

SUMMARY

sunitinib

**SUTENT 12.5 mg, 25 mg
and 50 mg,****hard capsules****Reassessment at the request of the CT /
following ministerial referral****Original French opinion adopted by the Transparency Committee on
19 July 2023****The legally binding text is the original French opinion version****Transparency Committee's conclusions****Clinical Benefit**

- ➔ Pancreatic neuroendocrine tumours are life-threatening conditions.
- ➔ This is a medicinal product that aims to stabilise and/or reduce the tumour.
- ➔ The efficacy/adverse effects ratio remains low: the efficacy is still inadequately established and sunitinib has a complex safety profile.
- ➔ Medicinal and non-medicinal alternatives are available.
- ➔ This is a first or second-line treatment in view of the therapies available (see 5.1).

➔ Public health benefit

The additional response of SUTENT to the identified public health need remains undetermined.

SUTENT (sunitinib) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of SUTENT (sunitinib) hard capsules remains moderate in the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.

The Committee issues a favourable opinion for maintenance of inclusion of SUTENT (sunitinib) 12.5 mg, 25 mg and 50 mg hard capsules in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.

The Committee highlights the fact that the new clinical data, including the post-registration study presented, do not meet the requirements of the Ministry of Health. The conclusions of the previous opinion are maintained by default rather than by confirmation.

- ➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use in the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults: 30%**

Clinical Added Value

The results of the reassessment are not of a nature to modify the Committee's conclusions of 21/09/2011.

The Committee considers that SUTENT (sunitinib) 1.5 mg, 25 mg, 50 mg hard capsules provide no clinical added value (CAV V) in the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.