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DIAGNOSIS
New medicinal product
April 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

IASOTOC (gallium (^{68}Ga) edotreotide), diagnostic product for tumour detection

No clinical benefit demonstrated in the diagnostic management of neuroendocrine tumours and meningiomas

Main points

- IASOTOC has a Marketing Authorisation in the diagnosis of neuroendocrine tumours and meningiomas.
- It is intended for positron emission tomography (PET) and binds specifically to somatostatin receptors.
- Studies have not demonstrated any benefit in relation to its clinically relevant comparators.
- No conclusive results are available on its possible impact on the organisation of the care system in terms of optimising therapeutic management in the treatment of neuroendocrine tumours and meningiomas

Diagnostic use

- The most common neuroendocrine tumours (NETs) are those of the small intestine, appendix, stomach, rectum, pancreas and bronchi. More than half of NETs are diagnosed at the metastatic stage, primarily in the liver. Accurate detection and delineation of the primary tumour and its secondary lesions are essential for making appropriate therapeutic decisions. Somatostatin receptor scintigraphy remains the first-line diagnostic test for gastroenteropancreatic NETs.
- Meningiomas are generally benign tumours. The expression of somatostatin receptors is one of the characteristics of meningiomas. Morphological imaging test (MRI) remains the standard examination for the diagnosis of meningiomas.
- **Role of the proprietary medicinal product in the therapeutic strategy**
  PET with IASOTOC has a role in the diagnosis of suspected or known gastroenteropancreatic or bronchial neuroendocrine tumours as part of the initial assessment (extension assessment), follow-up of an NET or prognostic determination of a metastatic NET.
  In meningiomas, functional PET imaging with IASOTOC can supplement MRI in some limited situations such as, for example, a diagnosis on uncertain imaging tests, in case of invasive or aggressive forms (stage II or III), or in the context of a pre-therapeutic assessment of extensive or multicentric lesions.

Clinical data

- In neuroendocrine tumours, one study compared ^{68}Ga-edotreotide versus pentetreotide in 84 patients in the context of a suspected NET (n=13), staging (n=36) or therapeutic follow-up (n=35). Of the 84 patients, 33 received pentetreotide alone, 33 received 99mTc-HYNIC-TOC and 18 received both 111In-DOTA-TOC and 99mTc-HYNIC-TOC. The results in terms of specificity (Sp) and sensitivity (Se) seem to favour ^{68}Ga-edotreotide with, for ^{68}Ga-edotreotide: Se 97%, Sp 92% and for the comparators SPECT Se 52%, Sp 92%, CT Se 61%, Sp 71%. The comparator, which was not exclusively pentetreotide, and the reduced numbers of each group limited the scope of the observed results.
- Nine studies compared ^{68}Ga-edotreotide to morphological imaging, including 4 retrospective studies. A single study compared ^{68}Ga-edotreotide to F-DOPA, but on a low number of 15 patients with NET before an unsealed source radiotherapy.
- In meningioma, 3 studies, all retrospective, which is a significant methodological limitation, included a number of 26 to 134 patients. A retrospective study over a period of 6 years compared the diagnostic precision of MRI and ^{68}Ga-edotreotide in 134 patients with meningioma before radiotherapy. The use of ^{68}Ga-edotreotide made it

possible to detect 190 meningiomas, while the MRI detected 171 (i.e. 90% of the meningiomas detected by ^{68}Ga-edotreotide).
- No study results are available on its possible impact on the organisation of the care system in terms of optimising therapeutic management in the treatment of NETs and meningiomas.
- The available data do not reveal any safety signals.

Special prescribing conditions

- Medicinal product reserved for hospital use.
- Radiopharmaceutical medicinal product.

Benefit of the medicinal product

- The actual benefit* of IASOTOC is substantial.
- IASOTOC does not provide clinical added value (CAV V) in diagnostic management that includes clinically relevant comparators.
- Recommends inclusion on the list of reimbursable products for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 05 April 2017 (CT-15806) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a 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”.