Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Kynamro (mipomersen)

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

Medications	Quantity Limit
Kynamro (mipomersen)	May be subject to quantity limit

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 diagnosis of homozygous familial hypercholesterolemia (HoFH), based on the presence of the following (Cuchel 2014, Singh 2015):

   A. Genetic confirmation of two mutant alleles at the LDL receptor, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene locus; **OR**
   B. One of the following:
      1. An untreated LDL-cholesterol (LDL-C) concentration greater than 500 mg/dL (13 mmol/L); **OR**
      2. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) **AND** one of the following:
         a. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
         b. Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL);

AND

II. Individual has had an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and titration of Repatha or Repatha Pushtronex and achieved suboptimal lipid lowering response, despite at least 90 days of compliant therapy (AACE 2017).

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.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Note: Kynamro (mipomersen sodium) has a black box warning for risk of hepatotoxicity. Kynamro can cause elevations in 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 restricted distribution REMS programs.

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

Key References:

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4. Grundy SM, Stone NJ, Bailey AL, et. al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. J Am Coll Cardiol. 2018. https://doi.org/10.1016/j.jacc.2018.11.003.
5. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. Endocr Pract. 2017;23(Suppl 2):1-87.
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7. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Overview. Last updated: April 15, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 10, 2019.
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9. Singh S, Bittner V. Familial hypercholesterolemia--epidemiology, diagnosis, and screening. Curr Atheroscler Rep. 2015; 17(2):482.