

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Icosapent ethyl (Vascepa)

**Notes:**

- Quantity limits: Yes

**Initiation (new start) criteria:** Non-formulary **icosapent ethyl (Vascepa)** will be covered on the prescription drug benefit for when the following criteria are met:

**Reduction of Risk of Cardiovascular Disease** (subcategorized into established cardiovascular disease and diabetes)

*Established cardiovascular disease*

- Documented established cardiovascular disease\* - AND-
- Age 45 years or older - AND-
- Receiving maximally tolerated statin therapy or rationale as to why member cannot take a statin is provided - AND-
- Fasting triglycerides (TG) 150-499 mg/dL within the last 3 months - AND-
- Low-density lipoproteins (LDL) 41-100 mg/dL within the last 3 months

\* Established cardiovascular disease:

- 1) Documented coronary artery disease (CAD)
  - a. Documented multi-vessel CAD ( $\geq 50\%$  stenosis)
  - b. Documented prior MI
  - c. Hospitalization for high-risk non-ST elevation ACS (NSTE-ACS)
- 2) Documented cerebrovascular or carotid disease
  - a. Documented prior ischemic stroke
  - b. Symptomatic carotid artery disease with  $\geq 50\%$  carotid arterial stenosis
  - c. Asymptomatic carotid artery disease with  $\geq 70\%$  stenosis per angiography
  - d. History of carotid revascularization
- 3) Documented peripheral arterial disease (PAD)
  - a. Ankle-brachial index (ABI)  $< 0.9$  with symptoms of intermittent claudication
  - b. History of aorto-iliac or peripheral arterial intervention

*Diabetes*

- Diagnosis of diabetes mellitus and one additional cardiovascular risk factor\*\* - AND-
- Age 50 years or older - AND-
- Receiving maximally tolerated statin therapy or rationale as to why member cannot take a statin is provided - AND-
- Fasting triglycerides (TG) 150-499 mg/dL within the last 3 months - AND-
- Low-density lipoproteins (LDL) 41-100 mg/dL within the last 3 months

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Effective: 02/18/21

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## CRITERIA FOR DRUG COVERAGE

### Icosapent ethyl (Vascepa)

\*\*Cardiovascular risk factors:

- 1) Men  $\geq$  55 years of age and women  $\geq$  65 years of age
- 2) Cigarette smoker
- 3) Hypertension (BP  $\geq$  140/90) or on antihypertensive medications
- 4) HDL  $\leq$  40 mg/dL for men or  $\leq$  50 mg/dL for women
- 5) Hs-CRP  $>$  0.3 mg/dL
- 6) Renal dysfunction (CrCl 30-59 mL/min)
- 7) Retinopathy
- 8) Micro- or macroalbuminuria
- 9) ABI  $<$ 0.9 without symptoms of intermittent claudication

#### Severe Hypertriglyceridemia

- Diagnosis of hypertriglyceridemia (TG  $\geq$  500 mg/dL), lipid panel drawn within the last 3 months
- Has failure, contraindication, or intolerance to statin therapy - AND-
- Has failure, contraindication, or intolerance to generic fenofibrate or gemfibrozil - AND-
- Has failure, contraindication, or intolerance to OTC omega-3 fatty acid and omega-3-acid ethyl esters (generic Lovaza)

Failure = TG is not within normal limits or has not dropped at least 50% from baseline

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## CRITERIA FOR DRUG COVERAGE

### Icosapent ethyl (Vascepa)

**Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously:** Non-formulary **icosapent ethyl (Vascepa)** will be covered on the prescription drug benefit for when the following criteria are met:

**Reduction of Risk of Cardiovascular Disease** (subcategorized into established cardiovascular disease and diabetes)

*Established cardiovascular disease*

- Documented established cardiovascular disease\* - AND-
- Age 45 years or older - AND-
- Receiving maximally tolerated statin therapy or rationale as to why member cannot take a statin is provided - AND-
- Fasting triglycerides (TG) 150-499 mg/dL within the last 3 months - AND-
- Low-density lipoproteins (LDL) 41-100 mg/dL within the last 3 months

\* Established cardiovascular disease:

