Kynamro® (mipomersen sodium)
Effective 11/26/18

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 apoB mutations.

Coverage Guidelines

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

1. Member is ≥ 18 years of age.
2. Member has already been started and stabilized on Kynamro®.

OR

Authorization may be granted when the following criteria are met:

- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH **AND**
- Patient is ≥ 18 years of age **AND**
- Patient is new to AllWays Health Partners and has already been started and stabilized on Kynamro®
  OR
- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
- Patient is ≥ 18 years of age **AND**
- Patient is adherent to a low-fat diet (< 20% of energy supplied by dietary fat intake) **AND**

- Patient 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 **AND**
- Patient has had an inadequate response, treatment failure, or has a contraindication to lipid apheresis therapy **AND**
- Patient 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)
- If female, patient has had a negative pregnancy test prior to initiation of treatment with Kynamro®

Limitations

1. A quantity limit of 4 syringes per 28 days applies.

References

1. Kynamro (mipomersen) [prescribing information]. Cambridge, MA: Genzyme Corporation; December 2016.
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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

02/26/18 – Reviewed
06/01/18 – Effective
11/26/18 – Reviewed

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.