# New oncology reimbursements in Belgium

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Overview of Belgian reimbursement news
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## CHAPTER VIII FOR "PERSONALISED DRUGS"

From July 1st 2019, a new chapter will be introduced in the reimbursement of drugs: "chapter VIII". This chapter collects drugs for which reimbursement is conditioned by the presence/absence of a molecular biomarker. Chapter VIII very much resembles chapter IV: the reimbursement conditions of the drugs are listed in different paragraphs and a priori authorisation by the Insurance Agency is required. Next to a list of these drugs, chapter VIII also holds a list of the coupled predictive biomarkers. This makes it possible to link the reimbursement of both drug and biomarker, so both can be assessed in the same reimbursement procedure and reimbursement can start simultaneously after a uniform decision. For the moment, chapter VIII only holds drugs with a companion molecular biology test. Drugs that are merely linked to an immunohistochemistry or hereditary test are not in this scope and stay in chapter IV. Some drugs have an indication linked to a molecular biomarker and another indication without a link. These drugs will have a paragraph in chapter VIII but also a paragraph in chapter IV. More information on the new chapter and the linked reimbursement can be found on the RIZIV/INAMI website.

Drugs that are reimbursed via chapter VIII as of July 1st are: tretinoin, trastuzumab, imatinib, arsenic trioxide, erlotinib, cetuximab, panitumumab, lapatinib, gefitinib, nilotinib, vemurafenib, crizotinib, bosutinib, dabrafenib, pertuzumab, afatinib, trastuzumab emtansine, ibrutinib, dasatanib, idelalisib, ponatinib, ceritinib, osimertinib, trametinib, venetoclax, cobimetinib, alectinib, and midostaurine. Reimbursement demand forms for these drugs can be found at the same locations as the demand forms for drugs in chapter IV. As a transitional measure, authorisations for the drugs in chapter IV that were delivered before the entry into force of chapter VIII can retain their validity in accordance with the provisions stated on these authorisations.

## DURVALUMAB (IMFINZI®)

Durvalumab (Imfinzi®) is reimbursed when administered for any indication approved by the European Medicines Agency (EMA).

Durvalumab (Imfinzi®) as monotherapy is currently approved for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy.

The efficacy of durvalumab was evaluated in the **PACIFIC** study, a randomised, double-blind, placebo-controlled, trial in 713 patients with locally advanced, unresectable NSCLC who had completed at least two cycles of platinum based definitive chemotherapy with radiation within 1 to 42 days prior to initiation of the study and who had not progressed following chemoradiation. Patients were randomised 2:1 to receive durvalumab 10 mg/kg or placebo every two weeks

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for up to twelve months or until unacceptable toxicity or confirmed disease progression.

**TABLE 1.** Results of the PACIFIC study.

| | | Durvalumab | Placebo |
|---|---|---|---|
| N | | 476 | 237 |
| OS | | | |
| | median (months) | NR | 28.7 |
| | 95% CI | 34.7-NR | 22.9-NR |
| | HR | 0.68 | |
| | 95% CI | 0.53-0.87 | |
| | p | 0.00251 | |
| | at 24 months | 66.3% | 55.6% |
| | 95% CI | 61.7-70.4 | 48.9-61.3 |
| | p | 0.005 | |
| PFS | | | |
| | median (months) | 16.8 | 5.6 |
| | 95% CI | 13.0-18.1 | 4.6-7.8 |
| | HR | 0.52 | |
| | 95% CI | 0.42-0.65 | |
| | p | <0.0001 | |
| | at 12 months | 55.9% | 35.3% |
| | 95% CI | 51.0-60.4 | 29.0-41.7% |
| | at 18 months | 44.2% | 27.0% |
| | 95% CI | 37.7-50.5 | 19.9-34.5 |

*N: number of patiens; OS: overall survival; PFS: progression-free survival; CI confidence interval; HR: hazard ratio; NR: not reached*

The study demonstrated a statistically significant improvement in progression-free survival (PFS) and overall survival (OS) (co-primary endpoints) (*Table 1*).

## LIPOSOMAL IRINOTECAN (ONIVYDE®)

Liposomal irinotecan (Onivyde®) is reimbursed in association with 5-fluorouracil and leucovorin for the treatment of metastatic adenocarcinoma of the pancreas in irinotecan-naïve patients with an Eastern Cooperative Oncology Group performance status <2, progressing after gemcitabine.

In **NAPOLI-1**, 417 patients with metastatic adenocarcinoma of the pancreas who had documented progression after gemcitabine or gemcitabine-containing chemotherapy were randomised to receive liposomal irinotecan 70 mg/m² followed by folinic acid 400 mg/m² followed by 5-FU 2400 mg/m² over 46 hours every two weeks (n=117), or folinic acid 200 mg/m² followed by 5-FU 2000 mg/m² over 24 hours administered on day 1, 8, 15, and 22 of a six week cycle (n=149), or liposomal irinotecan 100 mg/m² every three weeks (n=151). Key eligibility criteria included Karnofsky Performance score (KPS) ≥70, normal bilirubin, albumin ≥3 g/dL.

The primary endpoint was OS. Median OS was 6.1 months (95% confidence interval [CI] 4.8-8.9) in patients assigned to liposomal irinotecan plus folinic acid/5-FU *vs.* 4.2 months (95% CI 3.3-5.3) in patients assigned to folinic acid/5-FU (HR 0.67; 95% CI 0.42-0.92; p=0.012).

There was no difference between patients who received liposomal irinotecan alone and those who received folinic acid/FU (HR 0.99; 95% CI 0.77-1.28; p=0.94).

## OSIMERTINIB (TAGRISSO®)

Osimertinib (Tagrisso®) is now also reimbursed as **first** line treatment in patients with locally advanced or metastatic NSCLC presenting an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation.