1. **Background:**

Step therapy programs are utilized to encourage use of lower cost, preferred alternatives for certain therapeutic classes. This program requires a member to try and fail Betaseron® (interferon β-1b) before providing coverage for Extavia® (interferon β-1b).*

Betaseron and Extavia are indicated for the treatment of patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.  

For the purpose of this program, adequate trial is defined as a medication trial lasting a minimum of four weeks. Treatment failure will be defined as:

- Increase in frequency, severity and/or sequelae of relapses OR
- Increase in disability progression [sustained worsening of Expanded Disability Status Score (EDSS) score or routine neurological observation] OR
- Change in Magnetic Resonance Imaging (MRI) such as increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions.

Members currently on Extavia as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. **Coverage Criteria**: 

   **A. Extavia**

   1. **Extavia** will be approved based on one of the following criteria:

      a. **Both** of the following:

         (1) As continuation of therapy

-AND-
(2) **One** of the following:

(a) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber’s office or any form of assistance from the Novartis sponsored Extavia® Go Program™ (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Extavia*

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber’s office or any form of assistance from the Novartis sponsored support programs **shall be required** to meet initial authorization criteria as if patient were new to therapy.

-OR-

(b) **Both** of the following:

i. Patient has received a manufacturer supplied sample at no cost in the prescriber’s office or any form of assistance from the Novartis sponsored Extavia® Go Program™ (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Extavia

-AND-

ii. History of failure following a trial for at least 4 weeks or history of intolerance to Betaseron (interferon beta-1b) (Document drug, date, and duration of trial)

-OR-

b. History of failure following a trial for at least 4 weeks or history of intolerance to Betaseron (interferon beta-1b) (Document drug, date, and duration of trial)

**Authorization will be issued for 12 months.**

*a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
• Extavia is typically excluded from coverage. Tried/Failed criteria may be in place for businesses unable to exclude. Please refer to plan specifics to determine exclusion status.
• Notification criteria may be in place for businesses with the ability to administer notification programs.

4. References:

<table>
<thead>
<tr>
<th>Program</th>
<th>Step Therapy - Extavia (interferon β-1b)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td>08/2013</td>
<td>Updated Background and step criteria agents in Coverage Criteria for Extavia. Removed Betaseron step criteria.</td>
</tr>
<tr>
<td>5/2014</td>
<td>Annual review. Expanded authorization to 60 months and added sample language. Updated background.</td>
</tr>
<tr>
<td>5/2015</td>
<td>Annual review. Added additional sample pack language. Updated background and references.</td>
</tr>
<tr>
<td>10/2015</td>
<td>Administrative update. Added Maryland Continuation of Care.</td>
</tr>
<tr>
<td>5/2016</td>
<td>Annual review. Reduced authorization to 12 months. Updated background and references.</td>
</tr>
<tr>
<td>7/2016</td>
<td>Added Indiana and West Virginia coverage information.</td>
</tr>
<tr>
<td>11/2016</td>
<td>Administrative change. Added California coverage information.</td>
</tr>
<tr>
<td>10/2017</td>
<td>Revised sample pack language.</td>
</tr>
<tr>
<td>10/2018</td>
<td>Annual review. Updated references.</td>
</tr>
<tr>
<td>10/2019</td>
<td>Annual review. Updated references and included conditions under relapsing forms of multiple sclerosis.</td>
</tr>
</tbody>
</table>