UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3023-9
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
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 at least two preferred agents [Avonex® (interferon β-1a), Betaseron® (interferon β-1b), Copaxone® (glatiramer acetate), Gilenya® (fingolimod), Aubagio® (teriflunomide), Plegridy™ (peginterferon β-1a), and/or Tecfidera™ (dimethyl fumarate)] before providing coverage for Rebif® (interferon β-1a).

Avonex, Betaseron, Copaxone, Gilenya, Aubagio, Plegridy, Rebif, and Tecfidera are indicated for the treatment of patients with relapsing forms of multiple sclerosis.[1-5]

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[6]
- Increase in disability progression (sustained worsening of EDSS score or routine neurological observation) OR[6]
- 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]:

A. Rebif

1. Rebif 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 from a prescriber's office or any form of assistance from the EMD Serono sponsored MS LifeLines® Access Made Simple 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® Access Made Simple 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® Access Made Simple program (ae.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)
- Copaxone 20 mg (glatiramer acetate)
- 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) Copaxone (glatiramer acetate)

(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:

- 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. November 2015.
2. Avonex [package insert]. Biogen Inc. Cambridge, MA. March 2016.
3. Betaseron [package insert]. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. August 2018.
4. Copaxone [package insert]. Teva Neuroscience, Inc. North Wales, PA. January 2018.
5. Tecfidera [package insert]. Biogen Inc. Cambridge, MA. December 2017.
6. Coyle PK. Switching algorithms: from one immunomodulatory agent to another. *J Neurol.* 2008 Mar;255 Suppl 1:44-50.
7. Aubagio [package insert]. Genzyme Corp. Cambridge, MA. November 2016.
8. Gilenya [package insert]. Novartis Pharmaceuticals Corp. East Hanover, NJ. May 2018.
9. Plegridy [package insert]. Biogen Inc. Cambridge, MA. July 2016.

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.