

Ophthalmic Complement Inhibitors

Goal(s):

- To ensure appropriate use of complement inhibitors in patients with geographic atrophy (GA) due to age-related macular degeneration (AMD).

Length of Authorization:

- Initial 12 months
- Maximum total cumulative lifetime treatment per affected eye:
 - pegcetacoplan: 24 months
 - avacincaptad pegol: 12 months

Requires PA:

- Pegcetacoplan (SYFOVRE); Avacincaptad Pegol (IZERVAY); (applies to both provider administered and pharmacy claims)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Dosage and Administration per FDA Labeling.

	Pegcetacoplan (SYFOVRE)	Avacincaptad pegol (IZERVAY)
Dose (per single affected eye)	15 mg (0.1 mL of 150 mg/mL solution)	2 mg (0.1 mL of 20 mg/mL solution)
Route of Administration	Intravitreal Injection	Intravitreal Injection
Frequency	Once every 25 to 60 days	Once monthly (approximately 28 ± 7 days)
Maximum Lifetime Limit	Unknown	12 months

Approval Criteria

1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the patient an adult with a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) supported by clinical documentation of appropriate testing (e.g. fundus autofluorescence (FAF), optical coherence tomography (OCT))?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Does the patient have any of the following: <ul style="list-style-type: none"> • active intraocular inflammation? • active ocular or periocular infections? • history of intraocular surgery or laser therapy in the macular region? 	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #4
4. Is the request for continuation of therapy for a patient who has received ≥ 6 months of initial therapy with the requested agent?	Yes: Go to Renewal Criteria.	No: Go to #5

Approval Criteria		
5. Is the agent being prescribed and administered by or under the supervision of an ophthalmologist?	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness
6. Does the patient have a best corrected visual acuity (BCVA) in the affected eye of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/320 Snellen equivalent)?	Yes: Go to #7	No: Pass to RPh. Deny; medical appropriateness
7. Is there evidence that the patient is currently receiving therapy with a different ophthalmic complement inhibitor or medication for GA treatment?	Yes: Go to #8	No: Go to #9
8. Is this a switch in GA therapy due to intolerance, allergy or ineffectiveness and has therapy with the previous agent been discontinued?	Yes: Go to #9	No: Pass to RPh. Deny; medical appropriateness
9. Does the patient have active choroidal neovascularization or wet age-related macular degeneration?	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #10
10. Is the dose, route, and frequency consistent with the FDA-labeling for the requested agent?	Yes: Approve for 12 months.	No: Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is this a request for avacincaptad pegol?	Yes: Go to #2	No: Go to #3
2. Has the patient already received 12 months of cumulative therapy in the affected eye(s)?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #3
3. Does the patient exhibit any evidence of the following: <ul style="list-style-type: none"> Unacceptable toxicity or adverse events (e.g. endophthalmitis, retinal detachment, or conversion to wet AMD)? Significant decline in visual acuity (loss of 10 or more letters on EDTRS chart)? 	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #4

Renewal Criteria

4. Has the prescriber documented a positive patient response to therapy such as disease stabilization or slowing in the growth rate of geographic atrophy lesions compared to pre-treatment baseline?

Yes: Approve for up to 6 months.

No: Pass to RPh. Deny; medical appropriateness

*P&T/DUR Review: 4/24 (DE)
Implementation: 5/1/24*