taltz® together™ (ixekizumab) injection

# Composing a Letter of Medical Necessity

**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).**

Many health plans require that a Letter of Medical Necessity (LMN) accompanies an Appeal Letter. The purpose of an LMN is to explain the prescribing healthcare provider's (HCP) rationale and clinical decision-making when choosing a treatment.* LMNs are often required by plans when submitting an Appeal Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter.

This resource, **Composing a Letter of Medical Necessity**, provides information on the process of drafting an LMN. A checklist is included below that can be followed when creating an LMN. In addition, a sample letter is attached to this document and includes information that plans often require. Note that some plans have specific Coverage Authorization Forms that must be utilized to document an LMN.

Follow the patient's plan requirements when requesting **Taltz® (ixekizumab) injection (80 mg/mL)**; otherwise, treatment may be delayed.

## LMN CONSIDERATIONS

- ☐ Include the patient's full name, plan identification number, date of birth, and the case identification number if a decision has already been rendered
- ☐ Provide a copy of the patient's records with the following details:
  - The patient's history, diagnosis with specific International Classification of Diseases (ICD) code, 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
- ☐ Include a recent photo(s) of the impacted area(s), if applicable
- ☐ Document prior treatments and the duration of each. It may be beneficial to include Current Procedural Terminology, 4th Edition (CPT-4) and/or J-codes to define prior services/treatments, so that the health plan can conduct research and make a timely determination request
  - Describe the rationale for why each treatment was discontinued
- ☐ Attach clinical documentation that supports your recommendation; this information may be found in the Taltz Prescribing Information and/or clinical peer-reviewed literature

*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.



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# Sample Letter of Medical Necessity

The purpose of an LMN is to explain the prescribing HCP's rationale and clinical decision-making when choosing **Taltz® (ixekizumab) injection (80 mg/mL)** for a patient. LMNs are often required by plans when submitting an Appeal Letter, Formulary Exception Request Letter, and Tiering Exception Request 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]**
**[Case identification]**

To whom it may concern:

I am writing to provide additional information to support my claim for **[patient's name]**'s treatment of **[moderate to severe plaque psoriasis OR active psoriatic arthritis]** with Taltz (ixekizumab). In brief, treatment with Taltz **[dose, frequency]** is medically appropriate and necessary for this patient. This letter includes the patient's medical history, previous treatments, disease severity, and a recent photo(s) of the impacted area(s) **[if applicable]** that support my recommendation for treatment with Taltz.

## 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

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

**[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]** 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 #]**

Encl: Medical records, clinical trial information, photo(s)

## 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:

I am writing to provide additional information to support my claim for **[patient's name]**'s treatment of **[moderate to severe plaque psoriasis OR active psoriatic arthritis]** with Taltz (ixekizumab). In brief, continued treatment with Taltz **[dose, frequency]** is medically appropriate and necessary for this patient. This letter includes the patient's medical history, previous treatments, disease severity, and a recent photo(s) of the impacted area(s) **[if applicable]** that support my recommendation for treatment with Taltz.

**[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.]**

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