

GCHP Medi-Cal Clinical Guidelines Evinacumab (Evkeeza™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	Homozygous familial hypercholesterolemia (HoFH), adjunct.
Exclusion Criteria	<ul style="list-style-type: none"> • Pregnancy. • Other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia.
Required Medical Information	<p>Must meet ALL of the following:</p> <ul style="list-style-type: none"> • Diagnosis of HoFH confirmed by at least one of the following: <ul style="list-style-type: none"> ○ Genetic testing showing mutations of pathogenic variants of the low-density lipoprotein receptor (LDL-R) gene, or pathogenic variants of the apolipoprotein (ApoB) gene, or homozygous mutations in the LDL-R adaptor protein-1. ○ Very high LDL-C (greater than 500 mg/dL untreated or greater than 300 mg/dL if on maximal lipid-lowering therapy), and cholesterol deposits in the first decade of life in the setting of a strong family history; AND physical manifestations such as xanthomas, xanthelasmas (cholesterol deposits in the eyelids or skin), or corneal arcus. ○ Low-density lipoprotein-cholesterol (LDL-C) level of equal to or greater than 190 mg/dL, or lower with strong family histories and/or physical findings such as xanthomas, xanthelasmas (cholesterol deposits in the eyelids or skin), or corneal arcus. • Tried and failed, is intolerant to or has a clinical contraindication to high dose statin therapy (with atorvastatin 80 mg or rosuvastatin 40 mg) or lower if indicated, and 10 mg ezetimibe. • Did not achieve LDL-C goal after three months on statin and ezetimibe and Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (for example: evolocumab) unless intolerant or clinically contraindicated. • Concurrent therapy with other LDL-C lowering therapies such as statins, ezetimibe, etc.
Age Restriction	5 years of age and older
Prescriber Restrictions	Lipid specialist or other specialist experienced in the treatment of HoFH (e.g., cardiologist).
Coverage Duration	Initial: Six months; Renewal: 12 months
Other Criteria / Information	Criteria adapted from DHCS April 2024



	HCPCS	Description	Dosing, Units
	J1305	Injection, evinacumab-dgnb, 5mg (Evkeeza TM)	15mg/kg IV every four weeks.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	5/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025