Background report assessing whether occipital neurostimulation for chronic cluster headache complies with established medical science and medical practice

Summary

In this assessment report, the *College voor Zorgverzekeringen* (CVZ) examines whether occipital neurostimulation, applied to patients with refractory chronic cluster headaches, complies with the established medical science and medical practice criterion, which would mean it could be included among the insured provisions within the framework of the *Zorgverzekeringswe*t (Zvw, Health Insurance Act).

Indication

Cluster headache (CH) is a relatively rare form of headache that occurs in attacks (clusters of headaches). These attacks are often accompanied by autonomous symptoms, including redness of the eyes or lacrimation, nasal congestion or rhinorrhea, facial perspiration, miosis and/or ptosis. Two types can be distinguished: episodic and chronic cluster headache (ECH and CCH, respectively). ECH means the clusters of headaches are intermittent, with pain-free periods between the headache clusters, but with CCH there are no pain-free periods or they last less than one month. About 10% of the patients with CCH do not respond – or respond insufficiently – to the drugs available (refractory CCH).

Occipital neurostimulation

Occipital neurostimulation is a treatment involving the unilateral or bilateral subcutaneous implantation of an electric stimulator in the region of the occipital nerves (nervus occipitalis major). This is attached, via subcutaneously implanted extension leads, to a pulse generator with a battery that is implanted in the patient's body. The stimulation parameters can be programmed using a remote control. The mechanism of action is as yet unknown.

Methods

In order to determine the efficacy of occipital neurostimulation on refractory chronic cluster headache, a literature search was carried out into the use of this treatment for the said indication. Reduction in frequency of headaches was chosen as outcome parameter. In keeping with current literature, a >50% reduction in frequency of headaches was deemed clinically relevant. Also included were other headache-related outcome parameters such as quality of life, headache intensity and duration of the headache.

Relevant outcome parameters

Efficacy

No comparative studies were found. Seven case series were identified, as well as one systematic review and two case

	studies. Occipital neurostimulation seems to have a favourable effect on some of the patients treated, as shown by a reduction in the frequency of headaches or an improved quality of life. Favourable alterations in the intensity of headaches were also reported in a number of cases. However, the quality of the studies is low as is the level of evidence: for example, the groups of patients were small and the duration of follow-up was heterogeneous.
Side effects	The stimulation-related side effects reported are generally of a mild nature, with re-operation being necessary in the worst cases, due to electrode-migration, inflammation and exhausted batteries. Too few patients were included in the studies, with too short a follow-up duration, to warrant making any statement about the severity and frequency of side effects that occurred. Therefore, the efficacy of occipital neurostimulation has been insufficiently demonstrated.
Conclusion	Occipital neurostimulation in cases of refractory chronic cluster headaches does not comply with the 'established medical science and medical practice' criterion.
Experts on the subject	Experts on the subject agree with the conclusion of this report regarding the inadequate evidence regarding the efficacy of occipital neurostimulation on refractory chronic cluster headaches.

The original text of the summary of this assessment report was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of the summary of the assessment report.
Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.