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

Reference Number: CP.PHAR.256
Effective Date: 08.01.16
Last Review Date: 05.18
Line of Business: Medicaid

Coding Implications
Revision Log

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

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

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Betaseron and Extavia are **medically necessary** when the following criteria are met:

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;
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;
6. Not prescribed concurrently with other disease modifying therapies for MS (*see Appendix C*);
7. Dose does not exceed 0.25 mg every other day (1 vial every other day).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Not prescribed concurrently with other disease modifying therapies for MS (*see Appendix C*);
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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents;

B. Primary progressive MS.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MS: multiple sclerosis
RRMS: relapsing-remitting MS

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®)	*Copaxone*: 20 mg SC QD or 40 mg SC TIW *Glatopa*: 20 mg SC QD	*Copaxone*: 20 mg/day or 40 mg TIW *Glatopa*: 20 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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: General Information

- Disease-modifying therapies for MS are: daclizumab (Zinbryta®), 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™).

V. 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

VI. 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

VII. 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. March 2017. Accessed January 5, 2018.
5. European Medicines Agency: Betaferon: EPAR – Product Information; September 2017. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000081/WC500053225.pdf. Accessed January 5, 2018.

6. European Medicines Agency: Extavia: EPAR – Product Information; January 2016. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000933/WC500034701.pdf. Accessed January 5, 2018.

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	P&T 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 to "Responding positively to therapy". Changed 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. Applied preferencing to members 18 and over. Removed contraindication, reasons to discontinue, and MRI requirement.	07.17	08.17
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	05.18

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.

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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.