ACTIMMUNE® (Interferon gamma-1b) Access Journey

A resource to help educate healthcare providers about patient access and coverage

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 pages 12-13 and see Full Prescribing Information.

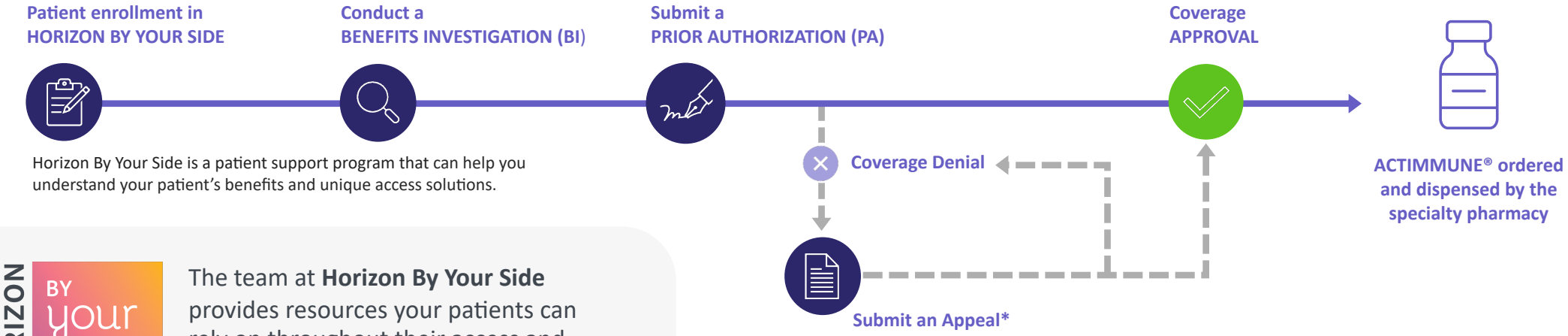
P-ACT-01019-2 05/21

HORIZON | ACTIMMUNE® (Interferon gamma-1b)

ACTIMMUNE® (Interferon gamma-1b) Patient Access Road Map

This resource can help you identify the steps in the access process as well as available resources.

You can navigate through the road map by clicking on areas of the map or by using the navigation bar above. In each section, you will find more detailed information and resources available for that step of the process.



HORIZON BY your side

The team at **Horizon By Your Side** provides resources your patients can rely on throughout their access and treatment journey.

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

Monday–Friday, 9 AM–8 PM ET

https://www.horizonbyyourside.com

*Submitting an appeal does not guarantee approval, and this process may need to be repeated.

Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Horizon Offers Patients a Range of Support Throughout Their Access and Treatment Journey

Coverage policies may vary, and the team at **Horizon By Your Side** can help identify policies early in the access process to help ensure maximum efficiency.

Horizon By Your Side

A partner your patients can rely on throughout their access and treatment journey that provides a wide array of patient-focused services. The team at Horizon By Your Side may provide nonmedical logistical treatment support and education about the insurance process.

Clinical Nurse Educator (CNE)

Provides dedicated, one-on-one support for your patient. The CNE works directly with individual patients to answer nonmedical logistical questions and provide support upon enrollment. Additionally, the CNE educates about navigating insurance processes and accessing treatment on your patient's behalf. The CNE has the expertise and tools to support the patient by educating on patient benefits, PA requirements, payer policies, and coding and claim submissions.

Horizon Case Manager

Can help healthcare providers to understand their patients' benefits and unique access solutions. A Case Manager assigned to your patients may also be in touch with your office to make sure important insurance information is properly shared.

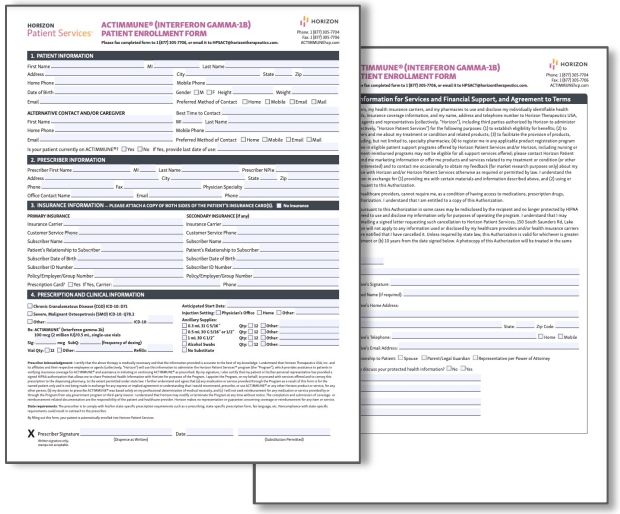
PA, prior authorization.

Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Initiate Patient Enrollment

Many treatments require initial action from the healthcare provider and office staff for patients to get access to ACTIMMUNE® (Interferon gamma-1b). The team at **Horizon By Your Side** provides a range of support tailored to meet the individual needs of your patients throughout their access and treatment journey with ACTIMMUNE®.



The Patient Enrollment Form (PEF) is the first step for your patient to receive support from the team at Horizon By Your Side, including:

- **BI** by researching insurance coverage, PA requirements, and appeal instructions if denied
- **Financial assistance** for eligible patients
- **Patient support** via a CNE who works directly with individual patients to answer nonmedical logistical questions and provide support throughout their journey
- **Insurance information** via a Case Manager who can help you understand your patient's benefits and unique access solutions

DOWNLOAD the PEF to initiate patient enrollment in Horizon By Your Side.

DOWNLOAD the Annotated PEF, a resource that provides details about the PEF.

BI, benefits investigation; CNE, Clinical Nurse Educator; PA, prior authorization.

Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Conduct a Benefits Investigation (BI)

Requirements for coverage will vary among health plans and a BI will identify requirements specific to ACTIMMUNE® (Interferon gamma-1b). A Case Manager can help educate you and your patient about the insurance process and accessing treatment.

A BI may help answer questions about:

ACTIMMUNE® coverage

- Is ACTIMMUNE® covered under the medical benefit or pharmacy benefit?

PA

- Will a PA be required for treatment with ACTIMMUNE®?
- If a PA is not required, is predetermination available?
- What is the process for obtaining a PA or predetermination?
- What information will be required, and how long will the process take?
- How long will the PA remain valid?

Benefits coordination

- Does the patient have any other supplemental insurance benefits that would require coordination? Which benefit is primary? Which is secondary?

Patient financial responsibility and out-of-pocket (OOP) costs

- What is the annual deductible amount the patient must meet?
  - Has this amount been met?
  - How much is left?
- What is the patient's co-payment or coinsurance for ACTIMMUNE®?
- Is there a maximum OOP amount that the patient must meet?
  - Has this amount been met?
  - How much is left?

Prescription information

- Is ACTIMMUNE® medically appropriate?
- Is ACTIMMUNE® being prescribed in accordance with generally accepted standards of medical practice?

DOWNLOAD the ACTIMMUNE® PA Checklist to help your office organize the information that may be needed for a PA.

PA, prior authorization.

Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Conduct a Benefits Investigation (BI) (cont'd)

Coding and claims submission

A BI can help answer questions such as:

- What are the specific coding and claims submission requirements for prescribing ACTIMMUNE® (Interferon gamma-1b) in this patient's plan?
- What type of documentation is required?

Reminder: Requirements for coverage will vary among health plans and a BI will identify requirements specific to ACTIMMUNE®, as well as what insurance your patient has.

ACTIMMUNE® ICD-10-CM Code*	
Code	Description
D71	Chronic granulomatous disease
Q78.2	Severe malignant osteopetrosis
J9216	Injection, interferon, gamma-1b, 3 million units

ACTIMMUNE® NDC Code	
Code	Description
75987-111-11	12 single-use vials in 1 carton; >0.5 mL in 1 vial, single-use

Once the team at Horizon By Your Side completes the BI, you will receive a Summary of Benefits notification generally within 1 to 2 business days of insurance verification.

*This may not be the only applicable code for coverage, nor does using this code guarantee coverage.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Submit a Prior Authorization (PA)

The PA process allows the health plan to review the reason for treatment with ACTIMMUNE® (Interferon gamma-1b) and to determine if it is medically appropriate. Clinical documentation requirements will vary among health plans.

Common criteria a health plan policy may require for a PA:

Diagnosis information

- Diagnosis/ICD-10-CM code
- Dihydrorhodamine (DHR) assay results
- Genetic testing results
- X-ray results (SMO only)
- Complete blood counts, differential and platelet counts
- Results of renal and liver function tests

Treatment history

- 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 nonserious and serious infections*
- Documentation of hospital admissions
- Note reauthorization criteria
- Note any consultations with a specialist (eg, immunologist, infectious disease physician, hematologist)

Including a letter of medical necessity with a PA is important and may help avoid delays.

