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.