Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 252.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Susvimo (ranibizumab implant)

I. Policy:
Susvimo (ranibizumab implant)

II. Purpose/Objective:
To provide a policy of coverage regarding Susvimo (ranibizumab implant).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Ranibizumab is a recombinant humanized monoclonal antibody fragment which binds to and inhibits human vascular endothelial growth factor A (VEGF-A). Ranibizumab inhibits VEGF from binding to its receptors and thereby suppressing neovascularization and slowing vision loss.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Susvimo (ranibizumab implant) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation patient has previously responded to at least two (2) intravitreal doses of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) additional intravitreal VEGF inhibitors (e.g. Eylea, Beovu, or Lucentis)

AND

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth Factor (VGEF) inhibitor administration to the same eye **OR**
- If the request is for use in combination with an intravitreal VEGF inhibitor administration to the same eye, <u>all</u> of the following must be met:
    - Medical record documentation Susvimo (ranibizumab) will be given in combination with intravitreal ranibizumab injection (Lucentis) **AND**
    - Medical record documentation intravitreal ranibizumab injection will be administered on an as needed basis, as determined by the prescriber

NOTE: Indicators of intravitreal bevacizumab (Avastin) failure may include:

- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

AUTHORIZATION DURATION: Approval will be given for an **initial duration of two (2) years** or less if the reviewing provider feels it is medically appropriate. After the initial two (2) year approval, subsequent approvals will be for a **lifetime duration** or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth (VEGF) inhibitor

QUANTITY LIMIT: 0.2mL (2 vials) per 24 weeks (to allow 2mg per 24 weeks per treated eye)

LIMITATION: Susvimo (ranibizumab) to be given in combination with intravitreal ranibizumab (Lucentis) injections after 92 weeks from the start of Susvimo therapy has not been studied in clinical trials and will require prior authorization.

Susvimo (ranibizumab implant) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation patient has previously responded to at least two (2) intravitreal doses of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) additional intravitreal VEGF inhibitor (e.g. Eylea, Beovu, or Lucentis)

AND

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth Factor (VGEF) inhibitor administration to the same eye **OR**
- If the request is for use in combination with an intravitreal VEGF inhibitor administration to the same eye, all of the following must be met:
    - Medical record documentation Susvimo (ranibizumab) will be given in combination with intravitreal ranibizumab injection (Lucentis) **AND**
    - Medical record documentation intravitreal ranibizumab injection will be administered on an as needed basis, as determined by the prescriber

NOTE: Indicators of intravitreal bevacizumab (Avastin) failure may include:

- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

AUTHORIZATION DURATION: Approval will be given for an **initial duration of two (2) years** or less if the reviewing provider feels it is medically appropriate. After the initial two (2) year approval, subsequent approvals will be for a **lifetime duration** or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth (VEGF) inhibitor

QUANTITY LIMIT: 0.2mL (2 vials) per 24 weeks (to allow 2mg per 24 weeks per treated eye)

LIMITATION: Susvimo (ranibizumab) to be given in combination with intravitreal ranibizumab (Lucentis) injections after 92 weeks from the start of Susvimo therapy has not been studied in clinical trials and will require prior authorization.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Susvimo [prescribing information]. South San Francisco, CA: Genentech Inc; April 2022.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/15/22

Revised: 5/17/22 (QL), 5/11/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added)

Reviewed: 5/10/24

MA UM Committee approval: 12/31/23