HAUTE AUTORITÉ DE SANTÉ

ONCOLOGY
Focus
April 2016

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

ALIMTA (pemetrexed), antimetabolite

Moderate clinical added value in first-line treatment of unresectable malignant pleural mesothelioma

Main points

- ALIMTA has marketing authorisation, in combination with ciscplatin for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.
- It is the standard treatment for this disease.

Therapeutic use

- Chemotherapy based on pemetrexed and platinum salt is the only recommended treatment. There is no second-line treatment.
- Due to the small number of therapeutic options, concern about the quality of life of the patient and their family should be ongoing throughout the duration of this disease and should influence therapeutic choices. Supportive and palliative care should be discussed in multidisciplinary meetings and organised with specialist teams and the attending physician.
- **Role of the medicinal product in the therapeutic strategy**
  ALIMTA, in combination with cisplatin, is the standard first-line treatment for patients with unresectable malignant pleural mesothelioma who have not received prior chemotherapy.

Clinical data

- In one randomised single-blind phase III study conducted in 456 adults with malignant pleural mesothelioma who did not receive prior systemic chemotherapy, the median overall survival (primary endpoint) with the pemetrexed/cisplatin combination (PEM/CIS) (12.1 months) was superior to treatment with cisplatin as a monotherapy (CIS) (9.3 months); HR=0.77; 95% CI=[0.61-0.96]; p=0.02.
- In one retrospective cohort study of 1,704 treatment naïve patients with malignant pleural mesothelioma, treated with pemetrexed in combination with a platinum salt in 13 countries (Europe + Canada):
  - The objective response rate (complete response and partial response according to the RECIST or SWOG criteria) was 26% (196/745) in the pemetrexed/cisplatin (PEM/CIS) group and 22% in the pemetrexed/carboplatin (PEM/CAR) group (163/752).
  - The median time to disease progression (time between the date of administration of the first dose and the date of documented progression) was 7.0 months in the PEM/CIS group and 6.9 months in the PEM/CAR group.
  - One-year survival rates were 63% in the PEM/CIS group and 64% in the PEM/CAR group.
- The toxicity of the pemetrexed/cisplatin combination was mainly haematological (neutropenia (28% of adverse events grade 3 or greater), leukopenia (18%), anaemia (5%), thrombocytopenia (6%)). The main non-haematological adverse events of grade 3 or greater were fatigue (10%), nausea (15%) and vomiting (13%).

Special prescribing conditions

- Medicine for hospital prescription.
- Prescription restricted to certain specialists.

Benefit of the medicinal product

- The actual benefit* of ALIMTA is substantial.

- ALIMTA provides moderate clinical added value** (CAV III) in this indication.
- Recommends continued inclusion on the list of reimbursable products for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 20 April 2016 (CT-15033) available at **www.has-sante.fr**

* 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 for hospital use.

** 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".