AUCTA PHARMACEUTICALS

WE ARE INNOVATING

Please see below a sample letter of medical exception. If your patient's health insurance provider excludes or has not made a coverage decision on MOTPOLY XR™ (lacosamide) extended release capsules, a letter of medical exception may be used to help your patients who need MOTPOLY XR obtain coverage for it. The following letter provides an example of the type of information that may be required when seeking coverage from a patient's insurance company.

Use of this template or the information within does not guarantee coverage. It is not intended to be a substitute for, or to influence the independent clinical decision of, the prescribing healthcare professional.

To use the template

Replace or delete all nonrelevant bracketed text with patient-specific relevant information.

[Practice Letterhead]
[Date:]

[Payer Company Name]
[Street/Building Address]
[City, State ZIP]

ATTN: *[Contact Name/ Contact Title]*

Re: Letter of MOTPOLY XR Medical Exception for *[Plan Member Name]*

[Plan member information:]
Name: *[First and Last]*
Date of Birth: *[MM/DD/YYYY]*
Policy Number: *[Number]*
Group Number: *[Number]*

Dear *[Pharmacy Director/Payer Contact Name]:*

I am writing to you on behalf of my patient *[Patient's Name]* to request approval for coverage of lacosamide extended release (MOTPOLY XR™) for *[his/her]* treatment. This letter explains my rationale for prescribing MOTPOLY XR for *[Patient's Name]*, who has a diagnosis of *[partial-onset seizures/ primary generalized tonic clonic seizures]* and has been in my care since *[Date]*.

Multiple studies have demonstrated the long-term efficacy and safety of lacosamide as both monotherapy and adjunctive therapy in patients with partial-onset seizures and as adjunctive therapy in patients with primary generalized tonic-clonic seizures.[1-4] MOTPOLY XR—lacosamide, now in a single daily dose—is the only once-a-day extended-release forumulation of lacosamide available in the United States. MOTPOLY XR has been FDA approved since May 2023 and is indicated for the treatment of partial-onset seizures and as adjunctive therapy for primary generalized tonic-clonic seizures for patients weighing at least 50 kgs.

During the time *[Patient's Name]* has been in my care, *[Insert information about patient's current therapy and previous treatments to manage seizures. Detail reasons for patient benefiting from once-daily dosing. Include instances of patient not following dosing regimen].*

Comorbidities, polypharmacy, and lifestyle are important issues in the treatment of epilepsy. These considerations factor into my decision to prescribe MOTPOLY XR for my patients who may benefit from once-daily dosing.

It is my view that MOTPOLY XR is medically necessary to treat *[Patient Name's] [partial-onset seizures/primary generalized tonic clonic seizures]* and I ask that you consider coverage of MOTPOLY XR on *[Patient Name's]* behalf.

Sincerely,

[Prescriber's Signature]

[Prescriber's Name]

INDICATION

MOTPOLY XR is indicated for adults and pediatric patients weighing at least 50 kg for treatment of partial-onset seizures and adjunctive therapy in the treatment of primary generalized tonic-clonic seizures.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- Antiepileptic drugs increase the risk of suicidal behavior and ideation. Monitor patients for the emergence or worsening of depression, suicidal thoughts or behaviors.
- MOTPOLY XR may cause dizziness and ataxia in patients. Advise patients not to operate machinery or motor vehicles until they know how MOTPOLY XR affects them.
- Obtain ECG before beginning MOTPOLY XR, and after titration to steady-state maintenance dose in patients with underlying proarrhythmic conditions or on concomitant medications that affect cardiac conduction. Closely monitor these patients.
- MOTPOLY XR may cause syncope.
- Gradually withdraw MOTPOLY XR to minimize the potential of increased seizure frequency.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/multi-organ hypersensitivity has been reported and can be life-threatening or fatal. If signs or symptoms are present, immediately evaluate the patient. Discontinue MOTPOLY XR if there is no alternative etiology.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in adults (≥10% and greater than placebo) are diplopia, headache, dizziness, nausea, and somnolence.

USE IN SPECIFIC POPULATIONS:

- Dose adjustment is recommended for severe renal impairment and mild or moderate hepatic impairment. Consider dose reduction in patients with renal or hepatic impairment taking strong inhibitors of CYP3A4 and CYP2C9.
- Use is not recommended in severe hepatic impairment.
- Based on animal data, MOTPOLY XR may cause fetal harm if used in pregnancy.

Please refer to the full **Prescribing Information** and **Medication Guide** for MOTPOLY XR for additional important information.

References: 1. Ben-Menachem E, Dominguez J, Szasz J, et al. Long-term safety and tolerability of lacosamide monotherapy in patients with epilepsy: results from a multicenter, open-label trial. *Epilepsia Open.* 2021;6:618-623. **2.** Hou L, Peng B, Zhang D, et al. Clinical efficacy and safety of lacosamide as an adjunctive treatment in adults with refractory epilepsy. *Front Neur.* 2021;12:712717.doi:10.3389/fneur.2021.7127172021. **3.** Chung S, Ben-Menachem E, Sperling MR, et al. Examining the clinical utility of lacosamide: pooled analyses of three phase II/III clinical trials. *CNS Drugs.* 2010;24(12):1041-1054. **4.** Wechsler RT, Li G, French J, et al. Conversion to lacosamide monotherapy in the treatment of focal epilepsy: results from a historical-controlled, multicenter, double-blind study. *Epilepsia.* 2014;55(7):1088-1098.

Enclosures: PI, Medication Guide

To learn more, patients please refer to MotpolyXR.com and US Healthcare Professionals refer to MotpolyXRhcp.com.