Drug Policy

Policy: 201306
Code(s): HCPCS J1826, J1830, J3590 and Q3027

SUBJECT: Interferon Beta - Multiple Sclerosis
Impacted Drugs:
- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Extavia (interferon beta-1b)
- Plegridy (peginterferon beta-1a)
- Rebif (interferon beta-1a)

Initial Effective Date: 01/16/2013
Annual Review Date: 01/16/2020
Last Revised Date: 01/16/2020

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW
Interferons represent a family of specific proteins (cytokines) produced in response to viruses and a variety of other natural and synthetic stimuli. Interferon beta is a Type I interferon that is produced by various cells, including fibroblasts and macrophages, and has both antiviral and immunoregulatory activities. Interferon beta increases the levels of 2',5'-oligoadenylate (2-5A) synthetase, an intracellular enzyme capable of degrading viral ribonucleic acid (RNA). This activity is thought to contribute to the antiviral and antiproliferative effects of interferon beta. Interferon beta inhibits the expression of pro-inflammatory cytokines, including interferon gamma (INF-γ), which is believed to be a major factor responsible for triggering the autoimmune reaction leading to multiple sclerosis (MS). Interferon beta-1a (e.g., Avonex®, Biogen Idec, Inc., Cambridge, MA; Rebif®, EMD Serono, Inc., Rockland, MA; Plegridy™, Biogen Idec, Inc., Cambridge, MA) and interferon beta-1b (e.g., Betaseron®, Bayer HealthCare Pharmaceuticals Inc., Montville, NJ; Extavia®, Novartis Pharmaceuticals Corp., East Hanover, New Jersey) are approved by the U.S. Food and Drug Administration (FDA) for treatment of relapsing-remitting multiple sclerosis (RRMS).

POLICY STATEMENT
This policy involves the use of interferon beta. Prior authorization is recommended for pharmacy and medical benefit coverage of interferon beta. Approval is recommended for those who meet the conditions of coverage in the Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics for the diagnosis provided. Waste Management applies for all covered conditions that are administered by a healthcare professional. Conditions Not Recommended for Approval are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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Because of the specialized skills required for evaluation and diagnosis of patients treated with interferon beta as well as the monitoring required for AEs and long-term efficacy, initial approval requires interferon beta be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of interferon beta is recommended in those who meet the following criteria:

The patient does NOT have Non-Relapsing Forms of Multiple Sclerosis. Note: An example of a non-relapsing form of multiple sclerosis (MS) is primary progressive MS. The efficacy of Avonex has not been established in patients with MS with non-relapsing forms of MS.\(^1\) AND;

The patient will not use the requested Beta Interferon concurrently with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS). Note: Examples of disease modifying agents used for multiple sclerosis include Avonex\(^\text{®}\) (interferon beta 1a injection [intramuscular]), Rebif\(^\text{®}\) (interferon beta-1a injection [subcutaneous]), Copaxone\(^\text{®}/\)Glatopa\(^\text{®}\) (glatiramer acetate injection), Plegridy\(^\text{®}\) (peginterferon beta-1a injection), Aubagio\(^\text{®}\) (teriflunomide tablets), Gilenya\(^\text{®}\) (fingolimod tablets), Mavenclad\(^\text{®}\) (cladribine tablets), Mayzent\(^\text{®}\) (siponimod tablets), Tecfidera\(^\text{®}\) (dimethyl fumarate delayed-release capsules), Ocrevus\(^\text{®}\) (ocrelizumab injection for intravenous use), Tysabri\(^\text{®}\) (natalizumab injection for intravenous infusion), and Lemtrada\(^\text{®}\) (alemtuzumab injection for intravenous use).\(^3\) AND;

1. Relapsing Forms of Multiple Sclerosis (MS) in Patients Who Are Not Currently Receiving a Beta Interferon. Approve for patients who meet the following criteria (a, b, c, d, e, and f):
   a) Patient is 18 years of age or older; AND
   b) The patient has a relapsing form of MS to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND
   c) The agent is prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of MS; AND
   d) Dosage and administration are consistent with U.S. Food and Drug Administration approved label\(\dagger\); AND
   e) The patient has previously failed or is intolerant to generic glatiramer acetate 20mg/mL or 40mg/mL according to the prescribing physician [documentation required].
      a. (NOTE: An exception to the requirement for a trial of generic glatiramer acetate can be made if the patient has already tried and cannot take brand Copaxone/Glatopa according to the prescribing physician [documentation required]. These patients who have already tried brand Copaxone/Glatopa are not required to “step back” and try generic glatiramer acetate.)
   f) Site of care medical necessity is met*.

