Utilization Review Policy 276A

POLICY: Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Susvimo Utilization Management Medical Policy

- Susvimo™ (ranibizumab intravitreal injection via ocular implant – Genentech/Roche)

EFFECTIVE DATE: 05/01/2022
REVIEW DATE: 4/23/2024

COVERAGE CRITERIA FOR: UCare Medicaid Plans Only (PMAP, Connect, MSC+, MnCare)

OVERVIEW

Susvimo, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with **neovascular** (wet) **age-related macular degeneration** (nAMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.[1]

Susvimo is supplied as an ocular implant which continuously delivers ranibizumab.[1] Susvimo ocular implant insertion is a surgical procedure that must be performed under aseptic conditions by a physician experienced in vitreoretinal surgery. The ocular implant is filled with 2 mg (0.02 mL) of ranibizumab 100 mg/mL solution, with refills administered once every 24 weeks (approximately 6 months) by a physician experienced in ophthalmic surgery.

Beovu® (brolucizumab-dbll intravitreal injection), Eylea® (aflibercept intravitreal injection), Lucentis® (ranibizumab intravitreal injection) are other VEGF inhibitors indicated for treatment of nAMD.[2-4] Bevacizumab intravenous infusion (Avastin®, biosimilars) is another agent that is repackaged and administered by intravitreal injection for off-label use in nAMD, diabetic macular edema (including patients with diabetic retinopathy), and other neovascular conditions of the eye.[5,6]

Clinical Efficacy

The efficacy of Susvimo was evaluated in one pivotal trial called Archway, which involved patients with nAMD and prior response to VEGF inhibitor injections.[7,8] Patients must have had at least three prior anti-VEGF intravitreal injections (bevacizumab, Eylea, or Lucentis) within 6 months of screening and a demonstrated anatomic and visual response to anti-VEGF treatment for nAMD (i.e., overall decreased disease activity and stable or improved best-corrected visual acuity [BCVA]). In the primary outcome of change in BCVA from baseline, Susvimo was non-inferior to Lucentis (+0.2 letters vs. +0.5 letters, respectively).

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Susvimo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Susvimo as well as the monitoring required for adverse events and long-term efficacy, approval requires Susvimo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Susvimo is recommended for requests meeting both the step therapy requirements and indication requirements:

Step Therapy Requirements (New Starts Only)

Criteria. *The patient must meet the following criteria (A, B, or C):*

A) For patients new to Susvimo therapy only, must have a trial of repackaged Avastin prior to approval of Susvimo. New starts to therapy defined as no use of Susvimo within the past 180 days for Medicaid patients.

B) Patient has diabetic retinopathy (without diabetic macular edema).

C) Patient has a contraindication or other clinical reason why repackaged Avastin cannot be tried before Susvimo.

Note: Step therapy only required for indications compendia supported for both Susvimo and Avastin.

FDA-Approved Indication

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1. Neovascular (Wet) Age-Related Macular Degeneration. Approve for 1 year if the patient meets the following (A and B):

A) Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, iii, iv, v, vi, and vii):

- **i.** Patient has responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor, according to the prescriber; AND
  Note: Examples of VEGF inhibitors include repackaged ophthalmic bevacizumab injection, Beovu (brolicizumab-dbll intravitreal injection), Eylea (aflibercept intravitreal injection), and Lucentis (ranibizumab intravitreal injection). Examples of a response to VEGF inhibitor injections include overall decrease in disease activity and stable or improved best-corrected visual acuity.
- **ii.** Patient does not have an ocular and/or peri-ocular infection; AND
- **iii.** Patient does not have active ocular inflammation; AND
- **ii.** Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab) unless supplemental treatment is necessary (supplemental treatment with a 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection into the affected eye while the Susvimo implant is in place may be necessary if the patient has had an insufficient response during initial or maintenance therapy with Susvimo administered every 24 weeks and it has been determined supplemental treatment is clinically necessary); AND
- **i.** Patient has not required removal of a Susvimo implant in the past; AND
- **ii.** Patient does not have a hypersensitivity to other ranibizumab products (i.e., Lucentis®, Byooviz™, etc.); AND
- **iii.** Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment.

B) Continuation Therapy: Approve for 1 year if the patient meets the following (i, ii, iii, iv, v, vi, vii, and viii):

- **i.** Patient does not have unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs, etc; AND

ii. Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition; AND
iii. Patient does not have an ocular and/or peri-ocular infection; AND
iv. Patient does not have active ocular inflammation; AND
v. Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab) unless supplemental treatment is necessary (supplemental treatment with a 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection into the affected eye while the Susvimo implant is in place may be necessary if the patient has had an insufficient response during initial or maintenance therapy with Susvimo administered every 24 weeks and it has been determined supplemental treatment is clinically necessary); AND
vi. Patient has not required removal of a Susvimo implant in the past; AND
vii. Patient does not have a hypersensitivity to other ranibizumab products (i.e., Lucentis®, Byooviz™, etc.); AND
viii. Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment.

Dosing. Approve if the requested dosing meets the following (A and B):
A) The dose is 2 mg administered into ocular implant for each eye being treated; AND
B) The dosing interval is not more frequent than once every 24 weeks for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Susvimo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Susvimo™ intravitreal injection via ocular implant [prescribing information]. South San Francisco, CA: Genentech/Roche; October 2021.
2. Beovu® intravitreal injection [prescribing information]. East Hanover, NJ: Novartis; June 2020.
3. Eylea® intravitreal injection [prescribing information]. Tarrytown, NY: Regeneron; March 2021.
4. Lucentis® intravitreal injection [prescribing information]. South San Francisco, CA: Genentech/Roche; March 2018.
5. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-related macular degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: www.aao.org/ppp. Accessed on November 3, 2021.
6. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp. Accessed on November 3, 2021.
7. Holekamp NM, Campochiaro PA, Chang M, et al; Archway Investigators. Archway randomized phase III trial of the port delivery system with ranibizumab for neovascular age-related macular degeneration. *Ophthalmology*. 2021 Sep 28. [Epub ahead of print].
8. Awh CC, on behalf of the Archway Investigators. Updated safety and efficacy results from the Archway Phase III trial of the port delivery system with ranibizumab (PDS) for neovascular AMD. Presented at: the American Society of Retina Specialists 39th Annual Meeting; San Antonio, TX; October 8-12, 2021.
9. Susvimo MN Department of Human Services PA Criteria. Available at: https://mn.gov/dhs/partners-and-providers/policies-procedures/minnesota-health-care-programs/provider/types/rx/pa-criteria/susvimo.jsp. Last Updated April 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/10/2021
UCare Update	Ucare identified Susvimo is participating in the Medicaid Drug Rebate program and therefore is eligible for coverage. This policy is an update from the prior policy which recommends denial due to safety concerns.	5/01/2022
Annual Revision	UCare updated clinical criteria as outlined by MN DHS PA criteria	11/15/2023
UCare Update	Minor grammatical error updated and clarification of supplemental treatment outlines	4/23/2024