Letter of Medical Necessity Guide

taltz® (ixekizumab) injection 80 mg/mL

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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 Lilly Support Services™ for Taltz® at 1-800-LillyRx (1-800-545-5979).

Composing a Letter of Medical Necessity

The purpose of a **Letter of Medical Necessity (LMN)** is to explain the prescribing healthcare provider's (HCP's) rationale and clinical decision-making for choosing a treatment.* Many health plans require that a LMN accompany submissions of **Appeal, Formulary Exception Request, and Tiering Exception Request Letters.**

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)**[1]; 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
  - **Describe the rationale for why each treatment was discontinued**
- Attach clinical documentation that supports your recommendation

Lilly Support Services for Taltz will work with you to help navigate patient access

For more information, please visit www.taltz.lilly.com/hcp/savings-support or call Lilly Support Services for Taltz at **1-800-LillyRx (1-800-545-5979)**.

* 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 click here.

INDICATIONS

Taltz is indicated for adults with active psoriatic arthritis (PsA), for adults with active ankylosing spondylitis (AS), and for adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. Taltz is also indicated for patients aged 6 years or older with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

SELECT 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.

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

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Sample Letter of Medical Necessity

taltz® (ixekizumab) injection 80 mg/mL

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Click here for an editable PDF

<Date>
<Prior authorization department>
<Name of health plan>
<Mailing address>

Re: **<Patient's name>**
<Plan identification number>
<Date of birth>

Include the patient's full name, plan ID number, and date of birth.

To whom it may concern:

I am writing to provide additional information to support my claim for **<patient's name>**'s treatment of **<diagnosis and ICD code>** 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.

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

Please detail all past treatments.

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

<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.>

<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. I look forward to receiving your timely response and approval of this claim.

Sincerely,

_____

<Physician's name and signature>
<Physician's contact information>

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

*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 Letter of Medical Necessity

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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 **<diagnosis and ICD code>** 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 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.>

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Indications and Important Safety Information

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INDICATIONS

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CONTRAINDICATIONS

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WARNINGS AND PRECAUTIONS

Infections

Taltz may increase the risk of infection. Serious infections have occurred. 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. In the post-marketing setting, serious bacterial, viral, and fungal opportunistic infections have been reported in patients receiving IL-17 inhibitors, including Taltz. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a serious infection or is not responding to standard therapy, monitor the patient closely and 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. Consider anti-TB therapy prior to initiating Taltz in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving Taltz should be monitored closely 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.

Eczematous Eruptions

In the postmarketing setting, cases of severe eczematous eruptions, including atopic dermatitis-like eruptions, dyshidrotic eczema, and erythroderma were reported in patients receiving Taltz; some cases resulted in hospitalization. The onset of eczematous eruptions was variable, ranging from days to months after the first dose of Taltz. Treatment may need to be discontinued to resolve the eczematous eruption. Some patients with limited psoriasis treatment options were successfully treated for eczema while continuing Taltz.

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

Taltz is available as an 80 mg/mL, 40 mg/0.5mL, 20 mg/0.25mL injection.

IX HCP ISI 20AUG2024

Reference: 1. Taltz. Prescribing Information. Lilly USA, LLC.

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