

SAMPLE LETTER OF MEDICAL NECESSITY

This sample letter, beginning on page two, along with the related information, is provided for informational purposes only.

It provides an example of the types of information that may be provided when responding to a request from a patient's health plan/insurer to provide a letter of medical necessity for KATERZIA® (amlodipine) Oral Suspension.

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 the information in this letter does not guarantee coverage or that the health plan will provide reimbursement for KATERZIA® (amlodipine) and is not intended to be a substitute for or to influence the independent medical judgment of the physician.

It is the responsibility of the prescriber and/or their office staff, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient.

The prescriber should refer to the Important Safety Information in the full Prescribing Information when determining whether the product is medically appropriate for a patient.

SAMPLE LETTER OF MEDICAL NECESSITY

Patient: _____
PATIENT NAME

Group/Policy Number: _____ Date(s) of service: _____
GROUP / POLICY NUMBER DATE(S) OF SERVICE

Diagnosis: _____
DIAGNOSIS CODE AND DESCRIPTION

Dear _____:
CONTACT NAME OR DEPARTMENT

I am writing on behalf of my patient, _____
PATIENT NAME

to _____
REQUEST PRIOR AUTHORIZATION/DOCUMENT MEDICAL NECESSITY

for treatment with KATERZIA® (amlodipine) Oral Suspension. KATERZIA® (amlodipine) is indicated for treatment of _____

_____ This letter serves to document
INDICATION STATEMENT

that _____ has a diagnosis of
PATIENT NAME

_____ and needs treatment with KATERZIA® (amlodipine) Oral Suspension. KATERZIA® (amlodipine) is medically necessary for
DIAGNOSIS / CODE

_____ as prescribed. On behalf of _____,
HIM/HER PATIENT NAME

I am requesting approval for use and subsequent payment for the treatment with KATERZIA® (amlodipine).

SUMMARY OF PATIENT MEDICAL HISTORY AND DIAGNOSIS

_____ is a _____-year-old _____.
PATIENT NAME AGE MALE/FEMALE

Diagnosed with _____
DIAGNOSIS

_____ has been in my care since _____.
PATIENT NAME DATE

As a result of _____
DIAGNOSIS

my patient _____
ENTER BRIEF DESCRIPTION OF PATIENT HISTORY AND RECENT PRESENTATION

In my professional opinion, _____'s likely prognosis without treatment with
PATIENT NAME

KATERZIA® (amlodipine), _____
PROVIDE SUMMARY OF MEDICAL OPINION

CLINICAL RATIONALE FOR KATERZIA® (AMLODIPINE) ORAL SUSPENSION

Given _____'s medical history, condition, and the supporting clinical
PATIENT NAME

information _____
ATTACHED SUPPORTING MEDICAL RECORDS, LABORATORY REPORTS, ETC.

I believe treatment of _____ with _____ is warranted,
PATIENT NAME PRODUCT

appropriate and medically necessary. KATERZIA® (amlodipine) is indicated for _____
DRUG INDICATION

The accompanying prescribing information provides the approved clinical information for KATERZIA® (amlodipine).

The plan of treatment is to start the patient on KATERZIA® (amlodipine), _____
PROVIDE TREATMENT COURSE

In summary, KATERZIA® (amlodipine) is medically necessary and reasonable for _____'s
PATIENT NAME

medical condition and warrants coverage. Please contact me at _____ if you require additional
PHYSICIAN TELEPHONE NUMBER

information about this case. Thank you for your prompt attention.

Sincerely,

PHYSICIAN NAME PHYSICIAN DEGREE

IMPORTANT SAFETY INFORMATION

KATERZIA® (amlodipine) Oral Suspension, 1 mg/mL

INDICATIONS

KATERZIA is a calcium channel blocker and may be used alone or in combination with other antihypertensive and antianginal agents for the treatment of:

- Hypertension in adults and children 6 years of age and older to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.
- Coronary Artery Disease:
 - Chronic Stable Angina
 - Vasospastic angina (Prinzmetal's or Variant Angina)
 - Angiographically documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%.

Important Limitation: Doses in excess of 5 mg daily have not been studied in pediatric patients.

*A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device. Ask your pharmacist or doctor for assistance in selecting a measuring device. **Shake well before using.***

ADDITIONAL IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

KATERZIA is contraindicated in patients with known sensitivity to amlodipine.

WARNINGS AND PRECAUTIONS:

Hypotension. Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. Because of the gradual onset of action, acute hypotension is unlikely.

Increased Angina or Myocardial Infarction. Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of KATERZIA, particularly in patients with severe obstructive coronary artery disease.

Patients with Hepatic Failure. Because KATERZIA is extensively metabolized by the liver and the plasma elimination half-life ($t_{1/2}$) is 56 hours in patients with impaired hepatic function, titrate slowly when administering KATERZIA to patients with severe hepatic impairment.

ADVERSE REACTIONS:

Most common adverse reaction to amlodipine is edema which occurred in a dose related manner. Other adverse experiences not dose related but reported with an incidence >1.0% are fatigue, nausea, abdominal pain, and somnolence.

These are not all the possible side effects of KATERZIA. Please see Full Prescribing Information for a full list.

DRUG INTERACTIONS:

Impact of Other Drugs on Amlodipine

Co-administration with CYP3A inhibitors (moderate and strong) results in increased systemic exposure to amlodipine and may require dose reduction. Monitor for symptoms of hypotension and edema when amlodipine is co-administered with CYP3A inhibitors to determine the need for dose adjustment. Blood pressure should be closely monitored when amlodipine is co-administered with CYP3A inducers.

Impact of Amlodipine on Other Drugs:

Co-administration of simvastatin with amlodipine increases the systemic exposure of simvastatin. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily.

Amlodipine may increase the systemic exposure of cyclosporine or tacrolimus when co-administered. Frequent monitoring of trough blood levels of cyclosporine and tacrolimus is recommended and adjust the dose when appropriate.

Please see Full Prescribing Information for a full list and Specific Drugs and Interactions.

USE IN SPECIFIC POPULATIONS:

Pregnancy: Limited data on post-marketing use of amlodipine in pregnant women are not sufficient to inform a drug-associated risk for major birth defects or miscarriages. There are risks to the mother and fetus associated with poorly controlled hypertension during pregnancy.

Lactation: Limited available data from a published clinical lactation study reports that amlodipine is present in human milk. No adverse effects of amlodipine on the breastfed infant have been observed.

Pediatric Use: Amlodipine (2.5 to 5 mg daily) is effective in lowering blood pressure in patients 6 to 17 years. The effect of amlodipine on blood pressure in patients less than 6 years of age is not known.

Geriatric Use: In general, dose selection for elderly patients should be cautious, usually starting with a lower initial dose.

Hepatic Impairment: A lower initial dose may be required for patients with hepatic insufficiency.

The Important Safety Information does not include all the information needed to use KATERZIA safely and effectively. Please see accompanying full Prescribing Information for KATERZIA.

To Report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.