Inclisiran (LEQVIO™)
Criteria for Use
June 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive inclisiran.

- ☐ End-stage renal disease on dialysis
- ☐ Advanced heart failure with limited prognosis
- ☐ Severe comorbid non-cardiovascular condition that is expected to limit life expectancy
- ☐ Pregnancy or lactating

Inclusion Criteria

One of the following criteria must be met.

- ☐ History of ASCVD[1]
- ☐ Severe hypercholesterolemia (e.g., HeFH[2], LDL-C[3] ≥ 190 mg/dL) without ASCVD

[1]ASCVD=Atherosclerotic cardiovascular disease

[2]HeFH=Heterozygous familial hypercholesterolemia

[3]LDL-C=Low density lipoprotein cholesterol

Additional Inclusion Criteria

All of the following criteria must be met.

- ☐ Contraindication, intolerance to or insufficient LDL-C reduction with maximally tolerated dose of statin[4] and needs further LDL-C lowering to reduce ASCVD risk consistent with established guidelines.
- ☐ Contraindication, intolerance to or insufficient LDL-C reduction with ezetimibe and needs further LDL-C lowering to reduce ASCVD risk consistent with established guidelines.
- ☐ Contraindication, intolerance to or insufficient LDL-C reduction with a monoclonal antibody inhibitor of PCSK9[5] and needs further LDL-C lowering to reduce ASCVD risk consistent with established guidelines
- ☐ Willing to return for subcutaneous administration of inclisiran by a healthcare provider at the initial visit, at 3 months and every 6 months thereafter.

[4]Maximally tolerated dose of statin may be none=Confirmed statin intolerance=Intolerant to at least 2 statins, one at the lowest approved daily dose

[5]Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitor

Additional Inclusion Criteria-Select if Applicable

For patients who can become pregnant

- ☐ Evaluate pregnancy status prior to initiating treatment since inclisiran may cause fetal harm.[6] Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy is recommended.

[6]Animal studies do not support embryo-fetal harm with inclisiran. However, there are no studies in pregnant patients. Although the treatment of hyperlipidemia is usually not necessary during pregnancy, the ongoing therapeutic needs of the individual patient should be considered.

Supplemental Information

- Clinical trials support a reduction in adverse cardiovascular (CV) events (e.g., CV death, myocardial infarction, stroke, etc.) with alirocumab and evolocumab when added to background statin therapy. However, the effect of inclisiran on CV morbidity or mortality has not been established.
- There is a lack of evidence supporting better or worse adherences rates with every 6-month administration of inclisiran vs. every 2 to 4-week administration of alirocumab or evolocumab.

Refer to the following link for guidance on managing statin intolerance: National Academic Detailing Services - 10-1695_Dyslipidemia_Provider_StatinIntolerance_P97132 - Group by Campaign (sharepoint.com)

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