SUMMARY**(18F) PSMA-1007****RADELUMIN 1,300 and
2,000 MBq/mL****solution for injection****Indication extension****Original French opinion adopted by the Transparency Committee on
28 February 2024****The legally binding text is the original French opinion version****Summary of opinion**

Favourable opinion for reimbursement in the MA indication extension: "This medicinal product is for diagnostic use only.

RADELUMIN is indicated for the detection of prostate-specific membrane antigen (PSMA) positive lesions with positron emission tomography (PET) in adults with prostate cancer (PCa) [in the following clinical setting]: Primary staging of patients with high-risk PCa prior to primary curative therapy, [...]"

Transparency Committee's conclusions**Clinical Benefit**

- ➔ Prostate cancer is a serious, life-threatening disease.
- ➔ This is a diagnostic medicinal product.
- ➔ In view of the diagnostic performance data with [18F] PSMA-1007 PET in five studies (from a review of the literature) retained for analysis and despite the absence of robust data relative to the impact on patient management, the efficacy/adverse effect ratio is high for the primary staging of patients with high-risk PCa prior to primary curative therapy.
- ➔ There are diagnostic alternatives.
- ➔ [18F] PSMA-1007 PET represents an additional alternative for the primary staging (optional examination) of patients with high-risk PCa prior to primary curative therapy.

→ Public health benefit

Considering:

- the seriousness and high incidence of prostate cancer;
- the partially met medical need for the primary staging of patients with high-risk PCa prior to initial curative therapy with the abovementioned available alternatives;
- the absence of evidence of an additional impact on mortality, morbidity or quality of life compared to the available alternatives;
- the lack of additional impact on the care and/or life pathway;

RADELUMIN ([18F] PSMA-1007) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of RADELUMIN ([18F] PSMA-1007) solution for injection is substantial in the MA indication: “[...] for the detection of prostate-specific membrane antigen (PSMA) positive lesions with positron emission tomography (PET) in adults with prostate cancer (PCa) in [the following clinical setting]: Primary staging of patients with high-risk PCa prior to primary curative therapy, [...]”.

The Committee issues a favourable opinion for inclusion of RADELUMIN ([18F] PSMA-1007) solution for injection in the list of covered drugs for inpatients approved for use in this MA indication extension and at the MA dosages.

Clinical Added Value

Considering:

- the diagnostic performance data with [18F] PSMA-1007 PET in five studies (from a review of the literature) retained for analysis and the absence of robust data relative to the impact on patient management,
- the absence of evidence of an impact on mortality, morbidity or quality of life,
- its satisfactory safety profile,
- the medical need which remains partially met,

The Committee deems that RADELUMIN ([18F] PSMA-1007) solution for injection provides no clinical added value (CAV V) in the diagnostic strategy for prostate cancer, in the following clinical situation: primary staging of patients with high-risk PCa prior to primary curative therapy.