New oncology reimbursements in Belgium

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Overview of Belgian reimbursement news

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Erythropoietins

Erythropoietins can be reimbursed when prescribed by a specialist in clinical hematology, oncology, or medical oncology as supportive therapy in the following situations:

1) When prescribed for adult patients with solid tumors for the treatment of secondary anemia, caused by platinum-based chemotherapy, with exception of anemia from other causes (occult bleedings, iron deficiency, etc.).
2) When prescribed for adult patients receiving myelosuppressive therapy and whose haemoglobin levels have fallen below 11.0g/dl, once other causes of anemia have been excluded.

In all situations, the goal of chemotherapy should not be curative, reimbursement only covers advanced or metastatic disease. Furthermore, the goal for haemoglobin levels should never be higher than 12g/dl.

The initial dosing for solid tumors should be a weekly dose of 2.25μg/kg body weight for a period of 4 weeks. For hematological tumors (including lymphoma), the initial dose of 2.25μg/kg body weight can be given for 8 weeks.

In case the heamoglobin level has risen with at least 1g/dl during the initial therapy, without transfusions, the reimbursement can be prolonged for a maximum period of 8 weeks.

Trastuzumab, Herceptin®

Trastuzumab is eligible for reimbursement in breast cancer patients with an amplification of the HER2 gene. The HER2 amplification should be demonstrated by a positive in situ hybridisation (ISH) test. The ISH test is considered positive if more than 6 copies of the gene are observed in the nucleus or if the ratio between HER2 signals and signals of the centromere of chromosoom 17 is higher than 2. In case of an intermediate result (4 to 6 copies of HER, ratio 1.8-2.2), a second ISH test should be performed together with an immunohistochemical test of which the result should be 3+ in order to confirm overexpression of the protein.

Reimbursement is allowed in case:

- Of lymph node involvement of a tumor with a diameter of at least 10mm.
- The left ventricle ejection fraction is superior to 55% at the start of the trastuzumab therapy (as demonstrated using a MUGA scan or cardiac echo) in the absence of other cardiac contra-indications (e.g. history of heart failure, coronary disease with Q-wave myocard infarction, medically managed angor, uncontrolled arterial hypertension, instable arrhythmia, a clinically significant valve pathology)
- Trastuzumab is given within the framework of a therapeutic regimen containing a classical adjuvant chemotherapy with a posology for which efficacy has been demonstrated.

Trastuzumab can be reimbursed as monotherapy in patients who failed at least two previous chemo-

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therapy regimens including at least one anthracycline derivate and one taxane. Trastuzumab can also be reimbursed in association with paclitaxel in patients who did not receive chemotherapy for their metastatic disease or who are considered unfit for anthracyline-based chemotherapy. Lastly, trastuzumab may also be reimbursed in association with docetaxel in patients who did not receive chemotherapy for their metastatic disease as long as the reimbursement criteria for docetaxel have been met.

The number of reimbursed packages takes a maximum dose of 4mg/kg for the initial loading dose into account. This loading dose can only be reimbursed once. Afterwards, a maximum weekly dose of 2mg/kg is taken into account. The first request for reimbursement will be awarded for a maximum period of 2 months, renewable for periods of 6 months based on objective elements demonstrating the clinical efficacy of the treatment.