SUMMARY

gallium (68Ga) gozetotide

LOCAMETZ 25 microgrammes,

kit for radiopharmaceutical preparation

First assessment

Original French opinion adopted by the Inter-Committee on 4 April 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion on reimbursement 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 (PC) in the following clinical settings:**

- **primary staging of patients with high-risk PC prior to primary curative therapy,**
- **suspected PC recurrence in patients with increasing levels of serum prostate-specific antigen (PSA) after primary curative therapy,**

  identification of patients with PSMA-positive, progressive, metastatic, castration-resistant prostate cancer (mCRPC), for whom PSMA-targeted therapy is indicated."

Role in the diagnostic strategy?

LOCAMETZ (gallium (68Ga) gozetotide) plays a role in the diagnostic strategy:

- for the primary staging of patients presenting with high-risk PC before a primary curative treatment. It is an additional alternative as an optional examination, according to current recommendations.
- in case of suspected PC recurrence in patients with increasing levels of serum PSA after a primary curative treatment. It is a first-line examination, in the same way as RADELUMIN.
- for the identification of patients with PSMA-positive, progressive, mCRPC, for whom PSMA-targeted therapy is indicated. It is a first-line examination, for the identification of PSMA-positive patients.

Conclusions of the Inter-Committee (CT - CNEDIMTS)

Clinical Benefit

Primary staging of patients presenting with high-risk PC before a primary curative treatment

- Prostate cancer is a serious disease that is life-threatening.
- It is a diagnostic medicinal product.
- In view of the diagnostic efficacy of [68Ga] Ga-PSMA-11 PET judged as significant and of its impact on patient management, the efficacy/adverse effect ratio is significant for the primary staging of patients presenting with high-risk PC before a primary curative treatment.
- There are diagnostic alternatives which are mentioned in section 5.2.
- [68Ga] Ga-PSMA-11 PET represents an additional alternative for the primary staging (optional examination) of patients presenting with high-risk PC before a primary curative treatment.

- **Public health benefit**

In view of:

- the gravity and the high incidence of prostate cancer;
- the partially met medical need for the primary staging of patients presenting with high-risk PC before a primary curative treatment with the available alternatives mentioned;
- the absence of additional proven impact on mortality, morbidity or quality of life compared to the available alternatives;
- of the absence of additional impact on the care pathway and/or life course;

LOCAMETZ (gallium (68Ga) gozetotide) is not liable to have an additional impact on public health.

Suspected recurrence of PC in patients with increasing levels of serum PSA after a primary curative treatment

- Prostate cancer is a serious disease that is life-threatening.
- It is a diagnostic medicinal product.
- In view of the diagnostic efficacy of [68Ga] Ga-PSMA-11 PET which is judged significant and of its impact on management, the efficacy/adverse effect ratio is significant in case of suspected PC recurrence in patients with increasing levels of serum PSA after a primary curative treatment.
- There are diagnostic alternatives which are mentioned in section 5.2.
- [68Ga] Ga-PSMA-11 PET is a first-line examination, in the same way as RADELUMINn in case of the suspected PC recurrence in patients with increasing levels of serum PSA after a primary curative treatment compared to diagnostic alternatives.

- **Public health benefit**

In view of:

- the gravity and the high incidence of prostate cancer;
- the partially met medical need in case of suspected PC recurrence in patients with increasing levels of serum PSA after a primary treatment with the available alternatives mentioned;

- the absence of additional proven impact on mortality, morbidity or quality of life compared to the available alternatives;
- the potential improvement in the care pathway particularly given the improvement in territorial coverage compared to [18F] PSMA-1007;

LOCAMETZ (gallium (68Ga) gozetotide) is not liable to have an additional impact on public health.

Identification of patients with PSMA-positive, progressive mCRPC, for whom PSMA-targeted therapy is indicated

- Prostate cancer is a serious disease that is life-threatening.
- It is a diagnostic medicinal product.
- In view of the data on therapeutic efficacy with regard to progression-free survival and overall survival of [177Lu] Lu-PSMA-617 in patients identified by [68Ga] Ga-PSMA-11 PET, of the low inter- and intra-reader variability during the reading of the [68Ga] Ga-PSMA-11 PET scans, and of the need to select patients using the theranostic tool represented by the PSMA-ligand PET, despite the absence of data that would allow an assessment of the diagnostic performance and clinical utility of the [68Ga] Ga-PSMA-11 test in the targeted indication, the efficacy/adverse effect ratio is significant for the identification of patients with PSMA-positive, progressive mCRPC, for whom PSMA-targeted therapy is indicated.
- In patients with mCRPC, [68Ga] Ga-PSMA-11 PET is a first-line examination for the identification of patients who are PSMA-positive, with progressive disease, and therefore for whom PSMA-targeted therapy would be indicated in light of the diagnostic alternatives.

