Greater Manchester Shared Services

# Greater Manchester EUR Policy Statement on:

## Headache Disorders

GM Ref: GM017
Version: 1.0 (March 2017)

Greater Manchester Shared Services
Hosted by NHS Oldham CCG
on behalf of the Greater Manchester CCGs

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## Commissioning Statement

<table>
<tr><th colspan="2">Headache Disorders</th></tr>
<tr><td>Policy Exclusions</td><td>Treatment of headache in line with NICE CG150 as part of locally agreed contracts and / or pathways of care are excluded from this policy e.g. North West Headache Management Guideline for Adults – based on NICE CG150. Treatment in line with this guideline is not restricted in any way by this policy.<br><br>Treatment/procedures undertaken as part of an externally funded trial are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).</td></tr>
<tr><td>Policy Inclusion Criteria</td><td>Management of Headache in Adults is commissioned in line with the North West Headache Management Guideline for Adults – based on NICE CG150.<br><br>Treatments not covered by the North West Headache Management Guideline for Adults that may be commissioned are:<br><br>Acupuncture<br><br>Commissioned if the patient falls into the following category:<br><br>• The individual has migraine that impacts on their quality of life.<br><br><u>AND</u><br><br>• Both topiramate and propranolol are unsuitable or ineffective.<br><br>For this group an initial course of up to 10 sessions of acupuncture over 5–8 weeks can be tried. If effective, application can be made for ongoing treatment.<br><br>Funding Mechanism<br><br>Initial course: Individual prior approval provided the patient meets the above criteria. Requests should be submitted with all relevant supporting evidence, which <u>must</u> be provided with the request.<br><br>Ongoing treatment if initial course effective: Individual funding request (exceptional case) approval: Requests shouldbe submitted with all relevant supporting evidence, which <u>must</u> be provided with the request (this must include a report on the outcome of the initial course).<br><br>Botulinum Toxin Type A for the prevention of headaches in adults with chronic migraine<br><br>This is covered by NICE TA260 (Issued: June 2012). Patients must meet the requirements of TA260:<br><br>• Have had headaches on at least 15 days of each month, with migraine on at least 8 of these days).<br><br><u>AND</u><br><br>• Have already tried at least three different drug treatments to prevent chronic migraine headaches, but these have not worked.<br><br><u>AND</u><br><br>• Are not taking too many painkillers or using them too often.</td></tr>
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| | |
|---|---|
| | **Botulinum toxin type A treatment should be stopped if:**<br>• The number of days the patient has a chronic migraine headache each month hasn't reduced by at least 30% after two courses of botulinum toxin type A treatment.<br>**OR**<br>• The chronic migraine changes to episodic migraine (that is, fewer than 15 days with headaches each month) for 3 months in a row.<br><br>**Funding Mechanism**<br>Monitored Approval: Referrals may be made in line with the criteria without seeking funding. **NOTE:** May be the subject of contract challenges and/or audit of cases against commissioned criteria.<br><br>**The following interventions are NOT commissioned as they are considered unproven therapies based on the current evidence:**<br>• Occipital nerve stimulation for intractable chronic migraine (IPG 452 Issued: April 2013)*<br>• Acupuncture for Migraine (outside of a commissioned pathway for headaches)<br>• Spinal manipulation for cluster headache<br>• TENS for cluster headache / migraine<br>• Gamma Core external Vagal Nerve stimulator for Headache<br>• Transcranial magnetic stimulation for use during the aura before a migraine<br>• Percutaneous closure of patent foramen ovale for recurrent migraine<br>• Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache (currently only provided in 2 centres in the UK (Liverpool and London) the company who produce the device are funding a number of cases in these centres only.)<br><br>**Funding Mechanism**<br>Individual funding request (exceptional case) approval: Applications for the above should be made using the process outlined in the GM Experimental & Unproven Treatments Policy. Requests should be submitted with all relevant supporting evidence, which must be provided with the request.<br><br>***NOTE:** Occipital nerve stimulation for intractable chronic migraine is commissioned by NHS England. |
| **Clinical Exceptionality** | Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality.<br><br>Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:<br>• Significantly different to the general population of patients with the condition in question. |

| | |
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| | ***and as a result of that difference***<br>• They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition. |

## Contents

## Policy Statement

Greater Manchester Shared Services (GMSS) Effective Use of Resources (EUR) Policy Team in conjunction with GM EUR Steering Group have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

In creating this policy GMSS has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

## Equality & Equity Statement

GMSS/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMSS/CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMSS/CCG will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMSS Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMSS evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact policyfeedback.gmscu@nhs.net.

## Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

## Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.

- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

## Rationale behind the policy statement

This policy aims to ensure that evidence based practice is followed and to ensure that new and developing therapies are evidence based and targeted at the individuals who will benefit most from those therapies.

Treatments outside of the standard pathway for headache as outlined in NICE CG150 are unproven and potential side effects of treatment are still relatively unknown. This policy has been developed to ensure that when used these therapies are targeted at the appropriate patient groups with all safeguards in place for patient safety.

## Treatment / Procedure

Treatment for headache disorders depends on the nature and type of the headaches being treated. There are evidence based national clinical guidelines on the best management of each type of headache.

There are also new therapies for all types of headache being developed, not all of which currently have high quality research evidence to back up their use.

### What are headache disorders?

Headache disorders are among the most common disorders of the nervous system. Headache is a painful and disabling feature of a small number of primary headache disorders namely migraine, tension-type headache, and cluster headache. Headache can also be caused by or occur secondarily to a long list of other conditions, for example medication overuse headache.

### Types of headache disorders

Migraine, tension-type headache and medication-overuse headache are of public health importance as they are responsible for high population levels of disability and ill-health.

**Migraine**

- A primary headache disorder.
- Most often begins at puberty and most affects those aged between 35 and 45 years.
- It is caused by the activation of a mechanism deep in the brain that leads to release of pain-producing inflammatory substances around the nerves and blood vessels of the head.
- Migraine is recurrent, often life-long, and characterized by attacks.
- Attacks include features such as:
  - headache of moderate or severe intensity;
  - nausea (the most characteristic);
  - one-sided and/or pulsating quality;
  - aggravated by routine physical activity;
  - with duration of hours to 2-3 days;
  - attack frequency is anywhere between once a year and once a week; and
  - in children, attacks tend to be of shorter duration and abdominal symptoms more prominent.

**Tension-type headache (TTH)**

- TTH is the most common primary headache disorder.
- Episodic TTH is reported by more than 70% of some populations; chronic TTH affects 1-3% of adults.
- TTH often begins during the teenage years, affecting three women to every two men.
- Its mechanism may be stress-related or associated with musculoskeletal problems in the neck.
- Episodic TTH attacks usually last a few hours, but can persist for several days.
- Chronic TTH can be unremitting and is much more disabling than episodic TTH.
- This headache is described as pressure or tightness, like a band around the head, sometimes spreading into or from the neck.

**Cluster headache (CH)**

- A primary headache disorder.
- CH is relatively uncommon affecting fewer than 1 in 1000 adults, affecting six men to each woman.
- Most people developing CH are in their 20s or older.
- It is characterised by frequent recurring, brief but extremely severe headache associated with pain around the eye with tearing and redness, the nose runs or is blocked on the affected side and the eyelid may droop.
- CH has episodic and chronic forms.

**Medication-overuse headache (MOH)**

- MOH is caused by chronic and excessive use of medication to treat headache.
- MOH is the most common form of secondary headaches.
- It may affect up to 5% of some populations, women more than men.
- MOH is oppressive, persistent and often at its worst on awakening.

## Epidemiology and Need

### How common are headache disorders?

Globally, it has been estimated that prevalence among adults of current headache disorder (symptomatic at least once within the last year) is 47%. Half to three quarters of the adults aged 18-65 years in the world have had headache in the last year and among those individuals, more than 10% have reported migraine. Headache on 15 or more days every month affects 1.7-4% of the world's adult population. Despite regional variations, headache disorders are a worldwide problem, affecting people of all ages, races, income levels and geographical areas.

### What is the burden due to headache disorders?

Not only is headache painful, but also disabling. In the Global Burden of Disease Study, updated in 2004, migraine on its own was found to account for 1.3% of years lost due to disability (YLD).

Headache disorders impose a recognisable burden on sufferers including sometimes substantial personal suffering, impaired quality of life and financial cost. Repeated headache attacks, and often the constant fear of the next one, damage family life, social life and employment. The long-term effort of coping with a chronic headache disorder may also predispose the individual to other illnesses. For example, depression is three times more common in people with migraine or severe headaches than in healthy individuals.

**Migraine**

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**Cluster Headache**

- CH is relatively uncommon affecting fewer than 1 in 1000 adults, affecting six men to each woman.
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**Medication-overuse headache**

- MOH is the most common form of secondary headaches.
- It may affect up to 5% of some populations, women more than men.

## Adherence to NICE Guidance

This policy adheres fully to the recommendations made in NICE TA260; NICE CG150; NICE QS42; NICE IPG452; NICE IPG477; and NICE IPG370.

