MEDICAL POLICY STATEMENT		
Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
02/12/2014	**05/15/2015**	**05/15/2014**
Author		
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CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

Hyperlipidemia Management Policy

- **Statins**
  - ***Lovastatin**** **(Mevacor)**
  - **Lovastatin ER (Altoprev)**
  - ***Pravastatin**** **(Pravachol)**
  - ***Fluvastatin**** **(Lescol)**
  - ***Fluvastatin ER*** **(Lescol XL)**
  - ***Simvastatin**** **(Zocor)**
  - ***Atorvastatin**** **(Lipitor)**
  - **Pitavastatin (Livalo)**
  - **Rosuvastatin (Crestor)**
- **Fibric acid derivatives**
  - **Fenofibrate (Fibricor)**
  - ***Fenofibric Acid**** **(Lofibra)**
  - ***Fenofibric Acid*** **(Tricor)**
  - **Fenofibric Acid (Antara, Fenoglide, Lipofen, Triglide)**
  - ***Choline Fenofibrate*** **(Trilipix)**
- **Niacin**
  - ***Inositol Niacinate*** **(HDL Benefit, Flush Free Niacin)***
  - ***Niacin*** **(Endur-Acin, Slo-Niacin)***
  - ***Niacin ER*** **(Niaspan ER)**
- **Bile acid sequestrants**
  - ***Cholestyramine**** **(Questran, Revalite)**
  - **Colesevelam (Welchol)**
  - ***Colestipol**** **(Colestid)**
- **Cholesterol absorption inhibitors**
  - **Ezetimibe (Zetia)**
- **Omega 3 Fatty Acids**
  - **Lovaza**
  - **Vascepa**
  - ***OTC (Over the Counter) Fish Oils****
- **Lipid Lowering Combination Products**
  - **Lovastatin/Niacin (Advicor)**

- **Atorvastatin/ Ezetimibe (Liptruzet)**
- **Atorvastatin/Amlodipine (Caduet)**
- **Simvastatin/Niacin (Simcor)**
- **Simvastatin/Ezetimibe (Vytorin)**
- **Simvastatin/Sitagliptan (Juvisync)**

Legend: * = formulary ***Italics = generically available***

B. BACKGROUND

AACE recommends a comprehensive strategy to control lipid levels and to address associated metabolic abnormalities and modifiable risk factors such as hypertension, diabetes, obesity, and cigarette smoking. The first-line approach to primary prevention in patients with lipid disorders involves the implementation of lifestyle changes, including physical activity and medical nutrition therapy. Treatment may also involve pharmacotherapy, as well as patient education programs, to promote further risk reduction through smoking cessation and weight loss.

2013 brought to light a new set of guidelines from the American College of Cardiology/American Heart Association. The goals of the American College of Cardiology (ACC) and the American Heart Association (AHA) are to prevent cardiovascular (CV) diseases, improve the management of people who have these diseases through professional education and research, and develop guidelines, standards and policies that promote optimal patient care and cardiovascular health. Toward these objectives, the ACC and AHA have collaborated with the National Heart, Lung, and Blood Institute (NHLBI) and stakeholder and professional organizations to develop clinical practice guidelines for assessment of CV risk, lifestyle modifications to reduce CV risk, and management of blood cholesterol, overweight and obesity in adults.

These recommendations arose from careful consideration of an extensive body of higher quality evidence derived from RCTs and systematic reviews and meta-analyses of RCTs. Rather than LDL–C or non-HDL– C targets, this guideline used the intensity of statin therapy as the goal of treatment. Through a rigorous process, 4 groups of individuals were identified for whom an extensive body of RCT evidence demonstrated a reduction in ASCVD events with a good margin of safety from moderate- or high-intensity statin therapy:

4 Statin Benefit Groups:

1. Individuals with clinical ASCVD
2. Individuals with primary elevations of LDL–C ≥190 mg/dL
3. Individuals 40 to 75 years of age with diabetes and LDL–C 70 to189 mg/dL without clinical ASCVD
4. Individuals without clinical ASCVD or diabetes who are 40 to 75 years of age with LDL–C 70 to 189 mg/dL and have an estimated 10-year ASCVD risk of 7.5% or higher

Most importantly, our focus is on those individuals most likely to benefit from evidence-based statin therapy to reduce ASCVD risk. Implementation of these ASCVD risk reduction guidelines will help to substantially address the large burden of fatal and nonfatal ASCVD in the United States.

The patient selection criteria outlined was derived from the FDA-approved prescribing information for each of the above listed medication and the studies that were presented to the FDA in support of the pre-market approval application, and studies in the peer-reviewed published medical literature. CareSource also evaluated and took recommendations from the current guidelines presented by the American Association of Clinical Endocrinologists. The FDA label indication found in the manufacturer prescribing information and described below is hypercholesterolemia and hypertriglyceridemia. Coverage decisions for conditions other than the above FDA approved indications will be reviewed on a case by case basis if proven effective through research documentation. The requesting provider will need to support his exception request with the appropriate literature.

