

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION**IASOCHOLINE** (fluorocholine (^{18}F) chloride), radiopharmaceutical for diagnostic use

Minor improvement in the detection of bone metastases in high-risk prostate cancer patients.

Insufficient clinical benefit in the localisation of known lesions of well-differentiated hepatocellular carcinoma and the characterisation of liver nodules and/or staging in the search of lesions of hepatocellular carcinoma

Main points

▶ IASOCHOLINE has Marketing Authorisation:

- In the detection and localisation of bone metastases in prostate cancer.
- In the localisation of known lesions of well-differentiated hepatocellular carcinoma and the characterisation of liver nodules and/or staging of known or very likely lesions of hepatocellular carcinoma.

▶ This is an ^{18}F -labelled radiopharmaceutical product for imaging with positron emission tomography (PET) which only has clinical added value in the detection of bone metastases in prostate cancer but has not shown any diagnostic benefit in the localisation of lesions of hepatocellular carcinoma.

Therapeutic use

- In the diagnostic strategy for the detection of bone metastases in prostate cancer, ^{18}F -fluorocholine (FCH) PET is primarily used for the detection of bone metastases during staging or the biochemical recurrence of prostate cancer in patients at high metastatic risk.
- In the diagnostic strategy for hepatocellular carcinoma, FCH does not have a defined role due to the small amount of efficacy data provided and the low level of evidence of these data, and in agreement with the experts who say that FCH PET is rarely used in the context of hepatocellular cancers.

Clinical data

- In the diagnosis for prostate cancer:

In an open, crossover study, carried out in a very small number of patients (40 patients) with prostate cancer confirmed by biopsy and complaining of musculoskeletal pain, the specificity (primary endpoint) of PET/CT for the detection of bone metastases was higher for IASOCHOLINE (96%) compared with ^{18}F -sodium fluoride (91%), ($p = 0.02$) only in terms of detection by lesional site and in the subgroup of patients ($n = 22$) suspected of relapse or post-treatment progression.

The advantages in clinical practice, according to expert opinion, are:

- FCH PET is the most efficient test in the search for prostate cancer bone metastases in patients at high metastatic risk, particularly in relapse (better specificity, sensitivity at least equivalent to other exams).
- FCH PET allows a whole body scan and therefore has the double advantage of being efficient in the search for bone lesions and allowing, during the same exam, to look for recurrence in the prostate bed and lymph nodes.
- No diagnostic imaging techniques (non-interventional) can have an impact on the morbidity and mortality of a disease except through the changes in patient management it causes.

As such, the impact on therapeutic decisions could be established in roughly half the cases in this indication by changing the radiation fields based on the number of identified bone metastatic sites.

- In the diagnosis of hepatocellular carcinoma:
In a crossover, open study, carried out in 34 adults with hepatocellular carcinoma confirmed by biopsy or by the Barcelona criteria, the sensitivity of PET/CT in terms of diagnosis per lesional site was higher for 18-FCH versus ¹⁸F-fludeoxyglucose (FDG) (84% (58/69 true positives diagnosed) versus 67% (46/69), p = 0.01).
The sensitivity of PET/CT in terms of diagnosis per patient was not higher for FCH versus FDG (88% (30/34 TP diagnosed) versus 68% (23/34), p not significant).
- No specific adverse events were described in the studies or in the available pharmacovigilance data.

Benefit of the medicinal product

- The actual benefit* of IASOCHOLINE:
 - substantial in the indication "Prostate cancer: Detection of bone metastatic lesions in high-risk prostate cancer patients"
 - insufficient in the indication "Hepatocellular carcinoma: Localisation of known well-differentiated lesions of hepatocellular carcinoma and, in addition to FDG PET, characterisation of liver nodules and/or staging in the search for known or highly probable hepatocellular carcinoma lesions when FDG PET is non conclusive or when surgery or a transplant is scheduled".
- IASOCHOLINE provides clinical added value (CAV IV, minor) in the diagnostic strategy for the detection of prostate cancer bone metastases in high-risk patients.
- Recommends inclusion on the list of reimbursable products for hospital use in the indication "Prostate cancer: Detection of bone metastatic lesions in high-risk prostate cancer patients".



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ⁱ * The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".