

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.

This resource, **Drafting a Coverage Authorization Request Letter**, is intended to assist you in gathering and submitting supporting documentation that health plans may require in order to process coverage authorization requests. Please visit the [Taltz HCP website](#) to access the sample templates highlighted in this resource, as well as a **Coverage Authorization Appeals Letter** and **Letter of Medical Necessity**.

It is best practice for providers to use a plan's coverage authorization forms and follow its submission process when requesting coverage for **Taltz® (ixekizumab) injection (80 mg/mL)**¹; otherwise, treatment may be delayed for your patient.*

COMMON CLINICAL EVIDENCE REQUIRED FOR COVERAGE AUTHORIZATION REQUESTS AND LETTERS OF MEDICAL NECESSITY FOR TALTZ INCLUDE

- Patient's condition (diagnosis) and ICD code for which Taltz is/will be used
- Information about the current treatment being used for the patient's condition
- Previous therapies used, dates used, and reasons for discontinuation
- Active tuberculosis test results within the last 12 months
- Clinically relevant and patient-specific information that makes Taltz a preferred therapy for the patient

IF YOU NEED ADDITIONAL ASSISTANCE, YOUR TALTZ FIELD REIMBURSEMENT MANAGER (FRM) MAY BE ABLE TO PROVIDE YOU WITH

1. Coverage authorization requirements for your patient's plan
2. Online access to plan-specific forms, if available

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. Please fax the completed Taltz Together Enrollment Form (available at the [Taltz HCP website](#)) to Taltz Together at 1-844-344-8108.

If the patient's plan does not have specific forms available for requesting Taltz, please utilize the sample templates available on the [Taltz HCP website](#) and detailed in this resource.

*Please note that the Centers for Medicare & Medicaid Services has developed "Request for Medicare Prescription Drug Coverage Determination" model forms that are posted on its website. For more information, visit <https://www.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf>

Sample Coverage Authorization Request Letter

 [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>

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>.

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.>

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

<Please provide the clinical rationale for why your patient would benefit from using this agent prior to the payer-preferred agent when managing his/her condition.>

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, city, state, ZIP>.

Sincerely,

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

 <Patient's name and signature>

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

If this Coverage Authorization Request Letter is intended to request an exception to a plan's step therapy requirement, please add **STEP THERAPY INFORMATION** copy from page 3 in this section.

Provide the information that is applicable to the primary diagnosis (moderate to severe plaque psoriasis, active psoriatic arthritis, active ankylosing spondylitis, active non-radiographic axial spondyloarthritis).


*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.

ICD, International Classification of Diseases.

Sample Coverage Authorization Request Letter

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 or active ankylosing spondylitis or active non-radiographic axial spondyloarthritis 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 request an exception to a plan's step therapy requirement, please add text from the following section here.

STEP THERAPY INFORMATION

If this Coverage Authorization Request Letter is intended to request an exception to 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 the step therapy requirements are inappropriate for the patient. Include examples of previous trials and failures with other therapies due to lack of response or intolerance to the drug.>

A Letter of Medical Necessity and my patient's medical records are enclosed, which offer additional support for the plan-preferred (formulary) requirement exception request for Taltz.

For a step therapy through plan-preferred (formulary) requirement exception request, include the following

- A Letter of Medical Necessity
- Medical records, supporting documentation, photo(s), and clinical trial information

TIERING EXCEPTION INFORMATION

If this Coverage Authorization Request Letter is intended to request a tiering exception, sample copy should include the following:

The reason I am requesting a tiering exception is because the cost associated with the assigned tier for Taltz would present a financial burden to **<patient's name>**. Furthermore, it would prevent my patient from utilizing a medication that will help treat their **<patient primary indication>**.

<Explain why lower-tiered formulary drugs would not be as medically appropriate as Taltz. If the patient is currently being treated with Taltz, explain the benefits that the patient has experienced since starting Taltz and the expected outcomes if Taltz was to be discontinued.>

For a tiering exception request, include the following

- A Letter of Medical Necessity
- Medical records, statement of financial hardship from the patient, previous denial letter (if this is an appeal), medical notes in response to the denial (if this is an appeal)

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.

Indications

Taltz is indicated for adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. Taltz is indicated for adult patients with active psoriatic arthritis (PsA). Taltz is indicated for adult patients with active ankylosing spondylitis (AS). Taltz is also indicated for adult patients and pediatric patients as young as age 6 with moderate to severe plaque psoriasis (PsO) 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. 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. 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

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 ($\geq 1\%$) 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 see full [Prescribing Information](#) and [Medication Guide](#) for Taltz.

See [Instructions for Use](#) included with the device.

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

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