Clinical Policy: Interferon beta-1a (Avonex, Rebif)
Reference Number: ERX.SPMN.157
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-1a (Avonex®, Rebif®) 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 Avonex is requested, member has a contraindication to or failed a trial of Rebif or Betaseron AND at least one of the following agents: glatiramer acetate (Copaxone, Glatopa), Tecfidera, Gilenya, or Aubagio;
      4. Prescribed dose does not exceed:
         a. 30 mcg per week if Avonex is requested;
         b. 44 mcg three times per week if Rebif is requested;
      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:
         a. 30 mcg per week if Avonex is requested;
         b. 44 mcg three times per week if Rebif is requested;
      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:
Avonex and Rebif are both glycoproteins produced by recombinant DNA technology using genetically engineered Chinese Hamster Ovary cells into which the human interferon beta gene has been introduced. The amino acid sequence of Avonex and Rebif is identical to that of natural human interferon beta. The mechanism of action by which interferon beta-1a exerts its effects in patients with multiple sclerosis is unknown.

Formulations:
Avonex is supplied as single-use lyophilized powder vials, single-use prefilled syringes, and single-use prefilled autoinjector pens.
- Each vial is preservative-free and contains 33 micrograms of interferon beta-1a and 16.5 mg albumin (human).
- Each prefilled glass syringe is sterile, liquid, albumin-free, and contains 30 micrograms of interferon beta-1a (0.5 mL for intramuscular injection).
- Each prefilled autoinjector pen is sterile, liquid, albumin-free, and contains 30 micrograms of interferon beta-1a (0.5 mL for intramuscular injection).

Rebif is supplied as a sterile solution containing no preservative available in prefilled syringes (8.8 mcg, 22 mcg) and Rebisode autoinjectors (44 mcg).

FDA Approved Indication(s):
Avonex is an interferon beta/intramuscular injection indicated for:
- Treatment of patients with relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations.

Rebif is an interferon beta/subcutaneous injection indicated for:
- Treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability.

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.
HCPCS Codes | Description |
--- | --- |
Q3028 | Injection, interferon beta-1a, 1 mcg for subcutaneous use |
Q3027 | Injection, interferon beta-1a, 1 mcg for intramuscular use |

**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/16</td>
<td>09/16</td>
</tr>
</tbody>
</table>

Policy split from USS.SPMN.36 Multiple Sclerosis (MS) Treatments and converted to new template. Removed SPMS indication, added max dosing, clarified monotherapy restriction, modified trial/failure criteria to require trial/failure of another interferon therapy and an agent from a different class, and 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.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.