

evinacumab-dgnb (Evkeeza)

HCPs: J1305 - Injection, evinacumab-dgnb, 5 mg (Evkeeza)

LOB:	MCAL
Duration of Approval:	New: Six months; COC: One year
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	Yes
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Evkeeza (evinacumab) injection

PA CRITERIA FOR APPROVAL:**New Therapy**

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
 2. The medication was prescribed by a cardiologist, endocrinologist or lipidologist **AND**
 3. Diagnosis of homozygous familial hypercholesterolemia (HoFH) is confirmed by **ONE** of the following (**a or b**):
 - a. Genetic confirmation of two mutant alleles in the low-density lipoprotein receptor (LDLR), Apo-B, PCSK9 or LDLRAP1 gene locus
 - b. Untreated LDL level > 400 mg/dL or treated LDL level $\geq$ 300 mg/dL **AND** meets **ONE** of the following (**1 or 2**):
 - 1) Cutaneous or tendon xanthomas before age of 10 years
 - 2) Untreated elevated LDL-C levels consistent with heterozygous FH (HeFH) in both parents (LDL > 190 mg/dL)
- AND**
4. The member has tried **ALL** the following for at least three months and has treatment failure (defined as LDL $\geq$ 100 mg/dL **OR** $\geq$ 70 mg/dL for patients with atherosclerotic cardiovascular disease [ASCVD]):
 - a. Maximally tolerated dose of high intensity statin therapy (e.g., atorvastatin $\geq$ 40 mg, rosuvastatin $\geq$ 20 mg or simvastatin $\geq$ 40 mg) **OR** member is statin intolerant (see below)
 - b. Ezetimibe
 - c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha, Praluent)
- AND**
5. Evkeeza will be used in conjunction with other LDL-lowering therapies (e.g., statins, ezetimibe, PCSK9 inhibitors, LDL apheresis)

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or AHFS) indication **AND**
2. Documentation is provided showing positive response to therapy, such as > 20% reduction of LDL from baseline **AND**
3. The member will continue to use Evkeeza in conjunction with other LDL-lowering therapies (e.g., statins, ezetimibe, PCSK9 inhibitors, LDL apheresis)

OTHER INFORMATION:Statin intolerance is defined as any of the following:

- Adverse effects to any two statins (at least one at the lowest dose) such as myositis/myopathy (with creatine kinase above 10x upper limit of normal [ULN]) or persistent elevation of hepatic transaminase (alanine aminotransferase [ALT] or aspartate aminotransferase [AST] 3x above the ULN)

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- History of statin-associated rhabdomyolysis **OR** immune-mediated necrotizing myopathy (presence of 3-hydroxy-3-methylglutaryl-coenzyme [HMG-CoA] reductase antibodies) to any one statin

Note: Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the ULN), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a 0.5 mg/dL or more increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine])

HCPCS	Description	Brand name
J1305	Injection, evinacumab-dgnb, 5 mg	Evkeeza

REFERENCES:

1. Evkeeza Prescribing Information: www.regeneron.com/downloads/evkeeza_pi.pdf. 09/2025.
2. Regeneron Pharmaceuticals. Efficacy and Safety of Evinacumab in Patients with Homozygous Familial Hypercholesterolemia. cdn.clinicaltrials.gov/large-docs/86/NCT03399786/Prot_000.pdf. NLM Identifier: NCT03399786.
3. Cuchel M, Raal FJ, Hegele RA, et al. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023;44(25):2277-2291. www.ncbi.nlm.nih.gov/pmc/articles/PMC10314327/pdf/ehad197.pdf