NICE National Institute for Health and Care Excellence

NICE guidance

# Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache

HealthTech guidance

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# Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# Contents

This guidance replaces IPG527.

# 1 Recommendations

1.1 Current evidence on the efficacy of implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache, in the short term (up to 2 months), is adequate. With regard to safety, a variety of complications have been documented, most of which occur early and resolve; surgical revision of the implanted system is sometimes needed. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to implant a sphenopalatine ganglion stimulation device for chronic cluster headache should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and long-term efficacy and provide them with clear written information. Patients should be informed about other treatment options. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having sphenopalatine ganglion stimulation (see NICE's interventional procedure outcomes audit tool).

1.3 The selection of patients for implantation of a sphenopalatine ganglion stimulation device and their management should be done by multidisciplinary teams specialising in refractory headache.

1.4 Clinicians should enter details about all patients being implanted with a sphenopalatine ganglion stimulation device onto the national Neuromodulation register hosted by the National Institute for Cardiovascular Outcomes Research (NICOR). Clinical outcomes should also be reviewed locally.

1.5 NICE encourages further research on sphenopalatine ganglion stimulation for chronic cluster headache. Reported outcomes should include long-term efficacy and device durability.

# 2 Indications and current treatments

2.1 Cluster headaches are characterised by episodes of unilateral periorbital pain, conjunctival injection, lacrimation and rhinorrhoea. This form of neurovascular headache most commonly affects middle-aged men. Headache attacks can last from a few minutes to several hours and can occur many times a day, over several days. Chronic cluster headaches can be separated by headache-free periods of less than 1 month, or not separated at all.

2.2 The usual treatments for acute cluster headache attacks are oxygen inhalation and/or medications such as triptans. Medications such as corticosteroids, verapamil and occipital nerve blocks are used to prevent or reduce the number of attacks. Surgical treatments are reserved for patients with distressing symptoms that are refractory to medical treatments. They include deep brain stimulation to modulate central processing of pain signals and radiofrequency ablation to interrupt trigeminal sensory or autonomic pathways.

# 3 The procedure

3.1 It is believed that cluster headaches are caused by a trigeminal-autonomic reflex mediated through the sphenopalatine ganglion. This procedure aims to relieve pain and reduce the frequency of cluster headache attacks by implanting a device in the pterygopalatine fossa to stimulate the sphenopalatine ganglion with small electrical currents.

3.2 Implantation of the neurostimulator device is performed with the patient under general anaesthesia. A small incision is made in the mucogingival margin adjacent to the maxillary first or second molar on the affected side. Under X-ray control, the lead of the neurostimulator device is advanced subperiosteally along the posterior maxilla in order to place stimulating electrodes in the pterygopalatine fossa. Through the same incision in the mucogingival margin, the main body of the device is fixed medial to the zygoma by means of a small plate. After implantation, the device is tested to assess electrode functionality and the patient's physiological responses to stimulation.

3.3 When cluster headaches occur, the patient activates the neurostimulator (up to a pre-determined maximum dose) by placing a handheld control unit on their cheek, over the area where the main body of the device is implanted.

# 4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 In a randomised sham-controlled crossover study of 32 patients who randomly had full stimulation, sub-perception stimulation or sham stimulation during each cluster headache attack, a reduction in pain at 15 minutes after neurostimulation was reported in 67% (127/190) of attacks treated by full stimulation and 7% (15/192) of attacks treated by sham stimulation ($p<0.001$). A reduction in pain at 15 minutes after neurostimulation was reported in 7% (14/184) of attacks treated by sub-perception stimulation ($p=0.96$ compared against sham stimulation). Complete resolution of pain at 15 minutes after neurostimulation was reported in 34% (65/190) of attacks treated by full stimulation and 2% (3/192) of attacks treated by sham stimulation ($p<0.001$). Complete resolution of pain at 15 minutes after neurostimulation was reported in 2% (3/184) of attacks treated by sub-perception stimulation ($p=0.97$ compared against sham stimulation).

4.2 In the randomised sham-controlled crossover study of 32 patients, a reduction in pain at 90 minutes after neurostimulation was reported in 60% of cluster headache attacks treated by full stimulation and 13% of attacks treated by sham stimulation ($p<0.001$).

4.3 In the randomised sham-controlled crossover study of 32 patients, the mean attack frequency reduced from 17.4 attacks per week to 12.5 attacks per week at 2-month follow-up, for the 28 patients who completed the experimental period ($p=0.005$).The frequency of headaches reduced by a minimum of 50% in 43% (12/28) of patients.

4.4 In the randomised sham-controlled crossover study of 32 patients, mean Headache Impact Test scores (scores range from 36 to 78 with lower scores indicating better quality of life) improved by 6.8±10.2 points (from 66 to 59) at 2-month follow-up, for the 28 patients who completed the experimental period ($p=0.002$). Mean SF-36 physical function scores (scores range from 0 to 100 with higher scores indicating better outcomes) improved from 38.0 to 43.5 at 2-month

follow-up (p=0.005). Mean SF-36 mental function scores improved from 34.5 to 39.0 (p=0.02).