## Audit Requirements

Clinicians should enter details about all patients undergoing ONS for intractable chronic migraine onto the UK Neuromodulation Register when access to that database is available. They should audit and review clinical outcomes locally and should document and consider their relationship to patient characteristics.

Data on all patients having percutaneous closure of patent foramen ovale for recurrent migraine should be submitted to the UK Central Cardiac Audit Database.

Details about all patients being implanted with a sphenopalatine ganglion stimulation device are entered onto the national Neuromodulation register hosted by the National Institute for Cardiovascular Outcomes Research (NICOR).

## Date of Review

One year from the date of approval by Greater Manchester Association Governing Group and thereafter at a date agreed by the Greater Manchester EUR Steering Group, unless new evidence or technology is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

## Glossary

| Term | Meaning |
|---|---|
| Acupuncture | A system of complementary medicine in which fine needles are inserted in the skin at specific points along what are considered to be lines of energy (meridians), used in the treatment of various physical and mental conditions. |
| Aura | Sensory warning signs or symptoms experienced with a migraine, such as flashes of light, blind spots, or tingling in your hand or face. |
| Gamma Core external Vagal Nerve stimulator | GammaCore is a non-invasive hand-held device that produces a mild electrical signal that is transmitted to the vagus nerve through the skin. Vagus nerve stimulation sends electrical signals along a nerve, called the vagus nerve, parts of which run through the neck to the brain. |
| Inflammatory | Relating to or causing inflammation of a part of the body |
| Inflammation | A localized physical condition in which part of the body becomes reddened, swollen, hot, and often painful, especially as a reaction to injury or infection. |
| Nervous system | The network of nerve cells and fibers which transmits nerve impulses between parts of the body. |
| NICE | National Institute for Health and Care Excellence |
| NICE CG | Clinical Guidance |
| NICE CKS | Clinical Knowledge Summaries |
| NICE IPG | Interventional Procedure Guidance |
| NICE QS | Quality Standards |
| NICE TA | Technology Appraisal |
| Occipital nerve stimulation | a form of neuromodulation therapy aimed at treating headache and craniofacial pain. This therapy involves an implantable device composed of an electrode and pulse generator. |
| Percutaneous closure of patent foramen ovale | Percutaneous closure is performed using local anaesthesia and intravenous sedation, or with the patient under general anaesthesia. A closure device is introduced using a guide wire and delivery sheath through a small incision in the groin into the femoral vein. It is then passed into the heart and across the patent foramen ovale (a hole between the left and right atria (upper chambers) of the heart. This hole exists in everyone before birth, but usually closes shortly after being born. PFO is what the hole is called when it fails to close naturally after a baby is born.). The closure device is released to close the defect using image guidance such as echocardiography. Devices of differing design and mechanism are available. |
| Sphenopalatine ganglion stimulation device | the neurostimulator is implanted via a small incision 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 the 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. When cluster headaches occur, the patient activates the |

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| | 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. |
| Spinal manipulation | A therapeutic intervention performed on spinal articulations which are synovial joints. These articulations in the spine that are amenable to spinal manipulative therapy include the z-joints, the atlanto-occipital, atlanto-axial, lumbosacral, sacroiliac, costotransverse and costovertebral joints. |
| TENS | The use of electric current produced by a device to stimulate the nerves for therapeutic purposes. |
| Transcranial magnetic stimulation | a procedure that uses magnetic fields to stimulate nerve cells in the brain to improve symptoms. |

## References


1. Greater Manchester Effective Use of Resources Operational Policy
2. British Association for the study of Headache: Guidelines for all Healthcare Professionals in the diagnosis and management of Migraine; Tension Type Headaches; Cluster Headache; Medication overuse headache. 3rd edition Published 2010.
3. WHO Fact sheet N°277: Headache Disorders October 2012


## Governance Approvals

| Name | Date Approved |
|---|---|
| Greater Manchester Effective Use of Resources Steering Group | 16/03/2016 |
| Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning | 14/02/2017 |
| Greater Manchester Association Governing Group | 07/03/2017 |
| Bury Clinical Commissioning Group | 05/04/2017 |
| Bolton Clinical Commissioning Group | 24/03/2017 |
| Heywood, Middleton & Rochdale Clinical Commissioning Group | 07/03/2017 |
| Central Manchester Clinical Commissioning Group | 15/03/2017 |
| North Manchester Clinical Commissioning Group | 15/03/2017 |
| Oldham Clinical Commissioning Group | 07/03/2017 |
| Salford Clinical Commissioning Group | 07/03/2017 |
| South Manchester Clinical Commissioning Group | 15/03/2017 |
| Stockport Clinical Commissioning Group | 07/03/2017 |
| Tameside & Glossop Clinical Commissioning Group | 07/03/2017 |
| Trafford Clinical Commissioning Group | 21/03/2017 |
| Wigan Borough Clinical Commissioning Group | 03/05/2017 |

