For Commercial Insurance

Writing a formulary exception request letter

A formulary exception is a type of coverage determination used when a drug is not included on a health plan's formulary or is subject to a National Drug Code (NDC) block. A formulary exception request letter may be able to help a patient gain access by outlining the reasons why a treatment is necessary to meet the medical needs of the patient.

Formulary exception request letter submission process

1. The formulary exception request letter may **originate from you**, **your patient**, **or your patient's legal representative**.*

2. Typically, your patient's **medical records** and a **letter of medical necessity (LMN)** are submitted with the letter.

3. **Both** you and your patient **should sign** the letter.

- Plans frequently provide specific formulary exception request templates that must be used when making the request. These forms may be downloaded from each plan's website
- Follow the plan's requirements when requesting product approval; otherwise, treatment may be delayed†

*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 Indication and Important Safety Information on page 4.

Please see full Prescribing Information at https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.

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Sample formulary exception request letter

This is an example of a letter you can use when your desired treatment option is not included on a health plan's formulary or is subject to an NDC block. This step may require you to submit an LMN with the formulary exception request letter.

[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:

My name is [HCP's name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a formulary exception for my patient, [patient's name], who is currently a member of [name of health plan].*

The prescription is for [product, dosage and frequency], which is medically appropriate and necessary for this patient who has been diagnosed with [condition], [ICD code(s)]. Therefore, I am requesting that the plan remove any relevant NDC blocks, so that [product] can be made available to my patient as a preferred medication.

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

___________% of BSA impacted

___________% of BSA involving only sensitive areas

___________Severity score index, assessed by: ☐ PASI ☐ Other (please list)_________________

___________As required by some health plans, indicate with a check mark that patient does not have tuberculosis or other serious infections. If 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

SAMPLE

Past Treatment(s)†	Start/Stop Dates	Reason(s) for Discontinuing
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc]
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc]

[Include the main reason for requesting this formulary exception].

A Letter of Medical Necessity and pertinent medical records are enclosed, which offer additional support for the formulary exception request for [product].

Please contact me, [name], at [telephone number] for a peer-to-peer review. I would be pleased to speak about why a [product] formulary exception is necessary for [patient's name]'s treatment of [diagnosis].

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), Letter of Medical Necessity]

BSA, body surface area; NPI, National Provider Identifier; 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.

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If this appeal has previously been denied, consider adding:

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

For previously denied appeals, include the following:

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

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies. For more information, please call an Access Specialist at 1.877.COMPLETE (1.877.266.7538).

Digital version available at CompletePro.com and SkyriziHCP.com.

Please see Indication and Important Safety Information on page 4.

Please see full Prescribing Information at https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.

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Writing a formulary exception letter and what to include

Make sure you include all of the information in the letter that is highlighted in red; otherwise, your appeal could be denied

Additional documents

- Recent photo(s) of impacted area(s)
- Letter of medical necessity
- A copy of your patient's records

For support in person or over the phone, call your Access Specialist at 1.877.COMPLETE (1.877.266.7538).

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Skyrizi™ COMPLETE

Skyrizi™
risankizumab-rzaa
75mg/0.83mL Injection

Indication and Important Safety Information for SKYRIZI

Indication[1]

SKYRIZI™ (risankizumab-rzaa) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Important Safety Information[1]

Infection

SKYRIZI™ (risankizumab-rzaa) may increase the risk of infection. Do not initiate treatment with SKYRIZI in patients with a clinically important active infection until it resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing SKYRIZI. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, closely monitor and discontinue SKYRIZI until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis (TB)

Prior to initiating treatment with SKYRIZI, evaluate for TB infection and consider treatment in patients with latent or active TB for whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SKYRIZI treatment. Do not administer SKYRIZI to patients with active TB.

Immunizations

Prior to initiating SKYRIZI, consider completion of all age appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with SKYRIZI.

Adverse Reactions

Most common (≥1%) adverse reactions associated with SKYRIZI include upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

Reference: 1. SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc.

Please see full Prescribing Information at https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.

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