

Coverage Authorization Guide for Healthcare Providers

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).

This educational resource will walk you through the coverage authorization and appeals processes when requesting approval for **Taltz[®] (ixekizumab) injection (80 mg/mL)** for the treatment of moderate to severe plaque psoriasis or active psoriatic arthritis. This guide serves as a general road map for you to follow; sample letters and checklists contain information that health plans may require when requesting authorizations for Taltz. Use this information to assist you when completing and submitting your patients' coverage authorization requests. See below for the detailed information required for each step.

Most of your patients' health plans will have specific coverage authorization forms that must be used when requesting Taltz; these forms can be found on each plan's website. Follow the plan's requirements when requesting Taltz; otherwise, treatment may be delayed.

Drafting a Coverage Authorization Request Letter

- Most health plans require a coverage authorization request and supporting documentation to cover a claim for Taltz. This resource, *Drafting a Coverage Authorization Request Letter*, provides guidance to healthcare providers (HCPs) when drafting the necessary letter
- For Medicare coverage authorization guidance or to download coverage authorization request forms, visit www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/coveragedeterminationsandexceptions.html

Preparing an 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 a Letter of Medical Necessity (LMN) to accompany the appeal letter

Composing a Letter of Medical Necessity

- The purpose of an LMN is to explain the prescribing HCP's rationale and clinical decision-making when choosing Taltz for a patient. LMNs are often required by plans when submitting an Appeal Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter

Drafting a Formulary Exception Request Letter

- A Formulary Exception Request Letter is used when Taltz is not included on a health plan's formulary or is subject to a National Drug Code block. This step may require the HCP to submit an LMN with the Formulary Exception Request Letter

Writing a Tiering Exception Request Letter

- A Tiering Exception Request Letter is used when Taltz is on a health plan's formulary but is placed in a non-preferred tier that has a higher co-pay or co-insurance. This step may require the HCP to submit an LMN with the Tiering Exception Request Letter

These sample letters are available on the HCP website or via email from your Field Reimbursement Manager. For further questions, contact your Taltz Field Reimbursement Manager.

Please see Important Safety Information on page 2 and click to access the [Prescribing Information](#) and [Medication Guide](#). Please see Instructions for Use included with the device.

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 $\leq 0.1\%$), 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 ($\geq 1\%$) 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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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.

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