Sample Letter of Formulary Exception

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 help a patient gain access by outlining the reasons why a treatment is necessary to meet the medical needs of the patient. The following is a template letter for FILSUVEZ that your office can customize based on your patient's medical history and demographic information. Accurate completion of coverage-related or reimbursement-related documentation is the responsibility of the physician and patient. Chiesi makes no guarantee regarding reimbursement for any product or service.

[Physician's Letterhead]
[Plan/Payer Name]
[Payer Full Address]

RE: Coverage for FILSUVEZ® (birch triterpenes) topical gel

For: **[Patient Name]**
[Group/Policy Number]
[DOB]
[Diagnosis & ICD-10-CM]
[Policyholder Name]

To Whom It May Concern:

I am writing on behalf of my patient, [Patient Name/Policy Number], to request a formulary exception for FILSUVEZ in treating their epidermolysis bullosa (EB) wounds. FILSUVEZ, a topical gel used to treat EB wounds in patients with dystrophic EB (DEB) or junctional EB (JEB), received FDA approval on December 19, 2023.

Indication: FILSUVEZ is indicated for the treatment of wounds associated with DEB and JEB in adult and pediatric patients aged 6 months and older.

Summary of Patient Diagnosis

[Patient Name] is [a/an] [age]-[year/month]-old [male/female] diagnosed with [DEB/JEB] on [Date]. [Patient Name] has been in my care since [Date]. Due to the patient's clinical condition, the plan of treatment is to start treatment with FILSUVEZ on [Date].

Rationale for Treatment

Based on [Patient Name]'s clinical history, it is my medical opinion that [initiating/continuing] treatment with FILSUVEZ is medically appropriate and necessary. Outlined below are additional details about [Patient Name]'s medical history and prognosis, and the rationale for treatment with FILSUVEZ.

[Include relevant clinical history and highlight the factors leading you to recommend treatment with FILSUVEZ, such as:

- Description of the patient's clinical history, current symptoms, and wound burden
- Current wound care plan
- Patient prognosis or disease progression
- Reasons why other covered treatments or standard wound care are not appropriate for your patient]

The enclosed medical records provide additional documentation of [Patient Name]'s clinical condition and medical necessity for treatment with FILSUVEZ.

Considering [Patient Name]'s medical history and current medical condition, I believe treatment with FILSUVEZ is warranted, appropriate, and medically necessary. Please consider coverage of FILSUVEZ on [Patient Name]'s behalf and approve use and subsequent payment for treatment. Please contact me at [physician phone number] or via email at [physician email] if you require any additional information or documentation. I look forward to your timely response.

Thank you for your prompt attention to this matter. If this request is denied, I am requesting an expedited review of appeal by a professional in my specialty.

Sincerely,

[Name and signature]
[NPI Number]
[Contact information]

Enclosures:

- [Medical records, clinical notes, and illustration of wound burden]
- FDA Approval Letter
- Prescribing Information
- Instructions for Use
- Journal article reprints