

Coverage Authorization Guide for Healthcare Providers

This resource will walk you through the coverage authorization and appeals processes when requesting approval for **Taltz® (ixekizumab) injection (80 mg/mL)**. This guide serves as a general roadmap for you to follow; sample letters and checklists contain information that health plans may require when requesting authorizations for biologic treatments. Use this information to assist you when completing and submitting your patients' coverage authorization requests. See below for the detailed information required at 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/coverage-determinations-and-exceptions.html

Preparing a Coverage Authorization Appeals Letter

- If the Coverage Authorization Request Letter is denied by the patient's health plan, it is necessary to proceed to Preparing a Coverage Authorization Appeals Letter. Some plans may require a Letter of Medical Necessity (LMN) to accompany the appeals 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 a Coverage Authorization Appeals 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

For further questions, contact your Taltz Field Reimbursement Manager.

Please see Important Safety Information on next page. Please see [Prescribing Information](#) and [Medication Guide](#). Please see Instructions for Use ([Autoinjector](#) and [Prefilled Syringe](#)) included with the device.

Indication and Usage for Taltz® (ixekizumab) injection (80 mg/mL)

Taltz is indicated for the treatment of adults with moderate to severe plaque psoriasis 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. The Taltz group had a higher rate of infections than the placebo group (27% vs 23%). 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. Patients receiving Taltz should be monitored closely for signs and symptoms of active TB during and after treatment.

Hypersensitivity

Serious hypersensitivity reactions, including anaphylaxis, angioedema and urticaria, have been reported with Taltz. If a serious hypersensitivity reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

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. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease.

Immunizations

Prior to initiating therapy with Taltz, consider completion of all age-appropriate immunizations according to current immunization guidelines. Live vaccines should not be given 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.

Please see Prescribing Information and Medication Guide. Please see Instructions for Use (Autoinjector and Prefilled Syringe) included with the device.

IX HCP ISI 18JAN2017

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 January 26, 2017. **2.** Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; 2017.

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