Clinical Policy: Interferon beta-1b (Betaseron, Extavia)
Reference Number: ERX.SPMN.158
Effective Date: 10/16
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that interferon beta-1b (Betaseron®, Extavia®) is medically necessary for the following indications:

I. Initial Approval Criteria
   A. Multiple Sclerosis (must meet all):
      1. Prescribed by or in consultation with a neurologist;
      2. MRI features consistent with multiple sclerosis (MS) and diagnosis of (a or b):
         a. Clinically isolated syndrome (CIS);
         b. Relapsing-remitting MS (RRMS);
      3. If Extavia is requested, member has a contraindication to or failed a trial of Betaseron or Rebif AND at least one of the following agents: glatiramer acetate (Copaxone, Glatopa), Tecfidera, Gilenya, or Aubagio;
      4. Prescribed dose does not exceed 0.25 mg every other day;
      5. Member will not use other disease modifying therapies for MS concurrently.

   Approval duration: 6 months

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy

II. Continued Approval
   A. Multiple Sclerosis (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Responding positively to therapy;
      3. Prescribed dose does not exceed 0.25 mg every other day;
      4. Member will not use other disease modifying therapies for MS concurrently.

   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.
Background

**Description/Mechanism of Action:**
Betaseron and Extavia are purified, sterile, lyophilized protein products produced by recombinant DNA techniques. Interferon beta-1b is manufactured by bacterial fermentation of a strain of Escherichia coli that bears a genetically engineered plasmid containing the gene for human interferon beta. The mechanism of action of interferon beta-1b in patients with multiple sclerosis is unknown.

**Formulations:**
Betaseron and Extavia are supplied as lyophilized powder in clear glass, single-use vials (3 mL capacity) for reconstitution. Each vial comes with a pre-filled single-use syringe containing 1.2 mL diluent (sodium chloride).

**FDA Approved Indication(s):**
Betaseron is an interferon beta/subcutaneous injection indicated for:
- Treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations.

Extavia is an interferon beta/subcutaneous injection indicated for:
- Treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations.

Appendices

**Appendix A: Abbreviation Key**
- CIS: clinically isolated syndrome
- DNA: deoxyribonucleic acid
- MRI: magnetic resonance imaging
- MS: multiple sclerosis
- RRMS: relapsing-remitting multiple sclerosis

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J1830</td>
<td>Injection interferon beta-1b, 0.25 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)</td>
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Reviews, Revisions, and Approvals

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<th>Description</th>
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<tr>
<td>Policy split from USS.SPMN.36 Multiple Sclerosis (MS) Treatments and converted to new template. Removed SPMS indication, added max</td>
<td>08/16</td>
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## Reviews, Revisions, and Approvals

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Dosing, clarified monotherapy restriction, modified trial/failure criteria to require trial/failure of another interferon therapy and an agent from a different class, modified approval duration to 6 months for initial and 12 months for re-auth.

## References


## Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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