UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 3013-14
Program	Step Therapy
Medication	Extavia® (interferon β-1b)*
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, 10/2019, 10/2020, 10/2021, 10/2022
Effective Date	1/1/2023; Oxford only: 1/1/2023

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 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.[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:

         (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 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 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.

***** Extavia is typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan.

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.
- Notification criteria may be in place for businesses with the ability to administer notification programs.

4. References:

1. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; November 2021.
2. Extavia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2021.
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.
10/2019	Annual review. Updated references and included conditions under relapsing forms of multiple sclerosis.
10/2020	Annual review. Minor updates to background and criteria but no change to clinical intent. Updated references.
10/2021	Annual review. Minor updates to exclusion verbiage but no change to clinical intent. Updated references.
10/2022	Annual review with no changes to coverage criteria. Updated references.