**SUMMARY**

iopromide

# ULTRAVIST 300 mg and 370 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 ULTRAVIST 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 ULTRAVIST in terms of meeting this medical meet, 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,

ULTRAVIST (iopromide) is unlikely to have an additional impact on public health.

**Considering all these elements, the Committee deems that the clinical benefit of ULTRAVIST 300 mg and 370 mg iodine/mL (iopromide) 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 ULTRAVIST 300 mg and 370 mg I/mL (iopromide) 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 ULTRAVIST 300 mg and 370 mg iodine/mL (iopromide) 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 ULTRAVIST 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 ULTRAVIST 300 mg and 370 mg iodine/mL (iopromide) solution for injection provides no clinical added value (CAV V) in the current care pathway, which includes the clinically relevant comparators cited.**