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Department of Origin: Pharmacy	**Effective Date:** 12/06/2023
Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	**Date Approved:** 12/06/2023
Pharmacy Clinical Policy Document: Ocrevus and Tysabri Prior Authorization	**Replaces Effective Policy Dated:** 5/24/2023
Reference #: PC/O004	**Page:** **1** of **6**

PURPOSE:
The intent of the Ocrevus and Tysabri Prior Authorization Pharmacy Clinical Policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost – effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria – Must satisfy any of the following: I – III

Table 1: Ocrevus (ocrelizumab) and Tysabri (natalizumab)

Biologic	Molecule	Is this a Biosimilar?	Reference Product	*MS* Type	Route of Administration	Drug Class	*PML* Warning
Ocrevus	ocrelizumab	N	N/A	relapsing or primary progressive	intravenous infusion	CD20 antibody	N
Tysabri	natalizumab	N	N/A	relapsing	intravenous infusion	integrin receptor antagonist	Y
Tyruko	natalizumab-szin	Y	Tysabri	relapsing	intravenous infusion	integrin receptor antagonist	Y

I. Initial request for Ocrevus (ocrelizumab) or Tysabri (natalizumab) for multiple sclerosis – must satisfy the following: A or B

A. Must satisfy the following: 1, and one of 2 – 4
   1. Prescribed by or in consultation with a neurologist; and
   2. The member is currently receiving the requested medication; or
   3. The member has not responded to (at least a 2 – month trial) one self- administered disease modifying medications (see Table 2); or
   4. The member has risk factors indicating highly active or aggressive disease – must satisfy two or more of the following: a – d
      a. Expanded Disability Status Scale (EDSS) ratings – must satisfy any of the following: 1) or 2)
         1) EDSS of 4 points within 5 years of onset of MS; or
         2) EDSS of 6 points by age 40
      b. MRI findings – must satisfy any of the following 1) – 6)
         1) T1 hypointense lesion(s) (black hole); or

2) Spinal cord lesion(s); or
3) Greater than 10 T2 lesions on baseline MRI; or
4) Equal to or greater than 2 or more enlarging T1 lesions over 1 year; or
5) Equal to or greater than 2 or more contrast (gadolinium) enhancing lesions; or
6) Any contrast enhancing (gadolinium) lesions despite treatment

c. Clinical characteristics – must satisfy any of the following: 1) – 3)
   1) Multifocal onset; or
   2) Pyramidal or sphincter symptoms; or
   3) Greater than one relapse in the previous 2 years
d. Conversion to secondary progressive MS (SPMS).

B. Initial request for Ocrevus for primary progressive multiple sclerosis – must be prescribe by or in consultation with a neurologist.

II. Initial request for Tysabri for Crohn's disease- must satisfy all of the following: A – C

A. Diagnosis of moderate to severe active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional Crohn's disease therapies and inhibitors of tumor necrosis factor – alpha (TNF – alpha) in members who are equal to or greater than 18 years of age; and

B. Prescribed by or in consultation with a gastroenterologist; and

C. The member has not responded to, is intolerant to, or responds to but cannot taper off without recurrent symptoms or is a poor candidate for Entyvio and one *infliximab* product.

III. Continuation request – Allow up to an additional 12 months

Table 2: Self – Administered Disease Modifying Medications for Multiple Sclerosis*

Drug	Generic/Molecule Name	Is this a Biosimilar?	Generics Available	*MS* Type	Route of Administration	Drug Class	*PML* Warning
Aubagio	teriflunomide	N	N	relapsing	oral	Selective immuno-suppressant	N
Avonex	interferon beta-1a	N	N	relapsing	intramuscular or subcutaneous injection	interferon	N
Bafiertam	monomethyl fumarate	N	N	relapsing and secondary progressive	oral	selective immuno-suppressant	Y
Betaseron	interferon beta – 1b	N	N	relapsing	subcutaneous injection	interferon	N
Copaxone	glatiramer acetate	N	Y	relapsing	subcutaneous injection	other immuno-stimulant	N
Extavia	interferon beta – 1b	N	N	relapsing	subcutaneous injection	interferon	N
Gilenya	fingolimod	N	Y	relapsing	oral	selective immuno-suppressant	Y
Glatopa	glatiramer acetate	N	Y	relapsing	subcutaneous injection	other immuno-stimulant	N
Kesimpta	ofatumumab	N	N	relapsing	subcutaneous injection	Anti-CD20 monoclonal antibody	N
Mavenclad	cladribine	N	N	relapsing and secondary progressive	oral	immune-modulator	N
Mayzent	siponimod	N	N	relapsing and secondary progressive	oral	immune-modulator	N
Plegridy	peginterferon beta- 1a	N	N	relapsing	subcutaneous injection	interferon	N
Ponvory	ponesimod	N	N	relapsing and secondary progressive	oral	immune-modulator	N

