

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

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| Plan | <input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX) | | <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| 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 AllWays Health Partners 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:

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| Kynamro 200mg/mL | 4 syringes per 28 days |
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References

1. Kynamro (mipomersen) [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2019.
2. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al; Writing Committee. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol*. 2016;68(1):92-125.[PubMed 27046161]
3. Akdim F, Visser ME, Tribble DL, et al. Effect of mipomersen, an apolipoprotein B synthesis inhibitor, on low-density lipoprotein cholesterol in patients with familial hypercholesterolemia. *Am J Cardiol*. 2010 May 15;105(10):1413-9. doi: 10.1016/j.amjcard.2010.01.003.
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.
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-Long-awaited-em-Kynamroem-Launch?result=3&total=142&searchquery=%253fq%253dmipomersen>. Accessed January 30, 2013.
8. Raal FJ, Santos RD, Blom DJ, et al. Mipomersen, an apolipoprotein B synthesis inhibitor, for lowering of LDL cholesterol concentrations in patients with homozygous familial hypercholesterolemia: a randomized, double-blind, placebo-controlled trial. *Lancet*. 2010 Mar 20;375(9719):998-1006. doi: 10.1016/S0140-6736(10)60284-X.
9. Raal FJ, Santos RD. Homozygous familial hypercholesterolemia: current perspectives on diagnosis and treatment. *Atherosclerosis*. 2012 Aug;223(2):262-8.
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.

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.