Vortioxetine in depression: No hint of added benefit

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Vortioxetine (trade name: Brintellix) has been approved since December 2013 for the treatment of depression in adults, but did not become actually available before May 2015. 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. Such an added benefit cannot be derived from the dossier because it contained no data evaluable for the assessment.

SSRI is drug component of comparator therapy

The Federal Joint Committee (G-BA) distinguished between three patient groups depending on the severity of the disease and specified a different appropriate comparator therapy for each of them: no drug treatment for mild episodes of depression, an antidepressant from the group of selective serotonin reuptake inhibitors (SSRIs) for moderate episodes and a combination of an SSRI and an offer of psychotherapy for severe episodes. In addition, differentiation between acute treatment and relapse prevention can be inferred from the Summary of Product Characteristics.

Only acute treatment investigated

However, the manufacturer only investigated acute treatment in its dossier. It presented no studies for the subgroup of mild episodes. It

compared moderate and severe episodes, for which the G-BA had specified an SSRI and an SSRI plus offer of psychotherapy as appropriate comparator therapy, with the drug citalopram without considering psychotherapy.

Only small part of the studies included in meta-analysis

Due to a lack of studies of direct comparisons, the company conducted an adjusted indirect comparison with studies that tested either vortioxetine or citalopram against placebo. It identified 14 studies with vortioxetine and 10 with citalopram, but included only 3 and 4 of these studies in the meta-analysis. This important limitation was not convincingly justified and inadequate. This resulted in an incomplete consideration of the evidence, which is why no added benefit can be derived from the results.

G-BA decides on the extent of added benefit

This dossier assessment is part of the early benefit assessment according to AMNOG supervised by the Federal Joint Committee (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.

An overview of the results of IQWiG's benefit assessment is given by a German-language executive summary. In addition, the Website gesundheitsinformation.de, published by IQWiG, provides easily understandable German-language Information.

More English-language information will be available soon (Sections 2.1 to 2.5 of the dossier assessment as well as subsequently published health information on informedhealthonline.org). If you would like to be informed when these documents are available, please send an e-mail to " info@iqwig.de.

More information: www.iqwig.de/download/A15-16_V … ertung-35a-SGB-V.pdf

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