Your office may need to connect with the referring physician to gather the clinical documentation required to complete the PA. The dedicated Case Manager has the local expertise to provide education about PA, medical exception, or appeal processes.

*Serious infection is defined as a clinical event requiring hospitalization and intravenous antibiotics.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; SMO, severe malignant osteopetrosis.

Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Submit a Prior Authorization (PA) (cont'd)

The PA process allows the health plan to review the reason for the requested therapy and to determine medical appropriateness. Clinical documentation requirements will vary between health plans. When submitting a PA for ACTIMMUNE® (Interferon gamma-1b), be sure to:

- **Submit the PA directly to the health plan or by using an electronic PA system, such as CoverMyMeds®**
- **Thoroughly complete every section of the PA form and review the medical policy carefully, as each health plan may have unique requirements**
- **Provide supporting documentation, including but not limited to:**
  - Medical records
  - Diagnosis confirmed by DHR and/or genetic testing
  - Chart notes
  - Publications and references
  - A letter of medical necessity
- **Inquire about how long the process will take once necessary documents have been submitted**

DOWNLOAD the PA Checklist for reminders and recommendations for submitting a PA.

DOWNLOAD the Letter of Medical Necessity Template for chronic granulomatous disease and print it out on your office letterhead.

DOWNLOAD the Letter of Medical Necessity Template for severe malignant osteopetrosis and print it out on your office letterhead.

DHR, dihydrorhodamine.

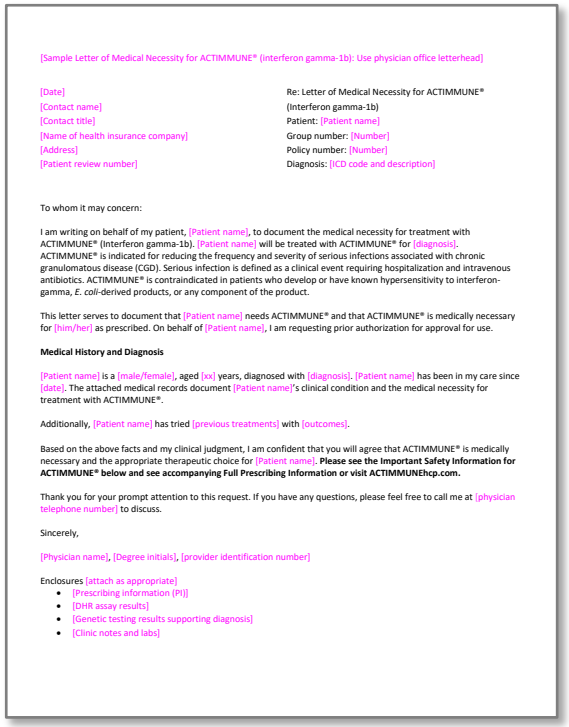
Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Submit a Prior Authorization (PA) (cont'd)

Writing a letter of medical necessity

A patient-specific letter of medical necessity explains the physician's rationale and clinical decision-making in choosing ACTIMMUNE® (Interferon gamma-1b).



[Sample Letter of Medical Necessity for ACTIMMUNE® (interferon gamma-1b): Use physician office letterhead]

[Date]
[Contact name]
[Contact title]
[Name of health insurance company]
[Address]
[Patient review number]

Re: Letter of Medical Necessity for ACTIMMUNE® (Interferon gamma-1b)
Patient: [Patient name]
Group number: [Number]
Policy number: [Number]
Diagnosis: [ICD code and description]

To whom it may concern:

I am writing on behalf of my patient, [Patient name], to document the medical necessity for treatment with ACTIMMUNE® (Interferon gamma-1b). [Patient name] will be treated with ACTIMMUNE® for [diagnosis]. ACTIMMUNE® is indicated for reducing the frequency and severity of serious infections associated with chronic granulomatous disease (CGD). Serious infection is defined as a clinical event requiring hospitalization and intravenous antibiotics. ACTIMMUNE® is contraindicated in patients who develop or have known hypersensitivity to interferon-gamma, *E. coli*-derived products, or any component of the product.