4.5 Specialist advisers listed key efficacy outcomes as acute treatment of headaches, reduction in attack frequency, reduction in acute medication use and improved quality of life as measured by the Headache Impact Test.

# 5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Lead revision or explantation of the device was needed for 16% (5/32) of patients, between 30 days and 1 year after the procedure, in a randomised sham-controlled crossover trial of 32 patients who randomly had full stimulation, sub-perception stimulation or sham stimulation during each cluster headache attack.

5.2 Lead revision, due to improper or suboptimal lead positioning, was needed in 13% (13/98) of patients in a case series of 98 patients. No further details were provided. In the same study, device explantation was needed in 6% (6/98) of patients due to dislodgement of an incorrectly sized neurostimulator (n=1), dysaesthesia/neurotic pain in the maxillary nerve (n=3), improper placement of the lead in the maxillary sinus (n=1), and infection within the surgical incision site (n=1).

5.3 Sensory disturbances (including localised loss of sensation, hypoaesthesia, paraesthesia, dysaesthesia and allodynia) were reported in 81% (26/32) of patients within 30 days of device implantation in the randomised sham-controlled crossover trial of 32 patients; symptoms resolved in 58% (15/26) of these patients. Sensory disturbances were reported in 16% (5/32) of patients between 30 days and 1 year after the procedure; symptoms resolved in 60% (3/5) of these patients.

5.4 Pain (facial, cheek, gum, temporomandibular joint, nose, incision site or periorbital) was reported in 38% (12/32) of patients within 30 days of device implantation in the randomised sham-controlled crossover trial of 32 patients. Severity of pain was not described and symptoms resolved in all of these patients. Pain was reported in 19% (6/32) of patients between 30 days and 1 year after the procedure: symptoms resolved in 50% (3/6) of these patients.

5.5 Headaches, that were not cluster headaches, were reported in 9% (3/32) of

patients within 30 days of device implantation in the randomised sham-controlled crossover trial of 32 patients; symptoms resolved in all of these patients. Headaches, that were not cluster headaches, were reported in 9% (3/32) of patients between 30 days and 1 year after the procedure; symptoms resolved in 1 of these patients.

5.6 Unspecified swelling was reported in 22% (7/32) of patients within 30 days of device implantation in the randomised sham-controlled crossover trial of 32 patients; symptoms resolved in 86% (6/7) of these patients.

5.7 Trismus was reported in 16% (5/32) of patients within 30 days of device implantation in the randomised sham-controlled crossover trial of 32 patients; symptoms resolved in 80% (4/5) of these patients.

5.8 Dry eye was reported in 9% (3/32) of patients within 30 days of device implantation in the randomised sham-controlled crossover trial of 32 patients; symptoms resolved in 1 of these patients. Dry eye was reported in 1 patient between 30 days and 1 year after the procedure; no further details were provided.

5.9 Mild paresis of the muscles around the nasolabial fold was reported in 6% (2/32) of patients within 30 days of device implantation in the randomised sham-controlled crossover trial of 32 patients; symptoms resolved in 1 of these patients.

5.10 Infection was reported in 6% (2/32) of patients within 30 days of device implantation in the randomised sham-controlled crossover trial of 32 patients; symptoms resolved in all patients following treatment with antibiotics. Infection was reported in 1 patient between 30 days and 1 year after the procedure; symptoms resolved following treatment with antibiotics.

5.11 Epistaxis, facial asymmetry, lacrimation, vomiting, lead migration and a maxillary sinus puncture (no details were provided) were each reported as occurring on single occasions in different patients within 30 days of device implantation, in the randomised sham-controlled crossover trial of 32 patients; symptoms resolved in all patients.

5.12 Itching, dry nose, dry skin, taste alterations, a depressed gag reflex and sensation in the infratemporal fossa (no details were provided) were each reported as occurring on single occasions in different patients, between 30 days and 1 year after the procedure in the randomised sham-controlled crossover trial of 32 patients.

5.13 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not highlight any anecdotal adverse events. They considered that damage to adjacent structures (such as the sinuses) was a theoretical adverse event.

# 6 Committee comments

6.1 The Committee was advised that, in most patients, cluster headaches respond to medical treatments. However, a small number of patients have headaches that do not respond and they may have very distressing symptoms. Treatment choices for these patients are limited and sphenopalatine ganglion stimulation may be 1 option for offering them some relief.

# Update information

**Minor changes after publication**

**January 2026:** Interventional procedures guidance 527 has been migrated to HealthTech guidance 378. The recommendations and accompanying content remain unchanged.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.