

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3023-10
Program	Step Therapy
Medication	Rebif® (interferon β-1a)
P&T Approval Date	8/2013, 5/2014, 5/2015, 5/2016, 10/2016, 10/2017, 10/2018, 10/2019
Effective Date	2/1/2020; Oxford only: 2/1/2020

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 at least two preferred agents [Avonex® (interferon β-1a), Betaseron® (interferon β-1b), glatiramer acetate (Mylan brand only), Gilenya® (fingolimod), Aubagio® (teriflunomide), Plegridy™ (peginterferon β-1a), and/or Tecfidera™ (dimethyl fumarate)] before providing coverage for Rebif® (interferon β-1a).

Avonex, Betaseron, glatiramer acetate, Gilenya, Aubagio, Plegridy, Rebif, and Tecfidera are indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.¹⁻⁸

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 OR⁶
- Increase in disability progression [sustained worsening of Expanded Disability Status Score (EDSS) score or routine neurological observation] OR⁶
- Change in MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions).⁶

Members currently on Rebif, 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:

<p>A. Rebif</p> <p>1. Rebif will be approved based on <u>one</u> of the following criteria:</p> <p>a. <u>Both</u> of the following:</p> <p>(1) As continuation of therapy</p>

-AND-

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

- (a) Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office or any form of assistance from the EMD Serono sponsored MS LifeLines® 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 Rebif[®]*

*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 EMD Serono sponsored MS LifeLines® program **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 from a prescriber's office or any form of assistance from the EMD Serono sponsored MS LifeLines® 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 Rebif

-AND-

- ii. History of failure following a trial for at least 4 weeks or history of intolerance or contraindication to **at least two** of the following (Document drug, date, and duration of trial):

- Aubagio (teriflunomide)
- Avonex (interferon β -1a)
- Betaseron (interferon β -1b)
- Glatiramer acetate (Mylan brand only; generic Copaxone)
- Gilenya (fingolimod)
- Plegridy (peginterferon β -1a)
- Tecfidera (dimethyl fumarate)

-OR-

- b. History of failure following a trial for at least 4 weeks **or** history of intolerance or contraindication to **at least two** of the following (Document drug, date, and duration of trial):

- (1) Aubagio (teriflunomide)
(2) Avonex (interferon β -1a)

- (3) Betaseron (interferon β -1b)
- (4) Glatiramer acetate (Mylan brand only; generic Copaxone)
- (5) Gilenya (fingolimod)
- (6) Plegridy (peginterferon β -1a)
- (7) Tecfidera (dimethyl fumarate)

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

4. References:

1. Rebif [package insert]. EMD Serono, Inc. Rockland, MA. July 2019.
2. Avonex [package insert]. Biogen Inc. Cambridge, MA. July 2019.
3. Betaseron [package insert]. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. August 2019.
4. Copaxone [package insert]. Teva Neuroscience, Inc. North Wales, PA. July 2019.
5. Tecfidera [package insert]. Biogen Inc. Cambridge, MA. July 2019.
6. Aubagio [package insert]. Genzyme Corp. Cambridge, MA. July 2019.
7. Gilenya [package insert]. Novartis Pharmaceuticals Corp. East Hanover, NJ. August 2019.
8. Plegridy [package insert]. Biogen Inc. Cambridge, MA. July 2019.
9. Coyle PK. Switching algorithms: from one immunomodulatory agent to another. *J Neurol.* 2008 Mar;255 Suppl 1:44-50.

Program	Step Therapy - Rebif (interferon β -1a)
Change Control	
8/2013	New step therapy criteria.
5/2014	Annual review. Added sample pack language and expanded authorization to 60 months. 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 references.
7/2016	Added Indiana and West Virginia coverage information.
10/2016	Added additional medications to the step criteria. Updated references.
10/2017	Annual review. Updated sample pack language and state mandate information. Updated references.
10/2018	Annual review. Updated references.
10/2019	Annual review. Updated references and name of the MS LifeLines® program.