New oncology reimbursements in Belgium

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Cabazitaxel, Jevtana®

Jevtana® is reimbursed when used in combination with prednisone in the management of patients with metastatic hormone-refractory prostate cancer who progressed on docetaxel-based chemotherapy. The reimbursement takes a maximal posology of 25mg/m² in a three-weekly administration into account. In order to be eligible for cabazitaxel reimbursement, the following conditions must be met:

- Serum castration levels <50ng/dL or <1.7nmol/L.
- Previous treatment with flutamide (last treatment at least four weeks ago) or bicalutamide (last treatment at least six weeks ago) or with second-line hormone manipulation.
- At least three cycles of docetaxel.
- Patient is not eligible for a second docetaxel regimen because progression occurred during the first three docetaxel cycles, or because progression was observed <5 months after the first docetaxel treatment.
- The patient has an ECOG status of 0 or 1.
- At least one of the following characteristics:
    - Three consecutive PSA rises within three weeks.
    - Progression of bone laesions (new bone metastasis or at least two bone laesions on bone scan).
    - Progression of soft tissue laesions based on RECIST criteria.
    - Occurence of one or more soft tissue or visceral laesions.

The reimbursed treatment should be stopped when either two of the following observations are made during the first twelve weeks of therapy, or one of the following observations is made after twelve weeks of therapy:

- PSA levels at least 2ng/mol and 25% higher than lowest value observed during the cabazitaxel treatment after at least three weeks.
- Progression of bone laesions.
- Progression of soft tissue laesions based on RECIST criteria.
- Occurence of one or more soft tissue or visceral laesions.

Tretinoin, Vesanoid®

Vesanoid® is the trade name for tretinoin also known as ATRA, or All-Trans Retinoic Acid. Vesanoid® is reimbursed when used in the management of patients with acute promyelocytic leukaemia.

Denosumab, XGEVA®

XGEVA® is reimbursed in patients older than 18 years of age with bone metastases from solid tumours. The aim of the XGEVA® therapy is to prevent complications associated with bone metastases such as pathological bone fractures, spinal

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cord compression, and radiotherapy or surgery to the bone. The reimbursement takes a posology of one subcutaneous administration of 12mg every four weeks for a period of 48 weeks into account. However, if justified, the reimbursement can be prolonged, each time for a period of 48 weeks. Simultaneous reimbursement of XGEVA® with a drug from category A82, B230 or B279 is not allowed.

Erlotinib, Tarceva®

Tarceva® is reimbursed as a first-line treatment in patients with locally advanced or metastatic NSCLC harbouring an activating EGFR mutation. All patients must undergo CT and MRI evaluation after eight weeks of therapy and at least every twelve weeks thereafter. If the CT or MRI scan shows progression, the Tarceva® treatment must be terminated. The reimbursement is allowed for a period of six months. However, this can be prolonged for additional periods of six months after completion of a standardised form indicating the absence of disease.

Tarceva was already reimbursed before when used as monotherapy for the treatment of patients with locally-advanced or metastatic non-small cell lung carcinoma (NSCLC) who failed at least one previous chemotherapy regimen. In order to be eligible for reimbursement, patients need to express EGFR with at least 10% positive cells on immunohistochemistry. Finally, Tarceva® is also reimbursed when used as monotherapy in the maintenance treatment of patients with NSCLC without progression after four cycles of standard, platinum-based first-line chemotherapy, who have a tumour harbouring an activating EGFR mutations.