Original Effective Date: 02/09/2022
Current Effective Date: 12/01/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C24231-A

Susvimo (ranibizumab) Intravitreal Implant

PRODUCTS AFFECTED

Susvimo (ranibizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Neovascular (wet) age-related macular degeneration, Diabetic macular edema, Diabetic retinopathy

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. NEOVASCULAR (WET) AMD, DIABETIC MACULAR EDEMA, DIABETIC RETINOPATHY:
   1. Documented diagnosis of neovascular (wet) age-related macular degeneration (AMD),Diabetic macular edema (DME), or diabetic retinopathy (DR)
      AND
   2. Documentation of baseline visual status with notation of eye(s) being treated [DOCUMENTATION

REQUIRED]
AND

3. Documentation of an inadequate response (defined as 1-2 injections with minimal to no improvement), clinically significant adverse effects, or contraindication to bevacizumab OR bevacizumab is indicated by the provider as unavailable
   AND
4. Documentation of medical rationale why ranibizumab intravitreal injection (Lucentis, Cimerli, Byooviz) cannot be used
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Susvimo (ranibizumab) include: ocular or periocular infections, active intraocular inflammation, known hypersensitivity]

CONTINUATION OF THERAPY:

A. NEOVASCULAR (WET) AMD, DIABETIC MACULAR EDEMA, DIABETIC RETINOPATHY:

1. Reauthorization request is for the same eye(s) as initial authorization
   NOTE: The continuation of therapy criteria is only for the same previously treated eye(s). If member has developed condition in an untreated eye, Prescriber must submit new request with Initial Coverage criteria.
   AND
2. Documentation of improvement or stabilization of disease state (e.g., retinal thickness, macular edema, etc.) and visual status [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse events or drug toxicity (e.g., endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, conjunctival blebs, septum dislodgement, etc.)

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified ophthalmologist, ophthalmic surgeon, or retinal specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

AMD, DME: 1 vial per affected eye every 24 weeks
Maximum Quantity Limits – 4 mg every 24 weeks (based on administration to both eyes)

DR: 1 vial per affected eye every 36 weeks
Maximum Quantity Limits – 4 mg every 36 weeks (based on administration to both eyes)

PLACE OF ADMINISTRATION:

The recommendation is that intravitreal medications in this policy will be for pharmacy or medical benefit coverage and the intravitreal injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravitreal implant

DRUG CLASS:
Vascular Endothelial Growth Factor (VEGF) Antagonists

FDA-APPROVED USES:
Indicated for the treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor and Diabetic Macular Edema (DME) who have previously responded to at least two intravitreal injections of a VEGF inhibitor and Diabetic Retinopathy (DR) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The best available evidence evaluating Susvimo in patients with nAMD is a published report on the pivotal phase 3 ARCHWAY study (Holekamp et al. 2021; FDA PI 2021).

Holekamp et al. (2021) evaluated the clinical efficacy and safety of the Susvimo eye implant in a randomized, multicenter, open-label Phase 3 study in patients with neovascular AMD. The study assessed Susvimo 100 mg/mL for intravitreal use administered via the Susvimo eye implant refilled every 6 months at fixed intervals, compared to monthly intravitreal injections of ranibizumab 0.5 mg in 415 patients with neovascular or “wet” AMD. It measured BCVA following 36–40 weeks of treatment. Per pre-specified study criteria, Susvimo was found to be non-inferior to monthly injections; patients who were given monthly injections gained 0.5 letters on average, while those who received injections via Susvimo gained 0.2 letters. The Archway study demonstrated that patients receiving a ranibizumab implant had visual acuity gains equivalent to patients receiving monthly ranibizumab injections and that approximately 98% could receive continuous treatment for 6 months before requiring a refill or supplemental ranibizumab.

This study included 415 participants (n = 248 in the Susvimo arm; n = 167 in the intravitreal ranibizumab arm) were treated in this study. Patients were diagnosed with nAMD within the 9 months prior to screening and received at least 3 anti-VEGF intravitreal agents in the study eye within the 6 months prior to screening. Each patient was required to have demonstrated a response to an anti-VEGF intravitreal agent prior to randomization. Patients were randomized to receive continuous delivery of Susvimo via the Susvimo implant every 24 weeks or 0.5 mg intravitreal ranibizumab injections every 4 weeks. The primary endpoint of the study was the change in BCVA score from baseline at the average of weeks 36 and 40. Secondary endpoints include safety, overall change in vision (BCVA) from baseline, and change from baseline in center point thickness over time. The primary efficacy endpoint of change from baseline in distance BCVA score averaged over Week 36 and Week 40 demonstrated that Susvimo was equivalent to intravitreal ranibizumab injections administered every 4 weeks. Susvimo was generally well-tolerated, with a favorable benefit-risk profile. Although well-tolerated with a favorable benefit-risk profile, the ranibizumab PDS implant has been associated with a threefold higher rate of endophthalmitis than monthly injections of ranibizumab. Further adverse events found in the Archway trial included conjunctival hemorrhage, conjunctival hyperemia, iritis, and eye pain. (ARCHWAY Study; NCT03677934).

