New oncology reimbursements in Belgium

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Overview of Belgian reimbursement news.

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Abiraterone acetate, Zytiga®

The reimbursement for Zytiga® has recently been extended to chemonaïve patients with metastatic prostate cancer which is resistent to castration. Eligible are patients who are asymptomatic or have minimal symptoms after androgen deprivation and for whom chemotherapy is not yet indicated. The following criteria should be fulfilled before Zytiga® may be reimbursed:

- Testosteron serum castration levels < 50ng/dL or < 1.7nmol/L
- Pain score 0 to 3 for worst pain in the last 24 hours according to BPI-SF
- At least one of the following signs of disease progression:
  - 3 consecutive PSA increases with at least 2 PSA levels > 2ng/ml representing a raise in PSA of 50% to the nadir.
  - progression of bone lesions.
  - progression of soft tissue lesions according to RECIST criteria: an increase of at least 20% and 5 mm in the sum of the diameters of all measurable lesions.
  - Development of 1 or more visceral or soft tissue metastases.
- The patient is no longer eligible for hormone therapy, nor is he eligible for the initiation of docetaxel therapy (the patient has a PSA doubling time which is longer than 6 months to be calculated according to *Arlen et al. (J Urol. 2008 June;179(6):2181-6)* or is for other reasons not eligible to start docetaxel treatment).

The reimbursement takes into account a maximal posology of 4 tablets of 250mg per day.

Bevacizumab, Avastin®

Avastin® is reimbursed in combination with paclitaxel and carboplatin for the first line treatment of stage IV epithelial ovarian cancer. Avastin is also reimbursed in combination with carboplatin and gemcitabine for platinum-sensitive patients with a first recurrence. The drug is reimbursed in the first line setting at a dose of 15mg/kg body weight every 3 weeks in combination with carboplatin or paclitaxel for a maximum of 6 cycles followed by monotherapy for a maximum of 15 months in total, or until disease progression or unacceptable toxicity. In the second line setting, avastin is reimbursed at a dose of 15mg/kg every 3 weeks in combination with carboplatin and gemcitabine for 6 cycles, with a maximum of 10 cycles. Thereafter, avastin is given as monotherapy until disease progression. In order to be eligible for reimbursement the patient may not have a history of arterial thromboembolism, nor suffer from hypertension that is not controlled by standard therapy. All patients must be evaluated after 3 and 6 cycles and the treatment should be stopped if the CT or MRI scan demonstrates disease progression. After the 6th cycle, the patient should be evaluated with CT or MRI at least every 3 months.

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