Transcorneal electrical stimulation for retinitis pigmentosa

Executive Summary

1 Translation of the executive summary of the assessment of potential Transkorneale Elektrostimulation bei Retinopathia Pigmentosa (Version 1.0; Status: 29 August 2014). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.
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2 Due to legal data protection regulations, employees have the right not to be named.
Executive summary

In accordance with §137e Social Code Book (SGB) V, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the potential of the method of transcorneal electrical stimulation (TES). The application was transferred to IQWiG on 3 July 2014.

According to the applicant, TES uses electrical stimulation of the retina to slow down the destruction of sensory cells in patients with retinitis pigmentosa (RP), thus preserving the visual performance of the patients for a longer time.

15 publications (including registry entries, conference presentations and manuscripts) were available for the assessment. 6 publications reported preclinical animal studies and were not included in the assessment. In 5 publications, study population, treatment method, or both, were not in line with the research question of the application. 4 publications (on 2 randomized controlled trials [RCTs]) were used for the assessment of the potential.

Results from 2 RCTs were available for the outcome “visual field”. One of the studies showed a significant effect in favour of TES. Both studies showed no statistical significance for the outcome “visual acuity”. Potentially unfavourable effects for the outcome “colour discrimination” were shown in 1 RCT. There were no data for the outcomes “contrast sensitivity”, “dark adaptation” and “health-related quality of life”. Serious adverse events were not observed in either of both RCTs.

Hence, on the basis of the application documents submitted, a potential of a patient-relevant benefit can be inferred for TES in patients with RP. This potential is primarily based on the available findings on the outcome “visual field”.

A testing study that is suited to obtain the necessary information for the assessment of the method’s benefit is basically possible.

Keywords: electric stimulation therapy, retinitis pigmentosa, assessment of potential