HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE

OPINION

23 OCTOBER 2019

sorafenib

NEXAVAR 200 mg, film-coated tablet

Reassessment

Key points

Not approved for continued reimbursement in the treatment of advanced renal cell carcinoma after failure of prior interferon alfa or interleukin 2 treatment, or in patients for whom these treatments are considered unsuitable

Actual clinical benefit now insufficient (previously high).

Role in the therapeutic improvement?

Until 2007, the therapeutic management strategy for advanced metastatic kidney cancer was based primarily on the use of cytokines [interleukin-2 or aldesleukin (PROLEUKIN) and interferon alpha or ROFERON-A)].

Currently, the recommended first-line treatments in cases of good or intermediate prognosis are: tyrosine kinase inhibitors (TKI) with SUTENT (sunitinib) and VOTRIENT (pazopanib); AVASTIN (bevacizumab)/interferon; and since 11/01/2019, immunotherapy with a combination of OPDIVO (anti-PD-1, nivolumab) and YERVOY (anti-CTLA-4, ipilimumab) for intermediate risk patients.

Second-line treatments for clear cell renal cell carcinoma include:

- in the event of failure of TKI [SUTENT (sunitinib), VOTRIENT (pazopanib)] or AVASTIN (monoclonal anti-VEGF antibody, bevacizumab) in combination with interferon: standard treatments are now OPDIVO (nivolumab) or CABOMETYX (cabozantinib). These treatments supplant AFINITOR (everolimus) given the demonstration of their superiority in terms of overall survival. INLYTA (axitinib) would remain an option. Unlike INLYTA (axitinib) or AFINITOR (everolimus), NEXAVAR (sorafenib) has not been granted an MA in patients who have experienced failure of sunitinib or any other targeted anti-VEGF therapy.

- in the event of cytokine failure, standard treatments were INLYTA (axitinib) or NEXAVAR (sorafenib).

The MA indication of NEXAVAR (sorafenib) in the treatment of advanced renal carcinoma is restricted to patients experiencing cytokine failure (interferon alfa or interleukin 2) or in patients for whom these treatments are considered unsuitable. The role of cytokines, however, is increasingly marginal due to the use of the so-called targeted therapies that have supplanted them. Thus, NEXAVAR, whose use stems from that of cytokines, no longer has a role in the current therapeutic strategy of advanced renal carcinoma.

Other clinical situations, particularly in the event of failure of a treatment other than cytokines (so-called targeted therapies, anti-PD-1 immunotherapy, etc.), do not fall within the scope of the NEXAVAR (sorafenib) MA.

COMMITTEE'S CONCLUSIONS

Actual benefit

◗ Advanced renal carcinoma is a serious, life-threatening disease.
◗ This proprietary medicinal product is part of a specific curative cancer treatment.
◗ The efficacy/adverse effects ratio of this proprietary medicinal product remains high after cytokine failure.
◗ There are medicinal alternatives.
◗ NEXAVAR (sorafenib) no longer has a role in the management of these patients (see paragraph 07 Role in the strategy) in the MA indication, restricted to patients with advanced renal carcinoma experiencing failure to cytokines (interferon alfa or interleukin 2), whose use is increasingly marginal, or in patients for whom these treatments are considered inadequate.

Public health benefit (PHB)
Considering:
- the severity of advanced clear-cell kidney cancer with good prognosis,
- the incidence of kidney cancer, estimated at 15,323 new cases per year in France in 2018,
- the lack of medical need after the failure of cytokines, whose role has become marginal,
- the lack of response provided by NEXAVAR (sorafenib) to the identified second-line medical need due to changes in management (see paragraph 02 Medical Need),
- lack of evidence to support an improvement in the care pathway or organisation of care,

NEXAVAR (sorafenib) is unlikely to have an impact on public health.

Given these elements and in light of current management, the Committee considers that the actual benefit of NEXAVAR (sorafenib) is insufficient to justify public funding cover in the MA indication.

Clinical Added Value

Not applicable.