Pharmacy Drug Policy & Procedure

Policy Name:	Evkeeza (evinacumab)	Policy #:	2837P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Evkeeza (evinacumab) for the treatment of homozygous familial hypercholesterolemia.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Evkeeza (evinacumab) under the Specialty Medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Homozygous Familial Hypercholesterolemia (HoFH)

1.1 Documented diagnosis of Homozygous Familial Hypercholesterolemia, confirmed by gene mutations or a supported clinical diagnostic tool
- Defined as hyperlipidemia due to a genetic or inherited condition that causes high levels of LDL, or "bad" cholesterol

1.2 Documentation of ACC/AHA 10-year risk calculation of 7.5% or greater

1.3 LDL cholesterol level greater than 100mg/dL within the last 30 days

1.4 Age 5 years or older

1.5 Ordered by or in consultation with a cardiologist (doctor of the heart and blood vessels), endocrinologist (hormone doctor), or lipid specialist, to be used in combination with a low-fat diet and exercise

1.6 Member is currently taking a statin drug at the highest tolerated dose, plus ezetimibe, plus a PCSK9 inhibitor (Praluent or Repatha) for at least 90 days, but has not had adequate lipid-lowering response
- Defined as an *inability* to decrease LDL level by 50% with claims history showing that member has filled at least 150 days of all medications in the last 6 months, OR
- Defined as an *ability* to decrease the LDL level by 50% or more, but the member still does not reach the target LDL goal with claims history showing that member has filled at least 150 days of all medications in the last 6 months

1.7 Documented intolerance to statin therapy (defined as severe myalgias/muscle aches and/or creatine kinase levels greater than 10 times the upper limit of the lab reference range)

1.8 Request for coverage is reviewed by both a pharmacist and medical director

2. FDA-Approved Dosing

2.1 Dose: 15 mg/kg every 4 weeks

3. Approval Period

3.1 Initial approval: 12 months

3.2 Subsequent approvals: 12 months based on positive response to therapy

CPT Codes

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug

HCPCS Codes	
J1305	Injection, evinacumab-dgnb, 5mg

References

1. Evkeeza (evinacumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; March 2023.
2. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/ AGS/ APhA/ASPC/NLA/PCNA Guideline on theManagement of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019 Jun 25;73(24):e285- e350.
3. American College of Cardiology Solution Set Oversight Committee 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. J Am Coll Cardiol. 2022 Oct 4;80(14):1366-1418

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