

WAINUA™ (eplontersen) Access and Reimbursement Guide



The AstraZeneca Access 360™ program provides personal support to help streamline access and reimbursement for WAINUA.

Not an actual patient or healthcare provider.



For more information, please contact AstraZeneca Access 360™ at **1-844-2-WAINUA**, Monday through Friday, 8 AM - 6 PM ET.



1-844-2-WAINUA (1-844-292-4682)



www.MyAccess360.com



1-844-FAX-A360 (1-844-329-2360)



Access360@AstraZeneca.com



One MedImmune Way, Gaithersburg, MD 20878

INDICATION

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

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.

Welcome to the AstraZeneca Access 360™ Program!

Not an actual patient.



The AstraZeneca Access 360™ program provides personal support to help streamline access and reimbursement for WAINUA. Access 360 provides:

- ✓ Assistance with understanding patient insurance coverage and pharmacy options
- ✓ Prior authorization support
- ✓ Claims and appeal process support
- ✓ Eligibility requirements and enrollment assistance with AstraZeneca's Co-pay Savings Programs
- ✓ Referrals to the AZ&Me™ Prescription Savings Program, AstraZeneca's patient assistance program
- ✓ Information about independent charitable patient assistance foundations

To learn more about the Access 360 program, please call **1-844-2-WAINUA** (1-844-292-4682) Monday through Friday, 8 AM - 6 PM ET or visit www.MyAccess360.com.

Patients can visit www.azpatientsupport.com or call Access 360 to provide authorization.

This guide contains information to help you and your office staff understand the access and reimbursement process and provides links to additional Access 360 resources.

This description of the Access 360 program is for informational purposes only. Access 360 does not file claims or appeals on behalf of healthcare professionals or patients and makes no representation or guarantee concerning reimbursement or coverage for any service or item.

Field Reimbursement Managers

AstraZeneca Field Reimbursement Managers (FRMs) are a resource for patients, healthcare providers, and office staff. FRMs provide regional, patient-specific support and have extensive expertise that can help streamline access and reimbursement for select AstraZeneca medicines.

Your FRM can provide:



Access and reimbursement support for providers and office staff, onsite or via telephone*



Personalized support to help connect patients to affordability programs



Resources to educate providers and office staff about support services offered by Access 360



Timely responses to questions about access and reimbursement



Access to innovative technology resources such as the Access 360 Provider Portal

Patient Education Managers

Patient Education Managers (PEMs) serve as a dedicated point of contact for patients who have been prescribed WAINUA. While patients should always contact their healthcare provider with any questions, they can also connect directly with a PEM.

Each PEM can:



Offer information about hATTR-PN and WAINUA



Provide updates during the insurance approval process



Share resources on how to take WAINUA

*Please note that FRMs are not able to file claims on behalf of providers or office staff.
hATTR-PN=polyneuropathy of hereditary transthyretin-mediated amyloidosis.

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement.



 [Download the WAINUA Coding Resource.](#)

National Drug Code (NDC)¹

Dosage	10-digit NDC	11-digit NDC
45 mg/0.8 mL single-dose autoinjector	0310-9400-01	00310-9400-01

Diagnosis Codes²

ICD-10-CM Code	Description
E85.1	Neuropathic heredofamilial amyloidosis (transthyretin-related [ATTR] familial amyloid polyneuropathy)

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

One of the goals of Access 360 is to connect patients to appropriate affordability programs. This section provides information about the WAINUA Savings Program and other programs, including eligibility requirements.



↓ Learn more about [affordability resources for WAINUA](#).

WAINUA Savings Program

For eligible, commercially insured patients

The goal of the WAINUA Savings Program is to assist eligible, commercially insured patients with their out-of-pocket costs for WAINUA.

Eligible patients may pay as little as \$0 per month to assist with WAINUA out-of-pocket costs. There are no income requirements to participate in the program.

Eligibility requirements:

- Must have commercial insurance
- Must have a valid prescription for WAINUA
- Must have WAINUA approved by their insurance plan
- Must be a resident of the United States or Puerto Rico
- Must be enrolled in the WAINUA Savings Program

Patients who are enrolled in a state- or federally funded insurance program are not eligible. This includes patients enrolled in Medicare Part D, Medicaid, Medigap, Veterans Affairs, Department of Defense programs or TRICARE, and patients who are Medicare eligible and enrolled in an employer-sponsored group waiver plan or government-subsidized prescription drug benefit program for retirees. If patients are enrolled in a state- or federally funded prescription insurance program, they are not eligible even if elected to be processed as an uninsured (cash-paying) patient. Additional restrictions may apply.

Offer is invalid for claims and transactions more than 365 days from the date of service.

For additional information, please visit www.WAINUA.com or call Access 360 at **1-844-2-WAINUA (1-844-292-4682)**.

AZ&Me™

The AZ&Me Prescription Savings Program provides AstraZeneca medicines at no cost to qualifying patients.



Who can apply?

- Patients who are not receiving:
 - Prescription drug coverage under commercial insurance or a government program (except for Medicare), or
 - Any other assistance to help pay for medication
- Medicare beneficiaries who are not eligible or enrolled in Low Income Subsidy for Medicare Part D
- Patients who have experienced a life-changing event in the past year
- Patients who meet income eligibility requirements
- Residents of the United States



Learn more about the [AZ&Me Prescription Savings Program](#).



Other Resources for Patients Requiring Additional Assistance

AstraZeneca Access 360™ can provide information about independent foundations that may be able to assist with out-of-pocket costs.

- Access 360 does not guarantee support by independent foundations. Each foundation sets its own eligibility requirements and support determinations



Learn more about [affordability resources](#) for WAINUA.



These technology resources are designed to help you manage your patients' care and may help streamline access to WAINUA. Below is an overview of the different options available to you.

