Composing a Letter of Medical Necessity

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).

Many health plans require that a Letter of Medical Necessity (LMN) accompanies a Coverage Authorization Appeals Letter. The purpose of an LMN is to explain the prescribing healthcare provider's (HCP) rationale and clinical decision making when choosing a treatment.* LMNs are often required by plans when submitting a Coverage Authorization Appeals Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter.

This resource, **Composing a Letter of Medical Necessity**, provides information on the process of drafting an LMN. A checklist is included below that can be followed when creating an LMN. In addition, 2 sample letters are attached to this document and include information that plans often require. Note that some plans have specific Coverage Authorization Forms that must be utilized to document an LMN.

Follow the patient's plan requirements when requesting **Taltz® (ixekizumab) injection (80 mg/mL)**, otherwise treatment may be delayed.

LMN CONSIDERATIONS

- Include the patient's full name, plan identification number, date of birth, and case identification number if a decision has already been rendered
- Provide a copy of the patient's records with the following details:
  - The patient's history, diagnosis with specific International Classification of Diseases (ICD) code, and present-day condition and symptoms
  - The patient's recent history of infection(s), along with any allergies and existing comorbidities
- Note the severity of the patient's condition using the plan's preferred scoring system. Common scoring systems are
  - The Psoriasis Area Severity Index (PASI)
  - The Physician Global Assessment (PGA)
- Include a recent photo(s) of the impacted area(s)
- Document prior treatments and the duration of each. It may be beneficial to include Current Procedural Terminology, 4th Edition (CPT-4) and/or J-codes to define prior services/treatments, so that the health plan can conduct research and make a timely determination request
  - Describe the rationale for why each treatment was discontinued
- Attach clinical documentation that supports your recommendation; this information may be found in the Taltz prescribing information and/or clinical peer-reviewed literature

*For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip.

Sample Letters of Medical Necessity

The purpose of an LMN is to explain the prescribing HCP's rationale and clinical decision making when choosing **Taltz® (ixekizumab) injection (80 mg/mL)** 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.

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

[Date]
[Payer department]
[Name of health plan]
[Mailing address]

Re: **[Patient's name]**
[Plan identification number]
[Date of birth]
[Case identification]

To whom it may concern:

I am writing to provide additional information to support my claim for **[patient's name]**'s treatment of moderate to severe plaque psoriasis with Taltz® (ixekizumab). In brief, treatment with Taltz **[dose, frequency]** is medically appropriate and necessary for this patient. This letter outlines the patient's medical history, severity scoring index, previous treatments, and a recent photo(s) of the impacted area(s) that support my recommendation for treatment with Taltz.

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

____ % of BSA impacted
____ % of BSA involving only sensitive areas
____ Severity score index ☐ PASI ☐ Other (please list)_____
____ Indicate here, by adding a check mark, 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

Past Treatment(s)†	Start/Stop Dates	Reason(s) for Discontinuing

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

[Provide clinical rationale for this treatment; this information may be found in the Taltz prescribing information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Taltz.]

Please feel free to contact me, **[HCP name]**, at **[office phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

_____

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

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

BSA, body surface area; PASI, Psoriasis Area Severity Index
*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.
†Identify drug name, strength, dosage form, and therapeutic outcome.

Sample Letters of Medical Necessity

The purpose of an LMN is to explain the prescribing HCP's rationale and clinical decision making when choosing **Taltz® (ixekizumab) injection (80 mg/mL)** 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.

HCPs can follow this format for patients who **HAVE** been treated with Taltz and have had treatment interruptions

[Date]
[Payer department]
[Name of health plan]
[Mailing address]

Re: **[Patient's name]**
[Plan identification number]
[Date of birth]
[Case identification]

To whom it may concern:

I am writing to provide additional information to support my claim for **[patient's name]**'s treatment of moderate to severe plaque psoriasis with Taltz® (ixekizumab). In brief, continued treatment with Taltz **[dose, frequency]** is medically appropriate and necessary for this patient. This letter outlines the patient's medical history, severity scoring index, previous treatments, and a recent photo(s) of the impacted area(s) that support my recommendation for treatment with Taltz.

[In this section, describe the severity of plaque psoriasis symptoms at the time when the patient was first prescribed Taltz. In addition, include a summary of the patient's clinical response to Taltz and list improvements in symptoms and severity scoring since treatment began. It may be necessary to review past medical records.]

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

____ % of BSA impacted

____ % of BSA involving only sensitive areas

____ Severity score index ☐ PASI ☐ Other (please list) _____

____ Indicate here, by adding a check mark, 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

Past Treatment(s)†	Start/Stop Dates	Reason(s) for Discontinuing

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

[Provide clinical rationale for this treatment; this information may be found in the Taltz prescribing information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Taltz.]

Please feel free to contact me, **[HCP name]**, at **[office phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

_____

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

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

BSA, body surface area; PASI, Psoriasis Area Severity Index
*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.
†Identify drug name, strength, dosage form, and therapeutic outcome.

Please see Important Safety Information on page 4 and Prescribing Information and Medication Guide.
Please see Instructions for Use 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 (≥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 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 January 27, 2017. **2.** Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; 2017.