# Appendix 1 – Evidence Review

**Headache Disorders**
**GM017**

## Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; BMJ Clinical Evidence; and the relevant royal college websites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken. The results from these and any other sources are included in the table below. If nothing is found on a particular website it will not appear in the table below:

| Database | Result |
|---|---|
| NICE | • NICETA 260: Botulinum toxin type A for the prevention of headaches in adults with chronic migraine, Issued: June 2012<br>• NICE CG150: Headaches: Diagnosis and management of headaches in young people and adults, Issued: September 2012<br>• NICE QS42: Headaches in young people and adults, Issued: August 2013 (not cited below but should be used if contracting for this type of service)<br>• NICE IPG452: Occipital nerve stimulation for intractable chronic migraine, Issued: April 2013<br>• NICE IPG477: Transcranial magnetic stimulation for treating and preventing migraine, Issued: January 2014<br>• NICE IPG370: Percutaneous closure of patent foramen ovale for recurrent migraine, Issued: December 2010 |
| NHS Evidence and NICE CKS | • NICE CKS: Cluster Headache<br>• NICE CKS: Medication Overuse<br>• NICE CKS: Migraine |
| SIGN | SIGN 107: Diagnosis and management of headache in adults - A national clinical guideline, Issued: Nov 2008 |
| Cochrane | • **Cochrane Database Systematic Review: Acupuncture for migraine prophylaxis,** Linde K, Allais G, Brinkhaus B, Manheimer E, Vickers A, White AR, Published: 2009<br>• **Cochrane Review: Non-invasive physical treatments for chronic/recurrent headache,** Gert Brønfort, Niels Nilsson, Mitchell Haas, Roni L Evans, Charles H Goldsmith, Willem JJ Assendelft, Lex M Bouter, Published: 2009 (*currently considered out of date and under review but correct at time of publication – see below)* |
| BMJ Clinical Evidence | • **BMJ Clinical Review: Cluster headache,** Manjit Matharu, Search date: June 2009<br>• **BMJ Clinical Review: Headache (chronic tension-type),** Anita Krishnan and Nicholas Silver, Search date: March 2007 |
| General Search (Google) | Not done due to the number of NICE documents available |
| Medline / Open Athens | Not done due to the number of NICE documents available |
| Other | Not done due to the number of NICE documents available |

## Summary of the evidence

There is a clear pathway for the management of headache outlined in NICE CG 150. Care is predominantly within primary care with the exception of “red flag” headaches which are managed by urgent referral within contract.

There are emerging treatments for cluster headaches and migraine most of which are at the developmental stage and therefore should be managed as “unproven therapies”. The two areas where there is more evidence that may allow routine commissioning with clear criteria are acupuncture and Implantation of a sphenopalatine ganglion stimulation device, the NICE IPGs for these therapies suggest moderate to good evidence for their use in selected patients.

Evidence for TMS and ONS is currently limited and low grade, however findings are positive and both therapies may be preferable to the alternative drug therapies but further studies are needed.

## The evidence

| **Levels of evidence** | |
|---|---|
| Level 1 | Meta-analyses, systematic reviews of randomised controlled trials |
| Level 2 | Randomised controlled trials |
| Level 3 | Case-control or cohort studies |
| Level 4 | Non-analytic studies e.g. case reports, case series |
| Level 5 | Expert opinion |

### 1. LEVEL N/A: NICE TECHNOLOGY APPRAISAL

**NICE TA 260: Botulinum toxin type A for the prevention of headaches in adults with chronic migraine,** Issued: June 2012

1.1 Botulinum toxin type A is recommended as an option for the prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine) that has not responded to at least three prior pharmacological prophylaxis therapies **and** whose condition is appropriately managed for medication overuse.

1.2 Treatment with botulinum toxin type A that is recommended according to 1.1 should be stopped in people whose condition:

- is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles) **or**
- has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months.

1.3 People currently receiving botulinum toxin type A that is not recommended according to 1.1 and 1.2 should have the option to continue treatment until they and their clinician consider it appropriate to stop.

