Clinical Policy: Interferon beta-1a (Avonex, Rebif)

Reference Number: PA.CP.PHAR.255
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for interferon beta-1a (Avonex®, Rebif®).

FDA Approved Indication(s)
Avonex and Rebif are indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability. Patients with MS in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Avonex and Rebif are **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of one of the following (a, b, or c):
   a. Clinically isolated syndrome;
   b. Relapsing-remitting MS (RRMS);
   c. Secondary progressive MS, and member has active relapsing disease;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 2 years (for Rebif requests) or ≥ 18 years (for Avonex requests);
4. For Rebif request and age ≥ 18 years, member meets the following (a and b), or the patient is currently stabilized on therapy:
   a. If diagnosis of RRMS, failure of one of the following: glatiramer (Copaxone, Glatopa), Tecfidera, or Gilenya, at up to maximally indicated doses unless contraindicated or clinically significant adverse effects;
   b. Failure of Avonex and Plegridy at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Member will not use other disease modifying therapies for MS concurrently;
6. Dose does not exceed:
   a. Avonex: 30 mcg per week;
   b. Rebif: 44 mcg three times per week.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Multiple Sclerosis (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Status Scale score or reduction in relapses or magnetic resonance imaging lesions;
3. Member is not using other disease modifying therapies for MS concurrently;
4. If request is for a dose increase, new dose does not exceed:
   a. Avonex: 30 mcg per week;
   b. Rebif: 44 mcg three times per week.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - 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 (22 mcg, 44 mcg).

Appendices
Appendix A: Abbreviation Key
DNA: deoxyribonucleic acid
FDA: Food and Drug Administration
MS: 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
J1826	Injection, interferon beta-1a, 30 mcg
Q3027	Injection, interferon beta-1a, 1 mcg for intramuscular use
Q3028	Injection, interferon beta-1a, 1 mcg for subcutaneous use

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added coverage for SPMS per AAN guidelines; added age restriction for Avonex per prescribing information; added redirection to 2 preferred INF agents; references reviewed and updated.	01.05.18	

References
1. Avonex Prescribing Information. Cambridge, MA: Biogen Inc.; March 2016. Available at http://www.avonex.com. Accessed January 5, 2018.
2. Rebif Prescribing Information. Rockland, MA: EMD Serono, Inc; November 2015. Available at http://www.rebif.com. Accessed January 5, 2018.
3. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002; 58(2): 169-178.
4. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. July 2016. January 5, 2018.
5. European Medicines Agency: Rebif: EPAR – Product Information. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000136/WC500048681.pdf. January 5, 2018.