MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
07/29/2013	09/26/2016	10/20/2015
Policy Name		**Policy Number**
Biologic Cholesterol Agents		**SRX-0027**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that 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. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Cholesterol Agents for Homozygous or Heterozygous Familial Hypercholesterolemia

- **Kynamro (mipomersen)**
- **Juxtapid (lomitapide)**
- **Repatha (evolocumab)**
- **Praluent (alirocumab)**

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 Familial Hypercholesterolemia and clinical atherosclerotic cardiovascular disease 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. DEFINITIONS

- **FH**- Familial Hypercholesterolemia

D. POLICY

I. Medications used to treat **Homozygous or Heterozygous Familial Hypercholesterolemia** must meet **ALL** the following in addition to the drug specific criteria:
   A. Prescribed by a cardiologist, gastroenterologist or lipid specialist
   B. Requested medication will be used in conjunction with Crestor or Lipitor
   C. Patient is on a low fat diet

   AND has **one** of the following diagnoses:
   D. Patient has a diagnosis of **Homozygous** Familial Hypercholesterolemia (HoFH) confirmed by **1 (one)** of the following:
      1. Two mutations in a single or 1 mutation in 2 separate PCSK9, LDLR, LDLRAP or APOB genes
      2. Patient has untreated LDL-C > 500mg/dL and **1 (one) or more** of the following:
         2.1 Tendinous and/or cutaneous xanthoma prior to age 10 years
         2.2 Documentation of elevated LDL-C > 190mg/dL prior to lipid-lowering therapy consistent with HeFH in both parents
         2.3 In case a parent was not available, a history of coronary artery disease in a first degree male relative of the parent younger than 55 years or first degree female relative of the parent younger than 60 years
   E. Patient has a confirmed diagnosis of **Heterozygous** Familial Hypercholesterolemia (HeFH) by **1 (one) or more** of the following:
      1. Single mutation in the PCSK9, LDLR, LDLRAP or APOB gene
      2. Patient has a score of 9 or greater on the WHO/Dutch Lipid Network Criteria

II. Kynamro (mipomersen) is considered **medically necessary** when **ALL** of the following criteria are met:
   A. Patient is 12 years of age or older, has diagnosis of and meets criteria under the Homozygous Familial Hypercholesterolemia

III. Juxtapid (lomitapide) is considered **medically necessary** when **ALL** of the following criteria are met:
   A. Patient is 18 years of age or older, has a diagnosis of and meets the criteria under Homozygous Familial Hypercholesterolemia

IV. Repatha (evolocumab) is considered **medically necessary** when **1 (one)** of the following criteria is met:
   A. Patient is 18 years of age or older, has a diagnosis of and meets the criteria under Heterozygous Familial Hypercholesterolemia

V. Praluent (alirocumab) is considered **medically necessary** when **ALL** of the following criteria are met:
   A. Patient is 18 years of age or older, has a diagnosis of and meets criteria under Heterozygous Familial Hypercholesterolemia

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 a prior authorization request. These medical records may include, but are not limited to, test reports, chart notes from provider's office, or hospital admission notes.

ALL other uses of Kynamro, Juxtapid, Repatha and Praluent 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.

CONDITIONS OF COVERAGE
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.

HCPCS
CPT

Step Therapy
Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

AUTHORIZATION PERIOD
Approved initial authorizations are valid for 3 (three) months. Continued treatment may be considered when the member has shown biological response to treatment and there is documentation that the member has been adherent to the requested medication and with a statin and as demonstrated by consistent pharmacy claims. A reauthorization after successful initiation period will be placed for 1 (one) year. **ALL** authorizations are subject to continued eligibility.

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued:	07/29/2013
Date Reviewed:	07/29/2013, 09/26/2014, 07/26/2015
Date Revised:	09/26/2014, 07/26/2015 10/20/2015 – Add Repatha & Praluent to policy, new format, statin intolerance defined, additional step therapy for Juxatpid and Kynamro

G. 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, 2014. http://www.factsandcomparisons.com
4. Add Repatha package insert when available
5. Praluent [package insert]. Bridgewater, NJ: Regeneron Pharmaceuticals; April 2015.
6. Pijlman AH, Huijgen R, Verhagen SN, et al. Evaluation of cholesterol lowering treatment of patients with familial hypercholesterolemia: a large cross-sectional study in The Netherlands. Atherosclerosis.;209: 189-194.
7. National Lipid Association Annual Summary of Clinical Lipidology 2015
8. Homozygous familial hypercholesterolemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolemia of the European Atherosclerosis Society
9. Identification and management of familial hypercholesterolemia NICE guidelines

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

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

Independent Review – October 2015