### 2. LEVEL N/A: NICE CLINICAL GUIDELINES

**NICE CG 150: Diagnosis and management of headaches in young people and adults,** Issued: September 2012

**EXTRACT OF GUIDANCE:**

***1.1 Assessment***

1.1.1 Evaluate people who present with headache and any of the following features, and consider the need for further investigations and/or referral:

- worsening headache with fever

- sudden-onset headache reaching maximum intensity within 5 minutes
- new-onset neurological deficit
- new-onset cognitive dysfunction
- change in personality
- impaired level of consciousness
- recent (typically within the past 3 months) head trauma
- headache triggered by cough, valsalva (trying to breathe out with nose and mouth blocked) or sneeze
- headache triggered by exercise
- orthostatic headache (headache that changes with posture)
- symptoms suggestive of giant cell arteritis
- symptoms and signs of acute narrow-angle glaucoma
- a substantial change in the characteristics of their headache.

1.1.2 Consider further investigations and/or referral for people who present with new-onset headache and any of the following:

- compromised immunity, caused, for example, by HIV or immunosuppressive drugs
- age under 20 years and a history of malignancy
- a history of malignancy known to metastasise to the brain
- vomiting without other obvious cause.

1.1.3 Consider using a headache diary to aid the diagnosis of primary headaches.

1.1.4 If a headache diary is used, ask the person to record the following for a minimum of 8 weeks:

- frequency, duration and severity of headaches
- any associated symptoms
- all prescribed and over the counter medications taken to relieve headaches
- possible precipitants
- relationship of headaches to menstruation.

### *1.2 Diagnosis*

**Tension-type headache, migraine (with or without aura) and cluster headache**

1.2.1 Diagnose tension-type headache, migraine or cluster headache according to the headache features in the table. Note: table not shown here.

1.2.2 Suspect aura in people who present with or without headache and with neurological symptoms that:

- are fully reversible **and**
- develop gradually, either alone or in succession, over at least 5 minutes **and**
- last for 5–60 minutes.

1.2.3 Diagnose migraine with aura in people who present with or without headache and with one or more of the following typical aura symptoms that meet the criteria in recommendation 1.2.2:

- visual symptoms that may be positive (for example, flickering lights, spots or lines)
- and/or negative (for example, partial loss of vision)
- sensory symptoms that may be positive (for example, pins and needles) and/or
- negative (for example, numbness)
- speech disturbance.

1.2.4 Consider further investigations and/or referral for people who present with or without migraine headache and with any of the following atypical aura symptoms that meet the criteria in recommendation 1.2.2:

- motor weakness **or**
- double vision **or**
- visual symptoms affecting only one eye **or**
- poor balance **or**
- decreased level of consciousness.

**Menstrual-related migraine**

1.2.5 Suspect menstrual-related migraine in women and girls whose migraine occurs predominantly between 2 days before and 3 days after the start of menstruation in at least 2 out of 3 consecutive menstrual cycles.

1.2.6 Diagnose menstrual-related migraine using a headache diary (see recommendation 1.1.4) for at least 2 menstrual cycles.

**Medication overuse headache**

1.2.7 Be alert to the possibility of medication overuse headache in people whose headache developed or worsened while they were taking the following drugs for 3 months or more:

- triptans, opioids, ergots or combination analgesic medications on 10 days per month for 3 months or more
- paracetamol, aspirin or an NSAID, either alone or in any combination, on 15 days per month or more.

### *1.3 Management*

**All headache disorders**

1.3.1 Consider using a headache diary:

- to record the frequency, duration and severity of headaches
- to monitor the effectiveness of headache interventions
- as a basis for discussion with the person about their headache disorder and its impact.

1.3.2 Consider further investigations and/or referral if a person diagnosed with a headache disorder develops any of the features listed in recommendation 1.1.1.

1.3.3 Do not refer people diagnosed with tension-type headache, migraine, cluster headache or medication overuse headache for neuroimaging solely for reassurance.

**Information and support for people with headache disorders**

1.3.4 Include the following in discussions with the person with a headache disorder:

- a positive diagnosis, including an explanation of the diagnosis and reassurance that other pathology has been excluded **and**
- the options for management **and**
- recognition that headache is a valid medical disorder that can have a significant impact on the person and their family or carers.

1.3.5 Give the person written and oral information about headache disorders, including information about support organisations.

1.3.6 Explain the risk of medication overuse headache to people who are using acute treatments for their headache disorder.

**Tension-type headache**

Acute treatment

1.3.7 Consider aspirin, paracetamol or an NSAID for the acute treatment of tension type headache, taking into account the person's preference, comorbidities and risk of adverse events.

1.3.8 Do not offer opioids for the acute treatment of tension-type headache.

Prophylactic treatment

1.3.9 Consider a course of up to 10 sessions of acupuncture over 5–8 weeks for the prophylactic treatment of chronic tension-type headache.

