Mass General Brigham
Health Plan

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

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
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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5. Goldberg AC, Hopkins PN, Toth PP, et al. Familial hypercholesterolemia: screening, diagnosis and management of pediatric and adult patients: clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. J Clin Lipidol. 2011;5(3 Suppl): S1-S8.
6. Grundy SM, Coleman JI, Merz NB, et al. Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. Circulation. 2004; 110:227-39.
7. Hayes E. Genzyme/Isis Gear Up for Long-awaited KYNAMRO launch. The Pink Sheet Daily. January 30, 2013. Available by subscription at http://www.elsevierbi.com/Publications/The-Pink-Sheet-Daily/2013/1/30/GenzymeIsis-Gear-Up-For-Longawaited- em Kynamroem-Launch?result=3&total=142&searchquery=%253fq%253dmipomersen. Accessed January 30, 2013.
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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.
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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.