Sample Letter of Medical Necessity

This sample letter is for instructional purposes only and is not meant to substitute in any way for a physician's independent clinical decision-making. There is no requirement that any patient or eye care professional use any Astellas Pharma US, Inc. product in exchange for this information. A letter of medical necessity may be required to obtain a prior authorization decision and/or if there is a denial of coverage for IZERVAY™ (avacincaptad pegol intravitreal solution). This template provides information that may be requested when sending a letter of medical necessity to a patient's health plan on behalf of a patient being treated with IZERVAY for geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Submitting a letter of medical necessity does not guarantee coverage. It is important to review the specific health plan requirements and each plan's submission process before you use this template. Please refer to the Important Safety Information in the full Prescribing Information when determining whether therapy is medically appropriate for your patient.

Please replace the pink, bracketed content with appropriate details and place the template in your standard practice letterhead.

[Date]

[Health plan name] [Patient's name]

ATTN: [Department] [Patient's plan-specific member ID]

[Medical/Pharmacy director name (if available)] [Date of birth]

[Health plan address] [Case number]

[City, State, ZIP code] [Dates of service]

Re: Letter of Medical Necessity for IZERVAY™ (avacincaptad pegol intravitreal solution)

Dear [Medical/Pharmacy director name],

I am [Eye care professional name, credentials, specialty], writing on behalf of my patient, [Patient's first and last name], who I have been treating with IZERVAY since [Date] for geographic atrophy (GA) secondary to age-related macular degeneration (AMD) [ICD-10 codes].

I am requesting coverage for IZERVAY for my patient because [include rationale for why you believe there is a medical necessity for continued treatment with IZERVAY].

In my medical opinion, initiating/continuing treatment with IZERVAY is medically necessary for [Patient's first name] given the medical history provided below:

[Explain why you believe the administration of IZERVAY is appropriate for this patient. This can include but is not limited to the following information to support your treatment decision, and should be based on your own clinical judgment for your specific patient - Remove this section in gray when you place in your practice letterhead]

- [Your clinical opinion on the patient's potential progression of GA and its impact on further vision loss/decline with and without continued treatment with IZERVAY (eg, potential impact to the patient's daily activities)]
- [Clinical considerations associated with treatment switch/stop based on your clinical judgment, patient's response to IZERVAY to date, and why you are recommending continuance of IZERVAY treatment for your patient]
- [Patient testimonial]

If you have any further questions about this matter, please feel free to contact me at [Eye care professional phone number] or via email at [Eye care professional email]. Thank you for your time and consideration.

Sincerely,

[Eye care professional's signature] [Eye care professional name] [Eye care professional NPI] [Name of practice] [Phone number]

Enclosures: [List and attach additional documents as needed]

- [IZERVAY Prescribing Information
- IZERVAY FDA Approval Letter
- Your clinical notes/medical records
- Other relevant medical studies, peer-reviewed articles, and publications regarding IZERVAY
- Recent/new/upcoming clinical support documentation for IZERVAY
- Result summary of tests (eg, OCT/fundus photos/autofluorescence/fluorescein angiogram
- Any other information requested by the payer]