HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
AND
NATIONAL COMMITTEE FOR THE EVALUATION OF MEDICAL DEVICES AND HEALTH TECHNOLOGIES

HAVING MET IN APPLICATION OF ARTICLE L. 161-41 OF THE FRENCH SOCIAL SECURITY CODE

SUMMARY
08 JUNE 2022

The legally binding text is the original French opinion version

Monopeak indocyanine green
INFRACYANINE 25 mg/10 mL powder and solvent for solution for injection

New indication

Key points

Favourable opinion for reimbursement in intraoperative detection of sentinel lymph nodes and lymphatic pathways in patients with breast cancer.

What therapeutic improvement?

No clinical added value in the diagnostic strategy for intraoperative detection of sentinel lymph nodes and lymphatic pathways in patients with breast cancer.

Role in the diagnostic pathway?

In breast cancer, the performance of selective Sentinel lymph node (SLN) dissection makes it possible to avoid extensive lymphadenectomy, depending on the pathology results. SLN dissection is recommended, and indicated in the event of an invasive, unifocal breast tumour of small size (< 2 cm) and in the absence of any detected malignant lymph node involvement, clinical and radiological N0 status. It can be proposed for certain cases of extensive or palpable ductal cancers in situ, treated by total mastectomy or when physicians suspect the presence of microinvasion (on radiological examinations or biopsy). In about 70% of cases where the SLN technique is indicated, the SLN is free of tumour cells, so lymphadenectomy is pointless and even harmful, since it is responsible for non-negligible morbidity, including early lymphocele and late lymphoedema, sensory and motor sequelae and aesthetic sequelae. In these defined indications, this technique makes it possible to reserve axillary lymphadenectomy for only those tumours that require it (the remaining 30%), in the event of lymph node involvement.

In breast cancer, lymphoedema is one of the most common complications of axillary lymphadenectomy, reported in 25 to 30% of patients. With the sentinel lymph node method, this percentage is estimated to be less than 10%.

The sentinel lymph node procedure was traditionally performed by dual detection using patent blue dye (PB) and a nanocolloid radiolabelled with Technetium 99 (Tc99m). However, cases of anaphylactic shock have been reported with PB, leading teams to gradually abandon this SLN identification method and to use Technetium 99-radiolabelled nanocolloids alone.

Role of the medicinal product in the care pathway:

INFRACYANINE (indocyanine green monopic) has a role in the diagnostic strategy, in the same way as nanocolloids radiolabelled with Technetium 99 (Tc99m), when the applicable guidelines recommend intraoperative detection of sentinel lymph nodes and lymphatic pathways in patients with breast cancer.

JOINT COMMITTEE CONCLUSIONS

Considering all of this information and further to debate and voting, the Joint Committee considers:

Clinical benefit

◗ The seriousness of the condition is defined on the basis of the results of the investigation.

◗ INFRACYANINE (monopeak indocyanine green) is a medicinal product for diagnostic use.

◗ The efficacy/adverse effects ratio is high.

◗ There are alternative diagnostic methods.

◗ INFRACYANINE (monopeak indocyanine green) is a first-line medicinal product in intraoperative detection of sentinel lymph nodes and lymphatic pathways in patients with breast cancer.

Public health benefit
Considering:
- the seriousness and high incidence of breast cancer and the benefit of avoiding lymphadenectomy and its sequelae when it is not necessary,
- the partially met medical need, but with the persistence of a need to have access to new non-invasive tests with demonstration of a better-quality diagnostic performance in this strategy,
- the lack of demonstrated additional impact on mortality, morbidity or quality of life compared to the diagnostic methods available,
- the lack of expected additional impact on the care and/or life pathway,
INFRACYANINE (indocyanine green monopic) is unlikely to have an additional impact on public health.

Considering all these elements, the Joint Committee deems that the clinical benefit of INFRACYANINE (monopeak indocyanine green) is substantial in the MA indication.

The Joint Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication.

Clinical Added Value

Considering the absence of conclusive evidence of a potential advantage in terms of diagnostic performance compared to nanocolloids radiolabelled with Technetium 99 (Tc99m) used in the same indication, INFRACYANINE (monopeak indocyanine green) provides no clinical added value (CAV V) compared to the radiopharmaceutical products indicated in sentinel lymph node detection in breast cancer.