SIMVASTATIN ORAL SUSPENSION

Generic	Brand	HICL	GCN	Exception/Other
SIMVASTATIN	FLOLIPID		41189 41192	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
   - Previous trial of or contraindication to simvastatin tablets
   - Prescriber documentation that the patient has dysphagia, difficulty swallowing tablets, or has a feeding tube (e.g., G-tube or J-tube)

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient also requesting a zero dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID with the following quantity limits (NOTE: Override the PA edit only, no change in copay):**
   - **Flolipid 20mg/5mL (GPID 41189): 150mL (#1 bottle) per 30 days.**
   - **Flolipid 40mg/5mL (GPID 41192): 150mL (#1 bottle) per 30 days.**

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GUIDELINES FOR USE (CONTINUED)

3. Is the patient between 40-75 years of age without a history of cardiovascular disease and has **NOT** used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on the patient's prescription claims profile or medical records?
   - Aspirin/dipyridamole (Aggrenox)
   - Clopidogrel (Plavix)
   - Dipyridamole
   - Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
   - Prasugrel (Effient)
   - Praluent Pen
   - Repatha
   - Ticagrelor (Brilinta)
   - Ticlopidine
   - Vorapaxar sulfate (Zontivity)

   If yes, **approve for 12 months by GPID at zero cost share with the following quantity limits (NOTE: Override the PA edit and update the copay amount field with ZERO copay):**
   - **Flolipid 20mg/5mL (GPID 41189): 150mL (#1 bottle) per 30 days.**
   - **Flolipid 40mg/5mL (GPID 41192): 150mL (#1 bottle) per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires that the patient had a previous trial of or contraindication to simvastatin tablets and prescriber documentation that the patient has dysphagia, difficulty swallowing tablets, or has a feeding tube (e.g., G-tube or J-tube).
Requests for zero dollar cost share also requires that the patient is between 40-75 years of age without a history of cardiovascular disease and has not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on the patient's prescription claims profile or medical records:
- Aspirin/dipyridamole (Aggrenox)
- Clopidogrel (Plavix)
- Dipyridamole
- Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
- Prasugrel (Effient)
- Praluent Pen
- Repatha
- Ticagrelor (Brilinta)
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RATIONALE

Ensure appropriate utilization of SIMVASTATIN ORAL SUSPENSION based on FDA approved indication and dosage.

ACA/EHB

In November 2016, the US Preventive Services Task Force (USPSTF) issued its final recommendations on statin use for the primary prevention of cardiovascular disease (CVD) in adults. CVD is a broad term that includes a number of conditions such as coronary heart disease and cerebrovascular disease, which ultimately manifest as heart attack and stroke, respectively. CVD is the leading cause of morbidity and mortality in the US, accounting for one out of every three deaths among adults.

Based on the well-established benefit of statin therapy in reducing the risk of CVD events and mortality, the USPSTF now recommends that adults without a history of CVD use a low- to moderate-dose statin for the primary prevention of CVD events and mortality when all of the following criteria are met (Grade B recommendation):
(1) Age 40 to 75 years
(2) One or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking)
(3) Calculated 10-year risk of a cardiovascular event of 10% or greater

Under the Affordable Care Act (ACA), plans are required to cover USPSTF preventive recommendations that have an A or B rating.

FDA APPROVED INDICATIONS

Flolipid is indicated as an adjunctive therapy to diet to:

- Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events.
- Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia.
- Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia.
- Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia.
- Reduce elevated total-C, LDL-C, and Apo B in boys and postmenarchal girls, 10 to 17 years of age with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.

- Limitations of Use Simvastatin has not been studied in Fredrickson Types I and V dyslipidemias.

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SIMVASTATIN ORAL SUSPENSION

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION
The usual dosage range of Flolipid is 5 to 40mg/day. Flolipid should be taken in the evening on an empty stomach. The recommended usual starting dose is 10 or 20mg once a day.

For patients at high risk for a CHD event due to existing CHD, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease, the recommended starting dose is 40 mg/day. It is recommended to use Flolipid 40 mg/5 mL for dosages greater than or equal to 40 mg.

Due to the increased risk of myopathy, including rhabdomyolysis, associated with an 80-mg dose of Flolipid, patients unable to achieve their LDL-C goal utilizing the 40-mg dose of FLOLIPID should not be titrated to an 80-mg dose, but should be placed on alternative LDL-C-lowering treatment(s) that provides greater LDL-C lowering.

DOSAGE FORMS AND STRENGTHS
- Flolipid is available in 150mL bottles in the following strengths: 20mg/5mL oral suspension and 40mg/5mL oral suspension

REFERENCES
- Flolipid [Prescribing Information]. Brooksville, FL: Salerno Pharmaceuticals LP; October 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18
Created: 03/18
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P&T Approval: 01/18