**PLEASE NOTE:** This is a Sample Letter of Appeal and may not include all the necessary information to support your appeal. Requirements will vary based on health plan guidelines and patient benefit design. This is not intended to substitute for your medical judgment when providing a diagnosis of a patient’s medical condition or recommendation for a particular treatment. The requesting provider is entirely responsible for ensuring the accuracy, adequacy, medical necessity, and supportability of all information required. Use of this sample letter does not guarantee coverage or reimbursement.

**INSTRUCTIONS:** Please copy this sample letter to your practice’s letterhead before printing and please remember to provide your medical professional opinion and all other necessary patient information.

[Healthcare Professional Letterhead]

[Month day, year]

**Attention:**

[Medical/Appeals Reviewer]

[Payer name]

[Payer contact name] [Payer address]

Re: Letter of Appeal for XOLREMDITM (mavorixafor)

**Regarding:**

**Patient:** [Patient’s first and last name]

**Date of Birth:** [Patient’s date of birth]

**Insurance:** [Patient’s insurance company]

**Subscriber ID #:** [Insurance ID #]

**Group #:** [Insurance group #]

| **Reference Number** | **Therapy** | **Submission Date** | **Denial Date** |
| --- | --- | --- | --- |
| [Reference number] | XOLREMDI | [Submission date] | [Denial date] |

Dear [Medical/Appeals Reviewer Name],

I am writing to request [appeal/redetermination/reconsideration] for my patient, [patient name], for the above-referenced line item[s]. I understand from your denial letter, dated [month day, year], that treatment with XOLREMDI has been denied because [quote denial reason as communicated in the denial letter].

**Patient Diagnosis**

The case in question involves my patient, [patient name], who was diagnosed with [diagnosis name] on [month day, year]. As a result of this [diagnosis], my patient [enter brief description of patient history]. Additionally, [patient name] has received [state previous therapies] and [state outcomes]. Please see the enclosed documentation, which discusses my patient’s medical history and provides supporting information relating to my request to reconsider treatment for [patient name] with XOLREMDI.

**Treatment Information**

XOLREMDITM (mavorixafor) is a CXC chemokine receptor 4 (CXCR4) antagonist indicated in patients
12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.

The safety and efficacy profiles of XOLREMDI make it medically necessary and appropriate for [patient name], so I ask you to reconsider your denial of coverage. [Include any additional clinical rationale explaining the medical necessity of this treatment.]

**Supporting Documentation**

Please see the enclosed documentation for [patient name]’s detailed medical history, as well as supporting information for the use of XOLREMDIfor [diagnosis name].

The following items are enclosed [Note: the items below are suggested enclosures and anything not applicable can be deleted]:

* [Package Insert for XOLREMDI]
* [XOLREMDI clinical trial publication]
* [Medical literature regarding the use of XOLREMDI for (diagnosis name)]
* [Relevant clinical documentation such as a medical history and results of a physical, progress notes, treatment history, genetic testing results, and Letter of Medical Necessity]
* [Applicable coverage policies]
	+ [REMINDER: If a payer has a published policy, include here]
	+ [REMINDER: If state statute exists, include here]

I appreciate your prompt review of this appeal. I am readily available at my office phone number, [physician’s phone number], to address any questions or concerns you might have regarding this appeal.

Thank you for your time and consideration.

 Sincerely,

[Physician’s signature]

[Physician’s name and credentials]

[Associated ID Numbers]

**INDICATION**

XOLREMDITM (mavorixafor) is a CXC chemokine receptor 4 (CXCR4) antagonist indicated in patients
12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATION**

XOLREMDI is contraindicated with drugs highly dependent on CYP2D6 for clearance.

**WARNINGS AND PRECAUTIONS**

**Embryo-Fetal Toxicity:** Based on its mechanism of action, XOLREMDI is expected to cause fetal harm. Verify pregnancy status of female patients of reproductive potential prior to starting XOLREMDI. Advise females of reproductive potential to use effective contraception during treatment with XOLREMDI and for three weeks after the final dose.

**QTc Interval Prolongation:** XOLREMDI causes concentration-dependent QTc prolongation. Correct any modifiable risk factors for QTc prolongation, assess QTc at baseline, and monitor QTc during treatment as clinically indicated in patients with risk factors for QTc prolongation or receiving concomitant medications that increase XOLREMDI exposure and/or drugs with a known potential to prolong the QTc interval. Dose reduction or discontinuation of XOLREMDI may be required.

**ADVERSE REACTIONS**

The most common adverse reactions (in $\geq $10% patients and more frequently reported than placebo) were thrombocytopenia, pityriasis, rash, rhinitis, epistaxis, vomiting, and dizziness.

**DRUG-DRUG INTERACTIONS**

Avoid co-administration of XOLREMDI and strong CYP3A4 inducers. Reduce XOLREMDI daily dosage when administered with strong CYP3A4 inhibitors. Monitor more frequently for adverse reactions associated with an increase in exposure of XOLREMDI when used concomitantly with moderate CYP3A4 inhibitors or P-gp inhibitors and reduce XOLREMDI daily dosage if necessary.

**USE IN SPECIFIC POPULATIONS**

Advise females that breastfeeding is not recommended during treatment with XOLREMDI and for three weeks after the final dose.

The safety and effectiveness of XOLREMDI have not been established in pediatric patients younger than 12 years of age.

XOLREMDI is not recommended in patients with severe renal impairment, end-stage renal disease, or moderate to severe hepatic impairment.

To report suspected adverse reactions, contact X4 Pharmaceuticals at 1-866-MED-X4MI (1-866-633-9464) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Please see the full**[**Prescribing Information**](https://www.xolremdihcp.com/pdf/prescribing-information.pdf) **for XOLREMDI.**

XOLREMDI is a trademark of X4 Pharmaceuticals, Inc.

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