

# Patient Enrollment Form Guide

The Patient Enrollment Form (PEF) must be completely filled out in order to get your patients started on ACTIMMUNE<sup>®</sup> (Interferon gamma-1b) and initiate their enrollment in Amgen By Your Side, a patient support program. This guide is designed to help you understand the different fields on the form and how to complete the form accurately for submission.

## Three easy steps to initiate the patient enrollment process for ACTIMMUNE:



Fill out all required fields on pages 1 and 2 as indicated by the asterisks, including the prescriber signature and date within the Prescriber section



Obtain the patient consent (“I Consent” check box), patient signature and date within the Patient Consent and Authorization section at the top of page 2, if possible



Send both the front and back of the patient’s insurance card(s) along with all 4 pages of the PEF

### Two ways to submit the Patient Enrollment Form:

- Email: [ACTIMMUNEABYS@amgen.com](mailto:ACTIMMUNEABYS@amgen.com)
- Fax: 1-877-305-7706

## 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-1b, *E. coli*-derived products, or any component of the product

**Please see additional Important Safety Information throughout.**

**If you have any questions while completing the form, please contact Amgen By Your Side at 1-877-305-7704.**

# ACTIMMUNE® (INTERFERON GAMMA-1B) PATIENT ENROLLMENT FORM

Once complete, submit pages 1-4 by fax 1 (877) 305-7706, or email ACTIMMUNEABYS@amgen.com

Initiate the patient enrollment process by completing ALL REQUIRED FIELDS indicated by \*.  
For patient support and/or assistance obtaining patient signature, call Amgen By Your Side at 1-877-305-7704



ACTIMMUNE  
(interferon gamma-1b)

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## 1. PATIENT INFORMATION

Jane Smith  
 First name\* Last name\* Primary language  
 123 Main Street White Plains NY 10605  
 Address\* City\* State\* ZIP\*  
 100-000-0001 Primary 100-000-0002 Home phone\* 01 / 01 / 2012 Gender\*:  Male  Female  
 Mobile phone\* Date of Birth\*  
 jane.smith@email.com Home phone\* Height\* Weight\*: 55 lbs or \_\_\_\_ kg  
 Email\* Height\*  
 Is the patient currently on ACTIMMUNE?\*  Yes  No If Yes, provide last date of use: 02/19/2021

## ALTERNATIVE CONTACT AND/OR CAREGIVER

John Smith 100-000-0003 Primary  
 First name Last name Mobile phone  
 100-000-0001 Home phone  Primary john.smith@email.com Father  
 Home phone Email Relationship to patient

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## 2. PRESCRIBER INFORMATION

Maria Davis 0000000000 00-0000000 12121212  
 First name\* Last name\* NPI#\* State license\* Tax ID\*  
 123 Medical Way White Plains NY 10605  
 Address\* City\* State\* ZIP\*  
 100-000-0004 100-000-0005 Immunologist  
 Phone\* Fax number\* Prescriber specialty\*  
 Sam Wilson sam.wilson@email.com 100-000-0006  
 Office contact name\* Office contact email\* Office contact phone\*

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## 3. INSURANCE INFORMATION

Insurance Provider One  
 Primary insurance\*  
 000-100-0007  
 Insurance company phone\*  
 Policy type\*:  Commercial  Medicaid  Medicare  Other  
 000-000001-01 000001  
 Policy #\* Group #\*  
 John Smith  
 Policyholder's name\*  
 Father Policyholder's date of birth\* 02 / 02 / 1974  
 Relationship\* (MM/DD/YYYY)  
 Prescription card\*:  Yes  No Prescription Rx 100-222-0000  
 If yes, carrier Phone  
 000-000001-04 000001  
 Identification # Policy/Group #  
 John Smith Policyholder's date of birth 02 / 02 / 1974  
 Policyholder name Relationship (MM/DD/YYYY)  
 Father  
 Relationship

Complete signatures and prescription information on next page >>

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### 1 Patient Information

Provide the patient's demographic and contact information; only one patient phone number required, mobile OR home

- Required fields are needed to conduct a benefits investigation, contact the patient for any follow-up, and provide support from Amgen By Your Side
- Alternate contact information is optional
- It may help to include a caregiver's contact information

