

## HUB Instructions Regarding Letters of Medical Necessity

Some payers may require that the prescribing physician document a patient's medical necessity for the treatment to get insurance coverage for the agent. The following letter is only intended as a sample Letter of Medical Necessity that outlines the information a payer may request. Health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient's health plan before completing a Letter of Medical Necessity. Use of this letter does not guarantee coverage or reimbursement for the drug.

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 support, call 866-524-6546.

The provider should refer to the full prescribing information when determining whether Lopressor<sup>®</sup> (metoprolol tartrate) oral solution is medically appropriate for the patient. It is the sole responsibility of the healthcare provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Make sure you have the following for an efficient submission of your Letter of Medical Necessity:

- Patient's insurance policy/ID number
- Case ID number if a decision has already been rendered
- Patient's full name, plan identification number, and date of birth
- A brief medical history, including diagnosis, allergies, existing comorbidities, and *International Classification of Diseases (ICD)* code(s)
- Clinical support for your recommendation
- Your office contact information

For support in person or by phone, call 866-524-6546.

Please see Indications and Important Safety Information at the end of this sample letter.

[Please note – this sample letter is intended to support the development of a Letter of Medical Necessity. Providers and their staff are responsible for confirming a diagnosis, establishing a treatment plan, and preparing the content and appropriate supporting materials for individual patients. The letter should be on the physician’s letterhead and have his or her practice name and contact information.]

[Contact name of Pharmacy Director or other payer representative]  
[Contact title]  
[Name of health insurance company]  
[Address]  
[City, State ZIP]

RE: Letter of Medical Necessity for Lopressor<sup>®</sup> (metoprolol tartrate) oral solution

**Patient:** [Patient name]  
**Date of birth:** [Date]  
**Group/policy number:** [Number]  
**Policyholder:** [Policyholder’s name]  
**Diagnosis:** [Insert diagnosis]

Dear [Contact name]:

I am writing on behalf of my patient, [Patient name], to [Document medical necessity] for treatment with Lopressor<sup>®</sup> (metoprolol tartrate) oral solution. [Patient name] has a diagnosis of [Insert diagnosis], and I believe Lopressor<sup>®</sup> is medically necessary for the treatment of [Patient name]’s [Insert diagnosis] as prescribed. On behalf of the patient, I am requesting approval for the use of and subsequent payment for Lopressor<sup>®</sup> oral solution.

On April 10, 2025, the FDA approved Lopressor<sup>®</sup> 10 mg/mL oral solution, the only liquid formulation of metoprolol tartrate, for the treatment hypertension, hemodynamically stable patients with definite or suspected myocardial infarction and angina pectoris in adults<sup>1</sup>. Lopressor<sup>®</sup> oral solution is a selective inhibitor of cardio selective  $\beta$ -1 adrenergic receptors (also known as  $\beta$ -blockers).<sup>1</sup> The FDA considers Lopressor oral solution is bioequivalent to an immediate-release tablet formulation of metoprolol tartrate.<sup>2</sup>

The dosing regimen indicated for Lopressor<sup>®</sup> widely varies as per the therapeutic indication. To meet their specific dosing requirement, patients may often alter oral tablet medications, such as by cutting or crushing a tablet. However, modifying a medication’s dosage form by cutting or crushing may significantly change the pharmacokinetic profile (absorption, distribution, metabolism, or elimination, which may lead to unintended consequences, such as reduced efficacy or toxicity<sup>3</sup>.

The risk for swallowing difficulties, including dysphagia, increases with age, affecting an estimated 10% to 33% of older adults.<sup>4</sup> and the palatable neutral flavor of Lopressor<sup>®</sup> oral solution may allow patients to take their medication as prescribed.

## Patient Medical History and Diagnosis

[Provide a brief medical history, including diagnosis, allergies, existing comorbidities, and *International Classification of Diseases (ICD) code(s)*.]