CoverMyMeds®

The CoverMyMeds portal* allows pharmacists and providers to initiate, transmit, and track the status of prior authorization (PA) requests and to enroll in drug manufacturer resources, including Access 360.

covermymeds®

The CoverMyMeds portal offers:

- Ease in finding the correct PA request
- Ability to submit PA requests to any payer and often receive real-time determinations
- Access to drug-specific financial assistance and support programs with the enrollment process for Access 360 directly incorporated

Beyond the all-payer portal solution, CoverMyMeds is also integrated into 75% of EHR systems, offering electronic PA services within the workflow.



Access the [CoverMyMeds portal](#).

AstraZeneca Patient Support Website

The AstraZeneca Patient Support website allows online enrollment of eligible patients into the appropriate co-pay savings programs.

Patients or their legally authorized representatives can self-enroll in the WAINUA Savings Program. After selecting WAINUA on the home page, they will also provide consent in the same online form by signing the Access 360 Patient Authorization Form.

Providers can also enroll their patients into the WAINUA Savings Program through the website.



Access the [AZ Patient Support website](#).

*Available for select AstraZeneca medicines.

EHR=electronic health record.

The WAINUA Prior Authorization (PA) Considerations Guide can help ensure that you have all the necessary items prior to submitting a PA request to the patient's insurance.

 **Reach out to your FRM for the WAINUA PA Considerations Guide.**

PA Checklist

The items below may be necessary to obtain a PA decision from a health plan. Please ensure you have all the information listed below prior to submitting the PA request.

☐ **Completed PA request form (some health plans require specific forms)**

Include the following:

- ☐ Patient name, insurance policy number, and date of birth
- ☐ Patient diagnosis (ICD-10-CM code[s])
- ☐ Product NDC

☐ **Letter of medical necessity and relevant clinical support**

Include the following:

- ☐ Provider ID number in the letter

 **Download the [Sample Letter of Medical Necessity](#).**



☐ **Documentation that supports the treatment decision, such as:**

- ☐ Previous treatments/therapies
- ☐ Patient-specific clinical notes detailing the relevant diagnosis
- ☐ Relevant laboratory results
- ☐ Product Prescribing Information

PA requirements vary by health plan and may require preapproval. Please contact the patient's health plan for specific PA requirements to ensure efficient and timely review. Failure to obtain a PA can result in nonpayment by the plan.*

Prior to submission, please keep track of dates and methods of correspondence (phone, email, and written); record the names of insurance contacts and reviewers with whom you speak; and summarize conversations and written documents issued by the insurer.

*Providers and patients are encouraged to contact the patient's insurer for detailed instructions on completing a PA or appealing/overturning a denial.

Denial and Appeal Checklist

If the health plan denied a PA for an AstraZeneca medicine:

- ☐ **Review the denial notification** to understand the reason and circumstances that need to be addressed and explained in the appeal letter
- ☐ **Understand the plan's most recent explanation of benefits (EOB)** or contact a representative at the insurer to verify where the appeal should be sent and any deadlines
- ☐ **Write an appeal letter.** If you need additional information regarding this process, please contact Access 360 for examples

 **Download the [WAINUA Sample Letter of Appeal](#).**



If you or your patient has not received a decision within 30 days:

- ☐ **Follow up with the health plan.** Confirm the appeal letter was received and ask about its status. If the coverage denial was upheld, you could resubmit another appeal with new information or ask for a supervisor or manager to assist

If the denial is upheld again:

- ☐ **Ask for a onetime exception or a peer-to-peer medical review, or consider filing a complaint** with the state's insurance commissioner
- ☐ **If the insurer continues to deny the claim,** your patient may request an external appeal (the process varies by state law), in which an independent third party will review the claim and make a final, binding decision
- ☐ **Please contact your FRM** or Access 360 if you need additional support

 Download the [WAINUA Distribution Card](#).



Specialty Pharmacy Providers (SPPs)

WAINUA is available for order from this authorized SPP, which also provides support to help patients with their prescribed treatments:

Specialty Pharmacy	Phone	Fax	Website
Orsini Pharmaceutical Services	800-986-4975	877-369-5207	www.orsinispecialtypharmacy.com

Specialty Distributors (SDs)

WAINUA is available for purchase from these authorized SDs:

Specialty Distributor	Phone	Fax	Website
ASD Healthcare, a company of Cencora	800-746-6273	800-547-9413	www.asdhealthcare.com
Besse Medical	800-543-2111	800-543-8695	www.besse.com
Cardinal Health Specialty Pharmaceutical Distribution	855-740-1871	888-345-4916	specialtyonline.cardinalhealth.com
CuraScript SD	877-599-7748	800-862-6208	www.curascriptsd.com
Dakota Drug Inc.	866-210-5887	763-421-0661	www.dakdrug.com
DMS Pharmaceutical Group, Inc.	877-788-1100	847-518-1105	www.dmspharma.com
McKesson Plasma and Biologics (Hospitals, IDNs, VA)	877-625-2566	888-752-7626	https://www.mckesson.com/Pharmaceutical-Distribution/Plasma-Biologics/
Optum SD	614-698-5000	614-698-5010	Email: OSD_OH_Distribution@Optum.com

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

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

Please read additional Important Safety Information on page 1 and full [Prescribing Information](#), including [Patient Information](#), for WAINUA.

You may [report side effects related to AstraZeneca products](#). 

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Please read Important Safety Information on pages 1 and 11 and full [Prescribing Information](#), including [Patient Information](#), for WAINUA.

References: 1. WAINUA™ (eplontersen) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023. 2. AAPC. 2022 ICD-10-CM Expert: Diagnosis Codes for Providers & Facilities. 2021. Accessed October 25, 2023. <https://aapc.vitalsource.com/#/>