**Migraine with or without aura**

Acute treatment

1.3.10 Offer combination therapy with an oral triptan and an NSAID, or an oral triptan and paracetamol, for the acute treatment of migraine, taking into account the person's preference, comorbidities and risk of adverse events. For young people aged 12–17 years consider a nasal triptan in preference to an oral triptan.

1.3.11 For people who prefer to take only one drug, consider monotherapy with an oral triptan, NSAID, aspirin (900 mg) or paracetamol for the acute treatment of migraine, taking into account the person's preference, comorbidities and risk of adverse events.

1.3.12 When prescribing a triptan start with the one that has the lowest acquisition cost; if this is consistently ineffective, try one or more alternative triptans.

1.3.13 Consider an anti-emetic in addition to other acute treatment for migraine even in the absence of nausea and vomiting.

1.3.14 Do not offer ergots or opioids for the acute treatment of migraine.

1.3.15 For people in whom oral preparations (or nasal preparations in young people aged 12–17 years) for the acute treatment of migraine are ineffective or not tolerated:

- offer a non-oral preparation of metoclopramide or prochlorperazine **and**
- consider adding a non-oral NSAID or triptan if these have not been tried.

Prophylactic treatment

1.3.16 Discuss the benefits and risks of prophylactic treatment for migraine with the person, taking into account the person's preference, comorbidities, risk of adverse events and the impact of the headache on their quality of life.

1.3.17 Offer topiramate or propranolol for the prophylactic treatment of migraine according to the person's preference, comorbidities and risk of adverse events. Advise women and girls of childbearing potential that topiramate is associated with a risk of fetal malformations and can impair the effectiveness of hormonal contraceptives. Ensure they are offered suitable contraception if needed.

1.3.18 If both topiramate and propranolol are unsuitable or ineffective, consider a course of up to 10 sessions of acupuncture over 5–8 weeks or gabapentin (up to 1200 mg per day) according to the person's preference, comorbidities and risk of adverse events.

1.3.19 For people who are already having treatment with another form of prophylaxis such as amitriptyline, and whose migraine is well controlled, continue the current treatment as required.

1.3.20 Review the need for continuing migraine prophylaxis 6 months after the start of prophylactic treatment.

1.3.21 Advise people with migraine that riboflavin (400 mg once a day) may be effective in reducing migraine frequency and intensity for some people.

**Combined hormonal contraceptive use by women and girls with migraine**

1.3.22 Do not routinely offer combined hormonal contraceptives for contraception to women and girls who have migraine with aura.

**Menstrual-related migraine**

1.3.23 For women and girls with predictable menstrual-related migraine that does not respond adequately to standard acute treatment, consider treatment with frovatriptan (2.5 mg twice a day) or zolmitriptan (2.5 mg twice or three times a day) on the days migraine is expected.

**Treatment of migraine during pregnancy**

1.3.24 Offer pregnant women paracetamol for the acute treatment of migraine. Consider the use of a triptan or an NSAID after discussing the woman's need for treatment and the risks associated with the use of each medication during pregnancy.

1.3.25 Seek specialist advice if prophylactic treatment for migraine is needed during pregnancy.

**Cluster headache**

Acute treatment

1.3.26 Discuss the need for neuroimaging for people with a first bout of cluster headache with a GP with a special interest in headache or a neurologist.

1.3.27 Offer oxygen and/or a subcutaneous or nasal triptan for the acute treatment of cluster headache.

1.3.28 When using oxygen for the acute treatment of cluster headache:

- use 100% oxygen at a flow rate of at least 12 litres per minute with a non rebreathing mask and a reservoir bag **and**
- arrange provision of home and ambulatory oxygen.

1.3.29 When using a subcutaneous or nasal triptan, ensure the person is offered an adequate supply of triptans calculated according to their history of cluster bouts, based on the manufacturer's maximum daily dose.

1.3.30 Do not offer paracetamol, NSAIDS, opioids, ergots or oral triptans for the acute treatment of cluster headache.

Prophylactic treatment

1.3.31 Consider verapamil for prophylactic treatment during a bout of cluster headache. If unfamiliar with its use for cluster headache, seek specialist advice before starting verapamil, including advice on electrocardiogram monitoring.

1.3.32 Seek specialist advice for cluster headache that does not respond to verapamil.

1.3.33 Seek specialist advice if treatment for cluster headache is needed during pregnancy.

**Medication overuse headache**

1.3.34 Explain to people with medication overuse headache that it is treated by withdrawing overused medication.

1.3.35 Advise people to stop taking all overused acute headache medications for at least 1 month and to stop abruptly rather than gradually.

1.3.36 Advise people that headache symptoms are likely to get worse in the short term before they improve and that there may be associated withdrawal symptoms, and provide them with close follow-up and support according to their needs.