[Discuss rationale for using <product name> vs other treatments. Insert your recommendation summary here, including your professional opinion of your patient's likely prognosis or disease progression without treatment.]

Based on the above, as well as the enclosed medical records, which offer additional support for the formulary exception request for [Product name], I respectfully request that [Payer name] cover [Product name] as prescribed for [Patient name].

Please refer to the prescribing information enclosed [and any appropriate supporting documents] for further details, and please don't hesitate to contact me if you have any further questions regarding this request. [Insert appropriate contact information.]

Thank you for your prompt attention to this matter.

Sincerely,

[Prescriber's name], [Credential]

cc: [Patient name]

Optional Enclosures: Lopressor® Prescribing Information (PI), clinical notes and records, [variable published literature].

### **References:**

1. Lopressor® Oral Solution. Prescribing Information. Validus Pharmaceuticals LLC; 2025.
2. US Food and Drug Administration. Orange Book Cumulative Supplement 06. FDA Law Blog. Updated June 2025. Accessed July 16, 2025. <https://www.fda.gov/media/72973/download>
3. Blaszczyk A, Brandt N, Ashley J, Tuders N, Doles H, Stefanacci RG. Crushed Tablet Administration for Patients with Dysphagia and Enteral Feeding: Challenges and Considerations. *Drugs Aging*. 2023 Oct;40(10):895-907.
4. Thiyagalingam S, Kulinski AE, Thorsteinsdottir B, Shindelar KL, Takahashi PY. Dysphagia in older adults. *Mayo Clin Proc*. 2021;96(2):488-497.

## IMPORTANT SAFETY INFORMATION

### INDICATIONS AND USAGE

LOPRESSOR is a beta-adrenergic blocker indicated in adult patients:

- For the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions.
- In the long-term treatment of angina pectoris.
- In the treatment of hemodynamically stable patients with definite or suspected myocardial infarction, to reduce the risk of cardiovascular mortality when used in conjunction with intravenous metoprolol therapy

### CONTRAINDICATIONS

LOPRESSOR is contraindicated in severe bradycardia, second- or third-degree heart block, cardiogenic shock, systolic blood pressure <100, decompensated heart failure, sick sinus syndrome (unless a permanent pacemaker is in place), and in patients who are hypersensitive to any component of this product.

### WARNINGS AND PRECAUTIONS

#### Abrupt Cessation of Therapy

Abrupt cessation of LOPRESSOR can cause exacerbations of angina pectoris and in some cases, myocardial infarction. Taper the dose over a period of 1–2 weeks and monitor closely particularly in patients with ischemic heart disease. If angina markedly worsens or acute coronary ischemia develops, promptly reinstate LOPRESSOR, and take measures appropriate for the management of unstable angina. Warn patients not to interrupt therapy without their physician's advice. Because coronary artery disease is common and may be unrecognized, avoid abruptly discontinuing LOPRESSOR in patients treated only for hypertension. .

#### Heart Failure

LOPRESSOR may temporarily worsen cardiac failure during up-titration. If such symptoms occur, increase diuretics and restore clinical stability before advancing the dose of LOPRESSOR. Dose reduction or temporary discontinuation may be needed, but such episodes do not preclude subsequent successful titration of LOPRESSOR.

#### Bronchospastic Disease

Patients with bronchospastic disease, in general, should not receive beta-blockers, including LOPRESSOR. Because of its relative beta1 cardio-selectivity, however, LOPRESSOR may be used in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment.

#### Pheochromocytoma

If LOPRESSOR is used in the setting of pheochromocytoma, it should be given in combination with an alpha blocker, and only after the alpha blocker has been initiated

#### Major Surgery

Avoid initiation of a high-dose regimen of beta-blocker therapy in patients undergoing non-cardiac surgery, since such use in patients with cardiovascular risk factors has been associated with bradycardia, hypotension, stroke and death. Chronically administered beta-blocking therapy should not be routinely withdrawn prior to major surgery, however, the impaired ability of the heart to respond to reflex adrenergic stimuli may increase the risks of general anesthesia and surgical procedures.