C. POLICY

CareSource will approve the use of **the lipid lower agents listed above** and consider their use as medically necessary when the following criteria have been met for:

Hypercholesterolemia and Hypertriglyceridemia

Requests for other uses should be reviewed using CareSource Policy for Off-Label Use and Excluded Indications.

Statins

Statins are indicated for the treatment of adult patients (age 18 years and older) with primary hypercholesterolemia and mixed dyslipidemia.

Prior Authorization Criteria:

- Failure of a 90 day trial of atorvastatin or simvastatin

Fibric Acid Derivatives

Fibric Acid Derivatives are indicated for the treatment of adult patients (age 18 years and older) with hypercholesterolemia and hypertriglyceridemia.

Prior Authorization Criteria:

- Failure of a 90 day trial of atorvastatin or simvastatin or an intolerance or allergy to atorvastatin or simvastatin
  AND
- A 90 day trial of fenofibrate (Lofibra)
  AND
- A Clinical reason (supported by chart notes) why the non-formulary product would be effective

Niacin

Niacins are indicated for the treatment of adult patients (age 18 years and older) with hypercholesterolemia and hypertriglyceridemia

Prior Authorization Criteria:

- Failure of a 90 day trial of atorvastatin or simvastatin or an intolerance or allergy to atorvastatin or simvastatin
  AND
- A 90 day trial of OTC Niacin
  AND
- A Clinical reason (supported by chart notes) why the non-formulary product would be effective

Bile Acid Sequestrants

Bile Acid Sequestrants are indicated for the treatment of adult patients (age 18 years and older) with hypercholesterolemia and hypertriglyceridemia.

Prior Authorization Criteria:

- Failure of a 90 day trial of atorvastatin or simvastatin or an intolerance or allergy to atorvastatin or simvastatin
  AND

- Failure of a 90 day trial of colestipol or cholestyramine
  OR
- Unable to tolerate or has a medical contraindication to colestipol or cholestyramine

Cholesterol Absorption Inhibitors

Cholesterol Absorption Inhibitors are indicated for the treatment of adult patients (age 18 and up) with hypercholesterolemia.

Prior Authorization Criteria:

- Failure of a 90 day trial of atorvastatin, simvastatin or fenofibrate (Lofibra)
  OR
- Unable to tolerate or has a medical contraindication to atorvastatin, simvastatin AND fenofibrate (Lofibra)

Omega 3 Fatty Acids

Omega 3 Fatty Acids are indicated for the treatment of adult patients (age 18 years and older) with hypertriglyceridemia.

Prior Authorization Criteria:

- Failure of a 90 day trial of atorvastatin or simvastatin or an intolerance or allergy to atorvastatin or simvastatin
  AND
- 90 day trial of OTC Fish Oils
  AND
- A Clinical reason (supported by chart notes) why the non-formulary product would be effective
  OR
- Total Triglyceride level of greater than or equal to 500 mg/dL

Lipid Lowering Combination Products

Lipid lowering combination products are indicated for the treatment of adult patients (age 18 years and older) with hypertriglyceridemia/hyperlipidemia.

Prior Authorization Criteria:

- Failure of a 90 day trial of the ingredients separately if formulary; if non-formulary must trial the formulary preferreds per that drugs requirements
  AND
- A Clinical reason (supported by chart notes) why the non-formulary combination product would be effective

Note: Documented diagnosis and other therapies tried must be supplied on the prior authorization request form to be considered for approval.

Drug class	Drug Names	↓ LDL	↓ Trig	↑ HDL
HMG-CoA reductase inhibitors (statins)	lovastatin, pravastatin, fluvastatin, simvastatin, atorvastatin, rosuvastatin, pitavastatin	21%-55%	6%-30%	2%-10%
Fibric acid derivatives	gemfibrozil, fenofibrate, fenofibric acid	20%-25% (fenofibrate)	20%-35%	6%-18%
Niacin	nicotinic acid	10%-25%	20%-30%	10%-35%
Bile acid sequestrants	cholestyramine, colestipol, colesevelam hydrochloride	15%-25%	May ↑ serum TG	
Cholesterol absorption inhibitors	ezetimibe	10%-18%		

Conditions of Coverage

Quantity Limitations	Per package inserts and UFF
Authorization Period	Approved authorizations are valid for 12 months. Continued treatment may be considered when the member has shown biological response to treatment. ALL authorizations are subject to continued eligibility.
Data Required on Request	Diagnosis Treatment Failures

D. REVIEW / REVISION HISTORY

/ /

E. REFERENCES

Facts and Comparison: http://online.factsandcomparisons.com/index.aspx

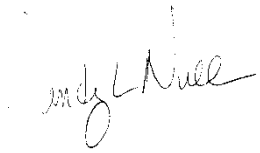
2013 ACC/AHA Guideline on treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. published online November 12, 2013; Circulation.

Statement by the American Association of Clinical Endocrinologists' Guidelines for Management of Dyslipidemia and Prevention of Atherosclerosis. Endocrine Practive Vol 18 (Suppl 1) March/April 2012

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

5/20/2014

Chief Medical Officer **Date**



5/20/2014

Director of Pharmacy Operations **Date**