Clinical Policy: Amlodipine/Atorvastatin (Caduet)

Reference Number: CP.PMN.176
Effective Date: 12.01.18
Last Review Date: 11.25
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Amlodipine/atorvastatin (Caduet®) is a combination of amlodipine, a calcium channel blocker, and atorvastatin, an HMG CoA-reductase inhibitor.

FDA Approved Indication(s)

Caduet is indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate.

Amlodipine is indicated for the treatment of:

- Hypertension, to lower blood pressure
- Coronary artery disease (CAD)
  - Symptomatic treatment of chronic stable angina
  - Treatment of confirmed or suspected vasospastic angina (Prinzmetal's or variant angina)
  - Angiographically documented CAD
    - To reduce the risk of hospitalization for angina and to reduce the risk of a coronary revascularization procedure in patients with recently documented CAD by angiography and without heart failure or an ejection fraction < 40%

Atorvastatin is indicated:

- To reduce the risk of:
  - Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD
  - MI and stroke in adults with type 2 diabetes with multiple risk factors for CHD but without clinically evident CHD
  - Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure (CHF), and angina in adults with clinically evident CHD
- As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in:
  - Adults with primary hyperlipidemia
  - Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)
- As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH)
- As an adjunct to diet for the treatment of adults with:
  - Primary dysbetalipoproteinemia
  - Hypertriglyceridemia

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Caduet is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. All FDA-Approved Indications (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, or d):
   a. Hypertension;
   b. Chronic stable angina;
   c. Confirmed or suspected vasospastic angina (Prinzmetal's or variant angina);
   d. CAD documented by angiography and without heart failure or an ejection fraction < 40%;
2. Diagnosis of hyperlipidemia or one of the diagnoses for which atorvastatin is FDA-approved;
3. Member must instead use the individual components (atorvastatin and amlodipine) concurrently, unless contraindicated to excipients or clinically significant adverse effects are experienced;
4. Failure to achieve National Cholesterol Education Program (NCEP) goals (*see Appendix D)* after a trial of at least one generic formulary statin (e.g., lovastatin, pravastatin, simvastatin, atorvastatin), followed by ezetimibe/simvastatin (Vytorin®) or rosuvastatin (Crestor®), unless clinically significant adverse effects are experienced or all are contraindicated;
5. Dose does not exceed (a and b):
   a. 80 mg per day of atorvastatin;
   b. 1 tablet per day.

Approval duration:
Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All FDA-Approved Indications (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a and b):
   a. 80 mg per day of atorvastatin;
   b. 1 tablet per day.

Approval duration:
Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CAD: coronary artery disease
CHD: coronary heart disease
CHF: congestive heart failure
FDA: Food and Drug Administration
HeFH: heterozygous familial hypercholesterolemia
HoFH: homozygous familial hypercholesterolemia

LDL: low-density lipoprotein cholesterol
MI: myocardial infarction
NCEP: National Cholesterol Education Program

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
atorvastatin (Lipitor®)	10 to 80 mg PO QD	80 mg/day
amlodipine (Norvasc®)	2.5 to 10 mg PO QD	10 mg/day
lovastatin (Mevacor®)	10 to 80 mg PO QD or BID	80 mg/day
pravastatin (Pravachol®)	10 to 80 mg PO QD	80 mg/day
simvastatin (Zocor®)	5 to 40 mg PO QD (Note: coverage of the 80 mg strength requires PA)	80 mg/day
ezetimibe/simvastatin (Vytorin®)	10/10 mg to 10/80 mg PO QD (Note: coverage of the 10/80 mg strength requires PA)	10/80 mg/day
rosuvastatin (Crestor®)	5 to 40 mg PO QD	40 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): acute liver disease or decompensated cirrhosis; hypersensitivity to amlodipine, atorvastatin, or any excipients in Caduet
- Boxed warning(s): none reported

Appendix D: NCEP Goals

Risk Category	LDL Goal
CHD or CHD risk equivalents (10-year risk* > 20%)	< 100 mg/dL
Multiple (2+) risk factors and 10-year risk* ≤ 20%	< 130 mg/dL
0 to 1 risk factor	< 160 mg/dL

**Refer to Framingham point scores for 10-year risk %*
*(*https://www.nhlbi.nih.gov/files/docs/guidelines/atglance.pdf*)*

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
For patients whom treatment with both amlodipine and atorvastatin is appropriate	Initial Adults: 2.5/10 mg PO QD Pediatrics (age 10 to 17 years): 2.5/10 mg PO QD	Adult: 10/80 mg/day Pediatric: 5/20 mg/day

VI. Product Availability

Tablets: 2.5/10 mg*, 2.5/20 mg*, 2.5/40 mg*, 5/10 mg, 5/20 mg, 5/40mg, 5/80 mg, 10/10 mg, 10/20 mg, 10/40 mg, 10/80 mg

**Available as generic product only*

VII. References

1. Caduet Prescribing Information. New York, NY: Pfizer, Inc.; November 2024. Available at: https://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=531. Accessed July 24, 2025.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2025. Available at: https://www.clinicalkey.com/pharmacology/. Accessed July 24, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: no significant changes; medical justification language revised to must use language per template; references reviewed and updated.	06.28.21	11.21
4Q 2022 annual review: modified approval duration from Length of Benefit to 12 months for Medicaid and 12 months or duration of request for Commercial; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.21.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	07.31.23	11.23
RT4: per updated PI, revised language in FDA Approved Indications section for atorvastatin (no change to criteria required) and updated contraindications in Appendix C (including removal of removed pregnancy/lactation contraindications).	05.29.24	
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.19.24	11.24
4Q 2025 annual review: no significant changes; references reviewed and updated.	07.10.25	11.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does

not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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