### 2 Prescriber Information

Provide the prescriber's name, contact information, NPI, tax ID, and state license numbers, which are required for processing

### 3 Insurance Information

Provide the patient's primary insurance information (required to conduct a benefits investigation)

Include secondary insurance information, if applicable, to improve the accuracy of the benefits investigation

If the patient does not have any insurance, fill in the circle next to "Patient is uninsured to my knowledge"

- ! Please include the front and back of your patient's insurance card(s), if available, along with the completed Patient Enrollment Form

**Disclaimer:** The information provided on this form is for demonstration purposes only and does not represent any real person.

## IMPORTANT SAFETY INFORMATION (CONT'D) 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
  - Myelosuppression or receiving other potentially myelosuppressive agents
  - Severe renal insufficiency
  - Age <1 year

Please see additional Important Safety Information throughout.

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**4. PATIENT CONSENT AND AUTHORIZATION (Required—please see language on pages 3-4.)**

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You must read the Consent to Health Data Processing on page 4 and then select one of the below responses.

Select **"I consent"** to proceed with enrollment. If you select **"I do not consent,"** you will not be able to enroll in Amgen By Your Side.

- I consent to the collection, processing, and disclosure of my Health Data for the purposes set forth on page 4.  
 I do not consent to the collection, processing, or disclosure of my Health Data for the purposes set forth on page 4.

By signing below, I am indicating that I have read and understood the Authorization for Use and Disclosure of Protected Health Information (pages 3-4), that I am legally authorized to consent, and that I am providing my consent as the patient or the patient's legal representative for Amgen and its contractors and business partners to use and share the personal information I provide for the purposes described within the Authorization for Use and Disclosure of Protected Health Information.

Jane Smith Patient Name\* John Smith Name of Legal Representative (if needed)  
 John Smith Signature of Patient (or Legal Representative)\* 02 / 23 / 2021 Date\* (MM/DD/YYYY)

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**5. PRESCRIPTION AND CLINICAL INFORMATION**

Jane Patient first name\* Smith Patient last name\* 01 / 01 / 2012 Date of birth\* (MM/DD/YYYY)  
 Chronic Granulomatous Disease (CGD) ICD-10: D71 Anticipated Start Date: ASAP  
 Patient Genotype\*:  X-linked  X-linked carrier Injection Setting:  Physician's Office  Home  
 Autosomal Recessive  Other:  
 Severe Malignant Osteopetrosis (SMO) ICD-10: Q78.2 Ancillary Supplies:  
 Other: ICD-10: Qty:  0.3 ml 31 G 5/16"  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  
 Rx: ACTIMMUNE® (Interferon gamma-1b) 100 mcg (2 million IU)/0.5 mL, single-use vials  
 Sig: XX mcg Subq: 3x/weekly (frequency of dosing) Allergies\*:  No known drug allergies (NKDA)  
 Vial Qty:  12  Other: Refills: 12

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.

Signature below indicates prescription authorization and prescriber certification.

Maria Davis Prescriber Signature (Dispense as Written)\* 02 / 23 / 2021 Date\* (MM/DD/YYYY)  
 Prescriber Signature (Substitutions Allowed)

Written or e-signature only; stamps not acceptable.

**Prescriber Certification:** I certify that the above therapy is medically necessary, that the information provided is accurate to the best of my knowledge and that my patient is being administered ACTIMMUNE (Interferon gamma-1b), Injection, 100 mcg (2 million IU)/0.5 mL, for subcutaneous injection in accordance with the labeled use of the product. I represent that my patient has requested and authorized the disclosure of their personal information to Amgen, Inc. and its affiliates and their respective employees or agents (collectively, "Amgen") for Amgen to administer the Amgen By Your Side program (the "Program"), which provides patient-focused support, including providing logistical and non-medical treatment support for ACTIMMUNE, as prescribed, and educating about the insurance process. I further represent that I have explained to the patient, and the patient indicated they understand and have consented to, the following: 1) Amgen will use the patient's name, date of birth, contact information, prescriptions, and other necessary health information to administer the Program; 2) Amgen will then disclose the patient's personal information to the patient's insurer(s) for the same purposes; 3) the patient can withdraw their consent by contacting Amgen at 1-844-469-4297 or visiting www.amgen.com/DataSubjectRights, but if the patient does not agree to, or withdraws consent for, these uses and disclosures, the patient cannot receive these patient support services for this medication which necessarily requires Amgen to process the patient's personal information; and 4) the patient can view more details about Amgen's privacy practice at www.amgen.com/privacy; I authorize Amgen to transmit this prescription on my behalf to the appropriate pharmacy designated by the patient utilizing their benefit plan by any means allowed under applicable 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 Amgen 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 Amgen may modify or terminate the Program at any time without notice. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Amgen makes no representation or guarantee concerning coverage or reimbursement for any item or service.

