Drug Coverage Policy

Effective Date 6/15/2025
Coverage Policy Number.....IP0349
Policy Title.....Susvimo

Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Susvimo

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

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The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Ranibizumab intravitreal injection (Susvimo) is considered to be experimental, investigational, or unproven for Neovascular (Wet) Age-Related Macular Degeneration (AMD) or Diabetic Macular Edema (DME) due to insufficient data establishing safety, efficacy, and improved health outcomes for any condition, regardless of U.S. Food and Drug Administration (FDA) approval status. Criteria will be updated as new published data are available.

1. **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). And, 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.

2. **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). And, 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, other ocular adverse events were more frequent with Susvimo vs. intravitreal ranibizumab injection.

Overview

OVERVIEW

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

- **Neovascular (wet) age-related macular degeneration (AMD)**, in patients who have **previously responded to at least two intravitreal injections of a VEGF inhibitor medication**.
- **Diabetic macular edema (DME)**, 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] Many of these events were associated with conjunctival retractions or erosions. When including extension phases of clinical trials, 2% (n = 11/555) of patients receiving Susvimo experienced an episode of endophthalmitis.

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.

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]

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven:

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

References

1. Susvimo™ intravitreal injection via ocular implant [prescribing information]. South San Francisco, CA: Genentech; February 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	5/15/2024
Annual Revision	No criteria changes **Coding Information:** **Added** coding table & HCPCS J2779	2/15/2025
Annual Revision	**Diabetic Macular Edema:** This condition was added to the considered to be experimental, investigational, or unproven section.	6/15/2025

The policy effective date is in force until updated or retired.