

Tips for Filing an Appeal of Treatment Denial

If you prescribed CYSTADROPS to your patient and received a coverage denial from the patient's insurance company, a letter of appeal may be needed. An appeal letter should follow the requirements of the patient's health plan, including the use of plan-specific coverage authorization forms. Contact the specific health plan for information that is pertinent to your appeal. Once you have this information, it may be helpful to follow the tips and checklist in this document as you write the appeal.

The focus of this document is to assist you in the preparation of a comprehensive appeal that may meet the requirements of a specific health plan. Use of the information in this document does not guarantee that the health plan will reverse its denial, and it is not intended to be a substitute for, or an influence on, your independent medical judgment.

Use of this document is for HCP office staff only.

Why Was the Request Denied?

Determine (in writing) why your prior authorization request has been denied by the patient's health plan. This information may be outlined in the explanation of benefits (EOB) letter that can be obtained from the health plan. Check the health plan's online portal for more information.

Understand the Appeal Guidelines

Appeal periods vary, so it is important to find out the deadline for submitting an appeal. Also determine the number of appeals because some plans allow only one. Confirm routine information, such as the current mailing address/fax number for the appeal. Consider setting up a consultation with the insurance company's representative to discuss.

Phone the Health Plan's Review Department

If the denial letter includes a phone number for the review department, the prescribing physician should call to learn of any details regarding why the request was denied. If the reviewer approves treatment during the call, then confirm the appeal process is complete and documented. If this does not happen, then continue with the process.

Draft the Appeal Letter

Write the appeal letter and include all of the supporting documentation that you may need. You may also need to schedule a peer-to-peer consultation in order to obtain required details or documentation.

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including Instructions for Use.

Submit Final Appeal Letter and Supporting Documentation

The appeal should include all relevant medical documentation. This documentation may include clinical notes and test results, as well as any other relevant information regarding the patient's current condition. Additional documents may also be required depending on the specific payor.

Determine the Timeline

Confirm the appeal review timeline with the health plan. Typically, you will hear from the health plan within 30 to 60 days of receipt of the appeal package. Follow up as needed.

Keep Comprehensive Records

Keep copies of all documents and notes associated with the appeal. Likewise, any communication occurring during and after the appeal is submitted should be carefully documented, including dates, the person with whom you spoke, and any details pertinent to the appeal.

Documents for Filing an Appeal

Each appeal may require different information based on the health plan's requirements. Review each denial and the plan's requirements to determine what to include in a patient's appeal package.

Below is a list of records that are commonly included in an appeal package.

Frequently Needed Documents for an Appeal Package

- ✓ Letter of appeal
- ✓ Letter of medical necessity
- ✓ Patient authorization and notice of release of information
- ✓ Copy of the patient's medical plan card and/or prescription card (front and back)
- ✓ Denial information, including the patient's denial letter and/or explanation of benefits
- ✓ Supporting documentation:
 - ✓ CYSTADROPS full Prescribing Information
 - ✓ CYSTADROPS clinical studies
 - ✓ Clinical documentation such as, but not limited to:
 - ✓ Genetic test confirming cystinosis
 - ✓ Treatment history, including therapeutics, dosage, and duration
 - ✓ Any relevant clinical/chart notes, including assessments of crystal density or accumulation based on slit-lamp photography or other imaging technology

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including Instructions for Use.

Indications and Usage

CYSTADROPS (cysteamine ophthalmic solution) 0.37% is a cystine-depleting agent indicated for the treatment of corneal cystine crystal deposits in adults and children with cystinosis.

Important Safety Information

- To minimize the risk of contamination, do not touch the dropper tip to any surface. Keep bottle tightly closed when not in use.
- Benign intracranial hypertension (or pseudotumor cerebri) associated with oral cysteamine or ophthalmic use of cysteamine (with concurrent oral cysteamine) has been reported, which has resolved with diuretic therapy.
- Contains benzalkonium chloride. Contact with soft contact lenses should be avoided. Remove contact lenses prior to application. Lenses may be reinserted 15 minutes following administration.
- The most common adverse reactions ($\geq 10\%$) are eye pain, vision blurred, eye irritation, ocular hyperaemia, instillation site discomfort, eye pruritus, lacrimation increased, and ocular deposits.
- **To report SUSPECTED ADVERSE REACTIONS, contact Recordati Rare Diseases Inc. at 1-888-575-8344, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Please see accompanying full Prescribing Information, including Instructions for Use.