Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Syfovre™ (pegcetacoplan injection)

Effective: October 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 (FDA) Approved Indications

Syfovre (pegcetacoplan) is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration.

Clinical Guideline Coverage Criteria

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

Initial Authorization Criteria

1. Documented diagnosis of geographic atrophy secondary to age-related macular degeneration

AND

2. Patient is at least 60 years of age

AND

3. Prescribed by an ophthalmologist

AND

4. Documentation of the absence of choroidal neovascularization in the treated eye(s)

Reauthorization Criteria

1. Documented diagnosis of geographic atrophy secondary to age-related macular degeneration

AND

2. Patient is at least 60 years of age

AND

3. Prescribed by an ophthalmologist

AND

4. Documentation of the absence of choroidal neovascularization in the treated eye(s)

AND

5. Documentation the patient is responding positively to therapy (e.g., disease stabilization or slowing of the rate of disease progression compared to pre-treatment baseline)

Limitations

- Initial coverage of Syfovre will be authorized for 6 months. Reauthorization of Syfovre will be provided in 12-month intervals.
- Patients new to the plan stable on Syfovre should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2781	Injection, pegcetacoplan, intravitreal, 1 mg

References:

1. Flaxel CJ, et al. Age-related macular degeneration preferred practice pattern. Ophthalmology. 2020;127(1):P1-65.
2. Syfovre (pegcetacoplan injection) [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; November 2023.

Approval And Revision History

July 11, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 1, 2023: Administrative update: Added new J code J2781 to Medical Necessity Guideline and removed expired C code C9151
- July 9, 2024: Administrative update to combine Medical Necessity Guidelines for RITogether and Commercial Products. Updated prescriber requirements to state “Prescribed by an ophthalmologist (eff 10/1/24),

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.