2. Relapsing Forms of Multiple Sclerosis (MS) in Patients Who Are Currently Receiving a Beta Interferon or Who Have Received the requested Beta interferon in the Past. Approve if the patient meets the following criteria (a, b, c, d, e f, and g):
   a) Patient is 18 years of age or older; AND
b) The patient has a relapsing form of MS to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND  
c) The agent is prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of MS; AND  
d) The patient has had beneficial response to the requested medication; AND  
e) The patient must meet one of the following criteria (a or b)  
a. The member has been established on the requested medication for equal to or greater than 120 days; OR  
b. The patient must have previously failed or is intolerant to generic glatiramer acetate 20mg/mL or 40mg/mL according to the prescribing physician [documentation required].  
i. (NOTE: An exception to the requirement for a trial of generic glatiramer acetate can be made if the patient has already tried and cannot take brand Copaxone/Glatopa according to the prescribing physician [documentation required]. These patients who have already tried brand Copaxone/Glatopa are not required to “step back” and try generic glatiramer acetate.); AND  
f) Dosage and administration are consistent with U.S. Food and Drug Administration approved label†; AND  
g) Site of care medical necessity is met*.  

**Dosing in interferon beta**  
*Dosing must meet the following: (medical benefit only)*

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
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<tr>
<td>Avonex</td>
<td>30 mcg weekly (maximum)</td>
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| Betaseron  | Initial: 0.0625 mg (0.25 ml) every other day  
            Maintenance: 0.25 mg (1.0 ml) every other day |
| Extavia    | Initial: 0.0625 mg (0.25 ml) every other day  
            Maintenance: 0.25 mg (1.0 ml) every other day |
| Plegidy    | 63 mcg on day 1, 94 mcg on day 15, 125 mcg on day 29, then continuing with 125 mcg every 14 days thereafter |
| Rebif      | 22 mcg or 44 mcg three times a week |

**Approval Duration**

- **Initial approval:** 365 days  
- **Reapproval:** 365 days

**Duration of Therapy in interferon beta is indefinite.**

Drug Policy

Labs/Diagnostics. None

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

FOR MEDICAL BENEFIT COVERAGE REQUESTS:


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**MMO Site of Care Medical Necessity Criteria:**

- Medications in this policy will be administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider’s office, free-standing ambulatory infusion center) unless at least one of the following are met†:
  1. Age less than 18 years*; or
  2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
  3. History of a severe adverse event from previous administration of the prescribed medication; or
  4. Requested medication is being administered as follows:
     - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
     - administered with dialysis; or
  5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
  6. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

No initial doses are allowed in a hospital based outpatient facility without other above criteria being met.

* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.
†This criterion does not apply to Medicare or Medicare Advantage members.

**Prior approval is required for HCPCS Codes J1826, J1830, J3590 and Q3027.**

†When unclassified drugs unclassified biologics (J3590) is determined to be Interferon Beta.

**Edits and Denials:**

**Prior approval:** Prior approval is required for interferon beta-1a and interferon beta-1b (HCPCS Codes J1826, J1830, J3590 and Q3027). Requests for prior approval will be authorized by a nurse reviewer if a valid diagnosis is present and submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within the Corporate Medical Policy.
**TOPPS:** Claims received with **HCPCS Codes J1826, J1830 and Q3027** will edit with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Claims received with **HCPCS Code J3590** will pend with **Remark Code PRR** and will be adjudicated in accordance with the Corporate Medical Policy.

**Liability:** A participating provider will be required to write off charges denied as not medically necessary.

<table>
<thead>
<tr>
<th>HCPCS Code(s):</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1826</td>
<td>Injection, interferon beta-1a, 30 mcg</td>
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<tr>
<td>J1830</td>
<td>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)</td>
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<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
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<tr>
<td>Q3027</td>
<td>Injection, interferon beta-1a, 1 mcg for intramuscular use</td>
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