1.3.37 Consider prophylactic treatment for the underlying primary headache disorder in addition to withdrawal of overused medication for people with medication overuse headache.

1.3.38 Do not routinely offer inpatient withdrawal for medication overuse headache.

1.3.39 Consider specialist referral and/or inpatient withdrawal of overused medication for people who are using strong opioids, or have relevant comorbidities, or in whom previous repeated attempts at withdrawal of overused medication have been unsuccessful.

1.3.40 Review the diagnosis of medication overuse headache and further management 4–8 weeks after the start of withdrawal of overused medication.

## 3. LEVEL N/A: NICE INTERVENTIONAL PROCEDURE GUIDANCE

**NICE IPG 452: Occipital nerve stimulation for intractable chronic migraine,** Issued: April 2013

1.1 The evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to undertake ONS for intractable chronic migraine should take the following actions:

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Selection of patients for treatment using ONS for intractable chronic migraine should be done by a multidisciplinary team, including specialists in headache, pain management and neurosurgery.

1.4 Clinicians should enter details about all patients undergoing ONS for intractable chronic migraine onto the UK Neuromodulation Register when access to that database is available. They should audit and review clinical outcomes locally and should document and consider their relationship to patient characteristics.

1.5 NICE encourages publication of further information from comparative studies and from collaborative data collection to guide future use of this procedure and to provide patients with the best possible advice. Publications should include full details of any complications, and of adjunctive or subsequent treatments. Outcomes should include measures of pain, function and quality of life, particularly in the long term.

1.6 NE may review the procedure on publication of further evidence.

## 4. LEVEL N/A

**SIGN 107: Diagnosis and management of headache in adults - A national clinical guideline,** Issued: Nov 2008

### *2 Key recommendations*

The following recommendations were highlighted by the guideline development group as being clinically very important. They are the key clinical recommendations that should be prioritised for implementation. The clinical importance of these recommendations is not dependent on the strength of the supporting evidence.

### 2.1 Symptoms and signs

**Patients who present with a pattern of recurrent episodes of severe disabling headache associated with nausea and sensitivity to light, and who have a normal neurological examination, should be considered to have migraine.**

Migraine has specific treatment options. It is often underdiagnosed with up to 50% of patients misdiagnosed with another headache type.17-20 Better recognition allows more effective treatment.

**Patients who present with headache and red flag features for potential secondary headache should be referred to a specialist appropriate to their symptoms for further assessment.**

Most patients have primary headache and do not require further investigation.12,20 Red flag warning features highlight which patients require further investigation for potential secondary headache.

**Patients with a first presentation of thunderclap headache should be referred immediately to hospital for same day specialist assessment.** Thunderclap headache is a medical emergency as it may be caused by subarachnoid haemorrhage.

**Giant cell arteritis should be considered in any patient over the age of 50 presenting with a new headache or change in headache.** Giant cell arteritis is a medical emergency because of the possibility of neurological and visual complications and availability of effective treatment.

### 2.2 Assessment tools

**Practitioners should consider using headache diaries and appropriate assessment questionnaires to support the diagnosis and management of headache.**

The use of diaries and questionnaires can aid diagnosis and prompt discussion of symptoms and the impact of the headaches on quality of life. This can help guide treatment and ensure appropriate follow up.

### 2.3 Investigations

**Neuroimaging is not indicated in patients with a clear history of migraine, without red flag features for potential secondary headache, and a normal neurological examination.**

Magnetic resonance imaging (MRI) and computerised tomography (CT) can identify neurological abnormalities incidental to the patient's presenting complaint, which may result in heightened patient anxiety and clinician uncertainty. Further investigation and treatment of incidental abnormalities can cause both morbidity and mortality and investigation should generally be reserved for patients with "red flag features".

**In patients with thunderclap headache, unenhanced CT of the brain should be performed as soon as possible and preferably within 12 hours of onset. C**

**Patients with thunderclap headache and a normal CT should have a lumbar puncture.**

Subarachnoid blood degrades rapidly. Performing CT brain imaging as soon as possible maximises the chance of accurate diagnosis. Even timely CT brain imaging may not pick up subarachnoid blood, so lumbar puncture is also required. Lumbar puncture should be delayed till 12 hours after headache onset.

### 2.4 Migraine

**Oral triptans are recommended for acute treatment in patients with all severities of migraine if previous attacks have not been controlled using simple analgesics.** Migraine is associated with significant disability and is often under-treated. A stepped approach for acute treatment of migraine is recommended, starting with aspirin or an NSAID. If this is not effective a triptan should be used. **D**

**Opioid analgesics should not be routinely used for the treatment of patients with acute migraine due to the potential for development of medication overuse headache.** Opioids and opioid-containing analgesics are associated with medication overuse headache and their use can result in dependence. They have no role in the treatment of migraine.

