Talimogene laherparepvec in melanoma: Added benefit not proven

October 6 2016

Talimogene laherparepvec (trade name: Imlygic) has been approved since December 2015 for adults with advanced melanoma. 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. However, since the manufacturer dossier contained no suitable data, no added benefit of talimogene laherparepvec could be derived from it.

The G-BA distinguished between three treatment situations

The drug talimogene laherparepvec is used for the treatment of advanced melanoma that cannot be surgically removed and that has spread to other parts of the body, but not to bone, brain, lung, and other internal organs.

For the assessment of the added benefit, the Federal Joint Committee (G-BA) distinguished between three treatment situations and specified a different appropriate comparator therapy for each of them. These appropriate comparator therapies depended on the pretreatment and on whether or not the gene for the BRAF enzyme has mutated in the tumour cells.

Medication in the control arm inadequate

For all three situations, the manufacturer cited a study of direct

comparison that tested talimogene laherparepvec against the granulocyte-macrophage colony-stimulating factor (GM-CSF). However, GM-CSF did not concur with the ACT specified by the G-BA for any of the research questions and is also not approved for the treatment of melanoma.

Since the manufacturer also presented no studies that allowed an indirect comparison, its dossier contained no data from which an added benefit could be derived. An added benefit of talimogene laherparepvec is therefore not proven.

Provided by Institute for Quality and Efficiency in Health Care