#### Hypoglycemia

Beta-blockers may prevent early warning signs of hypoglycemia, such as tachycardia, and increase the risk for severe or prolonged hypoglycemia at any time during treatment, especially in patients with diabetes mellitus or children and patients who are fasting (i.e., surgery, not eating regularly, or are vomiting). If severe hypoglycemia occurs, patients should be instructed to seek emergency treatment.

#### Thyrotoxicosis

Beta adrenergic blockade may mask certain clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of beta-blockade may precipitate a thyroid storm.

#### Risk of Anaphylactic Reaction

While taking beta-blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge, either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

#### Peripheral Vascular Disease

LOpressor can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease.

See Full Prescribing Information for additional warnings and precautions associated with LOPRESSOR.

### ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

- Worsening angina or myocardial infarction
- worsening heart failure
- worsening AV block

See Full Prescribing Information for additional adverse reactions associated with LOPRESSOR

### DRUG INTERACTIONS

#### Catecholamine Depleting Drugs

Catecholamine depleting drugs (e.g., reserpine, MAO inhibitors) can increase the risk of bradycardia or hypotension, which may produce vertigo, syncope, or postural hypotension.

#### Epinephrine

While taking beta-blockers, patients with a history of severe anaphylactic reactions to various allergens may exhibit increased sensitivity to repeated exposure and may not respond adequately to usual doses of epinephrine used for treating allergic reactions.

#### CYP2D6 Inhibitors

Strong CYP2D6 inhibitors—such as quinidine, fluoxetine, paroxetine, and propafenone—have been shown to double plasma concentrations of metoprolol. Although data on moderate or weak inhibitors are lacking, they may also elevate metoprolol levels. Increased plasma concentrations can reduce the cardioselectivity of metoprolol. If co-administration is unavoidable, patients should be monitored closely.

#### Negative Chronotropes

Digitalis glycosides, clonidine, diltiazem, and verapamil reduce the heart rate by slowing atrioventricular conduction. When used with beta-blockers, the risk of bradycardia may increase See Full Prescribing Information for additional potential drug interactions associated with LOPRESSOR.

### USE IN SPECIFIC POPULATIONS

#### Pregnancy

If high blood pressure or a heart attack is not treated during pregnancy, it can be harmful to both the mother and baby. Metoprolol can pass through the placenta, so babies born to mothers taking this medication may be at risk for low blood pressure, low blood sugar, a slow heart rate, and trouble breathing. Babies should be closely monitored after birth if the mother took metoprolol during pregnancy.

#### Lactation

No adverse reactions of metoprolol on the breastfed infant have been identified. There is no information regarding the effects of metoprolol on milk production.

#### Females and males of reproductive potential

Based on the published literature, metoprolol may cause erectile dysfunction and inhibit sperm motility.

#### Pediatric Use

Pediatric use of LOPRESSOR has not been studied.

#### Geriatric Use

In general, use a low initial starting dose in elderly patients given their greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

#### Hepatic Impairment

LOPRESSOR has not been studied in patients with hepatic impairment.

#### Renal Impairment

The systemic availability and half-life of metoprolol in patients with renal failure do not differ to a clinically significant degree from those in normal subjects. No reduction in dosage is needed in patients with chronic renal failure.

### OVERDOSAGE

Overdosage of LOPRESSOR may lead to severe bradycardia, hypotension, and cardiogenic shock. Clinical presentation can also include atrioventricular block, heart failure, bronchospasm, hypoxia, impairment of consciousness/coma, nausea and vomiting.

LOPRESSOR is available as a 10 mg/mL oral solution.

To report SUSPECTED ADVERSE REACTIONS, contact Validus Pharmaceuticals LC at 1-866-982-5438 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). Please see Full Prescribing Information at <https://liquid.lopressor.us.com/>

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