UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3013-10
Program	Step Therapy
Medication	Extavia® (interferon β-1b)* *Extavia is excluded from coverage for a majority of our benefits.
P&T Approval Date	6/9/09, 3/9/10, 3/8/11, 7/2011, 5/2012, 11/2012, 05/2013, 08/2013, 5/2014, 5/2015, 5/2016, 5/2017, 10/2017, 10/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

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.[1,2]

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[3]
- Increase in disability progression [sustained worsening of Expanded Disability Status Score (EDSS) score or routine neurological observation] OR[3]
- Change in Magnetic Resonance Imaging (MRI) such as increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions.[3]

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]:

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:

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(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.

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3. **Additional Clinical Rules:**
   - 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:**

1. Betaseron [package insert]. Bayer HealthCare Pharmaceuticals. Whippany, NJ. August 2018.
2. Extavia [package insert]. Novartis Pharmaceuticals Corporation. East Hanover, NJ. May 2016.
3. Coyle PK. Switching algorithms: from one immunomodulatory agent to another. *J Neurol.* 2008 Mar;255 Suppl 1:44-50.

Program	Step Therapy - Extavia (interferon β-1b)
Change Control	
08/2013	Updated Background and step criteria agents in Coverage Criteria for Extavia. Removed Betaseron step criteria.
5/2014	Annual review. Expanded authorization to 60 months and added sample language. Updated background.
5/2015	Annual review. Added additional sample pack language. Updated background and references.
10/2015	Administrative update. Added Maryland Continuation of Care.
5/2016	Annual review. Reduced authorization to 12 months. Updated background and references.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
5/2017	Annual Review. Revised sample pack language. Added requirement for documentation of drug, dates, and duration of trial medications. Updated state mandate reference language.
10/2017	Revised sample pack language.
10/2018	Annual review. Updated references.

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