ConnectiCare

Commercial/Healthcare Exchange PA Criteria

Effective: January 8, 2020

Prior Authorization: Simvastatin/Atorvastatin Oral Suspension

Products Affected: FloLipid (simvastatin) oral suspension, Simvastatin oral suspension, Atorvaliq suspension

Medication Description: Simvastatin is a prodrug and is hydrolyzed to its active β-hydroxyacid form, simvastatin acid, after administration. Simvastatin is a specific inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase, the enzyme that catalyzes the conversion of HMG-CoA to mevalonate, an early and rate limiting step in the biosynthetic pathway for cholesterol. In addition, simvastatin reduces VLDL and TG and increases HDL-C.

Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is indicated as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate. In patients with coronary heart disease (CHD) or at high risk of CHD, simvastatin can be started simultaneously with diet.

Covered Uses:

1. Reductions in risk of CHD mortality and cardiovascular events
2. Hyperlipidemia
3. To reduce to reduce total-C, LDL-C, and Apo B levels in adolescent boys and girls with heterozygous familial hypercholesterolemia

Exclusion Criteria:

1. Hypersensitivity to simvastatin (or atorvastatin)
2. Conditions where the major abnormality is elevation of chylomicrons (i.e., hyperlipidemia Fredrickson types I and V).
3. Concomitant administration of strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin, nefazodone, and cobicistat-containing products)
4. Concomitant administration of gemfibrozil, cyclosporine, or danazol
5. Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels
6. Women who are pregnant or may become pregnant
7. Nursing mothers

Required Medical Information:

1. Diagnosis
2. Previous therapies tried
3. Medical history

Age Restrictions:

Hyperlipidemia, Reductions in Risk of CHD Mortality and Cardiovascular Events: 18 years of age or older
Heterozygous familial hypercholesterolemia: 10 years of age and older

Prescriber Restrictions: None

Coverage Duration: 12 months

Other Criteria:

1. Reductions in Risk of CHD Mortality and Cardiovascular Events and Hyperlipidemia

A. Patient has a diagnosis of hyperlipidemia OR medication will be used to reduce the risk of CHD mortality and cardiovascular events; **AND**
B. Medication is being used as an adjunctive therapy to diet; **AND**
C. Patient has had a trial/failure with, intolerance, or contraindication to generic oral simvastatin tablets; **AND**
D. The patient is unable to ingest simvastatin oral tablets due to one of the following:
    a. Oral/motor difficulties; **OR**
    b. Dysphagia

2. Heterozygous familial hypercholesterolemia

A. Patient has a diagnosis of heterozygous familial hypercholesterolemia; **AND**
B. Patient is between 10-17 years old and are at least one year post-menarche; **AND**
C. Patient has had an adequate trial of diet therapy; **AND**
D. LDL cholesterol remains ≥190 mg/dL; **OR**
E. LDL cholesterol remains ≥160 mg/dL; **AND**
    a. There is a positive family history of premature cardiovascular disease (CVD); **OR**
    b. Two or more other CVD risk factors are present in the adolescent patient; AND
F. Patient has had a trial/failure with, intolerance, or contraindication to generic oral simvastatin tablets; **AND**
G. The patient is unable to ingest simvastatin oral tablets due to one of the following:
    a. Oral/motor difficulties; **OR**
    b. Dysphagia

References:

1. Product Information: simvastatin oral suspension, simvastatin oral suspension. Perrigo (per FDA), Minneapolis, MN, 2016.
2. Product Information: ATORVALIQ® oral suspension, atorvastatin calcium oral suspension. CMP Pharma Inc (per FDA), Farmville, NC, 2023

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/08/2020

2	Update Policy	Added Atorvaliq suspension to Products Affected, added hypersensitivity to atorvastatin to exclusion criteria, Changed prior authorization name from "simvastatin oral suspension" to "simvastatin/atorvastatin oral suspension"	Products Affected, Exclusion Criteria, Prior Authorization name	4/27/2023