Medical Necessity Guidelines

Medical Benefit Drugs

Multiple Sclerosis Agents: Lemtrada® (alemtuzumab), Ocrevus® (ocrelizumab), Ocrevus Zunovo® (ocrelizumab and hyaluronidase-ocsq)

Effective: December 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Lemtrada (alemtuzumab) is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Lemtrada is not recommended for use in patients with clinically isolated syndrome because of its safety profile.

Ocrevus (ocrelizumab) is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults, and primary progressive MS, in adults.

Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults, and primary progressive MS, in adults.

Clinical Guideline Coverage Criteria

Lemtrada (alemtuzumab)

The plan may authorize coverage of Lemtrada for Members when the following criteria are met:

1. Documented diagnosis of **one (1)** of the following relapsing forms of multiple sclerosis:
    a. Relapsing-remitting multiple sclerosis
    b. Active secondary progressive disease

AND

2. Prescribed by or in consultation with a neurologist

AND

3. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to **two (2)** or contraindication to all of the following:
        i. teriflunomide (Aubagio)
        ii. fingolimod (Gilenya)
        iii. glatiramer acetate therapy (Copaxone)
        iv. interferon therapy
        v. ocrelizumab (Ocrevus)
        vi. dimethyl fumarate (Tecfidera)
    b. Patient is new to the plan and stable on Lemtrada

Ocrevus (ocrelizumab), Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)

The plan may authorize coverage of Ocrevus for Members when the following criteria are met:

1. Documented diagnosis of **one (1)** of the following:
    a. Relapsing-remitting multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
    b. Primary progressive MS

AND

2. Prescribed by or in consultation with a neurologist

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0202	Injection, alemtuzumab, 1 mg
J2350	Injection, ocrelizumab, 1 mg
J2351	INJ OCRELIZUMAB 1MG HYA-OCSQ

References

1. Goodin DS, Frohman EM, Garman GP et al. Disease-modifying therapies in multiple sclerosis: report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002; 58:169-78.
2. Harrison DM. In the clinic. Multiple sclerosis. Ann Intern Med. 2014; 160(7):ITC4-2-ITC4-18.
3. Lemtrada (alemtuzumab). [package insert]. Cambridge, MA. Genzyme Corporation; May 2024.
4. Lublin FD, Reingold SC, Cohen JA et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. Neurology. 2014; 83: 278-86.
5. Montalban X, Hauser SL, Kappos L et al. Ocrelizumab versus placebo in primary progressive multiple sclerosis. N Engl J Med. 2017; 376(3): 209-20.
6. National Institute for Health and Care Excellence (NICE). Ocrelizumab for treating primary progressive multiple sclerosis

[ID938]. 2017a January. URL: https://www.nice.org.uk/guidance/indevelopment/gid-ta10153. Available from Internet. Accessed 2017 March 16.
7. National Institute for Health and Care Excellence (NICE). Ocrelizumab for treating relapsing multiple sclerosis [ID937]. 2017b January. URL: https://www.nice.org.uk/guidance/indevelopment/gid-ta10152. Available from Internet. Accessed 2017 March 16.
8. Ocrevus (ocrelizumab) [prescribing information]. South San Francisco, CA: Genentech Inc.; June 2024.
9. Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) [prescribing information]. South San Francisco, CA: Genentech Inc.; September 2024.
10. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease- modifying therapies for adults with multiple sclerosis. Neurology. 2018 April;90(17):777-88.
11. Ryan M, Deno S, Zwibel HL. Review of the clinical debate regarding interventions for multiple sclerosis. JMCP. 2009; 15(1):S2-17.
12. Scolding N, Barnes D, Cader S et al. Association of British neurologists: revised (2015) guidelines for prescribing disease-modifying treatments in multiple sclerosis. Pract Neurol. 2015; 15(4):273- 9.
13. Wingerchuk DM, Weinshenker BG. Disease modifying therapies for relapsing multiple sclerosis. BMJ. 2016; 354: i3518.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2024: Expanded diagnosis requirements for Ocrevus to align with FDA-approved indications. Minor wording updates (eff 12/1/2023).
- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- October 8, 2024: No changes (eff 10/8/24)
- November 12, 2024: Added Ocrevus Zunovo to the Medical Necessity Guideline (eff 12/1/24).
- March 11, 2025: Administrative Update: Added J Code, J2351 (eff 4/1/25)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.