**Prior Authorization and Step Therapy Policy**

Betaseron® and Extavia® (interferon beta-1b for subcutaneous [SC] injection – Berlex, Novartis)

To Initiate a Coverage Review, Call 1-800-417-1764

**Overview**

Betaseron/Extavia is indicated for the treatment of relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations. Extavia and Betaseron are essentially the same formulation of interferon beta-1b. The only difference is that Extavia is supplied with a 27 gauge needle compared to a 30 gauge needle that is given with Betaseron. Patients with MS in whom efficacy has been demonstrated include those who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS. The recommended dosing for this condition is 0.25 mg subcutaneously (SC) every other day (QOD). The dose may be titrated. Various trials have established the effectiveness of Betaseron/Extavia in patients with MS (e.g., decrease in the annualized relapse rate). MS is a chronic demyelinating disabling disease of the central nervous system (CNS) characterized by recurrent and progressive neurologic dysfunction. MS lesions occur in many different parts of the CNS and the symptoms and clinical course of the disease are highly variable. Some common signs and symptoms of the disease include vision problems, (e.g., nystagmus), ambulation problems, pain, fatigue, spasticity, cognitive dysfunction, depression, ataxia, sensory loss, bladder disturbances, bowel dysfunction, dizziness, and vertigo. Most people are diagnosed between the ages of 20 and 50 years, but MS can manifest in young children and older adults. Approximately 400,000 people are living with MS in the US and 200 people are newly diagnosed weekly.

**Policy Statement**

Prior authorization is required for prescription benefit coverage of Betaseron/Extavia. Because of the specialized skills required for evaluation and diagnosis of patients treated with Betaseron/Extavia as well as the monitoring required for adverse events and long-term efficacy, approval requires Betaseron/Extavia to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 12 months in duration unless otherwise noted below.

**Authorization Criteria**

Coverage of Betaseron is provided to those who meet the following criteria:

**Food and Drug Administration (FDA)-Approved Indication**

1. **Multiple Sclerosis (MS).** Approve if the patient meets the following criteria (a and b):
   a) The medication is prescribed by, or after consultation with, a neurologist or a physician who specializes in the treatment of MS; AND
   b) The patient has a diagnosis of MS or has experienced an attack and is at risk of MS.
Coverage of Extavia is provided to those who meet the following criteria:

**Food and Drug Administration (FDA)-Approved Indication**

1. **Multiple Sclerosis (MS).** Approve if the patient meets the following criteria (a and b and c):
   a) The medication is prescribed by, or after consultation with, a neurologist or a physician who specializes in the treatment of MS; AND
   b) The patient has a diagnosis of MS or has experienced an attack and is at risk of MS; AND
   c) The patient has previously tried or been intolerant to Avonex, Betaseron, Copaxone or Glatopa.

**PREFERRED PRODUCTS AND STEP THERAPY**

Step 1: Avonex, Betaseron, Copaxone, Glatopa

Step 2: Extavia

**EXCLUSIONS**

Coverage of Betaseron/Extavia is not provided in the following circumstance: **Concurrent Use of Betaseron/Extavia with Other Disease-Modifying Agents Used for MS (i.e., Avonex® [interferon beta-1a injection {intramuscular}], Rebif® (interferon beta-1a injection {subcutaneous}), Copaxone®, Glatopa™, Tysabri® [natalizumab injection], Gilenya® [fingolimod tablets], Aubagio® [teriflunomide tablets] and Tecfidera™ [dimethyl fumarate delayed-release capsules]).** These agents are not indicated for use in combination.

**REFERENCES**

2. Extavia® [prescribing information]. East Hanover, NJ: Novartis; March 2012.

**POLICY IMPLEMENTATION/REVISION INFORMATION**

Prior Authorization and Step Therapy

Original Implementation Date: 10/06/2008

Revision Information:

<table>
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<tr>
<th>July 2015</th>
<th>Added Glatopa as a step 1 product</th>
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July 2015