

STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service Prior Authorization Criteria

KYNAMRO® (mipomersen)

Effective 1/01/2018

Prior Authorization Request Form

KYNAMRO is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non-HDL-C) in patients with with homozygous familial hypercholesterolemia (HoFH).

CRITERIA FOR APPROVAL

- 1) Diagnosis of Homozygous familial hypercholesterolemia (HoFH); AND
- 2) Prescriber must be enrolled in the Kynamro REMS program; AND
- 3) Patient has had a minimum 8-week trial of Repatha, used in combination with other lipid-lowering therapies; **AND**
- Patient is currently receiving other lipid-lowering therapies (low-fat diet, apheresis, and lipid lowering agents including HMG-CoA inhibitors at the maximum tolerable dose);
 AND
- 5) Measurement of ALT, AST, alkaline phosphatase and bilirubin before initiation of therapy and every month during the first twelve (12) months of therapy. After the first year, all levels must be measured every three (3) months. Lipid levels (total cholesterol [C], LDL-C, HDL-C, triglycerides) should be monitored and documented at least every 3 months for the first year.

REFERENCES

- 1) Lexicomp monograph on Kynamro reviewed 11/12/2017
- 2) Package Insert for Kynamro (rev 5/2016)
- 3) UpToDate Monograph: Familial hypercholesterolemia in adults: Treatment