GEORGIA DEPARTMENT OF COMMUNITY HEALTH

GEORGIA MEDICAID FEE-FOR-SERVICE
LIPOTROPICS, OTHER PA SUMMARY

Preferred	Non-Preferred
Ezetimibe generic Niacin extended-release generic Omega-3-acid ethyl esters generic	Juxtapid (lomitapide) Nexletol (bempedoic acid) Nexlizet (bempedoic acid and ezetimibe) Praluent (alirocumab) Repatha (evolocumab) Vascepa (icosapent ethyl)

All formulations of a medication have the same coverage as the brand name.

LENGTH OF AUTHORIZATION: Varies

PA CRITERIA:

Juxtapid

- Approvable for members 18 years of age or older with a diagnosis of homozygous familial hypercholesterolemia (HoFH) who are following a low-fat diet (supplying <20% of calories from fat) and have failed to achieve maximum results from low-density lipoprotein (LDL)-apheresis or are not candidates for LDL-apheresis (due to clinical reasons or proximity to treatment center) and have failed to reach LDL-C goal with high-dose statin therapy, with high-dose statin therapy in combination with ezetimibe (Zetia) and with Repatha for 3 months each, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy, ezetimibe (Zetia) and Repatha

AND

- Diagnosis of HoFH must be confirmed by the following:
  - Genetic evidence of mutation in the LDL receptor, ApoB or PCSK9 genes

  OR
  - Xanthomas, corneal arcus, xanthelasmas, life-threatening cardiovascular event at a young age, aortic valve disease, chest pain or other signs of coronary artery disease at a young age OR a family history of heterozygous familial hypercholesterolemia (LDL-C ≥190 mg/dL) in both parents

  AND
  - Untreated LDL-C ≥500 mg/dL OR treated LDL-C ≥330 mg/dL.

Nexletol and Nexlizet

- Approvable for members 18 years of age or older with a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who are following a low-fat diet (supplying <20% of calories from fat) and are on a maximally tolerated statin therapy and have failed to reach LDL-C goal with high-dose statin therapy for 3 months

AND

- ❖ Diagnosis of HeFH must be confirmed by the following:
  - Genetic evidence of mutation in the LDL receptor, ApoB or PCSK9 genes

  OR
  - Untreated or pretreatment LDL-C ≥190mg/dL

  AND
  - First-degree relative with LDL-C ≥190mg/dL OR with early/premature coronary artery disease (CAD)/coronary heart disease (CHD)/ASCVD (<55 years of age in a first-degree male relative or <60 years of age in a first-degree female relative)

  OR
  - Documented assessment of member using Dutch Lipid Clinic Network diagnostic criteria with a score of ≥9 points (e.g., definite FH)

OR

- ❖ Diagnosis of ASCVD must be confirmed by one of the following:
  - Acute coronary syndrome
  - History of myocardial infarction
  - Stable or unstable angina
  - Coronary or other arterial revascularization procedure (e.g., PTCA, CABG)
  - Stroke
  - Transient ischemic attack (TIA)
  - Peripheral arterial disease (PAD) presumed to be of atherosclerotic origin.
- ❖ In addition for Nexletol, members must have also failed to reach LDL-C goal with high-dose statin therapy in combination with ezetimibe (Zetia) for 3 months or have experienced allergy, contraindication, drug-drug interaction or intolerable side effect with ezetimibe (Zetia).

Praluent

- ❖ Approvable for members 18 years of age or older with a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who are following a low-fat diet (supplying <20% of calories from fat), are on a maximally tolerated lipid-lowering regimen and have failed to reach LDL-C goal with high-dose statin therapy and with high-dose statin therapy in combination with ezetimibe (Zetia) for 3 months each, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy and ezetimibe (Zetia)

AND

- ❖ Diagnosis of HeFH must be confirmed by the following:
  - Genetic evidence of mutation in the LDL receptor, ApoB or PCSK9 genes

  OR
  - Untreated or pretreatment LDL-C ≥190mg/dL

  AND
  - First-degree relative with LDL-C ≥190mg/dL OR with early/premature coronary artery disease (CAD)/coronary heart disease (CHD)/ASCVD (<55 years of age in a first-degree male relative or <60 years of age in a first-degree female relative)

  OR

- Documented assessment of member using Dutch Lipid Clinic Network diagnostic criteria with a score of ≥9 points (e.g., definite FH)

OR

- ❖ Diagnosis of ASCVD must be confirmed by one of the following:
  - Acute coronary syndrome
  - History of myocardial infarction
  - Stable or unstable angina
  - Coronary or other arterial revascularization procedure (e.g., PTCA, CABG)
  - Stroke
  - Transient ischemic attack (TIA)
  - Peripheral arterial disease (PAD) presumed to be of atherosclerotic origin.
- ❖ Approvable for members 18 years of age or older to reduce the risk of myocardial infarction, stroke or unstable angina requiring hospitalization (prevention of cardiovascular events) who have established cardiovascular disease, additional cardiovascular risk factors, LDL-C ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL and have failed to reach LDL-C goal with high-dose statin therapy and with high-dose statin therapy in combination with ezetimibe (Zetia) for 3 months each, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy and ezetimibe (Zetia).
- ❖ Approvable for members 13 years of age or older with a diagnosis of homozygous familial hypercholesterolemia (HoFH) who are following a low-fat diet (supplying <20% of calories from fat), are on a maximally tolerated lipid-lowering regimen and have failed to reach LDL-C goal with high-dose statin therapy and with high-dose statin therapy in combination with ezetimibe (Zetia) for 3 months each, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy and ezetimibe (Zetia)

AND

- ❖ Diagnosis of HoFH must be confirmed by the following:
  - Genetic evidence of mutation in the LDL receptor, ApoB or PCSK9 genes

  OR
  - Xanthomas, corneal arcus, xanthelasmas, life-threatening cardiovascular event at a young age, aortic valve disease, chest pain or other signs of coronary artery disease at a young age OR a family history of heterozygous familial hypercholesterolemia (LDL-C ≥190 mg/dL) in both parents

  AND
  - Untreated LDL-C ≥500 mg/dL OR treated LDL-C ≥330 mg/dL.

Repatha

- ❖ Approvable for members 18 years of age or older with a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who are following a low-fat diet (supplying <20% of calories from fat), are on a maximally tolerated lipid-lowering regimen and have failed to reach LDL-C goal with high-dose statin therapy and with high-dose statin therapy in combination with ezetimibe (Zetia) for 3 months each as well as with Praluent, or who have experienced allergies, contraindications, drug-

drug interaction or intolerable side effects with high-dose statin therapy, ezetimibe (Zetia) and Praluent

AND

- Diagnosis of HeFH must be confirmed by the following:
  - Genetic evidence of mutation in the LDL receptor, ApoB or PCSK9 genes

  OR
  - Untreated or pretreatment LDL-C ≥190mg/dL

  AND
  - First-degree relative with LDL-C ≥190mg/dL OR with early/premature coronary artery disease (CAD)/coronary heart disease (CHD)/ASCVD (<55 years of age in a first-degree male relative or <60 years of age in a first-degree female relative)

  OR
  - Documented assessment of member using Dutch Lipid Clinic Network diagnostic criteria with a score of ≥9 points (e.g., definite FH)

OR

- Diagnosis of ASCVD must be confirmed by one of the following:
  - Acute coronary syndrome
  - History of myocardial infarction
  - Stable or unstable angina
  - Coronary or other arterial revascularization procedure (e.g., PTCA, CABG)
  - Stroke
  - Transient ischemic attack (TIA)
  - Peripheral arterial disease (PAD) presumed to be of atherosclerotic origin.
- Approvable for members 13 years of age or older with a diagnosis of homozygous familial hypercholesterolemia (HoFH) who are following a low-fat diet (supplying <20% of calories from fat), are on a maximally tolerated lipid-lowering regimen and have failed to reach LDL-C goal with high-dose statin therapy and with high-dose statin therapy in combination with ezetimibe (Zetia) for 3 months each as well as with Praluent for members 18 years of age older, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy and ezetimibe (Zetia) as well as with Praluent for members 18 years of age older

AND

- Diagnosis of HoFH must be confirmed by the following:
  - Genetic evidence of mutation in the LDL receptor, ApoB or PCSK9 genes

  OR
  - Xanthomas, corneal arcus, xanthelasmas, life-threatening cardiovascular event at a young age, aortic valve disease, chest pain or other signs of coronary artery disease at a young age OR a family history of heterozygous familial hypercholesterolemia (LDL-C ≥190 mg/dL) in both parents

  AND
  - Untreated LDL-C ≥500 mg/dL OR treated LDL-C ≥330 mg/dL.
- Approvable for members 18 years of age or older to reduce the risk of myocardial infarction, stroke or coronary revascularization (prevention of cardiovascular events) who have

established cardiovascular disease, additional cardiovascular risk factors, LDL-C ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL and have failed to reach LDL-C goal with high-dose statin therapy and with high-dose statin therapy in combination with ezetimibe (Zetia) for 3 months each as well as with Praluent, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy, ezetimibe (Zetia) and Praluent.

Vascepa

- Approvable for members 18 years of age or older with a diagnosis of severe hypertriglyceridemia (triglyceride level ≥ 500 mg/dL) who have received a kidney transplant or who have experienced ineffectiveness, allergies, contraindications, drug-drug interactions or intolerable side effects with niacin, a fibric acid derivative and omega-3-acid ethyl esters.
- Approvable for members 18 years of age or older to reduce the risk of myocardial infarction, stroke, coronary revascularization or unstable angina requiring hospitalization (prevention of cardiovascular events) with triglyceride level ≥ 150 mg/dL who have received a kidney transplant.
- Approvable for members 18 years of age or older to reduce the risk of myocardial infarction, stroke, coronary revascularization or unstable angina requiring hospitalization (prevention of cardiovascular events) with triglyceride level ≥ 150 mg/dL who have established cardiovascular disease (CVD) or diabetes mellitus with 2 or more additional risk factors for cardiovascular disease and who are taking maximally tolerated statin therapy and will continue taking maximally tolerated statin therapy.

EXCEPTIONS:

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827.**

PREFERRED DRUG LIST:

- For online access to the Preferred Drug List (PDL), please go to http://dch.georgia.gov/preferred-drug-lists.

PA AND APPEAL PROCESS:

- For online access to the PA process, please go to www.dch.georgia.gov/prior-authorization-process-and-criteria and click on Prior Authorization (PA) Request Process Guide.

QUANTITY LEVEL LIMITATIONS:

- For online access to the current Quantity Level Limits (QLL), please go to www.mmis.georgia.gov/portal, highlight Pharmacy and click on Other Documents, then select the most recent quarters QLL list.