

Writing a Tiering Exception 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).

A tiering exception is a type of coverage determination. This type of exception is used when a medication is on a plan's formulary, but it is placed in a non-preferred tier that has a higher co-pay or co-insurance. Plans may make a tier exception when the drug is demonstrated to be medically necessary. The healthcare provider (HCP) submits a Tiering Exception Request Letter to request that the medication be offered at a lower co-pay that is usually reserved for preferred drugs. A Tiering Exception Request Letter can help make medication more affordable for patients covered through Medicare or TRICARE who may not be eligible to participate in savings programs.

This resource, [Writing a Tiering Exception Request Letter](#), provides information to HCPs when drafting such a letter. A checklist is included below on what to include in the letter. A sample letter is attached to this document and includes useful information that many health plans require to process the request. The patient's medical records and a Letter of Medical Necessity (LMN) are submitted with the letter. The Tiering Exception Request Letter may originate from the patient, HCP, or legal representative.* Both the prescribing HCP and patient should sign the letter.

Plans often have specific Tiering Request Forms that must be used. 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.†

TIERING EXCEPTION REQUEST LETTER CONSIDERATIONS

- Include the patient's full name, plan identification number, and date of birth
- Add the prescribing HCP's name, relationship to the requestor, National Provider Identifier (NPI) number, specialty, address, telephone number/fax number, and date of submission
- Record the patient's current diagnosis
- Provide a copy of the patient's records with the following details:
 - Patient's history, diagnosis and specific International Classification of Diseases (ICD) code(s), and present-day condition and symptoms
 - Patient's recent history of infection(s), along with any allergies and existing comorbidities
- Supply a recent photo(s) of the impacted area(s), if applicable
- Document prior treatments and the duration of each treatment
 - Describe the rationale for why each treatment was discontinued
- List the main reasons for requesting a tiering exception for Taltz
- Explain and attest to why the plan's preferred formulary agents are not appropriate for the patient (eg, medications have been or will be ineffective, not as effective, or cause adverse effects)
 - List dates of trial of preferred agents
- If this letter serves as an appeal, include the case number from the denial letter, a copy of the denial letter, and a response to the denial
- Include an LMN
- Include a statement of financial hardship, written by the patient

*Requests may originate from the subscriber, HCP, or legal representative. Please note for Medicare Part D subscribers: Under the Medicare Part D prescription drug benefit program, a Part D plan enrollee, the enrollee's representative, or the enrollee's doctor or other prescriber can request a coverage determination, including a request for a tiering or formulary exception. A request for a coverage determination can be made orally or in writing. **An enrollee, the enrollee's representative, or the enrollee's prescriber may submit a written request for a coverage determination in any format.**

†Please note that the Centers for Medicare & Medicaid Services (CMS) has developed "REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION" model forms that are posted on its website. For more information, visit <https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/coveragedeterminationsandexceptions.html>.

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.



Sample Tiering Exception Request Letter

A Tiering Exception Request Letter is used when **Taltz® (ixekizumab) injection (80 mg/mL)** 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.

 HCPs can follow this format for patients who are **NOT** currently receiving treatment with Taltz.

[Date] Re: [Patient's name]
[Prior authorization department] [Plan identification number]
[Name of health plan] [Date of birth]
[Mailing address] [Case identification]

To whom it may concern:

My name is [HCP's name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a tiering exception for my patient,* [patient's name], who is currently a member of [name of health plan]. The request is for Taltz (ixekizumab) [dose and frequency], which is medically appropriate and necessary for this patient who has been diagnosed with [moderate to severe plaque psoriasis OR active psoriatic arthritis], [ICD code(s)]. I am requesting that Taltz be made available to my patient as a preferred medication.

Sample wording from page 3 of this document can be added here if this appeal has been previously denied by the plan.

In the past, [patient's name] has attempted other treatments for [moderate to severe plaque psoriasis OR active psoriatic arthritis], but those trials have failed due to either inadequate efficacy or lack of tolerability.

FOR PATIENTS DIAGNOSED WITH MODERATE TO SEVERE PLAQUE PSORIASIS

Please detail all past treatments, including phototherapy, topical therapy, and/or DMARDs (eg, MTX).

<input type="text"/>	<input type="text"/>	<input type="text"/>
Past treatment(s) [†]	Start/stop dates	Reason(s) for discontinuing

The patient's present treatment(s) are as follows:

<input type="text"/>	<input type="text"/>	<input type="text"/>
Current treatment(s) [†]	Start/stop dates	Outcome(s)

Provide the information that is applicable to the primary diagnosis.

FOR PATIENTS DIAGNOSED WITH ACTIVE PSORIATIC ARTHRITIS

Please detail all past treatments, including any DMARDs (eg, MTX).

<input type="text"/>	<input type="text"/>	<input type="text"/>
Past treatment(s) [†]	Start/stop dates	Reason(s) for discontinuing

The patient's present treatment(s) are as follows:

<input type="text"/>	<input type="text"/>	<input type="text"/>
Current treatment(s) [†]	Start/stop dates	Outcome(s)

Currently, [patient's name] has the following unresolved symptoms:

- [Symptom 1]
- [Symptom 2]

List unresolved joint and skin symptoms as appropriate.

Check here to affirm that patient will not be taking Taltz in combination with another biologic therapy.

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[†]Identify drug name, strength, dosage form, and therapeutic outcome.
DMARD, disease-modifying antirheumatic drug; MTX, methotrexate

Along with this letter, I have enclosed a copy of the patient's medical records and a Letter of Medical Necessity. The letter describes why Taltz is medically necessary for my patient's care over the preferred drugs listed in the plan's formulary.

[Explain why lower-tiered formulary drugs would not be as effective as Taltz.]

The reason I am requesting a tiering exception is because the cost associated with Taltz's assigned tier would present a financial burden to [patient's name]. Furthermore, it prevents my patient from utilizing a medication that will help treat their [moderate to severe plaque psoriasis OR active psoriatic arthritis].

To summarize, I consider Taltz to be the best option in successfully treating [patient's name]'s [moderate to severe plaque psoriasis OR active psoriatic arthritis]. Please contact me, [physician's name], at [physician's telephone number] for a peer-to-peer review or to answer any pending questions.

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, Letter of Medical Necessity, photo(s), statement of financial hardship from [patient's name], previous denial letter (if this is an appeal), medical notes in response to the denial (if this is an appeal)

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:

My name is [HCP's name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a tiering exception for my patient,* [patient's name], who is currently a member of [name of health plan]. The request is for Taltz (ixekizumab) [dose and frequency], which is medically appropriate and necessary for this patient who has been diagnosed with [moderate to severe plaque psoriasis OR active psoriatic arthritis], [ICD code(s)].[†]The patient was receiving treatment with Taltz [dose, frequency] but had to discontinue treatment due to [HCP to list reason (eg, change in plan's formulary list or patient changed health plans during the past year)]. Therefore, I am requesting that Taltz be made available to my patient as a preferred medication.

Sample wording from the following section can be added here if this appeal has been previously denied by the plan.

TIERING EXCEPTION APPEAL

If this Tiering Exception Request Letter is an appeal, sample copy should include the following:

This is a tiering exception appeal. I have included a copy of the original denial letter and medical notes in response to the denial.

For appeals,[†] include the following:

- A copy of the denial letter
- Medical notes, written by the prescribing physician, in response to the denial letter

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[†]An external review board or hearing may apply in some situations.

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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