Kynamro® (mipomersen sodium)
Effective 02/01/2022

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Kynamro® (mipomersen sodium) is an antihyperlipidemic medication used as adjunct to dietary therapy and other lipid-lowering treatments to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol non-HDL-C in patients with homozygous familial hypercholesterolemia (HoFH).

Kynamro® (mipomersen sodium) is indicated for HoFH confirmed by laboratory testing confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutation, PCSK9 mutations and familial defective apo B mutations.

Coverage Guidelines

Authorization may be granted for members with homozygous familial hypercholesterolemia (HoFH) who are new to the plan when ALL the following criteria are met:

OR

Authorization may be granted for members with homozygous familial hypercholesterolemia (HoFH) when ALL the following criteria are met:

1. Member is ≥ 18 years of age.
2. Member is adherent to a low-fat diet (< 20% of energy supplied by dietary fat intake).
3. Member has had a documented side-effect, allergy, inadequate response, treatment failure, or contraindication to treatment with a high potency HMG Co-A reductase inhibitor (e.g., statin), including atorvastatin or rosuvastatin used in combination with ezetimibe, a fibric acid derivative, and/or cholestyramine.
4. Member has had an inadequate response, treatment failure, or has a contraindication to lipid apheresis therapy.

5. Member has had an inadequate response, treatment failure, or has a contraindication with a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor (i.e., Praluent or Repatha).
6. Note: **If female**, patient has had a negative pregnancy test prior to initiation of treatment with Kynamro®.

Limitations

1. Initial authorizations will be approved for 3 months.
2. Reauthorizations will be approved for 12 months.
3. The following quantity limits apply:

Kynamro 200mg/mL	4 syringes per 28 days

References

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4. Cuchel, M, Bruckert, E, Ginsberg, H.N. et al. Homozygous familial hypercholesterolemia: new insights for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolemia of the European Atherosclerosis Society. Eur Heart J. 2014; 35: 2146–2157.
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10. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in Adults: A report of the American College of Cardiology/American Heart Association. Circulation. 2013. Available at:

http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf+html. Accessed November 9, 2014.
11. 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. [PubMed 28437620] 10.4158/EP171764.APPGL
12. 5. Jacobson TA, Ito MK, Maki KC, et al. National lipid association recommendations for patient-centered management of dyslipidemia: part 1--full report. *J Clin Lipidol*. 2015;9(2):129-169. [PubMed 25911072] 10.1016/j.jacl.2015.02.003
13. Visser ME, Witztum JL, Stroes ES, et al. Antisense oligonucleotides for the treatment of dyslipidemia. Eur Heart J. 2012 Jun;33(12):1451-8. doi: 10.1093/eurheartj/ehs084. Epub 2012 May 24.

Review History

02/26/2018 – Reviewed
06/01/2018 – Effective
11/26/2018 – Reviewed
01/22/2020 – Updated approval durations
09/22/2021 – Reviewed at September P&T; removed diagnosis and age requirement for new members currently on Kynamro; references updated. Effective 02/01/2022.
09/21/2022 - Reviewed at Sept P&T; no clinical changes; Separated out Comm/Exch vs. MH

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