BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

**ROTOP-nanoHSA** *(99mTc-labelled human albumin nanocolloid), radiopharmaceutical agent*

No diagnostic benefit demonstrated by comparison with current diagnostic agents (NANOCIS, NANOCOLL) used in whole-body lymphoscintigraphy and sentinel lymph node detection

**Main points**

- ROTOP-nanoHSA has Marketing Authorisation:
  - in lymphoscintigraphy for visualisation of the lymphatic system and to differentiate between venous and lymphatic obstruction.
  - in lymphoscintigraphy for the detection of sentinel lymph nodes in malignant melanoma and breast cancer.
- *99mTc*-labelled albumin nanocolloids have been used for several years in the two indications of the Marketing Authorisation.
- No comparative study is available versus technetium *(99mTc)*-labelled rhenium sulfide nanocolloids (NANOCIS), or by comparison with any other proprietary medicinal product based on technetium *(99mTc)*-labelled albumin nanocolloids (NANOCOLL).

**Diagnostic use**

Clinical parameters are generally sufficient for the diagnosis of lymphoedema but some situations necessitate additional investigations. Isotopic lymphoscintigraphy can be used to diagnose difficult cases. Technetium-labelled nanocolloids are therefore used in lymphoscintigraphy in special cases.

Used with the intraoperative blue dye technique, sentinel lymph node detection is indicated in extensive, high-grade ductal carcinoma in situ (DCIS) for which mastectomy is required and in unifocal infiltrating breast cancer in stage T1-2, N0.

International guidelines take differing positions on excision of the sentinel lymph node in cutaneous melanoma. According to experts, lymphoscintigraphy is an examination that is commonly used in practice to assess metastatic spread.

**Clinical data**

- Technetium *(99mTc)*-labelled albumin nanocolloids are commonly used in nuclear medicine departments in the two indications of the Marketing Authorisation.
  
  The review of the literature supplied by the company confirms the contribution made by these substances in lymphoscintigraphy in terms of diagnostic performance in the two indications.
  
  The use of technetium *(99mTc)*-labelled albumin is well-established, but no comparative study has been supplied versus technetium-labelled rhenium sulfide nanocolloids (NANOCIS). In addition, another proprietary medicinal product based on technetium-labelled albumin nanocolloids (NANOCOLL) is on the market and in use. In clinical practice and according to the experts, NANOCIS (rhenium sulfide nanoparticle) has Marketing Authorisation in the detection of sentinel lymph nodes, unlike NANOCOLL (human albumin nanocolloid), but there is no difference between the two substances in terms of performance in the two indications (limb lymphoscintigraphy and sentinel lymph node detection).

- No adverse events have been identified with use of this substance.
Benefit of the medicinal product

- The actual benefit* of ROTOP-nanoHSA is substantial.

- On the basis of current data, and in the absence of any demonstrated difference between ROTOP-nanoHSA and its comparators, ROTOP-nanoHSA does not provide clinical added value** (CAV V) by comparison with NANOCOLL or NANOCIS in lymphoscintigraphy for visualisation of the lymphatic system and to differentiate between venous and lymphatic obstruction.

- On the basis of current data, and in the absence of any demonstrated difference between ROTOP-nanoHSA and its comparator NANOCIS, ROTOP-nanoHSA does not provide clinical added value** (CAV V) by comparison with NANOCIS in the detection of sentinel lymph nodes in malignant melanoma and breast cancer.

- Recommends inclusion on the list of reimbursable products for hospital use.

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** 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".