Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 254.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Leqvio (inclisiran)

I. Policy:
Leqvio (inclisiran)

II. Purpose/Objective:
To provide a policy of coverage regarding Leqvio (inclisiran).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Inclisiran is a small interfering ribonucleic acid, conjugated on the sense strand with triantennary N-Acetylgalactosamine to facilitate uptake by hepatocytes. In hepatocytes, inclisiran utilizes the RNA interference mechanism and directs catalytic breakdown of mRNA for PCSK9. This increases low-density lipoprotein-cholesterol (LDL-C) receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Leqvio (inclisiran) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Heterozygous familial hypercholesterolemia AND either:
    - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
    - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria

AND

- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy showing:
  - Low-density lipoprotein (LDL) greater than 100 if the member is using Leqvio for primary prevention **OR**
  - Low-density lipoprotein (LDL) greater than 70 if the member is using Leqvio for secondary prevention

AND

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha OR Praluent **AND**
- Medical record documentation that Leqvio is not being used in combination with another PCSK9 inhibitor

AUTHORIZATION DURATION: Initial authorizations for Leqvio will be approved for a period of **12 months**. Reauthorizations will be for a period of **12 months** each provided the following criteria are met:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy **AND**
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy (if statin tolerant) **AND**
- Medical record documentation that Leqvio continues to not be used in combination with another PCSK9 inhibitor

Leqvio (inclisiran) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Heterozygous familial hypercholesterolemia AND either:
    - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
    - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria

AND

- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy showing:
  - Low-density lipoprotein (LDL) greater than 100 if the member is using Leqvio for primary prevention **OR**
  - Low-density lipoprotein (LDL) greater than 70 if the member is using Leqvio for secondary prevention

AND

- Prescription is written by a cardiologist, endocrinologist, or lipidologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Leqvio is not being used in combination with another PCSK9 inhibitor

AND

- One of the following:
  - **For statin tolerant patients**: medical record documentation of an inability to achieve and maintain LDL goal with one of the following:
    - maximum tolerated dose of a high intensity statin (atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher) AND medical record documentation that patient intends to continue on maximal statin therapy once Leqvio is started **OR**
    - a maximally tolerated dose of any statin given that the patient has had a previous trial of either atorvastatin or rosuvastatin, with prescriber's documentation regarding length of previous trials of statins AND medical record documentation that patient intends to continue on maximal statin therapy once Leqvio is started
  - **For statin intolerant patients**: medical record documentation of reason for statin intolerance.

AUTHORIZATION DURATION: Initial authorizations for Leqvio will be approved for a period of **12 months**. Reauthorizations will be for a period of **12 months** each provided the following criteria are met:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Medical record documentation that member is still taking statin (if statin tolerant) **AND**
- Medical record documentation that Leqvio continues to not be used in combination with another PCSK9 inhibitor

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/15/22

Revised: 3/14/23 (LOB carve out, Medicaid business segment)

Reviewed: