SUMMARY

everolimus

AFINITOR 5 and 10 mg

tablets

Reassessment at the request of the CT

Original French opinion adopted by the Transparency Committee on 29 May 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for maintenance of reimbursement in "the treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin in adults with progressive disease".

Transparency Committee's conclusions

Clinical Benefit

- Neuroendocrine tumours of the pancreas are life-threatening conditions.
- This is a medicinal product that aims to stabilise and/or reduce the tumour.
- The efficacy/adverse effects ratio of everolimus remains high.
- Medicinal and non-medicinal alternatives are available.
- This is a first or second-line treatment in view of the therapies available.

Public health benefit

Reminder of the opinion of 28/03/20112: "In view of the available results from the only phase 3 study, a moderate theoretical impact of everolimus may be expected in terms of reduction in morbidity. In addition, no improvement in overall survival has been observed. In fact, it is difficult to assess the expected impact in terms of reducing mortality given that the median overall survival had not been reached at the time of analysis, and that patients with documented disease progression were allowed to switch treatments. Furthermore, no quality of life data are available. The transposability of the results of the pivotal study to clinical practice is acceptable. No impact on the health system is expected. Therefore, the proprietary medicinal product AFINITOR is unlikely to provide a response to the identified public health need. Consequently, given the small number of patients concerned, no impact on public health is expected for AFINITOR in this indication." **Insofar as the additional response of**

AFINITOR (everolimus) to the identified public health need remains undetermined, this conclusion is unchanged.

Considering all these elements, the Committee deems that the clinical benefit of AFINITOR (everolimus) 5 and 10 mg remains substantial in the treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin in adults with progressive disease.

The Committee issues a favourable opinion for maintenance of inclusion of AFINITOR (everolimus) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in this MA indication and at the MA dosages.

➔ **Reimbursement rate: 100%.**

Clinical Added Value

Considering:

- **the significant methodological limitations of the OPALINE post-registration study, which does not enable the efficacy of everolimus (AFINITOR) in terms of progression-free survival to be compared with that of sunitinib or of the other alternatives; this study does not therefore meet the expectations of the Committee,**
- **the absence of an expected additional benefit on overall survival compared to these alternatives,**
- **the absence of quality of life data,**
- **the poor safety profile of everolimus,**

the Committee now deems that AFINITOR (everolimus) provides no clinical added value (CAV V) in the care pathway of adult patients with unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin.