New oncology reimbursements in Belgium

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Everolimus, Afinitor®

Afinitor® is reimbursed for the treatment of patients with unresectable or metastatic, well-differentiated neuro-endocrine tumours (NETs) of the pancreas with disease progression. Approval of a multidisciplinary oncological consult (MOC) is necessary for the reimbursement of Afinitor®. While on treatment, patients need to undergo four monthly CT or MRI scans. Treatment should be stopped when patients present with progressive disease based on Response Evaluation Criteria In Solid Tumors (RECIST criteria). Treatment should also be stopped in the presence of clinical or biochemical progression.

For patients who received at least three months of Afinitor® in the context of a clinical trial, reimbursement is allowed if the criteria described above are met.

Panitumumab, Vectibix®

Vectibix® is reimbursed for the treatment of patients with metastatic colorectal cancer with wild-type KRAS. Reimbursement for Vectibix® is allowed when:

- It is used in combination with FOLFOX in the first-line treatment of patients with metastatic colorectal cancer with wild-type KRAS. At the start of treatment, patients should have a Karnofsky performance status of ≥80.
- It is used in combination with FOLFIRI in the second-line treatment of patients with metastatic colorectal cancer with wild-type KRAS, who received a fluoropyrimidine-containing regimen as first-line therapy (without irinotecan).
- It is used as monotherapy in patients who failed previous therapy with 5FU, oxaliplatin and irinotecan containing chemotherapy regimens.

Patients are not allowed to have a history of or indications for interstitial pneumonitis or pulmonary fibrosis at the start of the Vectibix® treatment. Vectibix® (monotherapy or in combination) is not reimbursed after treatment failure with Vectibix®.

After six weeks of treatment, all patients should be evaluated and the treatment should be stopped if the CT or MRI scan demonstrates tumour growth in line with the definition of disease progression (RECIST definition for progression: increase of 20% or more in the sum of the largest diameters of all reference laesions compared to the sum at the start of therapy). Re-evaluation of the disease is required in week twelve and eighteen after the start of therapy and every two months thereafter.

Dasatinib, Sprycel®

Sprycel® is reimbursed for the treatment of chronic myeloid leukaemia (CML) in the presence of the Philadelphia chromosome (presence of the Bcr/Abl fusion gene) demonstrated by cytogenetic evaluation and/or PCR, in case of resistance to a previously

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used treatment including another tyrosine kinase inhibitor, or in case of intolerance justifying discontinuation of the treatment with the other tyrosine kinase inhibitor. In order to be eligible for reimbursement, patients must be eighteen years or older and have CML in accelerated phase or in blast crisis. Sprycel® is also reimbursed for patients with acute lymphoblastic leukaemia (ALL), in the presence of the Philadelphia chromosome, in case of resistance to a previously used treatment, or in case of intolerance justifying discontinuation of the previously used therapy. Patients should be over 18 years of age.
The simultaneous reimbursement of Tasigna® and Sprycel® is never allowed.
In order for Sprycel® to be reimbursed, the attending physician needs to provide a protocol describing the requested analyses, the elements leading to the diagnosis and the course of the disease. If the efficacy of the Sprycel® therapy is no longer demonstrated, therapy should be stopped immediately. The drug is reimbursed for a maximum of twelve months.

Bevacizumab, Avastin®

Avastin® is reimbursed as first-line treatment of patients with metastatic colon or rectal cancer with the recommended dose of:

- 5mg/kg once every two weeks in combination with intravenous 5-fluorouracil/folic acid and irinotecan or 5-fluorouracil/folic acid and oxaliplatin.
- 7.5mg/kg once every three weeks in combination with capecitabine and oxaliplatin.

Before starting the therapy, the patient should meet the following criteria:

- Patient never received chemotherapy for his metastatic disease (i.e. excluding adjuvant chemotherapy) and did not previously receive Avastin®.
- Patient does not have a history of arterial thromboembolic events (cerebrovascular accident, transient ischaemic attack, myocard infarction, angina pectoris, periferal arterial insufficiency, other thromboembolic events)
- Patient does not suffer from hypertension that is not controlled with standard therapy.
- Patient has an ECOG performance status of 0 or 1.

After six weeks of treatment, all patients should be evaluated and the treatment should be stopped if the CT or MRI scan demonstrates tumour growth in line with the definition of disease progression (RECIST definition for progression: increase of 20% or more in the sum of the largest diameters of all reference laesions compared to the sum at the start of therapy). Re-evaluation of the disease with CT or MRI is required every nine weeks thereafter and treatment should be stopped if disease progression (as defined above) is observed.