

# Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

## Evinacumab-dgnb (Evkeeza)

### Notes:

- ^Statin intolerance is defined as statin-related rhabdomyolysis or statin-associated muscle symptoms with the symptoms occurring while receiving the statin and resolving upon discontinuation of statin. Patient must fail at least 4 statin therapies.
- \*Untreated means no prior therapy with any antihyperlipidemic agent
- \*\*Treated means after therapy with at least one antihyperlipidemic agent

Non-Formulary **evinacumab-dgnb (Evkeeza)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

**Initiation (new start) criteria:** Non-formulary **evinacumab-dgnb (Evkeeza)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a cardiologist or endocrinologist– AND-
- Patient age  $\geq$  12 years or older – AND-
- Patient is on maximally tolerated statin for at least 90 days or has statin intolerance<sup>^</sup> – AND-
- Patient is on ezetimibe and PCSK9 inhibitor for at least 90 days– AND-
- Current LDL-C  $\geq$  100 mg/dL within the last 6 months – AND-
- Documented diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by one of the following:
  - Documented variant in two low-density lipoprotein receptor (LDLR) alleles or the presence of homozygous or compound heterozygous variants in apolipoprotein B (ApoB) or proprotein convertase subtilisin/kexin type 9 (PSCK9)
  - Patient had untreated\* LDL-C  $\geq$  500 mg/dL and one of the following:
    - Both parents of the individual had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH)
    - Presence of cutaneous or tendinous xanthomas before the age of 10
  - Patient had treated\*\* LDL-C  $\geq$  250 mg/dL
    - Both parents of the individual had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH)
    - Presence of cutaneous or tendinous xanthomas before the age of 10

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## Evinacumab-dgnb (Evkeeza)

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-formulary **evinacumab-dgnb (Evkeeza)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a cardiologist or endocrinologist– AND-
- Patient age  $\geq$  12 years or older – AND-
- Patient is on maximally tolerated statin for at least 90 days or has statin intolerance<sup>^</sup> – AND-
- Patient is on ezetimibe and PCSK9 inhibitor for at least 90 days– AND-
- Current LDL-C  $\geq$  100 mg/dL within the last 6 months – AND-
- Documented diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by one of the following:
  - Documented variant in two low-density lipoprotein receptor (LDLR) alleles or the presence of homozygous or compound heterozygous variants in apolipoprotein B (ApoB) or proprotein convertase subtilisin/kexin type 9 (PSCK9)
  - Patient had untreated\* LDL-C  $\geq$  500 mg/dL and one of the following:
    - Both parents of the individual had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH)
    - Presence of cutaneous or tendinous xanthomas before the age of 10
  - Patient had treated\*\* LDL-C  $\geq$  250 mg/dL and one of the following:
    - Both parents of the individual had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH)
    - Presence of cutaneous or tendinous xanthomas before the age of 10

**Continued use criteria (12 months after initiation):** Non-formulary **evinacumab-dgnb (Evkeeza)** will continue to be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by a cardiologist or endocrinologist– AND-
- Patient is currently receiving concomitant antihyperlipidemic agents
- Patient has achieved and maintained an LDL-C reduction