

Market Applicability/Effective Date													
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Kynamro (mipomersen)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Kynamro (mipomersen)	1 prefilled syringe per week

APPROVAL CRITERIA

Requests for Kynamro (mipomersen) may be approved based on the following criteria:

- I. Individual is 18 years of age or older and has a clinical diagnosis of Homozygous Familial Hypercholesterolemia (HoFH), based on the presence of the following:
 - a. Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus; **OR**
 - b. One of the following:
 - i. An untreated LDL-cholesterol concentration > 500 mg/dL (13 mmol/L); **OR**
 - ii. Treated LDL-cholesterol \geq 300 mg/dL (7.76 mmol/L) **AND** one of the following:
 1. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
 2. Untreated LDL cholesterol levels consistent with heterozygous FH in both parents (> 190 mg/dL)

AND

- II. Individual has had an adequate trial and titration of Repatha or Repatha Pushtronex and achieved suboptimal lipid lowering response, despite at least 90 days of compliant therapy.

Kynamro (mipomersen) may **not** be approved for the following:

- I. Concurrent use with PCSK-9 Inhibitors; **OR**
- II. Individual with moderate or severe hepatic impairment (Child-Pugh B or C) or active liver disease.

Note: Kynamro is not indicated for the use with LDL apheresis. Kynamro (mipomersen sodium) has a black box warning for risk of hepatotoxicity. Kynamro can cause elevations in

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transaminases. Kynamro also increases hepatic fat (hepatic steatosis) with or without concomitant increases in transaminases. Because of the risk of hepatotoxicity, Kynamro is only available through a restricted program, Kynamro REMS.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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