

Step 1 | 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. A coverage authorization allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

This resource, **Step 1 Sample Process For: Drafting a Coverage Authorization Request Letter**, provides information to healthcare providers (HCPs) when drafting a Coverage Authorization Request Letter. A list of sample payer requirements and a checklist are included below and outline what to include in a Coverage Authorization Request Letter. Sample letters are attached to this document and include information that many health plans require to process the coverage authorization request.

Plans often have specific Coverage Authorization Request Forms that must be used for requests. These forms may be downloaded from each plan's website. Follow the plan's requirements when requesting Taltz® (ixekizumab) injection (80 mg/mL). Otherwise treatment may be delayed.

COVERAGE AUTHORIZATION REQUESTS: GUIDANCE AND RECOMMENDATIONS

1. All Taltz Coverage Authorization Request Forms should be completed and submitted to the plan by the HCP's office
2. Your Taltz Patient Reimbursement Specialist (PRS) may be able to provide you with coverage authorization requirements for specific plans and pharmacy benefit managers (PBMs). Benefit verifications performed by the Taltz Together Hub and/or specialty pharmacies can assist with identifying coverage authorizations, form requirements, and step edit therapies
3. FAX the completed Coverage Authorization Request Form to the health plan
4. FAX the Service Request Form (SRF) to Taltz Together at 1-844-344-8108
5. If the HCP expects that a plan-specified step edit therapy will not be well tolerated by the patient, an appeal may be submitted to the plan to bypass this requirement. For more information, refer to **Step 3: Composing a Letter of Medical Necessity (LMN)**
6. Plans will usually allow up to 3 levels of appeal for coverage authorization denials. The third appeal may include a review by an external review board or hearing. Refer to **Step 2: Preparing a Coverage Authorization Appeals Letter**

COVERAGE AUTHORIZATION CONSIDERATIONS

- Verify and record that all of the coverage authorization requirements for the plan have been met
- If applicable, provide evidence that all step edit therapy prerequisites have been met. For step edit therapy exception requests, when medically appropriate, include wording explaining why a particular step edit therapy as required by the plan is not medically appropriate for the patient
- Review the attached sample letters as examples
- If required, use the health plan's Coverage Authorization Request Form that can be found on the plan's website. Your Taltz PRS may also be able to assist you in locating the plan-specific form

Sample Coverage Authorization Request Letters



HCPs can follow this format for patients who are **NOT** currently receiving treatment with Taltz® (ixekizumab) injection (80 mg/mL)

[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, and group number] for the treatment of [diagnosis and ICD code].

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

- ___ % of body surface area (BSA) impacted
- ___ % of BSA involving only sensitive areas
- ___ Severity score index PASI[†] Other (please list) _____
- ___ Indicate here, by adding a checkmark, 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
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Past Treatments [‡]	Start/Stop Dates	Reason(s) for Discontinuing
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

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

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, state, ZIP].

Sincerely,

[Physician's name and signature]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

[Patient's name and signature]

- Encl: Medical records
Supporting documentation
Photo(s)
Clinical trial data

If this Coverage Authorization Request Letter is intended to appeal a plan's step edit requirement, please add text from page 4 in this section.

Please detail all that apply and add additional lines as necessary.

*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.

[†]PASI, Psoriasis Area Severity Index.

[‡]Identify drug name, strength, dosage form, and therapeutic outcome.



Sample Coverage Authorization Request Letters



HCPs can follow this format for patients who **HAVE** been treated with Taltz® (ixekizumab) injection (80 mg/mL), and have had treatment interruptions

[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, 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 plaque psoriasis symptoms at the time when the patient was first treated with Taltz. It may be necessary to review past medical records.]

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

- _____ % of body surface area (BSA) impacted
- _____ % of BSA involving only sensitive areas
- _____ Severity score index PASI[†] Other (please list) _____
- _____ Indicate here, by adding a checkmark, 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
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Past Treatments [‡]	Start/Stop Dates	Reason(s) for Discontinuing

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

Provide supporting references for your recommendation:

[In this section, provide clinical evidence that supports continued treatment with Taltz. Supplying clinical trial data from the Taltz prescribing information is helpful.]

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, state, ZIP].

Sincerely,

[Physician's name and signature]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

[Patient's name and signature]

Encl: Medical records
Supporting documentation
Photo(s)
Clinical trial data

If this Coverage Authorization Request Letter is intended to appeal a plan's step edit requirement, please add text from page 4 in this section.

Please detail all that apply and add additional lines as necessary.

*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.

[†]PASI, Psoriasis Area Severity Index.

[‡]Identify drug name, strength, dosage form, and therapeutic outcome.

Step Edit Therapy Information

If this Coverage Authorization Request Letter is intended to appeal a plan's step edit therapy requirement, sample copy to include

This plan currently lists **[insert required step edit therapies]** to be attempted prior to treatment with Taltz® (ixekizumab). These step edit therapies are not viable for this patient. We are requesting that the step edit therapy requirement be bypassed.

[Please provide statement(s) indicating why these step edit therapy requirements are inappropriate for this patient. Include examples of previous trials and failures with other therapies, due to lack of response or intolerance to the drug.]

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.

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 angioedema and urticaria (each $\leq 0.1\%$), occurred in the Taltz group in clinical trials. 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 full Prescribing Information and Medication Guide. Please see Instructions for Use included with the device.

IX HCP ISI 22MAR2016

Source: Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company.

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Taltz Together™ is a trademark of Eli Lilly and Company.

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