BETASERON Patient Setup & Enrollment Form

All information below is required. Completed forms may help speed service.

Fax completed form to BETAPLUS at 1-866-248-8575.

Questions? Call BETAPLUS at 1-800-788-1467.

BETASERON® (interferon beta-1b)
0.3 mg for SC injection

➤ STEP 1: BETAPLUS® ENROLLMENT

I have read the description of the BETAPLUS program and understand I am opting into BETAPLUS, including the below training selection.

☐ Provide training on BETASERON and/or autoinjector, including dispensing of autoinjector and training kit (placebo/syringe) as required

☐ No training or autoinjector required

STEP 2: PATIENT INFORMATION

Patient Name

Address

City | State | ZIP

Home Phone | Cell Phone

Preferred Time to Call

Sex: ☐ Male ☐ Female | Date of Birth

Patient Social Security #

Email

The following information should be filled out by your healthcare provider

STEP 3: INSURANCE INFORMATION

Primary Medical Insurance

☐ Uninsured/Self–pay

Policy Holder

ID # | Group #

Phone

Primary Pharmacy Benefit Manager (Please provide a copy of card)

ID # | Group #

Phone

BIN # | PCN #

STEP 4: PHYSICIAN INFORMATION

Physician Name

(check one) ☐ MD ☐ DO ☐ PA ☐ NP

NPI # | DEA #

Practice Name

Address

City | State | ZIP

Phone | Fax

Contact Name

Contact Email/Phone

STEP 5: PRESCRIPTION

Prescribe BETASERON® (interferon beta-1b)
Rx: BETASERON® (interferon beta–1b)

Dispense BETASERON (check one)
☐ 1 box (14 vials) 0.25 mg/1 mL with 12 refills (may supply up to 3 months at a time)
☐ 1 box (14 vials) 0.25 mg/1 mL _____ refills

Select Dosing (check one)
☐ Sig: Weeks 1–2: 0.0625 mg SC qod | Weeks 3–4: 0.125 mg SC qod
Weeks 5–6: 0.1875 mg SC qod | Weeks 7+: 0.25 mg SC qod
☐ Maintenance dose 0.25 mg SC qod
☐ Other Sig:

BETA Bridge Enrollment Request*
☐ If eligible, dispense a temporary supply of BETASERON to patient facing a coverage gap
Rx: BETASERON® (interferon beta–1b)

Dispense BETASERON (check one)
☐ 1 box (14 vials) 0.25 mg/1 mL with 12 refills (may supply up to 3 months at a time)
☐ 1 box (14 vials) 0.25 mg/1 mL _____ refills

Select Dosing (check one)
☐ Sig: Weeks 1–2: 0.0625 mg SC qod | Weeks 3–4: 0.125 mg SC qod
Weeks 5–6: 0.1875 mg SC qod | Weeks 7+: 0.25 mg SC qod
☐ Maintenance dose 0.25 mg SC qod
☐ Other Sig:

☐ Newly Diagnosed (New BETASERON Patient) ☐ Previously Diagnosed (New BETASERON Patient) ☐ Restart (Previous BETASERON Patient) ☐ Current BETASERON Patient

STEP 6: PHYSICIAN AUTHORIZATION AND STATEMENT OF MEDICAL NECESSITY

Primary diagnosis: ICD–10 Code CM G35: I certify that the prescribed therapy is medically necessary for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. This statement is accurate to the best of my knowledge.

Patient was previously treated with (list all): _____

Reason for discontinuation: _____

I authorize Bayer and its Healthcare Partners to be my designated agent(s) and (1) to provide any information on this form to the insurer of the above–named patient and (2) to forward the above prescription, by fax or any other mode of delivery, to the pharmacy.

Prescriber Signature | **Date**

To report any adverse events, product technical complaints, or medication errors associated with the use of Betaseron, contact Bayer at 1-888-842-2937, or send the information to DrugSafety.GPV.US@bayer.com

Please see full Prescribing Information.