- 4) Documented coronary artery disease (CAD)
  - a. Documented multi-vessel CAD ( $\geq$  50% stenosis)
  - b. Documented prior MI
  - c. Hospitalization for high-risk non-ST elevation ACS (NSTE-ACS)
- 5) Documented cerebrovascular or carotid disease
  - a. Documented prior ischemic stroke
  - b. Symptomatic carotid artery disease with  $\geq$  50% carotid arterial stenosis
  - c. Asymptomatic carotid artery disease with  $\geq$  70% stenosis per angiography
  - d. History of carotid revascularization
- 6) Documented peripheral arterial disease (PAD)
  - a. Ankle-brachial index (ABI)  $<$  0.9 with symptoms of intermittent claudication
  - b. History of aorto-iliac or peripheral arterial intervention

*Diabetes*

- Diagnosis of diabetes mellitus and one additional cardiovascular risk factor\*\* - AND-
- Age 50 years or older - AND-
- Receiving maximally tolerated statin therapy or rationale as to why member cannot take a statin is provided - AND-
- Fasting triglycerides (TG) 150-499 mg/dL within the last 3 months - AND-
- Low-density lipoproteins (LDL) 41-100 mg/dL within the last 3 months

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### Icosapent ethyl (Vascepa)

**\*\*Cardiovascular risk factors:**

- 10) Men  $\geq$  55 years of age and women  $\geq$  65 years of age
- 11) Cigarette smoker
- 12) Hypertension (BP  $\geq$  140/90) or on antihypertensive medications
- 13) HDL  $\leq$  40 mg/dL for men or  $\leq$  50 mg/dL for women
- 14) Hs-CRP  $>$  0.3 mg/dL
- 15) Renal dysfunction (CrCl 30-59 mL/min)
- 16) Retinopathy
- 17) Micro- or macroalbuminuria
- 18) ABI  $<$ 0.9 without symptoms of intermittent claudication

#### **Severe Hypertriglyceridemia**

- Diagnosis of hypertriglyceridemia (TG  $\geq$  500 mg/dL), lipid panel drawn within the last 3 months
- Has failure, contraindication, or intolerance to statin therapy - AND-
- Has failure, contraindication, or intolerance to generic fenofibrate or gemfibrozil - AND-
- Has failure, contraindication, or intolerance to OTC omega-3 fatty acid and omega-3-acid ethyl esters (generic Lovaza)

Failure = TG is not within normal limits or has not dropped at least 50% from baseline

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

#### **Reduction of Risk of Cardiovascular Disease** (subcategorized into established cardiovascular disease and diabetes)

##### *Established cardiovascular disease*

- Documented established cardiovascular disease\* - AND-
- Age 45 years or older - AND-
- Receiving maximally tolerated statin therapy or rationale as to why member cannot take a statin is provided - AND-

\* Established cardiovascular disease:

- 7) Documented coronary artery disease (CAD)
  - a. Documented multi-vessel CAD ( $\geq$  50% stenosis)
  - b. Documented prior MI
  - c. Hospitalization for high-risk non-ST elevation ACS (NSTE-ACS)

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- 8) Documented cerebrovascular or carotid disease
  - a. Documented prior ischemic stroke
  - b. Symptomatic carotid artery disease with  $\geq 50\%$  carotid arterial stenosis
  - c. Asymptomatic carotid artery disease with  $\geq 70\%$  stenosis per angiography
  - d. History of carotid revascularization
- 9) Documented peripheral arterial disease (PAD)
  - a. Ankle-brachial index (ABI)  $< 0.9$  with symptoms of intermittent claudication
  - b. History of aorto-iliac or peripheral arterial intervention

#### *Diabetes*

- Diagnosis of diabetes mellitus and one additional cardiovascular risk factor\*\* - AND-
- Age 50 years or older - AND-
- Receiving maximally tolerated statin therapy or rationale as to why member cannot take a statin is provided - AND-

#### \*\*Cardiovascular risk factors:

- 19) Men  $\geq 55$  years of age and women  $\geq 65$  years of age
- 20) Cigarette smoker
- 21) Hypertension (BP  $\geq 140/90$ ) or on antihypertensive medications
- 22) HDL  $\leq 40$  mg/dL for men or  $\leq 50$  mg/dL for women
- 23) Hs-CRP  $> 0.3$  mg/dL
- 24) Renal dysfunction (CrCl 30-59 mL/min)
- 25) Retinopathy
- 26) Micro- or macroalbuminuria
- 27) ABI  $< 0.9$  without symptoms of intermittent claudication

#### **Severe Hypertriglyceridemia**

- Diagnosis of hypertriglyceridemia (TG  $\geq 500$  mg/dL)
- Has failure, contraindication, or intolerance to statin therapy - AND-
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