Susvimo™ (ranibizumab)
(Intravitreal)

Document Number: IC-0634

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I. Length of Authorization

- Coverage will be provided every six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Susvimo 100 mg/mL solution for injection SDV: 1 vial per eye every 24 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

Neovascular Age-related Macular Degeneration

- 40 billable units (4 mg) every 24 weeks

(Max units are based on administration to both eyes)

III. Initial Approval Criteria [1-3]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient is free of ocular and/or peri-ocular infections; **AND**
- Patient does not have active ocular inflammation; **AND**
- Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab) unless supplemental treatment is necessary (see below); **AND**
- Patient has not required removal of a Susvimo implant in the past; **AND**
- Patient does not have a hypersensitivity to other ranibizumab products (i.e., Lucentis®, Byooviz™, etc.); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**

Neovascular (Wet) Age-Related Macular Degeneration (AMD) †

- Patient has previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor medication (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab)

† FDA Approved Indication(s)

IV. Renewal Criteria [1-3]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs, etc.; **AND**
- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition; **AND**
- *(Supplemental treatment only):* Patient has had an insufficient response during initial or maintenance therapy with Susvimo administered every 24 weeks and requires supplemental treatment with intravitreal ranibizumab *(Refer to Section V for dosing and administration)*

V. Dosage/Administration [1]

Indication	Dose
Neovascular (wet) Age-related Macular Degeneration (AMD)	<u>Initial/Maintenance</u> 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the Susvimo ocular implant with refills administered every 24 weeks (approximately 6 months) <u>Supplemental</u> Supplemental treatment with 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection may be administered in the affected eye while the Susvimo implant is in place and if clinically necessary
– *For intravitreal use via Susvimo ocular implant.* – *The initial fill and ocular implant insertion and implant removal procedures must be performed under aseptic conditions by a physician experienced in vitreoretinal surgery.* – *Susvimo ocular implant insertion is a surgical procedure that is performed in an operating room. No more than 30 minutes should pass between the initial fill of the ocular implant and the insertion into the patient's eye.* – *Removal of the Susvimo ocular implant is a surgical procedure that is performed in an operating room. The procedure must be performed under aseptic conditions by a physician experienced in vitreoretinal surgery.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologics *(Discontinue use on 07/01/2022)*
- J2779 – Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg; 1 billable unit = 0.1 mg *(Effective 07/01/2022)*
- C1889 – Implantable/insertable device, not otherwise classified *(Used for Susvimo Ocular Implant Device)*
- C9093 – Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg; 1 billable unit = 0.1 mg *(Discontinue use on 07/01/2022)*

NDC:

- Susvimo 100 mg/mL single-dose glass vial: 50242-0078-xx

VII. References

1. Susvimo [package insert]. South San Francisco, CA; Genentech, Inc; October 2021. Accessed December 2021.
2. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2017. Nov 2017.
3. Heimann F, Barteselli G, Brand A, Dingeldey A, Godard L, Hochstetter H, Schneider M, Rothkegel A, Wagner C, Horvath J, Ranade S. A custom virtual reality training solution for ophthalmologic surgical clinical trials. Adv Simul (Lond). 2021 Apr 16;6(1):12. doi: 10.1186/s41077-021-00167-z..

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
H35.3210	Exudative age-related macular degeneration, right eye, stage unspecified
H35.3211	Exudative age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212	Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization
H35.3213	Exudative age-related macular degeneration, right eye, with inactive scar
H35.3220	Exudative age-related macular degeneration, left eye, stage unspecified
H35.3221	Exudative age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222	Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization
H35.3223	Exudative age-related macular degeneration, left eye, with inactive scar
H35.3230	Exudative age-related macular degeneration, bilateral, stage unspecified
H35.3231	Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization

ICD-10	ICD-10 Description
H35.3232	Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization
H35.3233	Exudative age-related macular degeneration, bilateral, with inactive scar
H35.3290	Exudative age-related macular degeneration, unspecified eye, stage unspecified
H35.3291	Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization
H35.3292	Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization
H35.3293	Exudative age-related macular degeneration, unspecified eye, with inactive scar

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC