Utilization Review Policy 276B

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

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

EFFECTIVE DATE: 4/1/2022
REVIEW DATE: 11/15/2023

COVERAGE CRITERIA FOR: UCare Medicare Plans and Exchange Plans Only (UCare Medicare, UCare Medicare with M Health Fairview and North Memorial, EssentiaCare, Group Plans, MSHO, Connect + Medicare, UCare Your Choice, all Individual and Family Plans)

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]

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.[2,3] Patients must have had at least three prior anti-VEGF intravitreal injections 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]). For the primary efficacy endpoint of the change in BCVA from baseline, Susvimo was non-inferior compared with Lucentis® (ranibizumab intravitreal injection) [+0.2 letters vs. +0.5 letters, respectively].

Safety

Susvimo has a Boxed Warning regarding endophthalmitis, which occurred at a 3-fold higher rate with Susvimo vs. Lucentis (1.7% vs. 0.5% in active-controlled trials).[1] Additional Warnings associated with the implant and/or implant-related procedures unique to Susvimo 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.

POLICY STATEMENT

Due to the safety concerns, **approval is not recommended** for Susvimo. There are significant risks of 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. **Neovascular (Wet) Age-Related Macular Degeneration.** Due to the safety data, approval is not recommended for Susvimo. In the pivotal trial, Susvimo demonstrated non-inferiority compared with Lucentis.[1-3] However, ocular adverse events were more frequent with Susvimo vs. Lucentis; patients treated with Susvimo require regular monitoring to evaluate for presence of these adverse events. Notably, Susvimo labeling includes a unique Boxed Warning regarding endophthalmitis, which was three times more frequent with Susvimo vs. Lucentis.

2. 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. 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].
3. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/10/2021
Selected Revision	**Neovascular (Wet) Age-Related Macular Degeneration:** This condition was moved from the Recommended Authorization Criteria to the Conditions Not Recommended for Approval because of the significant risks of use based on the Boxed Warning regarding endophthalmitis.	11/17/2021
Annual Revision	No criteria changes.	11/15/2023