JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP080
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	Subject **Evkeeza**	*Revision Date*	04/19/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Evkeeza

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I. POLICY

A. Evkeeza (evinacumab-dgnb) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Evkeeza may be approved for patients who meet the following:
   1. Patient is 12 years of age or older
   2. Documentation has been submitted showing the following:
      a. A diagnosis of homozygous familial hypercholesterolemia confirmed by either of the following:
         I. Mutations in two alleles at the LDLR, APOB, PCSK9 or LDLRAP1 gene locus
         II. An untreated LDL-C of greater than 500 mg/dL or treated LDL-C greater than or equal to 300 mg/dL and either of the following:
            i. Presence of cutaneous or tendinous xanthomas before the age of 10 years
            ii. An untreated LDL-C level of greater than or equal to 190 mg/dL in both parents
      b. Patient has a treated LDL-C of greater than or equal to 100 mg/dL (or greater than or equal to 70 mg/dL with clinical atherosclerotic cardiovascular disease [ASCVD]
      c. Patient is receiving stable treatment with at least 3 lipid-lowering therapies (e.g., statins, ezetimibe, PCSK9 directed therapy) at the maximum tolerated dose
      d. Patient will continue to receive concomitant lipid-lowering therapy

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing a beneficial response to treatment, and the following:
   1. Patient 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. Patient is currently receiving concomitant lipid-lowering therapy

IV. EXCLUSIONS

A. Evkeeza will not be covered for the following:
   1. Any indications that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, evinacumab-dgnb, 5mg	J1305

VII. REFERENCES

1. Evkeeza [prescribing information]. 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.

VIII. APPROVALS

Signature on file at JHHC

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