

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: Lemtrada Prior Authorization	Replaces Effective Policy Dated: 5/24/2023
Reference #: PC/L004	Page: 1 of 4

PURPOSE:

The intent of the Lemtrada 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 – II

Table 1: Lemtrada (alemtuzumab)

<i>Biologic</i>	FYI ONLY			<i>MS Type</i>	Route of Administration	Drug Class	<i>PML Warning</i>
	Molecule	Is this a Biosimilar?	Reference Product				
Lemtrada	alemtuzumab	N	N/A	relapsing	intravenous infusion	CD20 antibody	N

- I. Request for Lemtrada (alemtuzumab) – must satisfy the following: A - B, and one of C - D
 - A. Diagnosis of relapsing-remitting or active secondary progressive multiple sclerosis (MS); and
 - B. Prescribed by or in consultation with a neurologist; and
 - C. The member has been previously treated with Lemtrada – at least 12 months has elapsed since the first treatment with Lemtrada, or 12 months will have elapsed prior to the next treatment with Lemtrada; or
 - D. The member has not been previously treated with Lemtrada – must satisfy all of the following: 1 and 2
 1. The member has not responded to (at least a 2-month trial), one self-administered medication (see Table 2); and
 2. The member has not responded to (at least a 4-week trial), is intolerant to, or is a poor candidate for Ocrevus, one *rituximab* product, or Tysabri.
- II. Continuation request – Authorize in 13-month increments

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

Drug	FYI ONLY			MS Type	Route of Administration	Drug Class	PML Warning
	Generic/ Molecule Name	Biosimilar	Generics available				
Aubagio	teriflunomide	N	Y	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

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

Drug	FYI ONLY			MS Type	Route of Administration	Drug Class	PML Warning
	Generic/ Molecule Name	Biosimilar	Generics available				
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
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.

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.

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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.

Rituximab:

Reference product or biosimilar

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: Approve for up to 18 months to allow for completion of first and second course; continued use, authorize in 13-month increments

Administer Lemtrada by intravenous infusion over 4 hours for 2 treatment courses:

First course: 12 mg/day on 5 consecutive days.

Second course: 12 mg/day on 3 consecutive days 12 months after first treatment course.

Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment course.

CODING: HCPCS - 2023

J0202 Injection, alemtuzumab, 10mg (Lemtrada)

REFERENCES:

1. Hughes BL. Update on new and emerging therapies for the treatment and symptom management of multiple sclerosis. 2011. *American Health & Drug Benefits Supplement*, 4(4):S97-S100.
2. Lemtrada [package insert]. Cambridge, MA; Genzyme Corporation; 2023.
3. 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 10-18-23.
4. Diaz C, Zarco LA, Rivera DM. Highly Active multiple Sclerosis: An update. *Multiple Sclerosis and Related Disorders*. Volume 30 (2019) 215–224.
5. Olek MJ, Mowry E. Disease-modifying therapies for multiple sclerosis: Pharmacology, administration, and adverse effects (Topic 129091 Version 20.0; last updated: 3/15/2023) In: Dashe JF, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2023. www.uptodate.com Accessed 10-18-23.
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:

Created Date: 04/16/21
Reviewed Date: 4/7/2022, 2/27/2023, 10/14/2023
Revised Date:

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

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

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

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator 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>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).