taltz together™
(ixekizumab)
injection
80 mg/mL

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.

This resource, **Preparing an Appeal Letter**, provides information to healthcare providers (HCPs) when appealing a coverage denial 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 that features information many plans require to process a coverage authorization appeal. Follow the patient's plan requirements when requesting **Taltz® (ixekizumab) injection (80 mg/mL)**[1]; 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

- Provide a copy of the patient's record with details on the patient's condition (diagnosis/diagnoses), International Classification of Diseases (ICD) code, and severity of disease for which Taltz is being/will be used
- Provide information about the current treatment(s) being used for the patient's condition
- Document the previous therapies used, dates used, and reasons for discontinuation
  - Highlight trials of the plan's preferred formulary agents
  - List dates/duration of trials
  - Describe the rationale for why each treatment was discontinued
- Document active tuberculosis test results within the past 12 months
- Provide clinically relevant and patient-specific information that makes Taltz a preferred therapy for this patient
- If the plan's preferred formulary agents were not used to treat this patient, provide the clinical rationale for why these agents were not appropriate for the patient
- Include an LMN

*For Medicare beneficiaries, specific requirements 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.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf.

Lilly

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Sample Appeal Letter

HCPs can follow this format for patients who are **NOT** currently receiving treatment with Taltz.

[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 this 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 a previous appeal has been denied by the plan.

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

Please detail all past treatments.

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

Provide the information that is applicable to the primary diagnosis (ie, moderate to severe plaque psoriasis, active psoriatic arthritis, active ankylosing spondylitis, active non-radiographic axial spondyloarthritis).

[Please provide information that indicates the patient does not have active tuberculosis or other serious infections (required by some health plans). If the patient does have serious infections, please include that information as follows:

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

[Please affirm that the patient will not be taking Taltz in combination with another biologic therapy.]

[Please provide the clinical rationale for why your patient would benefit from using this agent prior to the payer-preferred agent when managing his/her condition.]

[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 contact information]

[Patient's name and signature]

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

Double-click the paper clip to open a Microsoft Word document, which you can download for use on your office letterhead.

*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas as applicable.
†Identify drug name, strength, dosage form, and therapeutic outcome.

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Sample Appeal Letter

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 this 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 the diagnosis 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.

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Indications

Taltz is indicated for adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. Taltz is indicated for adult patients with active psoriatic arthritis (PsA). Taltz is indicated for adult patients with active ankylosing spondylitis (AS). Taltz is also indicated for adult patients and pediatric patients as young as age 6 with moderate to severe plaque psoriasis (PsO) 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. In clinical trials of adult 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 adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis. 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

Patients treated with Taltz may be at an increased risk of inflammatory bowel disease. In clinical trials, Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group than the placebo group. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease and if IBD occurs, discontinue Taltz and initiate appropriate medical management.

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 profiles observed in adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis were consistent with the safety profile in adult patients with plaque psoriasis, with the exception of influenza and conjunctivitis in psoriatic arthritis and conjunctivitis, influenza, and urticaria in pediatric psoriasis.

Please see full Prescribing Information and Medication Guide for Taltz.
See Instructions for Use included with the device.

IX HCP ISI 07MAY2020

Reference: 1. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; 2020.