Diagnosis
Sector: Hospital

HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
AND
NATIONAL COMMITTEE FOR THE EVALUATION OF MEDICAL DEVICES AND HEALTH TECHNOLOGIES

HAVING MET IN APPLICATION OF ARTICLE L. 161-41 OF THE FRENCH SOCIAL SECURITY CODE

SUMMARY

08 JUNE 2022

The legally binding text is the original French opinion version

[18F]PSMA-1007
RADELUMIN 1,300 MBq/mL solution for injection
First assessment

Key points

Favourable opinion for reimbursement in Positron Emission Tomography (PET) imaging in a patient with a biological recurrence of prostate cancer, following initial radical treatment, with a new elevation in prostate-specific antigen (PSA) levels.

What therapeutic improvement?

Therapeutic improvement in the diagnostic management of patients with a biological recurrence of prostate cancer, following initial radical treatment, with a new elevation in prostate-specific antigen (PSA) levels.

Role in the diagnostic pathway?

The initial diagnosis of prostate cancer generally includes a clinical assessment with palpation of the prostate, assay of serum PSA (prostate-specific antigen) levels and, to confirm the diagnosis, a prostate gland biopsy. When the biopsies are positive, a staging assessment is performed. Pelvic-prostatic MRI is performed to assess local spread, close to the prostate, and thoraco-abdomino-pelvic CT scans, as well as whole-body scintigraphy, are used to identify the presence of any distant metastases. Bone PET, or PET with choline or its fluorinated analogue, should be used in certain specific cases, particularly in the event of adenocarcinomas with a high metastatic risk.

The therapeutic options for the treatment of localised cancers are prostatectomy, radiotherapy or cryotherapy.

Following an initial treatment, the risk of biochemical recurrence, manifested by an increase in serum PSA levels, is between 27 and 53%. The elevation in serum PSA levels generally precedes metastatic progression of the cancer. It is for this reason that after an initial treatment, patients are actively monitored with, in particular, measurement of serum PSA levels. However, other factors (prostate volume, inflammation, infections, mechanical constraints) can increase serum PSA levels. Locating the cancer recurrence using an imaging method is necessary since it helps define the cancer grade, the prognosis and the choice of treatment. Several imaging methods can be envisaged: MRI, ultrasound, CT, PET.

It should also be noted that some prostate cancers can develop without being accompanied by an increase in PSA levels. PSA is neither a specific nor sensitive prostate cancer marker but it is useful since it enables selection of men in whom a biopsy is indicated.

According to the French Urology Society's 2022 guidelines, the reference methods for monitoring prostate cancer following initial treatment are:

- After surgery, 18F-choline or 68Ga-PSMA PET is the reference investigation. However, it is not essential in the event of low and low-velocity PSA levels, if salvage therapy with radiotherapy is envisaged. The role of pelvic MRI in this indication has not been validated.

- After radiotherapy, prostate MRI is the reference investigation for detection of local recurrence if the patient is a candidate for salvage therapy. 18F-choline or 68Ga-PSMA is the reference investigation for the detection of lymph node and metastatic recurrences.

Role of the medicinal product in the care pathway:

RADELUMIN ([18F]PSMA-1007) has a role in the diagnostic pathway when the applicable guidelines schedule the performance of PET imaging in a patient with a biological recurrence of prostate cancer, following initial radical treatment, with a new elevation in prostate-specific antigen (PSA) levels.

JOINT COMMITTEE CONCLUSIONS

Considering all of this information and further to debate and voting, the Joint Committee considers:

Clinical benefit

◗ Prostate cancer is a serious, life-threatening disease, particularly in the event of recurrence.

◗ The proprietary medicinal product RADELUMIN ([18F] PSMA-1007) is a medicinal product for diagnostic use.

◗ The efficacy/adverse effects ratio is high.

◗ There are alternative diagnostic methods.

◗ [18F]PSMA-1007 PET is a first-line investigation in the MA indication.

Public health benefit
Considering:
- the seriousness and high incidence of prostate cancer and recurrences,
- 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 demonstrated additional impact on mortality, morbidity or quality of life compared to the diagnostic methods available,
- the lack of expected 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 Joint Committee deems that the clinical benefit of RADELUMIN ([18F]PSMA-1007) is substantial in the MA indication.

The Joint Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication.

Clinical Added Value

Considering:
- demonstration in the ABX-CT-301 study of a superiority in diagnostic performance in terms of global detection rate for all metastatic lesions of prostate cancer: 77% for [18F]PSMA-1007 versus 57% for fluorocholine (18F))
- a favourable safety profile.
but in view of:
- the absence of a demonstrated impact of this diagnostic performance advantage on mortality, morbidity or quality of life,
the Committee considers that RADELUMIN ([18F]PSMA-1007) provides a minor clinical added value (CAV IV) in the diagnostic pathway for prostate cancer, following initial radical treatment, with a new elevation in prostate-specific antigen (PSA) levels.