CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY						
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**		**POLICY NO**	**600.08**
POLICY TITLE	**SUSVIMO® (Ranibizumab) INSERT or INJECTION**					
POLICY DATE	**01/01/2022**	**REVISION DATE**	**08/08/2022**	**APPROVAL DATE**		**08/10/2022**
DISCLAIMER LANGUAGE	- **Policy content and application may have state specific variance and considerations** - **Health Plan specific 'Indications and Limitations of Coverage' may apply as specified** - **Line of Business considerations (i.e., Medicaid, Medicare, Commercial) may apply as specified**					
EXCLUSIONS	- **This policy is not applicable to Medicaid in the state(s) of Delaware, District of Columbia, Georgia, Illinois, Kentucky, Louisiana, Nebraska, New Hampshire and Texas, as SUSVIMO® is not a covered benefit.** - **This policy is not applicable to Medicaid in the state(s) of North Carolina, as SUSVIMO® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**					

I. POLICY STATEMENT

Coverage of SUSVIMO® (ranibizumab) pars plana insert or injection will be provided when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To establish medical necessity for this service, Avēsis aligns its criteria with the evidence and consensus based clinical practice guidelines set forth by the American Academy of Ophthalmology (AAO). The AAO incorporates evidence based best practice and FDA approval and/or recommendations[1]. Avēsis Medical Directors and clinical staff are licensed medical professionals and review criteria and documentation submitted by requesting providers using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE

1.0 Coverage is limited to membership eligible at the time of the date of service and in accordance with continuity requirements, as applicable.

2.0 Coverage is indicated for treatment when enrollees have the following condition*:

- 2.1 Neovascular (Wet) age-related macular degeneration (AMD)

3.0 SUSVIMO® (Ranibizumab) will not be covered at a frequency that exceeds what is medically reasonable and necessary.

4.0 Coverage will be considered only for enrollees who have completed a minimum of three (3) months of Avastin® (bevacizumab) with unsatisfactory outcome as defined by:

- 4.1 Decrease in best corrected acuity; or
- 4.2 No decrease in macula changes as evidence by OCT or clinical exam and
- 4.3 Have had previously responded to at least 2 anti-vascular endothelial growth factor injections

5.0 Authorizations will be given for the time period of 6 months and will cover up to one implant during that time period.

- 5.1 Additional injections requested will be subject to review and determinations will be made on a case-by-case basis and subject to medical necessity.
- 5.2 When services are performed in excess of established parameters, they may be subject to peer and quality review.

[1] American Academy of Ophthalmology https://www.aao.org

**Note, refer to Section V for additional required detail*

III. TREATMENT RECOMMENDATIONS

1.0 The recommended dose for SUSVIMO® is 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)

2.0 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

IV. MEDICAL NECESSITY REQUIREMENTS for <u>APPLICABLE HCPCS CODE J3590</u>

1.0 To establish medical necessity all criterion points referenced below must be clearly & legibly documented in the medical record and made available to Avēsis upon submission of request.
- 1.1 Areas where 'white out' is used are not accepted.
- 1.2 Areas with 'black out' or 'scribble' will not be accepted.
  - 1.2.1 A single line through text where the text will remain readable is acceptable with provider initials and date.

2.0 Physician signature must be present on chart and procedural notes, orders, and testing interpretations.

3.0 The submitted documentation must clearly support medical necessity as outlined in Section II Indications and Limitations of Coverage.

4.0 Medical documentation must clearly state the clinical indication/medical necessity for the SUSVIMO® (ranibizumab) injection and the frequency of its usage.

5.0 Ocular Coherence Tomography (OCT) and/or fluorescein angiography (FA) test results must be interpreted and firmly establish/support diagnosis.

6.0 Procedure note must include:
- 6.1 Actual administered dosage of SUSVIMO® (ranibizumab) given
- 6.2 Site of injection
- 6.3 Route of administration
- 6.4 Injection Lot #
- 6.5 Injection expiration date
- 6.6 Post-injection vision ≥ CF

7.0 Medical documentation must provide evidence along with full informed consent, outlining all pertinent risks, inclusive of the following:
- 6.1 Date
- 6.2 Consent to perform
- 6.3 Consent to waive
- 6.4 Patient or Representative Signature
- 6.5 Surgeon/Physician Signature
- 6.6 Witness Signature

V. HCPCS/ICD-10 CODES SUPPORTING MEDICAL NECESSITY

For any code not listed below, please supply proper documentation with your prior authorization request, and Avēsis will review and make a determination based on medical necessity

Table 1: HCPCS/ICD-10 CODES

***SUSVIMO® (Ranibizumab) INSERT or INJECTION*:**	
HCPCS codes covered if selection criteria are met:	
J3590	*SUSVIMO® (Ranibizumab)*, pars plana insert or injection, 2 mg
ICD-10 codes covered if selection criteria are met:	
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
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