Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Izervay™ (avacincaptad pegol)

Effective: July 1, 2025

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

☒ 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

Geographic atrophy (GA) is caused by the gradual breakdown of light-sensitive cells in the macula, resulting in the growth of irreversible lesions in the retinal pigment epithelium that can lead to impaired vision or blindness. GA can be caused by age-related macular degeneration, but it is also associated with other conditions, such as Stargardt disease, which is caused by the accumulation of fatty material in the macula.

Approval of Izervay is based on the GATHER1 and GATHER2 trials which evaluated the safety and efficacy of treatment compared to sham treatment. Patients were required to be at least 50 years of age and have a diagnosis of nonfoveal GA secondary to age-related macular degeneration. After 12 months, the primary endpoint of these trials demonstrated a statistically significant reduction in the rate of GA lesion growth associated with Izervay, with a 35% and 18% reduction, respectively. Differences in baseline populations across the two trials is suggested to explain the difference in response to Izervay.

Food and Drug Administration - Approved Indications

Izervay (avacincaptad pegol) is a complement inhibitor indicated for the treatment of GA secondary to age-related macular degeneration

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Izervay for Members when **ALL** of the following criteria are met:

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

AND

2. Prescribed by an ophthalmologist

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2782	Injection, avacincaptad pegol, 0.1 mg

References:

1. Flaxel CJ, et al. Age-related macular degeneration preferred practice pattern. Ophthalmology. 2020;127(1):P1-65.
2. Jaffe GJ, et al. C5 Inhibitor avacincaptad pegol for geographic atrophy due to age-related macular degeneration: a randomized pivotal phase 2/3 trial. Ophthalmology. 2021;128(4):576-586.
3. Izervay (avacincaptad pegol) [package insert]. Parsippany, NJ: IVERIC bio, Inc.; March 2025.
4. Patel SS, et al. Avacincaptad pegol for geographic atrophy secondary to age-related macular degeneration: 18-month findings from the GATHER1 trial. Eye. 2023;37:3551-3557.

Approval And Revision History

December 12, 2023: Reviewed by the Pharmacy & Therapeutics Committee.
September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
September 10, 2024: No changes.
June 10, 2025: Removed the Limitation that Izervay will be approved for 12 months total. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template. Administrative update to HCPCS code table to list J2782 (eff 7/1/25)
June 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 7/1/25)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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.