Patient Authorization Form for BETASERON® (interferon beta-1b) Patients

PATIENT HIPAA AUTHORIZATION

I voluntarily provide this Authorization for the use and disclosure of my Protected Health Information ("PHI"), as such term is defined by the Health Insurance Portability and Accountability Act of 1996 (as amended, "HIPAA"). I understand that PHI is health information that identifies me or that could reasonably be used to identify me. I authorize my healthcare provider, including my physician and pharmacy, and my health plan, to disclose to Bayer and its contracted agents my name, address, telephone number, health insurance status and coverage, and such medical information as may be necessary for me to enroll in the BETAPLUS® program. I understand this disclosure(s) will contain PHI, including information about my current medical condition, treatment, coordination of treatment and receipt of medication. I allow the use and disclosure of my PHI to Bayer and its contracted agents for the following purposes:

- To verify my insurance information and coverage
- To ensure the accuracy and completeness of this form
- To help with my insurance coverage questions for Bayer medications
- To determine if I qualify for other Bayer patient support programs
- To determine my eligibility for other sources of prescription medication financial assistance
- To provide education, training, and ongoing support on the use of my Bayer medication
- To send me information on Bayer products and services related to my treatment
- To send me refill reminders for my Bayer prescription medication and to encourage its appropriate use
- To communicate with me, my healthcare providers and health plan about my medical care and treatment
- To contact me for market research feedback, sales support purposes, and as necessary to comply with applicable laws
- Bayer may contact me for potential adverse event follow-up information

I understand that:

- This Authorization will remain in effect until the end of my participation in the BETAPLUS program or 5 years unless subject to applicable law from the date of my signature on this Authorization, whichever occurs later.
- I may cancel this Authorization at any time by writing to: BETAPLUS, 6251 Chancellor Drive, Suite 101, Orlando, FL 32809; or faxing my request to 1-866-248-8575.
- If I cancel this Authorization, my healthcare provider and health plan will stop sharing my PHI with Bayer and its contracted agents. However, the revocation will not affect prior use or disclosure of my PHI in reliance on this Authorization.
- I may opt-out of being contacted for market research feedback, sales support purposes and still enroll in the patient support program.
- That entities that receive my PHI in accordance with this Authorization may not be required by law to keep the information private and that it will no longer be protected by the HIPAA privacy law. It may become available in the public domain.
- I do not need to sign this Authorization to receive (i) medical treatment or medication or (ii) coverage, payment, enrollment in or eligibility for benefits from my health plan. However, if I do not sign this Authorization, I may not participate in the BETAPLUS program or be eligible for other Bayer patient support programs.
- I understand that some of my health care providers, such as my pharmacies, may receive payment from Bayer in return for services that require use or disclosure of my PHI to Bayer and its contracted agents.

I have read and understand the terms of this Authorization and have had an opportunity to ask questions about the uses and disclosures of PHI. I understand that I am entitled to receive a signed copy of this Authorization and I can also get a copy by contacting BETAPLUS at 1-844-788-1470.

Signature of patient or authorized patient representative

Date

Printed name of authorized patient representative (if patient representative signs above)

Authorized patient representative's relationship to the patient (parent, guardian, etc.), if patient representative signs above

Separate along perforation. Patient: keep this page for your records. Doctor's office: please fax completed form on right to BETAPLUS at 1-866-248-8575. Questions? Call BETAPLUS at 1-800-788-1467.

Please see full Prescribing Information.

INDICATIONS

Betaseron (interferon beta-1b) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindications. BETASERON (interferon beta-1b) is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, Albumin (Human), mannitol, or any other component of the formulation.

Hepatic Injury. Severe hepatic injury including cases of hepatic failure has been rarely reported in patients taking BETASERON. In some cases, these events have occurred in the presence of other drugs or comorbid medical conditions that have been associated with hepatic injury. Consider the potential risk of BETASERON used in combination with known hepatotoxic drugs or other products (e.g., alcohol) prior to BETASERON administration, or when adding new agents to the regimen of patients already on BETASERON. Monitor patients for signs and symptoms of hepatic injury. Consider discontinuing BETASERON if serum transaminase levels significantly increase, or if they are associated with clinical symptoms such as jaundice.

Asymptomatic elevation of serum transaminases is common in patients treated with BETASERON. In controlled clinical trials, elevations of SGPT to greater than five times baseline value were reported in 12% of patients receiving BETASERON (compared to 4% on placebo), and increases of SGOT to greater than five times baseline value were reported in 4% of patients receiving BETASERON (compared to 1% on placebo), leading to dose-reduction or discontinuation of treatment in some patients. Monitor liver function tests.

Anaphylaxis and Other Allergic-Reactions. Anaphylaxis has been reported as a rare complication of BETASERON use. Other allergic reactions have included dyspnea, bronchospasm, tongue edema, skin rash and urticaria. Discontinue BETASERON if anaphylaxis occurs.

