Prior Authorization and Appeal Checklist

For Patients on a Takeda Therapy for Alpha-1 Antitrypsin Deficiency

To make the prior authorization (PA) and/or appeals process as smooth as possible, we have developed a checklist of documents to include.

Note that each insurer and/or patient may need different information for the prior authorization or appeals process. If making an appeal, review the denial and insurer guidelines to determine what documents should be included in your patient's appeal package. You may also use the below as a reference when creating your responses.

Statement of Medical Necessity (aka Letter of Medical Necessity or Appeal Letter)
Takeda has sample Statement of Medical Necessity Templates available for your reference.

Payer PA/Appeal forms, if available

Denial information, including the patient's denial letter (aka Explanation of Benefits [EOB] Letter)

Medical support, including clinical notes, medical history, or test results

Below is medical information commonly requested by PA Appeals departments. It may help to have this information readily available. Always consult the guidelines provided by the insurer for instructions on what information is necessary to fulfill the appeal request.

Medical History Over the Previous Year:

- AAT serum level, phenotype, and genotype (if available)
- Full Pulmonary Function Test (PFT)
- CXR and/or HRCT with report
- Past and current treatments
- Number of COPD exacerbations requiring hospitalizations and length of stay
- Number of emergency room visits or unscheduled visits to your office for increased symptoms of respiratory distress
- IgA level test results: AAT augmentation therapy is contraindicated in patients with immunoglobulin A (IgA) deficiency

CXR = chest X-ray

HRCT = high resolution computed tomography for lung parenchyma measurements

Clinical Guidance

Considerations for augmentation therapy:

- Never or ex-smokers with an FEV1 of 35%-60% predicted have been suggested as those most suitable for augmentation therapy (Evidence B*)
- The evidence for augmentation therapy efficacy varies according to the outcome studied. IV augmentation therapy has been recommended for individuals with AAT deficiency and FEV1 of ≤65% based on previous observational studies

Recommendation against augmentation therapy:

- Individuals without evidence of continued and rapid emphysema progression following smoking cessation

*Evidence Category B: Evidence is from randomized controlled trials (RCTs) with important limitations or there is a limited body of evidence.

Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2024 Report)

Patient re-authorization reminder

Remember, patients approved for treatment may have a limited approval period. Prior to the end date of approval period a new prior authorization will need to be submitted. This process could take 30 days or more and your patient may need to miss a treatment if the approval does not come through.

- When submitting re-authorizations, you may want to include updated and current documentation which may include PFTs with report, HRCT or CXR report, decrease in number of exacerbations and or hospitalizations (if applicable), ability and approval to return to work or resume other activities (volunteer, work, travel, other)

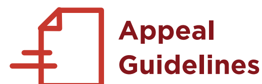
Here are a few helpful items to prepare a patient's appeals submission.

Denial Reason

There may be more than one reason for denying a claim (prior authorization denial, claim denial, etc). It is important to find out in writing why a claim was denied. Different reasons for the denial require different courses of action for resolution. The reason for denial should be on the letter of denial sent from the patient's health plan or on the EOB letter. If you did not receive either, one or both can be obtained from the insurer.

Phone Contact

Physicians may call the review department to discuss the claim. The phone number for the review department should be included on the denial letter. Be certain to have all the necessary paperwork to discuss the claim with the reviewer. If the reviewer sees the merits of your argument and then approves treatment for the patient during the call, it is strongly suggested that you request a written letter of appeal confirmation, in case there is any insurance disparity later.

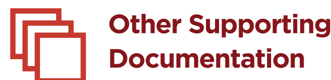


Appeal Guidelines

Contact the payer to determine the appeal guidelines and required paperwork. Some payers may have payer appeal forms that should be used first, if available. It is also important to learn the payer process for appeals. This information may include the appeal deadline; the number of appeals allowed; the mailing address or fax number for the appeal; and who submits the appeal, the patient or healthcare provider. The appeal time may vary as some insurers have short appeal periods while others may be longer. In addition, some plans only allow one appeal.

Written Appeal

Most insurers require a written appeal from the healthcare provider. The insurer is required to tell you what it needs and if any specific forms are required. A written appeals package includes an appeal letter and supporting documents.



Other Supporting Documentation

Your patient's appeal package should include any medical documentation supporting your case for coverage. This can include your healthcare provider notes and appropriate test results to support this choice of treatment.

Other Insurance Considerations

Is the treatment or service a covered benefit? Do state laws apply? Have your patient check the benefit plan or booklet to determine whether the requested treatment is excluded. If it is, be prepared to give written support why the plan should make an exception for your patient. You could also consult with your patient, and pursue an independent external review, depending on the state where your practice is located.

Certified Mail

It is strongly suggested that you send the appeals package via certified mail.

Follow-up

If the patient's insurer has not responded within 30 days of receipt of the appeals package, contact the insurer for the status.

Complete Records

Keep a copy of everything you send with the patient's appeal. Keep a log of phone calls you make to the patient's insurer. Write down the date and the name of the person with whom you spoke.

Questions? Contact us at 866-888-0660

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