This letter serves to document that [Patient name] needs ACTIMMUNE® and that ACTIMMUNE® is medically necessary for [him/her] as prescribed. On behalf of [Patient name], I am requesting prior authorization for approval for use.

Medical History and Diagnosis

[Patient name] is a [male/female], aged [xx] years, diagnosed with [diagnosis]. [Patient name] has been in my care since [date]. The attached medical records document [Patient name]'s clinical condition and the medical necessity for treatment with ACTIMMUNE®.

Additionally, [Patient name] has tried [previous treatments] with [outcomes].

Based on the above facts and my clinical judgment, I am confident that you will agree that ACTIMMUNE® is medically necessary and the appropriate therapeutic choice for [Patient name]. **Please see the Important Safety Information for ACTIMMUNE® below and see accompanying Full Prescribing Information or visit ACTIMMUNEhcp.com.**

Thank you for your prompt attention to this request. If you have any questions, please feel free to call me at [physician telephone number] to discuss.

Sincerely,

[Physician name], [Degree initials], [provider identification number]

Enclosures [attach as appropriate]
- [Prescribing information (PI)]
- [DHR assay results]
- [Genetic testing results supporting diagnosis]
- [Clinic notes and labs]

The following is a template letter of medical necessity for ACTIMMUNE® that can be customized based on your patient's medical history and demographic information. The template can help your office craft the letter and highlight the medical necessity for your patient.

NOTE: Some health plans may have specific forms that must be completed in order to document medical necessity.

- **Check with the health plan to identify specific documentation that needs to be submitted with a letter of medical necessity**
- **Provide relevant medical information and attach the patient's medical records and/or supporting documents for the health plan to review**
- **Include a copy of the Full Prescribing Information**

DOWNLOAD the Letter of Medical Necessity Template for chronic granulomatous disease and print it out on your office letterhead.

DOWNLOAD the Letter of Medical Necessity Template for severe malignant osteopetrosis and print it out on your office letterhead.

Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Submit an Appeal

An appeal letter may be needed if the PA for ACTIMMUNE® (Interferon gamma-1b) is denied. When writing an appeal letter, ensure that you address the specific details of the denial reason(s), refer to the letter of denial for specific language regarding the reason for denial, and address any concerns that are patient specific.

Supplemental documentation may include:

- Relevant clinical notes for your patient
- Recent test results
- Supporting scientific publications/journal articles
- A summary of your recommendation at the end of the letter
- A letter of medical necessity

Make sure you match the exact language from the denial letter.
It is imperative to address the specifics of the denial in the appeal letter.
Before you submit your appeal, make sure to:

- Check for any incomplete or missing information, as this is a common reason for denial
- Schedule a peer-to-peer meeting with the health plan
- Contact a Case Manager to learn about additional resources and next steps in the process

If a letter of medical necessity was not submitted with the PA, consider including it with the appeal letter.

Contact the health plan to learn about the appeal review timeline. One you have submitted the letter, along with any supporting documentation, the health plan will review and decide on coverage within approximately:

72 HOURS
for urgent care

30 DAYS
for nonurgent care

60 DAYS
for services already provided

To initiate an expedited appeal, contact your patient's health plan to confirm its instructions for expedited requests.

DOWNLOAD **the Appeal Letter Template to help your office draft an appeal letter.**

DOWNLOAD **the Payor Appeal Letter Checklist and Tips to help you through the appeal process.**

PA, prior authorization.

Please see Important Safety Information on pages 12-13 and see Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

Best Practices to Maintain Throughout the Access Journey

DOCUMENT
Keep a record of policy requirements, which may vary considerably among different health plans.

IDENTIFY
Ensure smooth transactions among the provider, health plan, and patient by identifying each health plan's policy early on.

KNOW
Health plan policies provide clarity for patients on their coverage and OOP expenses.

CONTACT
Our Case Managers are ready to assist you with your questions.

HORIZON BY your side

The team at **Horizon By Your Side** provides resources your patients can rely on throughout their access and treatment journey.

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OOP, out-of-pocket.

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ACTIMMUNE® (Interferon gamma-1b)

INDICATIONS and IMPORTANT SAFETY INFORMATION

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

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

Please see additional Important Safety Information on page 13 and Full Prescribing Information.

ACTIMMUNE® (Interferon gamma-1b)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **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.

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