

Prior Authorization DRUG Guidelines

BETASERON® (Interferon beta-1b)

Effective Date: 7/28/05

Date Developed: 7/13/05 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Description:

Interferon beta-1b is an agent that is approved by the Food and Drug Administration (FDA) for the treatment of relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations. Betaseron is an interferon. Interferon beta-1b differs from naturally occurring human protein by a single amino acid substitution and the lack of carbohydrate side chains. It alters the expression and response to surface antigens and can enhance immune cell activities. The properties of interferon beta-1b that modify biologic responses are mediated by cell surface receptor interactions; however, the mechanism in the treatment of MS is unknown.

Pre-Authorization Criteria: Multiple sclerosis (first and relapsing episodes)

EXCLUSIONS

Coverage of interferon beta-1b is *not* recommended in the following circumstances:

1. Concurrent use of interferon beta-1b with interferon beta-1a (Avonex[®], Rebif[®]) or glatiramer acetate (Copaxone[®]) is not recommended. These agents are not indicated for use in combination and studies that are currently under progress will determine the efficacy of these agents concurrently. Only limited data documents the use of these therapies in combination.^{10-11,15} Additional studies are needed to determine if combination therapy is effective and safe.
2. Patient is receiving natalizumab (Tysabri[®]). Natalizumab is indicated as monotherapy for MS patients with relapsing forms of the disease.¹²
3. Patient is concurrently receiving fingolimod. Use of interferon beta-1b SC with fingolimod has not been studied or established.
4. Coverage is not recommended for circumstances *not* listed in the *Recommended Authorization Criteria*.

VCHCP requires that Betaseron be prescribed by a neurologist.

MONITORING PARAMETERS — Hemoglobin, liver function, and blood chemistries

DOSING: ADULTS — Multiple sclerosis (relapsing-remitting): SubQ: 0.25 mg (8

million units) every other day

DOSING: PEDIATRIC — Not recommended in children <18 years of age

DOSING: ELDERLY — Refer to adult dosing.

DOSAGE FORMS — Injection, powder for reconstitution [preservative free]: 0.3 mg [9.6 million units] [contains albumin; packaged with prefilled syringe containing diluent]

ADMINISTRATION — Withdraw 1 mL of reconstituted solution from the vial into a sterile syringe fitted with a 27-gauge needle and inject the solution subcutaneously; sites for self-injection include arms, abdomen, hips, and thighs

CONTRAINDICATIONS — Hypersensitivity to E. coli-derived products, natural or recombinant interferon beta, albumin human or any other component of the formulation

WARNINGS / PRECAUTIONS — Interferons have been associated with severe psychiatric adverse events (psychosis, mania, depression, suicidal behavior/ideation) in patients with and without previous psychiatric symptoms, avoid use in severe psychiatric disorders and use caution in patients with a history of depression; patients exhibiting symptoms of depression should be closely monitored and discontinuation of therapy should be considered. Due to high incidence of flu-like adverse effects, use caution in patients with pre-existing cardiovascular disease, pulmonary disease, seizure disorders, myelosuppression, renal impairment or hepatic impairment. Severe injection site reactions (necrosis) may occur; patient and/or caregiver competency in injection technique should be confirmed and periodically re-evaluated. Safety and efficacy in patients <18 years of age have not been established.

DRUG INTERACTIONS

ACE inhibitors: Interferons may increase the adverse/toxic effects of ACE inhibitors, specifically the development of granulocytopenia. Risk: Monitor

Warfarin: Interferons may increase the anticoagulant effects of warfarin. Risk:

Monitor Zidovudine: Interferons may decrease the metabolism of zidovudine. Risk:

Monitor PREGNANCY RISK FACTOR — C

PREGNANCY IMPLICATIONS — Safety and efficacy in pregnant women has not been established. Treatment should be discontinued if a woman becomes pregnant, or plans to become pregnant during therapy. A dose-related abortifacient activity was reported in Rhesus monkeys.

LACTATION — Excretion in breast milk unknown/contraindicated

BREAST-FEEDING CONSIDERATIONS — Because its use has not been evaluated during lactation, breast-feeding is not recommended

PATIENT EDUCATION — Instruct patients on self-injection technique and procedures. If possible, perform first injection under the supervision of an appropriately qualified healthcare professional. Injection site reactions may occur during therapy. They are usually transient and do not require discontinuation of therapy, but careful assessment of the nature and severity of all reported reactions. Flu-like symptoms are not uncommon following initiation of therapy. Acetaminophen may reduce these symptoms. Do not change the dosage or schedule of administration without medical consultation. Inform prescriber immediately if you feel depressed or have any thoughts of suicide. Report any broken skin or black-blue discoloration around the injection site. Avoid prolonged exposure to sunlight or sunlamps.

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