

Preparing a Coverage Authorization Appeals Letter

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call Taltz Together™ at 1-844-TALTZ-NOW (1-844-825-8966).

If the Coverage Authorization Request Letter from **Drafting a Coverage Authorization Request Letter** is denied by the patient's health plan, the payer may require a Coverage Authorization Appeals Letter. Depending on the plan, there may be varying levels of appeals. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.

This resource, **Preparing a Coverage Authorization Appeals Letter**, provides information to healthcare providers (HCPs) when appealing a coverage authorization for a patient's plan. A checklist is included below that can be followed when creating a Coverage Authorization Appeals Letter. In addition, 2 sample letters are attached to this document and feature information that many plans require to process a coverage authorization appeal. Follow the patient's plan requirements when requesting **Taltz® (ixekizumab) injection (80 mg/mL)**, otherwise treatment may be delayed.

A Coverage Authorization Appeals Letter originates from the patient and the prescribing HCP.* It should be submitted with 2 additional items: the patient's medical records and a Letter of Medical Necessity (LMN).

COVERAGE AUTHORIZATION: APPEALS CONSIDERATIONS

- Include the patient's full name, plan identification number, and date of birth
- Add the prescribing HCP's National Provider Identifier (NPI) number and specialty
- Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with case identification number from the initial denial letter
- Provide a copy of the patient's records with the following details:
 - The patient's history, diagnosis and International Classification of Diseases (ICD) code(s), and present-day condition and symptoms
 - The patient's recent history of infection(s), along with any allergies and existing comorbidities
- Note the severity of the patient's condition using the plan's preferred severity scoring system. Common scoring systems are
 - The Psoriasis Area Severity Index (PASI)
 - The Physician Global Assessment (PGA)
- Supply a recent photo(s) of the impacted area(s)
- Document prior treatments and the duration of each
 - Describe the rationale for why each treatment was discontinued
- Explain why the plan's preferred formulary agents are not appropriate for the patient
 - List the dates of trial of the preferred agents
- Provide the clinical rationale for treatment; this information may be found in the Taltz prescribing information and/or clinical peer-reviewed literature
- Summarize your recommendation at the end of the letter
- Include an LMN

*For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApp/Griev/Downloads/Chapter18.zip>.

Please see **Important Safety Information** on page 4 and **Prescribing Information** and **Medication Guide**. Please see **Instructions for Use** included with the device.



Sample Coverage Authorization Appeals Letters

If the Coverage Authorization Request Letter is denied by the patient's health plan, it is necessary to proceed to **Preparing a Coverage Authorization Appeals Letter**. Some plans may require an LMN to accompany the appeals letter.



HCPs can follow this format for patients who are **NOT** currently receiving treatment with **Taltz® (ixekizumab) injection (80 mg/mL)**

[Date]

[Payer department]

[Name of health plan]

[Mailing address]

Re: [Patient's name]

[Plan identification number]

[Date of birth]

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Taltz® (ixekizumab) coverage. We understand that the reason for your denial is **[copy reason verbatim from the plan's denial letter]**. However, we believe that Taltz **[dose, frequency]** is the appropriate treatment for the patient. In support of our recommendation for Taltz treatment, we have provided an overview of the patient's relevant clinical history below.

Patient's history, diagnosis, condition, and symptoms*:

- ___ % of BSA impacted
- ___ % of BSA involving only sensitive areas
- ___ Severity score index PASI Other (please list) _____
- ___ Indicate here, by adding a check mark, that the patient does not have active tuberculosis or other serious infections (required by some health plans). If the patient has any serious infections, please list them below.

Infection name and affected part(s) of body	Treatment type(s)	Treatment start/stop dates	Anticipated resolution date
---	-------------------	----------------------------	-----------------------------

Past Treatment(s)*	Start/Stop Dates	Reason(s) for Discontinuing

[Provide clinical rationale for this treatment; this information may be found in the Taltz prescribing information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Taltz.]

Please feel free to contact me, **[HCP name]**, at **[office phone number]** or **[patient's name]** at **[phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

[Patient's name and signature]

Encl: Medical records and clinical notes, clinical trial information, photo(s), Letter of Medical Necessity, original denial letter

Sample wording from page 4 of this document can be placed after this sentence if this appeal has been previously denied by the plan.

Please detail all that apply and add additional lines as necessary.

BSA, body surface area; PASI, Psoriasis Area Severity Index

*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.

†Identify drug name, strength, dosage form, and therapeutic outcome.



Sample Coverage Authorization Appeals Letters

If the Coverage Authorization Request Letter is denied by the patient's health plan, it is necessary to proceed to **Preparing a Coverage Authorization Appeals Letter**. Some plans may require an LMN to accompany the appeals letter.



