

SUMMARY

rubidium chloride (Rb-82)

KALDENN 4.32 - 5.28 GBq

radionuclide generator

First listing

Adopted by the Transparency Committee on 28 August 2024

Summary of opinion

Favourable opinion for reimbursement: “This medicinal product is for diagnostic use only. The generator eluate (solution of rubidium-82 (Rb-82) chloride for injection) is used for Positron Emission Tomography (PET) imaging of the myocardium at rest or under pharmacologic stress conditions to evaluate regional myocardial perfusion in adults with suspected or known coronary artery disease (CAD).”

Transparency Committee's conclusions**Clinical benefit**

- ➔ The seriousness of the condition is defined on the basis of the results of the investigation. The diseases screened with PET using Rb-82 can be serious diseases that are life-threatening and/or severely impair quality of life.
- ➔ This is a diagnostic medicinal product.
- ➔ The efficacy/adverse effects ratio is high.
- ➔ There are alternative diagnostic methods.
- ➔ This is a first-line medicinal product when functional imaging stress tests are required in the context of diagnostic assessment of chronic coronary syndrome.

➔ Public health benefit

Considering:

- the seriousness and the high incidence of chronic coronary syndrome,
- the partially met medical need, but with the persistence of a need to have access to new non-invasive tests with demonstration of a better-quality diagnostic performance in this strategy,
- the lack of response to the identified need considering:
 - the absence of evidence of an additional impact on mortality, morbidity or quality of life compared to SPECT,

- the lack of any expected additional impact on the patient's care and life pathway compared to the other proprietary medicinal product containing rubidium-82;

KALDENN (rubidium-82 chloride) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of KALDENN (rubidium-82) chloride) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of KALDENN (rubidium-82 chloride) in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

The Committee considers that KALDENN (rubidium-82 chloride) provides no clinical added value (CAV V) compared to the other proprietary medicinal product containing rubidium-82 chloride (CARDIOGEN-82) already listed in the same indication (the generator eluate (solution of rubidium-82 (Rb-82) chloride for injection) is used for Positron Emission Tomography (PET) imaging of the myocardium at rest or under pharmacologic stress conditions to evaluate regional myocardial perfusion in adults with suspected or known coronary artery disease (CAD)).