Eribulin in liposarcoma: Added benefit not proven

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Eribulin (trade name: Halaven) has been approved since May 2016 for the treatment of adults with advanced liposarcoma. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether the drug offers an added benefit over the appropriate comparator therapy in these patients.

According to the findings, the dossier contained no data suitable for the assessment: In the only study of direct comparison, the dosage of the drug in the comparator arm was not in compliance with the approval. It was not ensured in an indirect comparison that the respective patient populations were sufficiently similar. An added benefit of eribulin is therefore not proven.

New therapeutic indication of eribulin

The Institute had assessed the added benefit of eribulin for women with advanced or metastatic breast cancer in two earlier dossier assessments (2012 and 2014). In May 2016, the approval of eribulin was expanded to treatment of unresectable liposarcoma, a type of cancer that develops in fat tissue, that cannot be surgically removed and that has already formed metastases. It is an option for adults who have already received chemotherapy with the drug anthracycline.

The appropriate comparator therapy specified by the Federal Joint Committee (G-BA) was antineoplastic drug treatment at the physician's

discretion under consideration of the respective approval status of the drugs currently used and of the prior therapies.

Drug not used in compliance with the approval in the control arm

In its dossier, the drug manufacturer used one study of direct comparison that tested eribulin against dacarbazine. In the control arm, dacarbazine was not used in compliance with the approval, however: Instead of administration in combination with another drug (doxorubicin), dacarbazine was used as monotherapy, and a different dosage was used in the beginning of the treatment. The results of the study were therefore unsuitable to derive an added benefit.

Similarity of the study population not ensured

The latter was also true for the data from an indirect comparison: Here, the manufacturer analysed studies that compared either eribulin or trabectedin with dacarbazine. To be able to derive benefit or harm from such an indirect comparison, however, it has to be ensured that the study participants are sufficiently similar. This was not the case. It could therefore not be excluded that differences in the treatment results were caused by differences between the study populations and not by the different drugs used.

G-BA decides on the extent of added benefit

The dossier assessment is 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 assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of the added benefit.

More information: www.iqwig.de/download/A16-31_E … ertung-35a-SGB-V.pdf

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