Edoxaban: Considerable added benefit for certain patients

November 5 2015

Edoxaban (trade name: Lixiana) has been approved since June 2015 for two therapeutic indications in adults: on the one hand, for prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation (NVAF) with other risk factors for stroke; on the other, for treatment and prevention of deep vein thrombosis and pulmonary embolism. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this drug offers an added benefit over the appropriate comparator therapy.

In conclusion, an indication of considerable added benefit in comparison with vitamin K antagonists was derived for the prevention of stroke and systemic embolism: Stroke, bleeding and severe side effects occurred less frequently under edoxaban. For the second therapeutic indication, suitable analyses were lacking in the drug manufacturer dossier.

Comparison with warfarin in both therapeutic indications

In compliance with the approval, IQWiG assessed edoxaban in two separate modules: firstly for prevention of stroke and systemic embolism in patients with NVAF with at least one other risk factor for stroke, such as hypertension, prior stroke, or diabetes mellitus (assessment module I); secondly for the treatment of deep vein thrombosis and pulmonary embolism, and to prevent recurrent thrombosis and pulmonary embolism (assessment module II).

The Federal Joint Committee (G-BA) specified vitamin K antagonists (VKAs) as appropriate comparator therapy for both therapeutic indications. In its dossier, the manufacturer compared edoxaban with warfarin in each case.

Positive effects in the prevention of stroke and embolism

Major bleeding was less frequent in the total population of study participants who were taking edoxaban. Some advantages of edoxaban for different outcomes were only shown in women: They had fewer haemorrhagic strokes, fewer nonmajor bleeding events requiring treatment, and fewer severe side effects than the comparator group. Fewer disabling strokes occurred in patients with a high risk of stroke (CHADS2 score > 3).

Overall, only positive effects of edoxaban in the prevention of stroke and systemic embolism remain. The probability of added benefit or lesser harm regarding several symptoms and complaints (morbidity) as well as side effects is "indication"; the extent varies from "considerable" to "minor" (see assessment module I).

No separate analyses according to treatment duration

In the second therapeutic indication, the treatment and prevention of (recurrent) deep vein thrombosis and pulmonary embolism, a distinction has to be made between two patient populations that require different treatment durations: either acute treatment and temporarily limited prevention of three to six months, or continuous prevention for longer than three to six months (long-term prevention). However, the manufacturer did not distinguish between these two patient populations in its dossier, and presented no separate analyses for the respective

patient group (see assessment module II). Hence there are no suitable analyses for an assessment in this therapeutic indication, and no hint of an added benefit can be derived.

More information: www.iqwig.de/download/A15-29_E … ertung-35a-SGB-V.pdf

Provided by Institute for Quality and Efficiency in Health Care