Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Atorvastatin (Lipitor®) is indicated for the treatment of hypercholesterolemia and the prevention of cardiovascular disease in individuals with multiple risk factors for coronary heart disease.

Amlodipine/atorvastatin (Caduet®) is indicated for the treatment of hypercholesterolemia and hypertension in individuals for whom treatment with both amlodipine and atorvastatin is appropriate.

The use of atorvastatin (Lipitor®) and amlodipine/atorvastatin (Caduet®) require prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Atorvastatin (Lipitor®) is an HMG-CoA reductase inhibitor. HMG-CoA reductase is the rate-limiting enzyme in de novo cholesterol synthesis. HMG-CoA reductase inhibitors are frequently used to reduce the levels of plasma total cholesterol and low-density lipoprotein (LDL) cholesterol in individuals with hypercholesterolemia. It is believed that HMG-CoA reductase inhibitors lower cholesterol levels by reducing the production of mevalonic acid, which results in the following:

- A reduction in hepatic cholesterol synthesis
- A compensatory increase in the expression of high-affinity LDL receptors on hepatocyte membranes
- Stimulation of LDL catabolism
Amlodipine/atorvastatin (Caduet®) is a combination of two drugs, a dihydropyridine calcium channel blocker (amlodipine) and an HMG-CoA reductase inhibitor (atorvastatin). The amlodipine component of amlodipine/atorvastatin (Caduet®) inhibits the transmembrane influx of calcium ions into vascular smooth muscles and cardiac muscle to cause a reduction in peripheral vascular resistance and a reduction in blood pressure.

**Policy Guideline Inclusion**

Atorvastatin (Lipitor®) or amlodipine/atorvastatin (Caduet®) is approved when all of the following inclusion criteria are met:

- Documentation of a minimum 30-day trial and failure or contraindication/intolerance/allergy to one of the following agents:
  - Lovastatin-containing product
  - Pravastatin-containing product
  - Simvastatin-containing product
- Documentation of a minimum 30-day trial and failure or contraindication/intolerance/allergy to rosvustatin calcium (Crestor®)

**Policy Guideline Exclusion**

Atorvastatin (Lipitor®) or amlodipine/atorvastatin (Caduet®) is denied when any of the following exclusion criteria are present:

- No documentation of a minimum 30-day trial and failure or contraindication/intolerance/allergy to one of the following agents:
  - Lovastatin-containing product
  - Pravastatin-containing product
  - Simvastatin-containing product
- No documentation of a minimum 30-day trial and failure or contraindication/intolerance/allergy to rosvustatin calcium (Crestor®)

**Policy List of Applicable Drugs**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caduet</td>
<td>amlodipine/atorvastatin</td>
</tr>
<tr>
<td>Lipitor</td>
<td>atorvastatin</td>
</tr>
</tbody>
</table>

**Dosing and Administration**

Refer to the specific manufacturer’s prescribing information for administration and dosage details for each specific agent.

**Policy References**


