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

Reference Number: CP.PHAR.255
Effective Date: 08/16
Last Review Date: 08/17

Coding Implications
Revision Log

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

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Avonex and Rebif are **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of clinically isolated syndrome or relapsing-remitting multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. If Rebif is requested, member meets one of the following (a or b):
   a. Age between 2 to 17 years;
   b. Age ≥ 18 years, and failure of Avonex or Plegridy and one of the following: Copaxone, Glatopa, Tecfidera, or Gilenya, at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Member will not use other disease modifying therapies for MS concurrently;
5. 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 CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Multiple Sclerosis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to 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).

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. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

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

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
Policy split from CP.PHAR.18 MS Treatments. Criteria: added max dosing, clarified monotherapy restriction, removed re-authorization requirement for documented adherence, updated reasons to discontinue, modified efficacy criteria to "Responding positively to therapy". Modified renewal approval duration to 12 months. Added requirement for the trial and failure of at least 2 preferred regimens from different classes with one being Avonex or plegridy; Removed specific strength requirement from glatiramer.	08/16	08/16
Added age requirement as safety and efficacy have not been established in pediatric populations. Removed MRI requirement, contraindication, and reasons to discontinue.	07/17	08/17

References

1. Avonex Prescribing Information. Cambridge, MA: Biogen Inc.; March 2016. Available at http://www.avonex.com. Accessed June 14, 2017.
2. Rebif Prescribing Information. Rockland, MA: EMD Serono, Inc; November 2015. Available at http://www.rebif.com. Accessed June 14, 2017.
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. Olek MJ. Diagnosis of multiple sclerosis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed June 13, 2017.
5. 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. Accessed June 13, 2017.
6. 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. Accessed June 21, 2017.

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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 clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.