Depression and Suicide. Depression and suicide have been reported to occur with increased frequency in patients receiving interferon compounds, including BETASERON. Patients treated with BETASERON should be advised to report immediately any symptoms of depression and/or suicidal ideation. Consider discontinuation of BETASERON if depression occurs.

Congestive Heart Failure. Monitor patients with pre-existing congestive heart failure (CHF) for worsening of their cardiac condition during initiation of and continued treatment with BETASERON. Cases of CHF, cardiomyopathy, and cardiomyopathy with CHF have been reported in patients without known predisposition to these events, and without other known etiologies being established. In some cases, these events have been temporally related to the administration of BETASERON. Recurrence upon rechallenge was observed in some patients. Consider discontinuation of BETASERON if worsening of CHF occurs with no other etiology.

Injection Site Necrosis and Reactions. Injection site reactions occurred in 78% of patients receiving BETASERON (compared to 26% on placebo) in controlled clinical trials with injection site necrosis reported in 4% of BETASERON patients (compared to 0% on placebo). For patients who continue BETASERON after injection site necrosis has occurred, BETASERON should not be administered into the affected area until it is fully healed. If multiple lesions occur, therapy should be discontinued until healing occurs. Patients should be advised of the importance of the use of aseptic technique and rotating injection sites.

Leukopenia. Leukopenia has been reported in 18% of patients receiving BETASERON (compared to 6% on placebo) in controlled clinical trials leading to a reduction in dose in some patients. Monitoring of complete blood and differential white blood cell counts is recommended. Patients with myelosuppression may require more intensive monitoring.

Thrombotic Microangiopathy. Cases of thrombotic microangiopathy (TMA), including thrombotic thrombocytopenic purpura and hemolytic uremic syndrome, some fatal, have been reported several weeks to years after starting interferon beta products. Discontinue BETASERON if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.

Pulmonary Arterial Hypertension. Cases of pulmonary arterial hypertension (PAH) have been reported in patients treated with interferon beta products, including BETASERON. PAH has occurred in the absence of other contributory factors and many cases have required hospitalization. PAH has developed at various time points after initiating therapy and may occur several years after starting treatment. Instruct patients to promptly report any new symptoms such as new or increasing fatigue or shortness of breath. Discontinue BETASERON and manage as clinically indicated if PAH is diagnosed and alternative etiologies have been ruled out.

Flu-like Symptom Complex. Flu-like symptom complex for patients on BETASERON was 57% (versus 37% on placebo) in controlled clinical trials. Analgesics and/or antipyretics on treatment days may help ameliorate flu-like symptoms.

IMPORTANT SAFETY INFORMATION

Seizures. Seizures have been temporally associated with the use of beta interferons.

Drug-induced Lupus Erythematosus. Drug-induced lupus erythematosus has been reported with interferon beta products, including BETASERON. Signs and symptoms of drug-induced lupus reported in BETASERON-treated patients have included rash, serositis, polyarthritis, nephritis, and Raynaud's phenomenon. Cases have occurred with positive serologic testing (positive anti-nuclear and/or anti-double-stranded DNA antibody testing). If patients develop new signs and symptoms of this syndrome, BETASERON therapy should be stopped.

Monitoring for Laboratory Abnormalities. In addition to those laboratory tests normally required for monitoring patients with multiple sclerosis, complete blood and differential white blood cell counts, platelet counts and blood chemistries including liver function tests are recommended at one, three and six months after introduction of BETASERON therapy, and periodically thereafter in the absence of clinical symptoms.

Most Common Adverse Reactions. The most commonly reported adverse reactions (at least 5% more frequent on BETASERON than on placebo) in controlled clinical trials were injection site reaction (78% vs 26% for placebo), lymphopenia (86% vs 66%), flu-like symptoms (57% vs 37%), myalgia (23% vs 14%), leukopenia (13% vs 4%), neutropenia (13% vs 5%), increased liver enzymes (SGPT to greater than five times baseline value [12% vs 4%], SGOT to greater than five times baseline value [4% vs 1%]), headache (50% vs 43%), hypertonia (40% vs 33%), pain (42% vs 35%), rash (21% vs 15%), insomnia (21% vs 16%), abdominal pain (16% vs 11%), and asthenia (53% vs 48%).

For additional important risk and use information, please see the full Prescribing Information.

You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Bayer

BETASERON®
(interferon beta-1b)
0.3 mg for SC injection