MEDICAL POLICY STATEMENT		
Original Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
7/29/2013	**9/26/2015**	**9/26/2014**
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CareSource

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

Cholesterol Lowering Agents for Homozygous Familial Hypercholesterolemia

- Mipomersen (Kynamro)
- Lomitapide (Juxtapid)

B. Background

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the Homozygous Familial Hypercholesterolemia (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and may also encourage the use of preferred agents.

C. POLICY

CareSource may consider all agents medically necessary when all of the following Prior Authorization Criteria are met:

- Documented diagnosis of Homozygous Familial Hypercholesterolemia
- Failure to reach target LDL on a trial of maximum dose simvastatin, atorvastatin; or Crestor (rosuvastatin)
  OR
- If intolerant to statins; then failure to reach target LDL on fenofibrate, colestipol, or other approved non-formulary LDL lowering medication

Note: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not be limited to, test reports, chart notes from provider's office, or hospital admission notes.

All other uses of Kynamro and Juxtapid **are considered experimental/investigational and therefore, will follow CareSource's off label policy.**

Refer to the product package insert for dosing, administration and safety guidelines.

For Medicare

Please refer to the CareSource policy
National and Local Coverage Determinations

Conditions of Coverage

J-Code	NA
Place Of Service	Office, Outpatient, Home *****Preferred place of service is in the home*.** This medication can be self-administered and can be billed through the pharmacy benefit. **Note:** CareSource supports administering inject able medications in various setting, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.
Authorization Period	Approved initial authorizations are valid for 3 months. Continued treatment may be considered when the member has shown biological response to treatment. A reauthorization after successful initiation period will be placed for 1 year. ALL authorizations are subject to continued eligibility.

D. REVIEW / REVISION HISTORY

E. REFERENCES

1 . Kynamro [package insert]. Cambridge, MA: Genzyme Corporation; January 2013.

2. Juxtapid [package insert]. Cambridge, MA: Aegerion Pharmaceuticals; May 2014.

3. Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2014.

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

9/30/2014

Chief Medical Officer **Date**

9/26/2014

Pharmacy Director **Date**