Rebif	interferon beta-1a	N	N	relapsing	intramuscular or subcutaneous injection	interferon	N

Table 2: Self- Administered Disease Modifying Medications for Multiple Sclerosis* (continued)

Drug	Generic/Molecule Name	Is this a Biosimilar?	Generics available	*MS* Type	Route of Administration	Drug Class	*PML* Warning
Tecfidera	dimethyl fumarate	N	Y	relapsing	oral	selective immuno-suppressant	Y
Vumerity	diroximel fumarate	N	N	relapsing and secondary progressive	oral	selective immuno-suppressant	Y
Zeposia	ozanimod	N	N	relapsing and secondary progressive	oral	immune-modulator	N

* Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

DEFINITIONS:

Biologic (BLA):

Biologic agents are derived from natural sources (human, animal, microorganisms); these are large complex proteins applicable to the prevention, treatment, or cure of a disease or condition of human beings. Given the complexity of the drug and the difficulty to characterize a biologic, the manufacturing process is proprietary. Licensed by the Public Health Services Act (PHS) (section 351), the 351(a) pathway is utilized for the approval of biologics. Examples of biologics include: vaccine, blood products, antitoxin, allergy shots and cellular therapies.

Infliximab:

Reference product or biosimilar

Multiple Sclerosis (MS) Disease Courses

- Relapsing-remitting MS – Most common form; episodes of acute worsening of neurologic function occur with some amount of recovery and no progression in between.
- Secondary progressive MS – Involves an initial relapsing-remitting course; disease transitions to a steadily progressive form with function loss.
- Primary progressive MS – Involves continued worsening of MS course from onset without specific relapses.
- Progressive relapsing MS – Occurs as a progressive disease at onset; occasional acute relapses occur but with continuing disease progression.

Progressive Multifocal Leukoencephalopathy (PML):

A neurological disorder characterized by destruction of cells that produce the myelin, an oily substance that helps protect nerve cells in the brain and spinal cord, also known as central nervous system (CNS) white matter. It can be caused by the John Cunningham virus (JCV) in immunocompromised individuals.

BACKGROUND:
This clinical policy is based on U.S. Food and Drug Administration (FDA) approved indications and dosing, expert consensus opinion and/or available reliable evidence.

Prior Authorization: Yes, per network provider agreement - up to 12 months. This is subject to the member's contract benefits.

CODING:
HCPCS - 2023
J2323 Injection, natalizumab, 1mg (Tysabri)
J2350 Injection, ocrelizumab, 1mg (Ocrevus)

REFERENCES:
1. American Academy of Neurology. Practice guideline recommendations summary: Disease-modifying therapies for adults with Multiple Sclerosis. April 2018. Retrieved from https://www.aan.com/Guidelines/home/GuidelineDetail/898 Accessed 10-14-23.
2. Diaz C, Zarco LA, Rivera DM. Highly Active multiple Sclerosis: An update. *Multiple Sclerosis and Related Disorders*. Volume 30 (2019) 215–224.
3. Ocrevus [package insert]. South San Francisco, CA; Genentech, Inc; 2023.
4. Olek MJ, Mowry E. Disease-modifying therapies for multiple sclerosis: Pharmacology, administration, and adverse effects (Topic 129091 Version 32.0; last updated:3/15/2023) In: Dashe JF, ed. *UpToDate*. Waltham. Mass.: UpToDate; 2022. www.uptodate.com Accessed 10-14-23.
5. Tysabri [package insert] Cambridge, MA; Biogen Idec, Inc; 2023.
6. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
7. Clinical Policy: MP/C009 Coverage Determination Guidelines
8. Pharmacy Clinical Policy: PP/O001 Off-label Drug Use
9. Pharmacy Clinical Policy: PP/O002 Off-label Drug Use for Business Process Outsourced Clients
10. Pharmacy Clinical Policy: PP/T002 Therapeutic Equivalence

DOCUMENT HISTORY:

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Created Date: 4/16/21
Reviewed Date: 4/7/2022, 2/27/2023, 10/14/2023
Revised Date:

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PCHP:
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- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

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Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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PreferredOne Insurance Company
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Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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