Draft New Policy: Do Not Implement

Ranibizumab (Susvimo®)

Requires Step Therapy See "Step Therapy Requirements for Provider Administered Specialty Medications" Document at: https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Susvimo is indicated for the treatment of:

- Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication.
- Diabetic Macular Edema (DME) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication.
- Diabetic Retinopathy (DR) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication.

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA

Neovascular (Wet) Age-Related Macular Degeneration

Authorization of 6 months may be granted for treatment of neovascular (wet) age-related macular degeneration when all of the following criteria are met:

- Member has a diagnosis of neovascular (wet) age-related macular degeneration.
- Member has previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor (e.g., Avastin, Eylea) within the past 6 months.
- Must be used in conjunction with the Susvimo ocular implant.

Diabetic Macular Edema

Authorization of 6 months may be granted for the treatment of diabetic macular edema when all of the following criteria are met:

- Member has a diagnosis of diabetic macular edema .

- Member has previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor (e.g., Avastin, Eylea).
- Must be used in conjunction with the Susvimo ocular implant.

Diabetic Retinopathy

Authorization of 9 months may be granted for the treatment of diabetic retinopathy when all of the following criteria are met:

- Member has a diagnosis of diabetic retinopathy.
- Member has previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor (e.g., Avastin, Eylea).
- Must be used in conjunction with the Susvimo ocular implant.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in coverage criteria section when the member has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Susvimo. [package insert]. San Francisco, CA: Genentech, Inc.; May 2025.
2. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp.
3. American Academy of Ophthalmology Retinal/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.

EFFECTIVE DATE

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