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

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

EFFECTIVE DATE: 4/1/2022
REVIEW DATE: 11/12/2025

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Susvimo, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the following uses:[1]

- **Diabetic macular edema (DME)**, in patients who have previously responded to at least two intravitreal injections of a VEGF inhibitor medication.
- **Diabetic retinopathy,** in patients who have previously responded to at least two intravitreal injections of a VEGF inhibitor medication.
- **Neovascular (wet) age-related macular degeneration (AMD)**, in patients who have previously responded to at least two intravitreal injections of a VEGF inhibitor medication.

In contrast to the other VEGF inhibitor products which are administered as intravitreal injections, Susvimo is an intravitreal implant.[1]

Safety

Susvimo has a **Boxed Warning** regarding endophthalmitis; this Boxed Warning is unique to Susvimo and the other VEGF inhibitors do not have this Boxed Warning. In the active-controlled trials in AMD, Susvimo has been associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal ranibizumab injection (Lucentis, biosimilars), 1.7% vs. 0.5%, respectively.[1] When including extension phases of clinical trials, 2% (n = 11/555) of patients receiving Susvimo experienced an episode of endophthalmitis. Reports occurred between Days 5 and 853 (median of 173 days). Many of these events were associated with conjunctival retractions or erosions.

In the active comparator period of the controlled clinical trial in DME, 0% of patients in the Susvimo group vs. 0.3% of patients in the intravitreal ranibizimab group experienced an episode of endophthalmitis.[1] When including the extension phase of the clinical trial, 0.7% (n = 4/556) of patients receiving Susvimo experienced an episode of endophthalmitis, which were reported between Days 625 and 1,016 (median of 824 days).

In the period with an observational comparator arm of the clinical trial in diabetic retinopathy, none of the patients in the Susvimo group experienced an episode of endophthalmitis.[1] When including the extension phase of the clinical trial, one patient (n = 1/128 [0.8%]) who received Susvimo experienced an episode of endophthalmitis, which was reported on Day 695.

Additional Warnings/Precautions associated with the Susvimo implant and/or implant-related procedures include rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion or retraction, conjunctival bleb, postoperative decrease in visual acuity, air bubbles causing improper filling of the implant, and deflection of the implant.[1]

POLICY STATEMENT

Due to safety concerns, **approval of Susvimo is not recommended**. There are significant risks associated with use based on the Boxed Warning regarding endophthalmitis.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

None.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Susvimo is not recommended in the following situations:

1. **Diabetic Macular Edema (DME)**. Due to the safety data, approval is not recommended for Susvimo. In the pivotal trial for DME, Susvimo demonstrated non-inferiority to intravitreal ranibizumab injection (Lucentis, biosimilars) administered every 4 weeks.[1] Although the incidence of endophthalmitis in the Susvimo group was not greater than that reported in the monthly intravitreal ranibizumab group in the pivotal study for DME, Susvimo labeling includes a Boxed Warning regarding endophthalmitis. In the active comparator period of the clinical trials in AMD, Susvimo was associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal ranibizumab injections (1.7% vs. 0.5%, respectively). When extension phases of clinical trials were included, 2% of patients in the Susvimo group experienced an episode of endophthalmitis. Many, but not all, of the cases of endophthalmitis reported a preceding or concurrent conjunctival retraction or erosion event. In addition, occurrence of other ocular adverse events were more frequent with Susvimo vs. intravitreal ranibizumab injection.

2. **Diabetic Retinopathy.** Due to the safety data, approval is not recommended for Susvimo. Efficacy of Susvimo was assessed in a study involving patients with moderately-severe to severe non-proliferative diabetic retinopathy without center-involved DME and who had not received prior treatment in the study eye for diabetic retinopathy. Prior to the implant procedure, patients in the Susvimo group received two loading doses of intravitreal ranibizumab in the study eye; patients in the observational comparator group did not receive loading doses of intravitreal ranibizumab. At Week 52, 80% of patients in the Susvimo group achieved a ≥ 2-step improvement on the Early Treatment Diabetic Retinopathy Study-Diabetic Retinopathy Severity Scale (ETDRS-DRSS) from baseline vs. 9% of patients in the observation group. Although none of the patients in the Susvimo group experienced an episode of endophthalmitis during the observational comparator portion of the study and one patient (n = 1/128 [0.8%]) who received Susvimo experienced an episode of endophthalmitis during the extension phase, Susvimo labeling includes a Boxed Warning regarding endophthalmitis. In the active comparator period of the clinical trials in AMD, Susvimo was

associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal ranibizumab injections (1.7% vs. 0.5%, respectively). When including the extension phases of clinical trials, 2% of patients in the Susvimo group experienced an episode of endophthalmitis. Many, but not all, of the cases of endophthalmitis reported a preceding or concurrent conjunctival retraction or erosion event. In addition, occurrence of other ocular adverse events were more frequent with Susvimo vs. intravitreal ranibizumab injection.

3. **Neovascular (Wet) Age-Related Macular Degeneration (AMD).** Due to the safety data, approval is not recommended for Susvimo. In the pivotal trial for AMD, results for the primary efficacy endpoint showed Susvimo to be equivalent to intravitreal ranibizumab injection (Lucentis, biosimilars) administered every 4 weeks.[1] However, ocular adverse events were more frequent with Susvimo vs. intravitreal ranibizumab injection; patients treated with Susvimo require regular monitoring to evaluate for these adverse events. Notably, Susvimo labeling includes a Boxed Warning regarding endophthalmitis. In the active comparator period of the clinical trials in AMD, Susvimo was associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal ranibizumab injections (1.7% vs. 0.5%, respectively). When including the extension phases of clinical trials, 2% of patients in the Susvimo group experienced an episode of endophthalmitis. Many, but not all, of the cases of endophthalmitis reported a preceding or concurrent conjunctival retraction or erosion event. In addition, occurrence of other ocular adverse events were more frequent with Susvimo vs. intravitreal ranibizumab injection.

4. 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; September 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/15/2023
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	11/20/2024
Selected Revision	**Diabetic Macular Edema:** This condition was added to the Conditions Not Recommended for Approval section.	03/26/2025
Selected Revision	**Diabetic Retinopathy:** This condition was added to the Conditions Not Recommended for Approval section.	06/11/2025
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/15/2025
Annual Revision	No criteria changes.	11/12/2025