HCPs can follow this format for patients who **HAVE** been treated with **Taltz® (ixekizumab) injection (80 mg/mL)** and have had treatment interruptions

[Date]

[Payer department]

[Name of health plan]

[Mailing address]

Re: [Patient's name]

[Plan identification number]

[Date of birth]

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications in this class. We are requesting that you reassess your recent denial of Taltz® (ixekizumab) coverage. We understand that the reason for your denial is **[copy reason verbatim from the plan's denial letter]**. However, we believe that Taltz **[dose, frequency]** is the appropriate treatment for the patient. In support of our recommendation for Taltz treatment, we have provided an overview of the patient's relevant clinical history below.

[In this section, describe the severity of plaque psoriasis symptoms at the time when the patient was first prescribed Taltz. In addition, include a summary of the patient's clinical response to Taltz and list improvements in symptoms and severity scoring since treatment began. It may be necessary to review past medical records to gather this information.]

Patient's history, diagnosis, condition, and symptoms*:

- ___ % of BSA impacted
- ___ % of BSA involving only sensitive areas
- ___ Severity score index PASI Other (please list) _____
- ___ Indicate here, by adding a check mark, that the patient does not have active tuberculosis or other serious infections (required by some health plans). If the patient has any serious infections, please list them below.

Infection name and affected part(s) of body	Treatment type(s)	Treatment start/stop dates	Anticipated resolution date
---	-------------------	----------------------------	-----------------------------

Past Treatment(s) [†]	Start/Stop Dates	Reason(s) for Discontinuing
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

[Provide clinical rationale for this treatment; this information may be found in the Taltz prescribing information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Taltz.]

Please feel free to contact me, **[HCP name]**, at **[office phone number]** or **[patient's name]** at **[phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

[Patient's name and signature]

Encl: Medical records and clinical notes, clinical trial information, photo(s), Letter of Medical Necessity, original denial letter

Sample wording from page 4 of this document can be placed after this sentence if this appeal has been previously denied by the plan.

Please detail all that apply and add additional lines as necessary.

BSA, body surface area; PASI, Psoriasis Area Severity Index

*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.

[†]Identify drug name, strength, dosage form, and therapeutic outcome.

Step Edit Therapy Information

If this Coverage Authorization Appeals Letter is intended to appeal a plan's step edit therapy requirement, sample copy should include the following:

This is our **[Add level of request]** coverage authorization appeal. A copy of the most recent denial letter is attached for reference. The patient's medical records are also included in response to the denial.

[Please provide statement(s) indicating why these step edit therapy requirements are inappropriate for this patient. Include examples of previous trials and failures with other therapies due to lack of response or intolerance to the drug.*]

Indication and Usage for Taltz® (ixekizumab) injection (80 mg/mL)

Taltz is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Important Safety Information

CONTRAINDICATIONS

Taltz is contraindicated in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections

Taltz may increase the risk of infection. The Taltz group had a higher rate of infections than the placebo group (27% vs 23%). Serious infections have occurred. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Taltz until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Taltz. Do not administer to patients with active TB infection. Initiate treatment of latent TB prior to administering Taltz. Patients receiving Taltz should be monitored closely for signs and symptoms of active TB during and after treatment.

Hypersensitivity

Serious hypersensitivity reactions, including anaphylaxis, angioedema and urticaria, have been reported with Taltz. If a serious hypersensitivity reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

Inflammatory Bowel Disease

Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease.

Immunizations

Prior to initiating therapy with Taltz, consider completion of all age-appropriate immunizations according to current immunization guidelines. Live vaccines should not be given with Taltz.

ADVERSE REACTIONS

Most common adverse reactions (≥1%) associated with Taltz treatment are injection site reactions, upper respiratory tract infections, nausea, and tinea infections.

Please see [Prescribing Information](#) and [Medication Guide](#). Please see Instructions for Use included with the device.

IX HCP ISI 18JAN2017

*An external review board or hearing may apply in some situations.

Sources: 1. Centers for Medicare & Medicaid Services. Part D enrollee grievances, coverage determinations, and appeals. In: *Prescription Drug Benefit Manual*. Baltimore, MD: Centers for Medicare & Medicaid Services; 2014. <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip>. Accessed January 26, 2017. 2. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; 2017.

Taltz® is a registered trademark of Eli Lilly and Company.
Taltz Together™ is a trademark of Eli Lilly and Company.

PP-IX-US-1254 02/2017 ©Lilly USA, LLC 2017. All rights reserved.