CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Evinacumab (Evkeeza)

Ultragenyx Pharmaceutical Inc.

Indication: Evinacumab is indicated as an adjunct to diet and 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).

November 2, 2023

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0778
Name of the drug and Indication(s)	evinacumab (Evkeeza) For the treatment of adult and pediatric patients aged 5 years and older with homozygous familial hypercholesterolemia (HoFH)
Organization Providing Feedback	FWG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	X
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	☐
	No requested revisions	☐

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons
Please clarify access to PCSK9i for HoFH. Currently, drug plans do not fund PCSK9i for HoFH (if they do fund, it is for HeFH). What is a relevant comparator? Please clarify if this medication is to be used after statin + ezetimibe (no PCSK9i) because Repatha were not evaluated for HoFH by CDEC. Please clarify definition of elevated LDL-C – what are the drug plans looking for in terms of adjudication.

Please clarify definition of adequate trial of lipid lowering therapies, including doses/duration.

Please clarify definition of accessible lipid lowering therapies. Of accessible lipid lowering therapy. Would it be 1) statin (any intensity? how many trials of statins) in combination with ezetimibe?

Can this be used as monotherapy if patient does not tolerate/failure of all accessible lipid lowering therapy?

Please clarify in objective terms the definition clincal beneficial of "defined as reduction in LDL-C from baseline that is considered **clinically beneficial** by the treating physician 24 weeks after initiation evinacumab treatment." What is the target for renewal?

For renewal, please clarify what drug plans may do in situations where the LDL-C achieved is more than the first renewal, but less than the pre-treatment LDL-C? What is the target for renewal? 20% reduction, 40% reduction in LDL-C?

Also, in scenarios such as high TGs, these patients do not a measurable LDL-C. How do you address these circumstances to ensure true LDL-C (e.g, retest, is there a formula to calculate LDL-C when TG is too high, etc.).

Suggest placing the clinical criteria of HoFH – within the reimbursement condition instead of implementation guidance.

c) Implementation guidance
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. 2.