

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

YTTRIGA (yttrium [^{90}Y]), radiopharmaceutical product for therapeutic use

Improvement in treatment by YTTRIGA on its own cannot be assessed.

Main points

- ▶ YTTRIGA has Marketing Authorisation as a radiopharmaceutical precursor intended for use only for the labelling of vector molecules, which have been specifically developed and authorised for labelling with this radionuclide.
- ▶ Yttrium chloride (^{90}Y), the active ingredient of YTTRIGA is a radiopharmaceutical medicinal product for use in radioimmunotherapy. Its place in the strategy depends on the vector molecule.
- ▶ In the absence of YTTRIGA/vector molecule versus YTRACIS/vector molecule comparison, the improvement that it brings cannot be assessed.

Therapeutic use

- Vectorised radiotherapy consists of the destruction of tumours by guiding a radioactive molecular probe to their immediate vicinity. A radiopharmaceutical medicinal product such as a peptide (radiopeptide therapy) or an antibody (radioimmunotherapy) labelled with a radioisotope is administered. The peptide or antibody selectively migrates to the tumour cells, binds itself to them, and bombards them with toxic radiation.
- This technique has demonstrated its efficacy in haematology in the treatment of B-cell lymphoma. A murine anti-CD20 monoclonal antibody (ibritumomab tiuxetan) labelled with yttrium-90 (ZEVALIN) may be used in the routine clinical treatment of CD20-positive follicular lymphoma in adults who are refractory to, or who have relapsed after treatment with rituximab, and leads to response rates of 70 to 80%, with 20 to 30% complete response (CR).
- **Role of the medicinal product in the therapeutic strategy**
The role in the therapeutic strategy depends on the vector molecule used.

Clinical data

- Only a clinical study including the yttrium/vector molecule combination in a given disease would permit an evaluation of the radiopharmaceutical medicinal product in question.
ZEVALIN, a murine anti-CD20 monoclonal antibody (ibritumomab tiuxetan) labelled with yttrium-90, indicated in the treatment of non-Hodgkin, CD20-positive, follicular B-cell lymphoma that has recurred after or failed to respond to treatment with rituximab, is the only propriety medicinal product radiolabelled with yttrium chloride that has so far been evaluated by the Transparency Committee (7 July 2004).
- Adverse effects following the intravenous injection of an yttrium (^{90}Y)-labelled medicinal product prepared by radiolabelling with YTTRIGA will depend on the specific medicinal product used. Free yttrium accumulates in the bones and can cause myelotoxicity. No particular safety signal has been observed since January 2010.

Benefit of the medicinal product

- The actual benefit* of YTTRIGA cannot be assessed given that the condition treated, the role in the therapeutic strategy, the efficacy and the adverse effects depend on the therapeutic entity, which comprises the YTTRIGA/vector molecule combination.
- In the current state of the data and in the absence of comparative studies of YTTRIGA/vector molecule versus YTRACIS/vector molecule, the clinical added value** of YTTRIGA compared with YTRACIS cannot be assessed.
- 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 by the National Health Insurance

** 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".