

SUMMARY

iohexol

**OMNIPAQUE 300 mg and
350 mg iodine/mL**

solution for injection

Indication extension

Adopted by the Transparency Committee on 11 September 2024

Summary of opinion**Favourable opinion for reimbursement only in patients:**

- with contraindications to MRI, in:
 - diagnostic dead end situations;
 - locoregional staging assessment;
 - tumour assessment before and after neoadjuvant chemotherapy;
- without contraindications to MRI, in locoregional staging assessment or before/after neoadjuvant chemotherapy, for the assessment of tumour size, in particular for its perfect match with mammography images.

Unfavourable opinion for reimbursement in the other situations covered by the MA indication.**Transparency Committee's conclusions****Clinical Benefit**

- ➔ Breast cancer is a life-threatening disease.
- ➔ This is a diagnostic medicinal product.
- ➔ The efficacy/adverse effects ratio is high given the diagnostic performance of contrast-enhanced mammography using OMNIPAQUE and its already well established safety profile.
- ➔ This is a diagnostic option as a contrast medium for contrast-enhanced mammography in patients:
 - with contraindications to MRI, in:
 - diagnostic dead end situations;
 - locoregional staging assessment;
 - tumour assessment before and after neoadjuvant chemotherapy;
 - without contraindications to MRI, in locoregional staging assessment or before/after neoadjuvant chemotherapy, for the assessment of tumour size, in particular for its perfect match with mammography images.

→ Public health benefit

Considering:

- the seriousness of the disease and its prevalence/incidence,
- the currently partially met medical need,
- the contribution of contrast-enhanced mammography with OMNIPAQUE in terms of meeting this medical need, given:
 - its diagnostic performance, but without evidence of an additional impact on morbidity and mortality and/or quality of life,
 - an expected, but not demonstrated, impact, which is non-quantifiable and nonetheless involves certain constraints, on the organisation of care or care and/or life pathway for the patient or their family,

OMNIPAQUE (iohexol) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of OMNIPAQUE 300 and 350 mg I/mL (iohexol) solution for injection is:

- **substantial only in patients:**
 - **with contraindications to MRI, in:**
 - **diagnostic dead end situations;**
 - **locoregional staging assessment;**
 - **tumour assessment before and after neoadjuvant chemotherapy;**
 - **without contraindications to MRI, in locoregional staging assessment or before/after neoadjuvant chemotherapy, for the assessment of tumour size, in particular for its perfect match with mammography images;**
- **insufficient to justify public funding cover in the other MA situations.**

The Committee issues the following opinions:

- **a favourable opinion for inclusion of OMNIPAQUE 300 and 350 mg I/mL (iohexol) solution for injection in the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages;**
- **an unfavourable opinion for inclusion of OMNIPAQUE 300 and 350 mg I/mL (iohexol) solution for injection in the list of covered drugs for inpatients approved for use in the other situations covered by the MA indication.**

Clinical Added Value

Considering:

- the data and conclusions of the report assessing the value of dual-energy contrast-enhanced spectral mammography in the diagnostic strategy for breast cancer produced by the HAS in 2021, and, in particular, the clinical situations in which the value of contrast-enhanced mammography has been recognised;
- the diagnostic performance of contrast-enhanced mammography with OMNIPAQUE based on publications in the literature in the same clinical situations as those explored in the 2021 report;
- the already well established safety profile of ULTRAVIST, with no new data calling into question this safety profile;

- the medical need currently partially met by the existence of diagnostic alternatives,

the Committee deems that OMNIPAQUE 300 and 350 mg I/mL (iohexol) solution for injection provides no clinical added value (CAV V) in the current care pathway, which includes the clinically relevant comparators cited.