OPINION ON MEDICINAL PRODUCTS

177 Lutetium oxodotreotide
LUTATHERA 370 MBq/mL

Solution for infusion

Reassessment

Adopted by the Transparency Committee on 21 September 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Approval of reimbursement only for the treatment of unresectable or metastatic, progressive, well-differentiated (G1 and G2) somatostatin receptor positive-pancreatic neuroendocrine tumours (NETs) in adults.

Therapeutic improvement?

No improvement in relation to the therapeutic strategy.

Role in therapeutic strategy?

The Committee points out that the initiation of LUTATHERA (^{177}Lutetium oxodotreotide) treatment must be discussed within the framework of multidisciplinary team meetings as part of the NET-specific national network, RENATEN, designated by INCa.

The treatment of pancreatic NETs consists of managing tumour syndrome and any potentially associated secretory syndrome, which has a significant impact on patient quality of life and morbidity.

Considering:

- non-comparative data from the phase II OCLURANDOM study and the phase IV NETTER-R study suggesting the efficacy of LUTATHERA;
- a benefit in progression-free survival which has yet to be confirmed by a randomised study;
- the known usage of this product in intestinal NETs;
- the known acceptable safety profile of this proprietary product,

the Commission considers that LUTATHERA (^{177}Lutetium oxodotreotide) is a second-line treatment for unresectable or metastatic, progressive, well-differentiated (G1 and G2), somatostatin receptors positive-pancreatic NETs expressing somatostatin receptors.

Due to the lack of comparative data, the role of radioligand therapy (RLT) compared to sunitinib or everolimus is not known.

Haematotoxic risk should be monitored, especially in patients with previous exposure to alkylating chemotherapy protocols.

Special recommendations

The Committee recommends that the initiation of LUTATHERA (^{177}Lutetium oxodotreotide) treatment should be discussed within the framework of multidisciplinary team meetings as part of the NET-specific national network, RENATEN, designated by INCa.

Committee's conclusions

Clinical Benefit

- Gastroenteropancreatic neuroendocrine tumours, particularly pancreatic and when metastatic, are severe, potentially life-threatening diseases.
- LUTATHERA (^{177}Lutetium oxodotreotide) is a medicinal product with curative intent.
- The efficacy/adverse effect ratio is high.
- Therapeutic alternatives are available.
- It is a second-line treatment for unresectable or metastatic, progressive, well-differentiated (G1, G2) somatostatin receptor positive-pancreatic NETs.

Public health benefit

Considering:

– the severity of gastroenteropancreatic neuroendocrine tumours,
– the incidence of GEP NETs of approximately 1.1/100,000 in men and 0.9/100,000 in women,
– the medical need for medicinal products demonstrating their superiority over conventional therapies in terms of overall survival and quality of life for these patients.
– the lack of comparative data on the efficacy of LUTATHERA in pancreatic NETs,
– the impact on the delivery of care with respect to available alternatives, given the radioprotection constraints associated with the radiopharmaceutical product characteristics and the co-administration of aa hyperosmolar amino acid infusion,

LUTATHERA (^{177}Lutecium oxodotreotide) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of LUTATHERA (^{177}Lutetium oxodotreotide) is substantial for the treatment of adult patients with unresectable or metastatic, progressive, well-differentiated (G1 and G2), somatostatin receptors positive-pancreatic neuroendocrine tumours (NETs).

Recommended reimbursement rate: 100%

Clinical Added Value

Considering:

- the lack of robustness of the LUTATHERA efficacy demonstration based on data from a non-comparative phase II study when a comparison was possible with the available alternatives. A randomisation with an internal control group of sunitinib-treated patients was performed, without the possibility of formal comparison to this group;
- the absence of data from an external comparison with an appropriate methodology;
- the lack of evidence of an impact on overall survival;
- the partially met medical need;

the Transparency Committee deems that, based on the data currently available, LUTATHERA (^{177}Lutetium oxodotreotide) provides no clinical added value (CAV V) in the management of adult patients with unresectable or metastatic, progressive, well-differentiated (G1 and G2) somatostatin receptors positive-pancreatic neuroendocrine tumours (NETs). .