Susvimo is also indicated for diabetic macular edema (DME) after VEGF response. This approval was

based on the Phase III Pagoda study, which evaluated the efficacy and safety of Susvimo delivered via an ocular implant refilled every 24 weeks, compared to monthly intravitreal ranibizumab injections. In the Pagoda study, 634 participants with DME were randomized to receive either Susvimo refilled every 24 weeks or monthly intravitreal ranibizumab injections. The primary endpoint was the change in best-corrected visual acuity (BCVA) from baseline, averaged over weeks 60 and 64. Results demonstrated that Susvimo was non-inferior to monthly injections, with BCVA improvements of 9.6 letters and 9.4 letters, respectively (difference of 0.2 letters; 95% confidence interval: -1.2 to 1.6). The most common ocular adverse reactions (≥10%) reported with Susvimo included conjunctival hemorrhage, conjunctival hyperemia, iritis, eye pain, conjunctival disorder, cataract, and vitreous hemorrhage. The safety profile observed in the Pagoda study was consistent with the known safety profile of Susvimo.

National and Specialty Organizations

The **American Academy of Ophthalmology (AAO)** (2019) preferred practice pattern for AMD addressed intravitreal injection therapy for neovascular AMD, noting 'the use of intravitreal injection therapy using anti-VEGF agents (e.g., aflibercept, bevacizumab, and ranibizumab) is the most effective way to manage nAMD and represents the first line of treatment.' This was reaffirmed in the 2024 practice pattern update.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Susvimo (ranibizumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Susvimo (ranibizumab) include: Ocular or periocular infections, active intraocular inflammation, and hypersensitivity.

Exclusions/Discontinuation:

Do not use Susvimo (ranibizumab) with other ophthalmic VEGF inhibitors (i.e., aflibercept, bevacizumab, brolucizumab, faricimab, ranibizumab, etc.).

OTHER SPECIAL CONSIDERATIONS:

Susvimo (ranibizumab) has a Black Box Warning for endophthalmitis. The Susvimo implant has been associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab. In clinical trials, 2.0% of patients receiving an implant experienced an episode of endophthalmitis.

In a minority of patients (about 5%), supplemental treatment with Lucentis (ranibizumab) 0.5 mg injections may be necessary while the Susvimo implant is in place. Consider this approach when member experiences a decrease in visual acuity by half from the baseline visual acuity (15 ETDRS letters are equivalent to a decrease in visual acuity by half); OR Increase of 150 µm or more in retinal thickness measured by central subfield thickness (CST) on spectral domain OCT (SD-OCT) from the lowest CST measurement; OR Increase of ≥ 100 µm on SD-OCT from lowest measurement and decrease of ≥ 10 letters from best recorded BCVA.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION

J2779	Injection, ranibizumab, via intravitreal implant (Susvimo), 0.1 mg

AVAILABLE DOSAGE FORMS:
Susvimo (Implant 1st Fill) SOLN 10MG/0.1ML
Susvimo (Implant Refill) SOLN 10MG/0.1ML

REFERENCES

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2. Genentech, Inc. Susvimo initial fill and implant procedure instructions for use. 2021.
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11. A phase III, multicenter, randomized study of the efficacy, safety, and pharmacokinetics of the port delivery system with ranibizumab in patients with diabetic retinopathy – NCT04503551. Cited December 2021. Available here.
12. A phase IIIb, global, multicenter, randomized, visual assessor-masked study of the efficacy, safety, and pharmacokinetics of a 36-week refill regimen for the port delivery system with ranibizumab in patients with neovascular age-related macular degeneration – NCT04657289 (Velodrome). Cited December 2021. Available here.
13. Phase III, multicenter, randomized, visual assessor-masked, active-comparator study of the efficacy, safety, and pharmacokinetics of the port delivery system with ranibizumab in patients with neovascular age-related macular degeneration – NCT03677934. Cited December 2021. Available here.
14. Campochiaro PA, et al. The port delivery system with ranibizumab for neovascular age-related macular degeneration: Results from the randomized phase 2 ladder clinical trial. Ophthalmology. 2019 Aug;126(8):1141-1154. doi: 10.1016/j.ophtha.2019.03.036. Epub 2019 Apr 1. PMID: 30946888. (Phase II multicenter dose-ranging randomized controlled trial evaluating Susvimo in patients with nAMD).
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Quantity FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation References	Q4 2025
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Background References	Q2 2025
REVISION- Notable revisions: Required Medical Information	Q1 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information References	Q4 2024
MCP Conversion	Q2 2024
Policy review. No changes in coverage criteria. Updated Summary of Medical Evidence and References	2/14/2024
Policy reviewed. Updated content. Revised verbiage and wording for clarity with no changes in intent. Updated references.	2/8/2023
New policy. IRO review 12/26/19. Practicing MD board-certified in Ophthalmology.	2/9/2022