Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

bempedoic acid

NILEMDO 180 mg

film-coated tablet

Inclusion on list

Adopted by the Transparency Committee on 12 February 2025

Summary of opinion

Favourable opinion for reimbursement of NILEMDO (bempedoic acid) only in adults at high or very high cardiovascular risk, who are statin-intolerant, or for whom a statin is contraindicated, to reduce cardiovascular risk by lowering LDL-c levels when goals have not been achieved despite optimised lipid-lowering treatment:

- **in the event of high risk of atherosclerotic cardiovascular disease (primary prevention);**
- **or in the event of established atherosclerotic cardiovascular disease (secondary prevention).**

Unfavourable opinion for reimbursement of NILEMDO (bempedoic acid) in the other clinical situations covered by the MA indication.

Transparency Committee's Conclusions

Clinical Benefit

- The cerebro- and cardiovascular diseases promoted by hypercholesterolaemia and mixed dyslipidaemia can be life-threatening and impact quality of life following disabling sequelae.
- This is a preventive medicinal product.
- The efficacy/adverse effects ratio is:
  - not adequately established in adults with hypercholesterolaemia or mixed dyslipidaemia given the absence of a direct comparison versus an active comparator, and a modest size effect on lowering of LDL-c levels in combination with other lipid-lowering therapies;
  - high in the management of adults in the event of high risk of atherosclerotic cardiovascular disease (primary prevention) or in the event of established atherosclerotic cardiovascular disease (secondary prevention), with evidence of an additional impact on morbidity and despite an impact on mortality and quality of life that remains to be demonstrated.
- Role in the care pathway:

- **In adults at high or very high cardiovascular risk who are statin-intolerant, or for whom a statin is contraindicated,** NILEMDO (bempedoic acid) is a treatment option in combination with optimised lipid-lowering therapy including at least ezetimibe:
  - in the event of high risk of atherosclerotic cardiovascular disease (primary prevention);
  - or in the event of established atherosclerotic cardiovascular disease (secondary prevention).
- **In the treatment of hypercholesterolaemia and mixed dyslipidaemia**, given the modest size effect on lowering of LDL-c levels and the absence of a direct comparison versus an active comparator, NILEMDO (bempedoic acid) has no role in the care pathway for adults with primary hypercholesterolaemia (heterozygous familial and nonfamilial) or mixed dyslipidaemia.
- **In the other clinical situations covered by the MA,** in the absence of clinical data, NILEMDO (bempedoic acid) has no role in the care pathway.

➔ Public health benefit

Considering:

- the seriousness of the disease and its high prevalence,
- the partially met medical need,
- the partial response to the medical need in the treatment of hypercholesterolaemia and mixed dyslipidaemia in adults given:
  - the modest impact demonstrated for NILEMDO (bempedoic acid) on LDL-c reduction, but in the absence of a fully demonstrated impact on morbidity and mortality,
  - the lack of evidence of an impact of NILEMDO (bempedoic acid) on quality of life and the organisation of care;
- the partial response to the medical need in the management of adults in the event of high risk of atherosclerotic cardiovascular disease (primary prevention) or in the event of established atherosclerotic cardiovascular disease (secondary prevention), given:
  - the expected additional impact on morbidity but with no evidence of impact on mortality and quality of life;
  - the lack of evidence of an impact of NILEMDO (bempedoic acid) on quality of life and the organisation of care;

NILEMDO (bempedoic acid) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of NILEMDO (bempedoic acid) 180 mg film-coated tablets is:

- **substantial only in adults at high or very high cardiovascular risk, who are statin-intolerant, or for whom a statin is contraindicated, to reduce cardiovascular risk by lowering LDL-c levels when goals have not been achieved despite optimised lipid-lowering treatment:**
  - **in the event of high risk of atherosclerotic cardiovascular disease (primary prevention);**
  - **or in the event of established atherosclerotic cardiovascular disease (secondary prevention);**
- **insufficient to justify public funding in the other clinical situations of the MA.**

The Committee issues the following opinions:

- **a favourable opinion for inclusion of NILEMDO (bempedoic acid) 180 mg film-coated tablets in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages;**
- **an unfavourable opinion for inclusion of NILEMDO (bempedoic acid) 180 mg film-coated tablets in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the other situations covered by the MA indication.**

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Considering:

- evidence of the superiority of NILEMDO (bempedoic acid) compared to placebo in terms of the reduction in the risk of occurrence of major cardiovascular events (MACE-4 and MACE-3) in subjects who are statin-intolerant and have established atherosclerotic cardiovascular disease or are at high risk of atherosclerotic cardiovascular disease (Clear-OUTCOMES study);
- the favourable safety profile of bempedoic acid;
- the currently partially met medical need;

but in view of:

- uncertainty with respect to the overall clinical effect of bempedoic acid on cardiovascular mortality and given the absence of evidence of a statistically significant difference versus placebo on the reduction of stroke, cardiovascular death and all-cause death;
- the absence of a comparison versus an active comparator, despite this being feasible, particularly in part of the primary prevention population;
- the absence of treatment compliance and quality of life data;

the Committee deems that NILEMDO (bempedoic acid) 180 mg film-coated tablets provides no clinical added value (CAV V) in the current care pathway for the management of adults in the event of high risk of atherosclerotic cardiovascular disease (primary prevention) or in the event of established atherosclerotic cardiovascular disease (secondary prevention).

In the other clinical situations covered by the MA indication: not applicable.