State requirements: I certify that the prescription I am submitting as part of this Patient Enrollment Form complies with my state's prescription requirements (e.g., e-prescribing, state-specific prescription form, fax language). I understand that noncompliance with my state's specific prescription requirements will result in outreach to me to obtain a compliant prescription.

By filling out and signing this form, the enrollment process in Amgen By Your Side has initiated; however, your patient must sign a Patient Authorization to complete enrollment in Amgen By Your Side. Please note that your patient will not benefit from the services and support offered by the Program unless your patient signs a Patient Authorization, consenting to receiving such services. If your patient does not sign the Patient Authorization contained within this form, Amgen will contact the patient to determine whether the patient is interested in signing a separate Patient Authorization.

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**Patient Consent and Authorization**

- Patient must sign and date form
- Patient must check "I consent" circle in order to be enrolled in Amgen By Your Side
- If the patient can't sign the form at your office, Amgen By Your Side can follow up to obtain consent

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**Prescription, Clinical Information and Prescriber Signature**

Complete in full the prescription and clinical information section

- Include patient name and date of birth within prescription section along with prescription information
- Provide diagnosis code
  - If there is no box for the primary diagnosis, select "Other" and note the primary diagnosis code
- Please complete the ancillary supply section based on the appropriate prescription
- Prescriber signature is required for processing the Patient Enrollment Form
  - Must be a written signature; stamps and digital signatures are not accepted

**Pages 3-4 of the PEF include the patient authorization and consent language. Once the PEF is submitted, you can provide these 2 pages to the patient for their reference.**

**IMPORTANT SAFETY INFORMATION (CONT'D)  
WARNINGS AND PRECAUTIONS**

- Monitoring:
  - Before starting ACTIMMUNE and every 3 months during treatment, hematologic tests, blood chemistries, and urinalysis are recommended for all patients
  - Patients begun on ACTIMMUNE before the age of 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

**Please see additional Important Safety Information throughout.**

## Connecting Patients with their Amgen By Your Side CNE

The Clinical Nurse Educator (CNE) is a dedicated support partner who helps investigate, explain, and educate on the steps in your patient's treatment experience. They are your patient's point of contact and champion while your patient is accomplishing their treatment goals.

Make sure the patient is aware their CNE will be calling them in the next few days to provide information on next steps and getting started on ACTIMMUNE

Have the patient save their CNE's contact in their phone

- **It is important that a patient answers the CNE's call**

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

Phone Number: \_\_\_\_\_

**Please ensure that all four pages of the enrollment forms are submitted by fax to 1-877-305-7706 or emailed to [ACTIMMUNEABYS@amgen.com](mailto:ACTIMMUNEABYS@amgen.com). Incomplete forms may delay enrollment.**

### IMPORTANT SAFETY INFORMATION (CONT'D) USE IN SPECIFIC POPULATIONS

- ACTIMMUNE should be used during pregnancy only if the potential benefit to the patient outweighs the potential risk to the fetus
- It is not known if ACTIMMUNE is excreted in human milk, so either ACTIMMUNE or nursing should be discontinued dependent on the importance of the drug to the patient
- In younger patients, long-term effects of ACTIMMUNE on fertility are not known
- In animal studies, both male and female fertility was negatively impacted by doses significantly higher than the maximum clinical dose

### 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](#) complete safety information.**