

[Name, Title]
[Address]
[City, State ZIP Code]
[Phone Number]
[Date]
[Contact Name], [Title], [Name of Health Insurance Plan or PBM]
[Address]
[City, State ZIP Code]

Re: [Letter of Medical Necessity for WAINUA® (eplontersen)]
[Request for Expedited Review Due to Medical Urgency]
Insured: [Name]; Member ID Number: [Insurance ID Number]; Group Number: [Number]
Date(s) of service: [Date(s)]

Dear [Contact Name],

I am a board certified [neurologist and ATTR specialist, cardiologist working with an ATTR specialist, or other] and am writing on behalf of my patient, [Name of Patient], to document the medical necessity of WAINUA® (eplontersen) for the treatment of [patient-specific diagnosis].

Patient Medical Overview

[Name of patient] is a [n] [age]-year-old [gender], born on [MM/DD/YYYY], who requires treatment with WAINUA after being diagnosed with [patient-specific diagnosis], confirmed by [include applicable testing regimen if available/appropriate] on [MM/DD/YYYY].

Medical History (Including Clinical Signs and Symptoms) [see page 3 of the WAINUA Letter of Medical Necessity Guide for additional information]

[Provide relevant diagnosis-specific details, including clinical signs and symptoms and describe the severity of disease of your patient's current presentation and disease progression (eg, patient's medical history) based on your medical opinion. Include specific clinical presentations, relevant patient-specific clinical scenarios demonstrating serious medical need, and previous treatments.]

FDA Approval

WAINUA is FDA-approved for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Medical Necessity

[If Policy Requires Step Therapy/Trial or Failure of Recommended Therapy]

Your policy requires a step through [preferred therapy per clinical policy]. In my medical opinion, [preferred therapy per clinical policy] is not appropriate for my patient. [Include rationale for ineligibility or failure of step therapies including worsening of signs or symptoms of disease state. If multiple steps are required, include reasons for each treatment.]

[Discuss rationale for using WAINUA. Include your professional opinion of your patient's likely prognosis or disease progression without treatment. Please refer to the list of potential considerations from the Letter of Appeal Guide for WAINUA (US-104806) on page 3.] In my medical opinion, WAINUA is the most appropriate treatment for [Name of Patient] with [patient-specific diagnosis], based on its demonstrated clinical efficacy and safety profile.

For Patients Transitioning to WAINUA (if relevant) [see page 4 of the WAINUA Letter of Medical Necessity Guide for additional information]

[Provide treatment rationale for transitioning your patient from an existing therapy to WAINUA.]

Treatment Plan

[Include expected treatment plan including dosing. If applicable you may also want to include direction relevant to administration methodology and/or continued use of prior treatments.]

Summary

Based on the information outlined above, WAINUA is medically necessary for the treatment of this patient. For your convenience, I am enclosing [add list of enclosures (eg, confirmatory genetic testing results and other patient chart notes)].

Please contact me at [Phone Number] if you have any questions or require additional information to facilitate prompt approval of WAINUA. Thank you for your timely consideration of this request.

Sincerely,

[Provider's Name]

[Provider's Identification Number]

[Provider's Practice Name]

[Provider's Phone Number]

[Provider's Fax Number]

[Provider's Email]

[Enclosures]

[Supporting clinical documentation. Examples include confirmatory genetic testing results and other patient chart notes, progress notes, clinical trials, guidelines or consensus statements, FDA approval letter, other relevant references and publications regarding prescribed medicine, etc.]

[Consider including Indication and Important Safety Information for WAINUA]

[Consider including full Prescribing Information, including Patient Information, for WAINUA]