Mass General Brigham
Health Plan

Evkeeza ® (evinacumab-dgnb)
Effective 11/01/2021

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
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
Evkeeza is indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH).

Coverage Guidelines
Authorization may be reviewed for members new to the plan who are currently receiving treatment with Evkeeza excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Documented diagnosis of homozygous familial hypercholesterolemia confirmed by ONE of the following:
    a. Laboratory test confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutations
    b. PCSK9 mutations
    c. Familial defective apoB mutations
2. Member has a current LDL-C level of at least 70 mg/dL
3. Provider is a specialist or being used in collaboration with a specialist (e.g. cardiologist, endocrinologist, lipid lowering specialist, vascular neurologist)
4. Member meets ONE of the following:
    a. Paid claims or provider documentation that Evkeeza is being used as add-on therapy with a high intensity statin, ezetimibe, and PSCK9 inhibitor
    b. Contraindication or other compelling clinical rationale for omitting one or more of the following high intensity statin, ezetimibe, and PSCK9 inhibitor
5. Member's current weight
6. Age $\geq$ 12 years of age

Continuation of Therapy

Reauthorization will be granted when provider documents the following authorization criteria:

1. Member has achieved or maintained an LDL-C reduction (i.e., LDL-C is now at goal or 40% reduction of LDL-C from baseline)
2. Member meets ONE of the following:
    a. Paid claims or provider documentation addressing adherence with a high intensity statin, ezetimibe, and PSCK9 inhibitor
    b. Contraindication or other compelling clinical rationale for omitting one or more of the following high intensity statin, ezetimibe, and PSCK9 inhibitor

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months

References

1. Evkeeza [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals Inc.; February 2021.
2. Raal FJ, Rosenson RS, Reeskamp LF, et al. Evinacumab for homozygous familial hypercholesterolemia. N Engl J Med. 2020;383:711-20. DOI: 10.1056/NEJMoa2004215.
3. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35:2146-2157.
4. Grundy SM, Stone NJ, Bailey, AL, Beam C, Birtcher KK, Blumenthal RS, Braun LT, de Ferranti S, Faiella-Tommasino J, Forman DE, Goldberg R, Heidenreich PA, Hlatky MA, Jones DW, Lloyd-Jones D, Lopez-Pajares N, Ndumele CE, Orringer CE, Peralta CA, Saseen JJ, Smith SC Jr, Sperling L, Virani SS, Yeboah J. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/ APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019;139:e1082– e1143. DOI: 10.1161/CIR.0000000000000625.

Review History

09/22/2021 – Created and Reviewed for Sept P&T. Effective 11/01/2021.