Mass General Brigham
Health Plan

Lipid Lowering Agents
Evkeeza (evinacumab-dgnb)
Leqvio (inclisiran)
Effective 06/01/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	Leqvio is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Evkeeza is an angiopoietin-like 3 (ANGPTL3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH).

Leqvio is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Evkeeza (evinacumab-dgnb)
ALL of the following:
1. Diagnosis of HoFH confirmed by **ONE** of the following:
    a. Laboratory test confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutations, PCSK9 mutations and familial defective apoB mutations
    b. **BOTH** of the following:
        i. Baseline LDL-C ≥ 400 mg/dL
        ii. Current LDL-C ≥ 100 mg/dL
    c. **ONE** of the following:

        i. Member had evidence of xanthoma before 10 years of age
        ii. Evidence of HeFH in both parents
2. Member is ≥ 5 years of age
3. Prescriber is a specialist (e.g. cardiologist, vascular neurologist, lipid lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided
4. **ONE** of the following:
    a. Agent to be used as add-on therapy with a high-intensity statin, ezetimibe, and PCSK9 inhibitor
    b. Contraindication or other well-defined clinical rationale for omitting one or more of the standard lipid-lowering therapies: statin, ezetimibe, and PCSK9 inhibitors
5. Member's current weight (use to verify correct dosing)
6. Appropriate dosing

Leqvio (inclisiran)
ALL of the following:

1. Diagnosis is hypercholesterolemia with **ONE** of the following:
    a. For members with a diagnosis of HeFH, current LDL-C is ≥70 mg/dL
    b. For members without a previous history of a cardiovascular event (with or without HeFH or HoFH), **BOTH** of the following:
        i. **ONE** of the following:
            1. Member has Type 2 diabetes
            2. Member has s ≥ 20% 10-year risk of a cardiovascular event (Framingham Risk Score for Cardiovascular Disease or equivalent)
        ii. Current LDL-C is ≥55 mg/dL
    c. For members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL
2. Member is ≥18 years of age
3. Prescriber is a specialist (e.g. cardiologist, vascular neurologist, lipid lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided
4. Inadequate response (defined as ≥ the last 3 months) or adverse reaction to **ONE** or contraindication to **BOTH** of the following*:
    a. Praluent (alirocumab)
    b. Repatha (evolocumab)
5. **ONE** of the following†:
    a. Inadequate response (defined as ≥ the last 3 months) to combination therapy with a high intensity statin and ezetimibe
    b. Adverse reaction or contraindication to ezetimibe AND inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy
    c. Adverse reaction to ONE high intensity statin or contraindication to ALL high intensity statins
6. Appropriate dosing

*Requests looking to bypass the required trial with Praluent (alirocumab) or Repatha (evolocumab) may be approved if the prescriber documents concerns with the member using self-injections (due to non-adherence or low health literacy)
† If the prescriber documents that the member has experienced an adverse reaction to a high intensity statin or has a contraindication to high intensity statins, requests may be approved without the requirement for ezetimibe monotherapy

Continuation of Therapy
Reauthorization should be reviewed for the following information:

Evkeeza (evinacumab-dgnb)

1. **ONE** of the following:
    a. Decrease in LDL-C from baseline and the member appears to be adherent to the regimen.
    b. Decrease in LDL-C from baseline and evidence of non-adherence to one or more agent(s) in the regimen.
2. Updated member weight (use to verify correct dosing; may take this information over the phone if missing on PA request)

Leqvio (inclisiran)

1. Member appears to be adherent to Leqvio, statin and/or ezetimibe therapy (consistent with regimen noted on initial approval) (at least 60 days of therapy within the last 90 days for the statin and ezetimibe)
2. **ONE** of the following:
    a. Decrease in LDL-C from baseline and the member appears to be adherent to the regimen.
    b. Decrease in LDL-C from baseline and evidence of non-adherence.
    c. If there is no decrease or an increase in LDL-C, or if an updated LDL-C is not provided and there is evidence of non-adherence.

Limitations

1. Initial approvals will be granted for **6 months**.
2. Reauthorizations will be granted for the following:
    a. Decrease in LDL-C from baseline and member is adherent: **12 months**.
    b. Decrease in LDL-C from baseline and non-adherence: **6 months**.
    c. No decrease or an increase in LDL-C or updated LDL-C not provided and non-adherence: **6 months**.

Appendix

I. Special Considerations in Lipid Lowering Therapy

Contraindication to Statin Therapy
The following should be considered for **approval** when reviewing requests: • Elevated serum transaminases with statin use • Elevated baseline serum transaminases (due to liver disease or other etiology) o All statins are cautioned in patients with liver disease; however, pravastatin has been studied in this population and is generally recommended at low doses

References

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Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Criteria was named as Lipid Lowering Agents. Note: Praluent and Repatha was combined to this criteria. Effective 4/1/23.
07/12/23 – Reviewed and updated for P&T. Formatting updates to drug table. Clarified approvable diagnoses. Praluent and Repatha criteria updated to become less restrictive. Appendix criteria for special populations who are statin intolerant was removed and now combined with its respective criteria. Low cost alternative trials language have been simplified throughout the policy. Praluent and Repatha trial may be bypassed for Leqvio if there are concerns with member using self injections. Caduet®(amlodipine/atorvastatin) was updated to only require medical necessity for use of the combination product instead of the commercially available separate agents. Evkeeza had an age expansion to members aged 5 and older. New drug, Atorvaliq, was added. Brand preferred and mandatory generic language was added under Limitations. Effective 7/31/23
09/13/23 – Reviewed and updated for P&T. Leqvio has been added to pharmacy benefit with PA and will remain on medical benefit with PA. Effective 10/2/23

05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. All agents except for Evkeeza and Leqvio were pharmacy benefit only and thus have been removed. Updated formatting & references accordingly. Criteria for Leqvio was updated to reflect expanded indication for members with increased cardiovascular risk. Effective 6/1/25