Pharmacy Medical Necessity Guidelines: Aubagio® (teriflunomide), Gilenya® (fingolimod), and Tecfidera® (dimethyl fumarate)

Effective: February 12, 2019

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Aubagio (teriflunomide) is a pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).

Gilenya (fingolimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of MS in patients 10 years of age and older.

Tecfidera (dimethyl fumarate), the methyl ester of fumaric acid, is indicated for the treatment of patients with relapsing forms of MS.

MS is a chronic disease of the central nervous system characterized by inflammation, demyelination, and axonal degeneration. Most people are diagnosed between the ages of 20 and 50, although MS can occur in young children and significantly older adults.

It is believed that MS consists of both inflammatory and neurodegenerative components. Inflammation may be related to acute relapses, and it is believed that these acute attacks are associated with axon damage which leads to permanent neurologic dysfunction. The neurodegenerative component may contribute to the progressive disability that occurs over time.

The symptoms and severity of MS vary, and the course of the disease in an individual patient is often unpredictable. Common symptoms include sensory disturbances in the limbs leading to gait and balance problems, optic nerve dysfunction and vision loss, dysphagia, bladder or bowel dysfunction, sexual dysfunction, fatigue, emotional lability, and cognitive impairment.

Four categories of MS are recognized. Approximately 85% of patients are initially classified as having relapsing-remitting MS (RRMS) which is characterized by episodic relapses with partial or complete remissions. The majority of patients with RRMS will go on to develop secondary progressive MS (SPMS) which is characterized by an initial period of relapses and remissions, followed by a sudden progressive decrease in CNS function without periods of remission. Primary progressive MS (PPMS) is characterized by a steady decrease in CNS function from the onset without remissions or clear attacks. In contrast, patients with progressive-relapsing MS (PRMS) experience a steady decrease in CNS function from the onset and have clearly identifiable attacks. PPMS is the initial diagnosis in approximately 10% of patients while 5% of patients have PRMS.

COVERAGE GUIDELINES

The plan may authorize coverage of Aubagio (teriflunomide), Gilenya (fingolimod), or Tecfidera (dimethyl fumarate) for Members when all the following criteria are met:

Aubagio and Tecfidera

1. Documented diagnosis of relapsing multiple sclerosis

AND

2. Documentation of one of the following:
    a) The Member has tried and failed treatment with ≥1 of the following or the provider has indicated clinical inapptopriatess with: glatiramer, Rebif, Avonex, Betaseron, Extavia, or Tysabri
    b) Member is new to the plan and stable on the requested medication

Gilenya

1. Documented diagnosis of relapsing multiple sclerosis

AND

2. Documentation of one of the following:
    a) For Members 18 years or older, the Member has tried and failed treatment with ≥1 of the following or the provider has indicated clinical inapptopriatess with: glatiramer, Rebif, Avonex, Betaseron, Extavia, or Tysabri
    b) Member is new to the plan and stable on Gilenya (fingolimod)
    c) Member is 10 to 17 years of age

LIMITATIONS

- The following quantity limitations apply:
    - Aubagio (teriflunomide): 30 tablets per 30 days
    - Gilenya (fingolimod): 30 capsules per 30 days
    - Tecfidera (dimethyl fumarate): 60 capsules per 30 days

CODES

None

REFERENCES

1. Aubagio (teriflunomide) [prescribing information]. Cambridge, MA: Genzyme Corporation; 2016 November.
2. 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.
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4. Killestein J, Rudick RA, Polman CH. Oral treatment for multiple sclerosis. Lancet Neurol. 2011; 10:1026-34.
5. Lublin FD, Reingold SC, Cohen JA et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014; 83: 278-86.
6. National Multiple Sclerosis Society. Changing therapy in relapsing multiple sclerosis: considerations and recommendations of a task force of the National Multiple Sclerosis Society. 2004. Available on the Internet. URL: http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Clinical_Bulletin_Changing-Therapy-in-Relapsing-MS.pdf. Accessed 2018 December 24.
7. Ryan M, Deno S, Zwibel HL. Review of the clinical debate regarding interventions for multiple sclerosis. JMCP. 2009;15(1):S2-17.
8. 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.
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APPROVAL HISTORY

January 20, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 4, 2014: No changes.
2. June 9, 2015: No changes.
3. January 1, 2016: Administrative change to rebranded template.
4. June 14, 2016: No changes.
5. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
6. June 13, 2017: No changes.
7. June 12, 2018: Effective August 7, 2018 this Medical Necessity Guideline applies to Tufts Health RITogether. Changed name of Medical Necessity Guideline from "Gilenya (fingolimod)" to "Aubagio (teriflunomide), Gilenya (fingolimod), and Tecfidera (dimethyl fumarate)" and added existing coverage criteria for Aubagio and Tecfidera into the Medical Necessity Guideline. No changes were made to Aubagio and Tecfidera. Coverage criteria for Gilenya was updated to address the May 2018 expanded indication for the treatment of patients at least 10 years of age.
8. February 12, 2019: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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