

Sample Letter of Medical Necessity for SUSVIMO® (ranibizumab injection)

Some Key Reminders:

- You may use a letter of medical necessity when one is required by your patient's health insurance plan. It may also be used to accompany a request for prior authorization for a treatment
 - Include the appropriate ICD-10-CM diagnosis code(s)
 - Please ensure the treating physician signs the letter
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[Date]

[Payer name]

ATTN: [Contact Title/Medical Director]

[Contact name (if available)]

[Payer address]

[City, State ZIP]

Re: Letter of Medical Necessity for SUSVIMO® (ranibizumab injection)

Patient: [Patient's first and last name]

Date of Birth: [MM/DD/YYYY]

Subscriber ID #: [Insurance ID #]

Subscriber Group #: [Insurance group #]

Case ID Number: [Case ID number (if available)]

Date(s) of Service: [Include all denied dates of service]

Dear [Contact Name/Medical Director],

I am writing on behalf of my patient, [Patient's first and last name], to [request prior authorization of/document medical necessity for] treatment with SUSVIMO. This letter provides information about the patient's medical history and diagnosis and a summary of the treatment plan.

Patient's Clinical History

[Patient's name] is [a/an] [age]-year-old [male/female/transgender/etc.] who has been diagnosed with neovascular (wet) age-related macular degeneration (AMD) and has previously responded to at least two intravitreal injections of a vascular endothelial growth factor inhibitor medication as of [date]. [He/She/They] [has/have] been in my care since [date], having been referred to me by [Referring physician name] for [reason].

[Brief summary of rationale for treatment with SUSVIMO. This includes a brief description of the patient's diagnosis, including the ICD-10-CM code, the severity of the patient's condition, prior treatment(s), the duration of each, responses to those treatments, the rationale for discontinuation, as well as other factors (e.g., underlying health issues, age) that have affected your treatment selection. See Additional Considerations for Documentation below for more factors]

Treatment Plan

On October 22, 2021, the US Food and Drug Administration (FDA) approved SUSVIMO for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor inhibitor medication.

[Include plan of treatment (dosage, length of treatment) and clinical practice guidelines that support the use of SUSVIMO. Consider mentioning experts in the field who also support the treatment.]

Summary

Based on the facts above, I believe SUSVIMO is indicated and medically necessary for this patient. If you have any questions about this matter, please contact me at [Physician phone number] or via email at [Physician email]. Thank you for your time and consideration.

Sincerely,

[Physician's name, credentials and signature]

Enclosures

List enclosures, which may include:

- SUSVIMO Prescribing Information
- Clinical notes/medical records
- Diagnostic test results
- Relevant peer-reviewed articles
- FDA approval letter for SUSVIMO
- Scans/imaging showing progressive disease
- Pathology reports, if relevant

Additional Considerations for Documentation

- Visual acuity, chief complaint and appropriate history of present illness (HPI)
- Recurrence of fluid and/or incomplete resolution of fluid
- Treatment plan:
 - For new patients, document why the specific medication was chosen
 - For established patients, document their response to the current medication and the reason for continuing treatment
 - When changing medications, document the reason
- Diagnosis supporting medical necessity and appropriate indication for use per payer policy and/or FDA indication
- Any relevant diagnostic testing services (such as OCT) with interpretation and report
- Risks, benefits and alternatives discussed
- Documentation showing that the patient desires surgery
- Physician's order that includes:
 - Date(s) of service
 - Medication name and dosage in mg and mL
 - Diagnosis
 - Physician signature
- Procedure record that includes:
 - Diagnosis
 - Route of administration and medication name
 - Site of injection (which eye(s) treated)
 - Dosage in mg and volume in mL and lot number
 - Record of wastage, as appropriate
 - A completed Advanced Beneficiary Notice of Noncoverage (ABN) for Medicare Part B beneficiaries or a waiver of liability all other patients, if applicable (e.g., diagnosis not indicated, exceeds frequency)
- Medical record that is legible and has patient identifiers (e.g., patient's name, date of birth) on all pages
- A legible physician's signature
- Paper medical records with a signature log
- Electronic Health Record with a secure electronic physician signature and a related

- practice policy that is readily available for audits
- Abbreviations that are consistent with an approved list and are readily available for audits
- Well-maintained, legible inventory logs and medication administration records (MARs)