Carrier: \_\_\_\_\_ Phone \_\_\_\_\_

**SECONDARY INSURANCE (if any)**

Insurance Carrier \_\_\_\_\_  
Customer Service Phone \_\_\_\_\_  
Subscriber Name \_\_\_\_\_  
Patient's Relationship to Subscriber \_\_\_\_\_  
Subscriber Date of Birth \_\_\_\_\_  
Subscriber ID Number \_\_\_\_\_  
Policy/Employer/Group Number \_\_\_\_\_

**4. PRESCRIPTION AND CLINICAL INFORMATION**

- Chronic Granulomatous Disease (CGD) ICD-10: D71
- Severe, Malignant Osteopetrosis (SMO) ICD-10: Q78.2
- Other: \_\_\_\_\_ ICD-10: \_\_\_\_\_

Rx: ACTIMMUNE® (Interferon gamma-1b)  
100 mcg (2 million IU)/0.5 mL, single-use vials  
Sig: \_\_\_\_\_ mcg SubQ: \_\_\_\_\_ (frequency of dosing)  
Vial Qty:  12  Other: \_\_\_\_\_ Refills: \_\_\_\_\_

Anticipated Start Date: \_\_\_\_\_

Injection Setting:  Physician's Office  Home  Other: \_\_\_\_\_

Ancillary Supplies:  
 0.3 mL 31 G 5/16" Qty:  12  Other: \_\_\_\_\_  
 0.5 mL 30 G 5/16" or 1/2" Qty:  12  Other: \_\_\_\_\_  
 1 mL 30 G 1/2" Qty:  12  Other: \_\_\_\_\_  
 Alcohol Swabs Qty:  12  Other: \_\_\_\_\_  
 No Substitute

**Prescriber Certification**

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I understand that Horizon Therapeutics plc and its affiliates and their respective employees or agents (collectively, "Horizon") will use this information to administer the Horizon Patient Services™ program (the "Program"), which provides assistance to patients in verifying insurance coverage for ACTIMMUNE® and assistance in initiating or continuing ACTIMMUNE® as prescribed. By my signature, I also certify that my patient or his/her personal representative has provided a signed HIPAA authorization that allows me to share Protected Health Information with Horizon for purposes of the Program. I appoint the Program, on my behalf, to proceed with services offered and to convey this prescription to the dispensing pharmacy, to the extent permitted under state law. I further understand and agree that (a) any medication or service provided through the Program as a result of this form is for the named patient only and is not being made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use ACTIMMUNE® or any other Horizon product or service, for any other person, (b) my decision to prescribe ACTIMMUNE® was based solely on my professional determination of medical necessity, and (c) I will not seek reimbursement for any medication or service provided by or through the Program from any government program or third-party insurer. I understand that Horizon may modify or terminate the Program at any time without notice.

State requirements: The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in outreach to the prescriber.

By filling out this form, you automatically enroll your patient into the Program, which includes assistance from Patient Access Managers (PAMs), unless the box below is checked.

Check here if you choose not to enroll this patient into the Program.

**X** Prescriber Signature \_\_\_\_\_ Date \_\_\_\_\_  
(Dispense as Written) (Substitution Permitted)

## HIPAA Authorization

I hereby authorize my healthcare providers, my health insurance carriers, and my pharmacies to use and disclose my individually identifiable health information, including my medical records, insurance coverage information, and my name, address and telephone number to Horizon Therapeutics plc and its affiliates and their respective agents and representatives (collectively, "Horizon"), including third parties authorized by Horizon to administer drug support and to dispense drugs (collectively, "Horizon Patient Services") for the following purposes: (1) to establish eligibility for benefits; (2) to communicate with healthcare providers and me about my medical care; (3) to facilitate the provision of products, supplies, or services by a third party including, but not limited to, specialty pharmacies; (4) to register me in any applicable product registration program required for my treatment; (5) to enroll me in eligible patient support programs offered by Horizon Patient Services™ and/or Horizon, including nursing or patient access support services (government-reimbursed programs may not be eligible for all support services offered; please contact Horizon Patient Services for determination); and (6) to send me marketing information related to my treatment or condition (or related products or services in which I might be interested) and to contact me occasionally to obtain my feedback (for market research purposes only) about my treatment, my condition, or my experience with Horizon and/or Horizon Patient Services otherwise as required or permitted by law. I understand the pharmacies may receive a fee from Horizon in exchange for (1) providing me with certain materials and information described above, and (2) using or disclosing certain health information pursuant to this Authorization.

I understand that Horizon, as well as my healthcare providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment, or other care, to sign this Authorization. I understand that I am entitled to a copy of this Authorization. I understand that information disclosed pursuant to this Authorization in some cases may be redisclosed by the recipient and no longer protected by HIPAA or other privacy laws. But Horizon has agreed to use and disclose my information only for purposes of operating the program.

I understand that I may cancel this Authorization at any time by mailing a signed letter requesting such cancellation to Horizon Patient Services, 150 South Saunders Rd, Lake Forest, IL 60045, but that this cancellation will not apply to any information used or disclosed by my healthcare providers and/or health insurance carriers based on this Authorization before they are notified that I have cancelled it. Unless required by state law, this Authorization is valid for whichever is greater: (a) the duration of remaining on this treatment or (b) 10 years from the date signed below.

A photocopy of this Authorization will be treated in the same manner as the original.

Date: \_\_\_\_\_

Patient's Printed Name: \_\_\_\_\_

Patient's/Legally Authorized Representative's Signature: \_\_\_\_\_

Legally Authorized Representative's Printed Name (if required): \_\_\_\_\_

Patient's/Legally Authorized Representative's Home Address:

Street Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Patient's/Legally Authorized Representative's Telephone: \_\_\_\_\_  Home  Mobile

Patient's/Legally Authorized Representative's Email Address: \_\_\_\_\_

Legally Authorized Representative's Relationship to Patient:  Spouse  Parent/Legal Guardian  Representative per Power of Attorney

Is there someone else with whom we may discuss your protected health information?  No  Yes

Name: \_\_\_\_\_

Relationship to you: \_\_\_\_\_

# INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR ACTIMMUNE<sup>®</sup>

## INDICATIONS AND USAGE

ACTIMMUNE<sup>®</sup> (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

## 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

## 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 the ACTIMMUNE<sup>®</sup> Full Prescribing Information available at [ACTIMMUNEhcp.com](http://ACTIMMUNEhcp.com).**