Public health benefit

In view of:

- the gravity and the high incidence of prostate cancer;
- the unmet medical need for the identification of patients with PSMA-positive, progressive mCRPC for whom PSMA-targeted therapy is indicated, with the exception of the PSMA ligand available via compassionate access;
- the absence of an additional proven impact on mortality, morbidity or quality of life compared to the available alternatives;
- the absence of additional impact on the care pathway and/or life course;

LOCAMETZ (gallium (68Ga) gozetotide) is not liable to have an additional impact on public health.

In view of all of these elements, the Inter-Committee considers that the clinical benefit provided by LOCAMETZ (gallium (68Ga) gozetotide), kit for radiopharmaceutical preparation is significant 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 (PC) in the following clinical settings:

- **primary staging of patients with high-risk PC prior to primary curative therapy,**
- **suspected PC recurrence in patients with increasing levels of serum prostate-specific antigen (PSA) after primary curative therapy,**
- **identification of patients with PSMA-positive, progressive, metastatic, castration-resistant prostate cancer (mCRPC), for whom PSMA-targeted therapy is indicated (see section 4.4)."**

The Inter-Committee gives a favourable opinion on the inclusion of LOCAMETZ (gallium (68Ga) gozetotide), kit for radiopharmaceutical preparation on the list of medicinal products approved for the use of communities in the indication and at the MA doses.

However, for the identification of patients with PSMA-positive, progressive, metastatic, castration-resistant prostate cancer (mCRPC), for whom PSMA-targeted therapy is indicated, the Inter-Commission emphasizes the necessity for the medicinal product PLUVICTO ([177Lu] Lu-PSMA-617) associated with LOCAMETZ, to be assessed with a view to its management.

Clinical Added Value

Primary staging of patients presenting with high-risk PC before a primary curative treatment

In view of:

- the data on diagnostic efficacy and impact on management in the literature showing the benefit of [68Ga] Ga-PSMA-11 PET, particularly compared to conventional mPET/CT + CT imaging,
- the absence of proven impact on mortality, morbidity or quality of life,
- its satisfactory tolerance profile,
- the medical need which remains partially met.

Suspected PC recurrence in patients presenting with increasing levels of serum PSA after a primary curative treatment

In view of:

- the data on diagnostic efficacy and impact on management in the literature showing the benefit of the [68Ga] Ga-PSMA-11 PET,
- the absence of proven impact on mortality, morbidity or quality of life,
- its satisfactory tolerance profile,
- the medical need which remains partially met.

Identification of patients with PSMA-positive, progressive, mCRPC, for whom PSMA-targeted therapy is indicated

In view of:

- the demonstration of the superiority of [177Lu] Lu-PSMA-617 in combination with BSoC compared to BSoC alone in terms of progression-free survival and overall survival in patients identified by [68Ga] Ga-PSMA-11 PET,
- the need to select patients using the theranostic tool represented by PSMA-ligand PET, despite the absence of data that would allow an assessment of the diagnostic performance and clinical utility of the [68Ga] Ga-PSMA-11 test in the targeted indication,
- its satisfactory tolerance profile,
- the unmet medical need.

The Inter-Committee considers that LOCAMETZ (gallium (68Ga) gozetotide), kit for radiopharmaceutical preparation, provides no clinical added value (CAV V) in the diagnostic strategy of prostate cancer, in the following clinical situations:

- **primary staging of patients presenting with high-risk PC before a primary curative treatment,**
- **suspected PC recurrence in patients with increasing levels of serum prostate-specific antigen (PSA) after a primary curative treatment,**
- **identification of patients with PSMA-positive, progressive, metastatic, castration-resistant prostate cancer (mCRPC), for whom PSMA-targeted therapy is indicated.**

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