Clinical Policy: Interferon beta-1b (Betaseron, Extavia)

Reference Number: PA.CP.PHAR.256
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-1b (Betaseron®, Extavia®).

FDA Approved Indication(s)
Betaseron and Extavia 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 Betaseron and Extavia 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 ≥ 12 years;
4. If diagnosis of RRMS, failure of one of the following: glatiramer (Copaxone, Glatopa), Tecfidera, Gilenya, or Aubagio, at up to maximally indicated doses unless contraindicated or clinically significant adverse effects, unless the patient is currently stabilized on therapy;
5. If age ≥ 18 years, failure of Avonex and Plegridy at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced, unless the patient is currently stabilized on therapy;
6. Member will not use other disease modifying therapies for MS concurrently;
7. Dose does not exceed 0.25 mg every other day (1 vial every other day).

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 0.25 mg every other day (1 vial every other day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and 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:
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).

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
J1830	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)

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

References

1. Betaseron Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; April 2016. Available at http://www.betaseron.com. Accessed January 5, 2018.
2. Extavia Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2016. Available at http://www.extavia.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: Betaferon: EPAR – Product Information; April 2017 Accessed January 5, 2018.
6. European Medicines Agency: Extavia: EPAR – Product Information; January 2016.. January 5, 2018.