Overview

This policy addresses the usage of Susvimo™ (ranibizumab) intravitreal injection via ocular implant.

Medical Necessity Criteria

Susvimo (ranibizumab) intravitreal injection via ocular implant for the treatment of Neovascular (Wet) Age-Related Macular Degeneration is considered experimental, investigational or unproven.

Note:
Susvimo is FDA approved 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; however, there is insufficient clinical safety data supporting this use.

Conditions Not Covered

Susvimo (ranibizumab) intravitreal injection via ocular implant is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):
1. **Neovascular (Wet) Age-Related Macular Degeneration.** There is insufficient data regarding the safety of Susvimo. In the pivotal trial, Susvimo demonstrated non-inferiority compared with Lucentis. 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.

**Background**

**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.

**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. 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). 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.

**References**

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.

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