

HUB Instructions Regarding Denial Appeal Letters

The following sample Denial Appeal Letter outlines the information a payer may request. Health plan requirements may vary, so the prescriber should refer to prior authorization or coverage information specific to their patient's health plan before completing a Denial Appeal Letter. Use of this sample 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.

You may want to submit an appeal letter if the payer:

- Denied payment
- Claimed treatment was not medically necessary
- Said the prescription is not covered by your patient's benefits

Depending on the reason for the denial, different materials and additional steps may be required, such as a formulary exception.

The provider should refer to the full prescribing information when determining whether Lopressor[®] (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.

The sample letter should be on the provider's office letterhead containing the physician's name and contact information.

For Medicare beneficiaries, there are specific requirements that need to be met for the healthcare provider to be considered a legal representative of the patient in an appeal. For additional information, please visit <https://www.cms.gov/medicare/appeals-grievances/prescription-drug/exceptions>.

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

[Please note – providers should be sure to follow individual payers’ requirements for preparing and submitting appeals. Although this sample letter is intended to support an appeal, providers may need to comply with additional requirements to appeal an adverse coverage decision.]

[Contact name of Pharmacy Director or other payer representative]

[Contact title]

[Name of health insurance company]

[Address]

[City, State ZIP]

RE: Appeal of denied claim for Lopressor[®] (metoprolol tartrate) oral solution

Patient: [Patient name]

Date of birth: [Date]

Group/policy number: [Number]

Policyholder: [Policyholder’s name]

Dear [Contact name]:

I am writing on behalf of my patient, [Patient name], to support [his/her] appeal of [Payer name]’s denial of a prior authorization request for Lopressor[®] (metoprolol tartrate) oral solution. I believe Lopressor[®] oral solution is medically necessary for the treatment of [Patient name]’s [Insert diagnosis].

On April 10, 2025, the FDA approved, Lopressor[®] 10 mg/mL oral solution, the only liquid formulation of metoprolol tartrate for the treatment of hypertension, hemodynamically stable patients with definite or suspected myocardial infarction and angina pectoris in adults¹ Lopressor[®] is a selective inhibitor of cardio selective β -1 adrenergic receptors (also known as β -blockers) .¹ The FDA considers Lopressor[®] oral solution to be bioequivalent to immediate-release tablet formulations of metoprolol tartrate.²

The dosing regimen indicated for Lopressor[®] 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 toxicity³.

The risk for swallowing difficulties, including dysphagia, increases with age, affecting an estimated 10% to 33% of older adults.⁴ The palatable neutral flavor of Lopressor[®] 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 [Payer name] to reconsider its denial of this prior authorization for the clinical rationale summarized above. If [Payer name] chooses to reject this appeal, please provide in writing the alternative therapy you are willing to cover for this patient.

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

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;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.

LOP-019-25.1

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. Please see Full Prescribing Information at <https://liquid.lopressor.us.com/>

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