taltz® together™
(ixekizumab) injection

Preparing an Appeal 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 an Appeal Letter. Depending on the plan, there may be varying levels of appeal. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.

This resource, **Preparing an Appeal 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 an Appeal Letter. In addition, a sample letter is attached to this document and features 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.

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

COVERAGE AUTHORIZATION: APPEAL 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 the 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
- ☐ Indicate the severity of the patient's condition, if applicable
- ☐ Supply a recent photo(s) of the impacted area(s), if applicable
- ☐ 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/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip.

Lilly

Sample Appeal Letter

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

taltz® together™ (ixekizumab) injection

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

[Date]
[Prior authorization 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.

Sample wording from page 3 of this document can be placed after this sentence if this appeal has been previously denied by the plan.

FOR PATIENTS DIAGNOSED WITH MODERATE TO SEVERE PLAQUE PSORIASIS

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

____ % of BSA impacted

____ % of BSA involving only sensitive areas ____ List sensitive areas involved _____

____ Other (please list) _____

Please detail all past treatments, including phototherapy, topical therapy, and/or DMARDs (eg, MTX).

Past treatment(s)†	Start/stop dates	Reason(s) for discontinuing

FOR PATIENTS DIAGNOSED WITH ACTIVE PSORIATIC ARTHRITIS

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

____ Check here to affirm that patient has been diagnosed with active psoriatic arthritis.

Please detail all past treatments, including any DMARDs (eg, MTX).

Past treatment(s)†	Start/stop dates	Reason(s) for discontinuing

Provide the information that is applicable to the primary diagnosis.

____ 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

____ Check here to affirm that patient will not be taking Taltz in combination with another biologic therapy.

*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.
BSA, body surface area; DMARD, disease-modifying antirheumatic drug; MTX, methotrexate

Sample Appeal Letter

taltz (ixekizumab) injection together™

[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

INFORMATION FOR PATIENTS WHO HAVE BEEN TREATED WITH TALTZ

HCPs can utilize the following language for patients who **HAVE** been treated with Taltz and have had treatment interruptions.

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.

[In this section, describe the severity of moderate to severe plaque psoriasis or psoriatic arthritis 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.]

Sample wording from the following section can be placed after this sentence if this appeal has been previously denied by the plan.

STEP THERAPY INFORMATION

If this Appeal Letter is intended to appeal a plan's step 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 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.*]

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

Indications and Usage for Taltz® (ixekizumab) injection (80 mg/mL)
Taltz is indicated for adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy and for adults with active psoriatic arthritis.

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. In clinical trials of patients with plaque psoriasis, the Taltz group had a higher rate of infections than the placebo group (27% vs 23%). A similar increase in risk of infection was seen in placebo-controlled trials of patients with psoriatic arthritis. 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. Closely monitor patients receiving Taltz for signs and symptoms of active TB during and after treatment.

Hypersensitivity
Serious hypersensitivity reactions, including angioedema and urticaria (each ≤0.1%), occurred in the Taltz group in clinical trials. Anaphylaxis, including cases leading to hospitalization, has been reported in post-marketing use with Taltz. If a serious hypersensitivity reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

Inflammatory Bowel Disease
During Taltz treatment, monitor patients for onset or exacerbations of 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 in patients with plaque psoriasis.

Immunizations
Prior to initiating therapy with Taltz, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated 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. Overall, the safety profile observed in patients with psoriatic arthritis was consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis.

Please click to access the Prescribing Information and Medication Guide.
Please see Instructions for Use included with the device.

IX HCP ISI 01DEC2017

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 October 31, 2017. **2.** Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; 2017.