New oncology reimbursements in Belgium

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(Belg J Med Oncol 2013;7(4):133)

Crizotinib (Xalkori®)

Xalkori® is reimbursed in the treatment of patients with ALK-positive non-small cell lung carcinoma, demonstrated with an immunohistochemistry test that is validated for lung carcinoma, confirmed by a positive, validated FISH test. Both tests must be performed by laboratories who can guarantee the validity of the analyses. The following patients are eligible for reimbursement:

- Adult patients with tumour progression after at least two cycles of standard chemotherapy with at least two cytostatic agents;
- Patients older than 65 years or adult patients with a poor performance status (i.e. PS of 2 or more) with tumour progression after at least two cycles of standard chemotherapy with at least 1 cytostatic agent.

All patients must be evaluated after twelve weeks of therapy, or earlier, depending on the clinical situation. From this first evaluation onwards, new evaluations (i.e. CT-scans or Medical Need Programme (NMR)) must be performed at least every twelve weeks for the rest of the treatment. Treatment will be continued until disease progression according to RECIST criteria evaluated by radiodiagnostic evaluation of the laesions.
Reimbursement is started after completion of a standardised form by a medical oncologist or by a pulmonologist with expertise in oncology who is responsible for the treatment. The number of reimbursed packages takes into account a posology scheme with a maximal recommended dose of 500mg/day.
Patients with ALK-positive non-small cell lung cancer, demonstrated by a validated FISH test, who experienced a response with Xalkori® and who are still being treated in the context of a MNR when this new regulation is introduced, need to be evaluated as discussed above.

Everolimus (Afinitor®)

Afinitor® is reimbursed in the treatment of hormone receptor positive, HER2 negative advanced breast cancer in combination with exemestane in postmenopausal women without symptomatic visceral disease following recurrence or progression on a non-steroidal arpmatase inhibitor like anastrozol or letrozole. In addition to this, the patient should be eligible for reimbursement of exemestane in the management of advanced breast cancer in postmenopausal women. A multidisciplinary oncological consult (MOC) needs to approve treatment with Afinitor® before it can be reimbursed. For patients treated with Afinitor® in the context of a clinical trial for at least twelve weeks, reimbursement is allowed as long as the patient fulfils the criteria described above.

Patients need to be evaluated with medical imaging every twelve weeks. If this evaluation shows progression according to RECIST criteria, the treatment should be stopped immediately.

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Conflict of interest: The authors have nothing to disclose and indicate no potential conflict of interest.