# Ramucirumab in colorectal and lung cancer: Partly added benefit, partly lesser benefit

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Ramucirumab (trade name: Cyramza) is a monoclonal antibody, which blocks a receptor, reducing the growth of blood vessels and so reducing blood supply to the tumours. This aims to slow the growth of the tumours. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in two early benefit assessments whether the drug offers an added benefit over the appropriate comparator therapies for adult patients with metastatic colorectal cancer (MCRC) or with locally advanced or metastatic non-small cell lung cancer (NSCLC).

According to the findings, there is an indication of a minor added benefit of ramucirumab for women with MCRC, and a hint of lesser benefit for men with MCRC. In NSCLC, the result was similarly split: There is proof of a minor added benefit for under 65-year-olds, but proof of lesser benefit for older patients in comparison with the comparator therapy.

**Colorectal cancer: differences between men and women**

The Federal Joint Committee (G-BA) specified a chemotherapeutic regimen called FOLFIRI as appropriate comparator therapy. The benefit assessment was based on the randomized controlled trial RAISE, in which adults with MCRC participated who were additionally treated with FOLFIRI in the ramucirumab arm, and only treated with FOLFIRI in the comparator arm.

Overall survival was longer in the ramucirumab arm of the study than in

the comparator arm. Only women lived statistically significant longer, however. In contrast to this indication of a considerable added benefit, in women, there were hints of negative effects with different extent, including greater harm of a major extent in the outcome category "serious/severe side effects". These did not completely outweigh the advantage in overall survival so that an indication of a minor added benefit of ramucirumab in comparison with the comparator therapy for female patients remains.

For male patients, in contrast, there was no survival advantage. Only negative effects occurred, which concerned symptoms, quality of life and side effects. This resulted in a hint that ramucirumab has lesser benefit for them than the comparator therapy.

**Lung cancer: differences between younger and older patients**

The G-BA cited different treatment options as appropriate comparator therapy, from which the drug manufacturer chose the chemotherapeutic drug docetaxel.

In the two randomized controlled trials REVEL and JVCG, on which the benefit assessment for NSCLC was based, patients were treated with ramucirumab in combination with docetaxel in the test arm and with docetaxel alone in the comparator arm. Participants survived longer in the test arms than in the control arms also here.

However, only patients under the age of 65 years benefited from this advantage. Besides this considerable added benefit in overall survival, there was also a hint of considerable lesser harm in the outcome category "serious/severe side effects" for them. Negative effects also occurred in the same category, but they did not completely outweigh the advantages. Hence there is proof of a minor added benefit of ramucirumab and docetaxel versus docetaxel alone for under 65-year-olds.

Older patients, in contrast, had no survival advantage, and only negative effects (more side effects) occurred, so that lesser benefit of ramucirumab plus docetaxel in comparison with docetaxel alone is proven for them.

## G-BA decides on the extent of added benefit

The dossier assessments are part of the early benefit assessment according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the G-BA. After publication of the dossier assessments, the G-BA conducts commenting procedures and makes final decisions on the extent of the added benefit.

**More information:** www.iqwig.de/download/A16-10_R … ertung-35a-SGB-V.pdf
www.iqwig.de/download/A16-11_R … ertung-35a-SGB-V.pdf

Provided by Institute for Quality and Efficiency in Health Care

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