GEORGIA MEDICAID FEE-FOR-SERVICE
FAMILIAL HYPERCHOLESTEROLEMIA AGENTS PA SUMMARY

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Non-Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Juxtapid (lomitapide) Kynamro (mipomersen sodium)</td>
</tr>
<tr>
<td></td>
<td>Praluent (alirocumab) Repatha (evolocumab)</td>
</tr>
</tbody>
</table>

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

LENGTH OF AUTHORIZATION: Initial: 6 months; Repeat: 1 year

PA CRITERIA:

_Juxtapid and Kynamro_

- 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 and Repatha

AND

- Alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase and total bilirubin levels must be obtained prior to treatment initiation and monitored as clinically indicated. Diagnosis of HoFH must be confirmed by the following:
  - Genetic evidence of mutation in the LDL receptor, ApoB or PCSK9 genes
  - 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.

- For Juxtapid, female members of reproductive potential must have a negative pregnancy test prior to treatment initiation and effective contraception must be used during treatment if applicable.
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

AND

- Diagnosis of HeFH must be confirmed by the following:
  - Genetic evidence of mutation in the LDL receptor, ApoB or PCSK9 genes
  - Untreated or pretreatment LDL-C ≥190mg/dL
  - 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)
  - 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.

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, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy and ezetimibe
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, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy and ezetimibe

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, or who have experienced allergies, contraindications, drug-drug interaction or intolerable side effects with high-dose statin therapy and ezetimibe.

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 http://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 Quantity Level Limits (QLL), please go to https://www.mmis.georgia.gov/portal, highlight Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services and select that manual.