taltz® together™ (ixekizumab) injection

Drafting a Coverage Authorization Request 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).

Most health plans require a coverage authorization request and supporting documentation to process and cover a claim for biologic treatments. A request allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

This resource, **Drafting a Coverage Authorization Request Letter**, provides information to healthcare providers (HCPs) when drafting such a letter. A list of sample payer requirements and a checklist are included below and outline what to include in the letter. A sample letter is attached to this document and includes information that many health plans require to process the coverage authorization request.

Plans often have specific Coverage Authorization Request Forms that must be used for requests. These forms may be downloaded from each plan's website. Follow the plan's requirements when requesting **Taltz® (ixekizumab) injection (80 mg/mL)**; otherwise, treatment may be delayed.

COVERAGE AUTHORIZATION REQUESTS: GUIDANCE AND RECOMMENDATIONS

1. Your Taltz Field Reimbursement Manager (FRM) may be able to provide you with coverage authorization requirements for specific plans and pharmacy benefit managers. Benefit verifications performed by the Taltz Together Hub and/or specialty pharmacies can assist with identifying coverage criteria, including any step therapies and plan-specific form requirements
2. All Taltz Coverage Authorization Request Forms should be completed and submitted to the plan by the HCP's office
3. Fax the completed Coverage Authorization Request Form to the health plan
4. Fax the Taltz Together Enrollment Form to Taltz Together at 1-844-344-8108
5. If the HCP expects that a plan-specified step therapy will not be well tolerated by the patient, an appeal may be submitted to the plan to bypass this requirement. For more information, refer to **Composing a Letter of Medical Necessity**
6. Plans will usually allow up to 3 levels of appeal for coverage authorization denials. The third appeal may include a review by an external review board or hearing. Refer to **Preparing an Appeal Letter**

COVERAGE AUTHORIZATION CONSIDERATIONS

- Verify and record that all of the coverage authorization requirements for the plan have been met
- If applicable, provide evidence that all step therapy prerequisites have been met. For step therapy exception requests, when medically appropriate, include wording explaining why a particular therapy as required by the plan is not medically appropriate for the patient
- Review the attached sample letter as an example
- If required, use the health plan's Coverage Authorization Request Form that can be found on the plan's website. Your Taltz FRM may also be able to assist you in locating the plan-specific form

Sample Coverage Authorization Request Letter

Most health plans require a coverage authorization request and supporting documentation to cover a claim for **Taltz® (ixekizumab) injection (80 mg/mL)**. This resource, **Drafting a Coverage Authorization Request Letter,** provides guidance to HCPs when drafting the necessary 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:

This letter serves as a coverage authorization request for Taltz (ixekizumab) for **[patient's name, plan identification number, and group number]** for the treatment of **[diagnosis and ICD code].**

If this Coverage Authorization Request Letter is intended to appeal a plan's step requirement, please add text from page 3 in this section.

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; ICD, International Classification of Diseases; MTX, methotrexate

Sample Coverage Authorization Request Letter

taltz (ixekizumab) injection together™

[Insert rationale for prescribing Taltz here, including your professional opinion of the patient's likely prognosis or disease progression without Taltz treatment.]

Provide supporting references for your recommendation:

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

Physician contact information:

The ordering physician is **[physician name, NPI #]**. The coverage authorization decision may be faxed to **[fax #]** or mailed to **[physician office mailing address]**. Please send a copy of the coverage determination decision to **[patient's name, street address, state, ZIP]**.

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, supporting documentation, photo(s), clinical trial information

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:

This letter serves as a coverage authorization request for Taltz (ixekizumab) for **[patient's name, plan identification number, and group number]** for the treatment of **[diagnosis and ICD code]**. This authorization is being requested for **[insert date]** to **[insert future date]**.

[In this section, describe the severity of moderate to severe plaque psoriasis or active psoriatic arthritis symptoms at the time when the patient was first treated with Taltz. It may be necessary to review past medical records.]

If this Coverage Authorization Request Letter is intended to appeal a plan's step requirement, please add text from the following section here.

STEP THERAPY INFORMATION

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

This plan currently lists **[insert required therapies]** to be attempted prior to treatment with Taltz. These therapies are not viable for this patient. We are requesting that the step therapy requirement be bypassed.

[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.]

NPI, National Provider Identifier

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.

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Source: Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; 2017.