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

Reference Number: PA.CP.PHAR.256
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

Description
Interferon beta-1b (Betaseron®, Extavia®) is an amino acid glycoprotein.

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;
   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 age ≥ 18 years, member meets the following (a and b):
   a. If relapsing-remitting MS, failure of one of the following at up to maximally indicated doses unless contraindicated or clinically significant adverse effects: glatiramer (*generic [including Glatopa®] is preferred*), Tecfidera®, or Gilenya®, unless the patient is currently stabilized on therapy;
   b. 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;

   **Prior authorization is required for all disease modifying therapies for MS*
5. Member will not use other disease modifying therapies for MS concurrently (*see Appendix D*);
6. Dose does not exceed 0.25 mg (1 vial) every other day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

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;
3. Member is not using other disease modifying therapies for MS concurrently (*see Appendix D*);
4. If request is for a dose increase, new dose does not exceed 0.25 mg (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.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MS: multiple sclerosis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Avonex®, Rebif® (interferon beta-1a)	*Avonex*: 30 mcg IM Q week *Rebif*: 22 mcg or 44 mcg SC TIW	*Avonex*: 30 mcg/week *Rebif*: 44 mcg TIW
Plegridy® (peginterferon beta-1a)	125 mcg SC Q2 weeks	125 mcg/2 weeks
glatiramer acetate (Copaxone®, Glatopa®)	20 mg SC QD or 40 mg SC TIW	20 mg/day or 40 mg TIW
Gilenya™ (fingolimod)	0.5 mg PO QD	0.5 mg/day
Tecfidera® (dimethyl fumarate)	120 mg PO BID for 7 days, followed by 240 mg PO BID	480 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): history of hypersensitivity to natural or recombinant interferon beta, albumin or mannitol
- Boxed warning(s): none reported

Appendix D: General Information

- Disease-modifying therapies for MS are: glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), fingolimod (Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocreliuzmab (Ocrevus™).

IV. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Interferon beta-1b (Betaseron)	Generally start at 0.0625 mg SC every other day, and increase over a six-week period to 0.25 mg SC every other day	0.25 mg QOD
Interferon beta-1b (Extavia)	Generally start at 0.0625 mg SC every other day, and increase over a six-week period to 0.25 mg SC every other day	0.25 mg QOD

V. Product Availability

Drug Name	Availability
Interferon beta-1b (Betaseron)	Single-use vial: 0.3 mg
Interferon beta-1b (Extavia)	Single-use vial: 0.3 mg

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	
2Q 2019 annual review: clarified that all re-directions apply only to members 18 years or older; removed Aubagio from list of step through agents as it is not preferred; specified that generic forms of glatiramer are preferred; references reviewed and updated.	04.17.19	

References

1. Betaseron Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2018. Available at http://www.betaseron.com. Accessed February 7, 2019.

2. Extavia Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018. Available at http://www.extavia.com/. Accessed February 7, 2019.
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. March 2017. Accessed February 4, 2019.
5. European Medicines Agency: Betaferon: EPAR – Product Information; December 2018. Available at: https://www.ema.europa.eu/documents/product-information/betaferon-epar-product-information_en.pdf. Accessed February 7, 2019.
6. European Medicines Agency: Extavia: EPAR – Product Information; July 2018. Available at: https://www.ema.europa.eu/documents/product-information/extavia-epar-product-information_en.pdf. Accessed February 7, 2019.
7. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788. Full guideline available at: https://www.aan.com/Guidelines/home/GetGuidelineContent/904.