**Instructions:**

This template is offered as a resource that a healthcare provider could use when responding to a request for a letter of appeal – BASED ON REQUIRED TESTING when prescribing AstraZeneca products. **Commonly recommended attachments to be included when submitting the completed letter of medical necessity are [original claim form, copy of denial or explanation of benefits, and any other additional supporting documents]**. If you need additional references, please contact the AstraZeneca Information Center at 1-800-236-9933.

**Use of this template does not guarantee reimbursement for the prescribed AstraZeneca product, and is not intended to be a substitute for or an influence on the independent medical judgment of the healthcare provider.**

**Sample Letter of Appeal-** BASED ON REQUIRED TESTING

*(Healthcare Provider Letterhead)*

**Date: [Date]**

**Payer Name: [Payer Name] Payer Address: [Payer Address]**

**City, State, ZIP Code: [City, State, ZIP Code]**

**Payer Phone and Fax Number: [Payer Phone and Fax Number]**

**Patient Name: [Patient Name]**

**Patient Date of Birth: [Patient Date of Birth] Policy Number: [Policy Number]**

**Group Number: [Number]**

RE: Appeal for WAINUA[™] (eplontersen)

Dear [Name of the Contact Person at the Payer]:

I am writing on behalf of my patient, [Name of Patient], to appeal [Name of Payer]’s decision to deny coverage for WAINUA, which has been prescribed the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis*.* It is my understanding, based on your letter of denial dated [Date], that coverage has been denied for the following reason(s), [List the Specific Reason(s) for the Denial as Stated in the Denial Letter].

[Name of Patient] is a [age]- year old [gender] who has been under treatment for [diagnosis]. Their treatment regimen has included [List past and/or existing treatment protocols as appropriate]. Despite these measures, [describe treatment outcome].

[Patient Name] has been diagnosed polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) with the following test confirming the diagnosis of a mixed phenotype. The member has a documented pathogenic TTR mutation on [Date] as recorded in the enclosed documentation, a Polyneuropathy Disability (PND) Score of [PND Score 0-IV], and/or a Familial Amyloid Polyneuropathy (FAP) stage of [FAP Stage 0-III]. I believe [Patient Name] would benefit from WAINUA to treat the polyneuropathy of hATTR.

Please see the accompanying enclosures and documentation from my office demonstrating the medical necessity of WAINUA. I would appreciate a prompt review of this information and authorization of WAINUA by a [neurologist/cardiologist]. I can be reached at [Provider Phone number] or by fax at [Provider Fax number] for additional information and discussion. Thank you for your consideration.

Sincerely,

[Physician’s Name]

[Physician’s Practice Name]

Enclosures

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

* **Reduced Serum Vitamin A Levels and Recommended Supplementation** WAINUA leads to a decrease in serum vitamin A levels. Supplement with recommended daily allowance of vitamin A. Refer patient to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency occur.

**ADVERSE REACTIONS**

Most common adverse reactions (≥9% in WAINUA-treated patients) were vitamin A decreased (15%) and vomiting (9%).

**INDICATION**

WAINUA injection, for subcutaneous use, 45 mg is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Please see full [Prescribing Information](https://www.azpicentral.com/pi.html?product=wainua).

References [Include other relevant references and publications regarding prescribed medicine] [Copy of patient denial letter]

[Clinical progress notes]

[Patient’s lab results]