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

Reference Number: LA.PHAR.256
Effective Date:
Last Review Date: 01.21 Coding Implications
Line of Business: Medicaid 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 include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Policy/Criteria

Prior authorization is required. 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 Louisiana Healthcare Connections 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, and:
            i. If request is for Extavia, member is contraindicated to both or has experienced clinically significant adverse effects to one of the following at up to maximally indicated doses: an interferon-beta agent (Avonex®, Betaseron®, Rebif®, or Plegridy®), glatiramer (Copaxone®, Glatopa®);
         b. Relapsing-remitting MS, and:
            i. If request is for Extavia, failure of two of the following at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated: Aubagio®, dimethyl fumarate (Tecfidera®), Gilenya™, an interferon-beta agent (Avonex, Betaseron, Rebif, or Plegridy), glatiramer (Copaxone, Glatopa);*
            **Prior authorization may be required for disease modifying therapies for MS*
         c. Secondary progressive MS;
      2. Prescribed by or in consultation with a neurologist;
      3. Age ≥ 12 years;

4. **Interferon beta-1b is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);**
5. **Documentation of baseline number of relapses per year and expanded disability status scale (EDSS) score;**
6. **Dose does not exceed 0.25 mg (1 vial) every other day.**

Approval duration:
Medicaid – 6 months

B. Other diagnoses/indications
1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. Multiple Sclerosis (must meet all):
1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member meets one of the following (a or b):**
   a. **If member has received < 1 year of total treatment: Member is responding positively to therapy;**
   b. **If member has received ≥ 1 year of total treatment: Member meets one of the following (i, ii, iii, or iv):**
      i. **Member has not had an increase in the number of relapses per year compared to baseline;**
      ii. **Member has not had ≥ 2 new MRI-detected lesions;**
      iii. **Member has not had an increase in EDSS score from baseline;**
      iv. **Medical justification supports that member is responding positively to therapy;**
3. **Interferon beta-1b is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);**
4. **If request is for a dose increase, new dose does not exceed 0.25 mg (1 vial) every other day.**

Approval duration:
Medicaid – first re-authorization: 6 months; second and subsequent re-authorizations: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
   Approval duration: Duration of request or 6 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

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 –LA.PMN.53 for Medicaid or evidence of coverage documents;**
B. **Primary progressive MS.**

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EDSS: expanded disability status scale
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 require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Aubagio® (teriflunomide)	7 mg or 14 mg PO QD	14 mg/day
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
dimethyl fumarate (Tecfidera®)	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®), diroximel fumarate (Vumerity™), monomethyl fumarate (Bafiertam™), fingolimod (Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), ocrelizumab (Ocrevus™), cladribine (Mavenclad®), siponimod (Mayzent®), and ozanimod (Zeposia®).**

- **Of the disease-modifying therapies for MS that are FDA-labeled for CIS, only the interferon products, glatiramer, and Aubagio have demonstrated any efficacy in decreasing the risk of conversion to MS compared to placebo. This is supported by the AAN 2018 MS guidelines.**

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.; August 2019. Available at http://www.betaseron.com. Accessed January 27, 2020.
2. Extavia Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2019. Available at http://www.extavia.com/. Accessed January 27, 2020.
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. Updated June 2019. Accessed January 27, 2020.
5. European Medicines Agency: Betaferon: EPAR – Product Information; October 2019. Available at: https://www.ema.europa.eu/documents/product-information/betaferon-epar-product-information_en.pdf. Accessed January 27, 2020.
6. European Medicines Agency: Extavia: EPAR – Product Information; October 2019. Available at: https://www.ema.europa.eu/documents/product-information/extavia-epar-product-information_en.pdf. Accessed January 27, 2020.
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.

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
Converted corporate to local policy	01.21

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

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