**Women with migraine with aura should not use a combined oral contraceptive pill.** Migraine with aura and the combined oral contraceptive pill are both independent risk factors for ischaemic stroke. Although the absolute increased risk of stoke is small, this increased risk is unacceptable when equally effective alternative methods of contraception are available.

### 2.5 Trigeminal autonomic cephalalgias

**A Subcutaneous injection of 6 mg sumatriptan is recommended as the first choice treatment for the relief of acute attacks of cluster headache.** Individual attacks of cluster headache are very severe and build up rapidly. The onset of action of oral triptans is too long and subcutaneous or nasal triptans are required.

### 2.6 Medication overuse headache

**Medication overuse headache must be excluded in all patients with chronic daily headache** *(headache ≥15 days / month for >3 months)* **D**

**Clinicians should be aware that patients using any acute or symptomatic headache treatment are at risk of medication overuse headache. Patients with migraine, frequent headache and those using opioid-containing medications or overusing triptans are at most risk.**

Medication overuse results in the development of chronic daily headache. Stopping the overused medication usually results in improvement in headache frequency and severity. The risks of medication overuse headache should be discussed with all patients when initiating acute treatment for migraine.

## 5. LEVEL 1: SYSTEMATIC REVIEW

**Cochrane Database Systematic Review: Acupuncture for migraine prophylaxis,** Linde K, Allais G, Brinkhaus B, Manheimer E, Vickers A, White AR, Published: 2009

### ABSTRACT

**Background:** Acupuncture is often used for migraine prophylaxis but its effectiveness is still controversial. This review (along with a companion review on 'Acupuncture for tension-type headache') represents an updated version of a Cochrane review originally published in Issue 1, 2001, of The Cochrane Library.

**Objectives:** To investigate whether acupuncture is a) more effective than no prophylactic treatment/routine care only; b) more effective than 'sham' (placebo) acupuncture; and c) as effective as other interventions in reducing headache frequency in patients with migraine.

**Search methods:** The Cochrane Pain, Palliative & Supportive Care Trials Register, CENTRAL, MEDLINE, EMBASE and the Cochrane Complementary Medicine Field Trials Register were searched to January 2008.

**Selection criteria:** We included randomised trials with a post-randomization observation period of at least 8 weeks that compared the clinical effects of an acupuncture intervention with a control (no prophylactic treatment or routine care only), a sham acupuncture intervention or another intervention in patients with migraine.

**Data collection and analysis:** Two reviewers checked eligibility; extracted information on patients, interventions, methods and results; and assessed risk of bias and quality of the acupuncture intervention. Outcomes extracted included response (outcome of primary interest), migraine attacks, migraine days, headache days and analgesic use. Pooled effect size estimates were calculated using a random-effects model.

**Main results:** Twenty-two trials with 4419 participants (mean 201, median 42, range 27 to 1715) met the inclusion criteria. Six trials (including two large trials with 401 and 1715 patients) compared acupuncture to no prophylactic treatment or routine care only. After 3 to 4 months patients receiving acupuncture had higher response rates and fewer headaches. The only study with long-term follow up saw no evidence that effects dissipated up to 9 months after cessation of treatment. Fourteen trials compared a 'true' acupuncture intervention with a variety of sham interventions. Pooled analyses did not show a statistically significant superiority for true acupuncture for any outcome in any of the time windows, but the results of single trials varied considerably. Four trials compared acupuncture to proven prophylactic drug treatment. Overall in these trials acupuncture was associated with slightly better outcomes and fewer adverse effects than prophylactic drug treatment. Two small low-quality trials comparing acupuncture with relaxation (alone or in combination with massage) could not be interpreted reliably.

**Authors' conclusions:** In the previous version of this review, evidence in support of acupuncture for migraine prophylaxis was considered promising but insufficient. Now, with 12 additional trials, there is consistent evidence that acupuncture provides additional benefit to treatment of acute migraine attacks only or to routine care. There is no evidence for an effect of 'true' acupuncture over sham interventions, though this is difficult to interpret, as exact point location could be of limited importance. Available studies suggest that acupuncture is at least as effective as, or possibly more effective than, prophylactic drug treatment, and has fewer adverse effects. Acupuncture should be considered a treatment option for patients willing to undergo this treatment.

## 6. LEVEL 1: META-ANALYSIS

**Cochrane Review: Non-invasive physical treatments for chronic/recurrent headache,** Gert Brønfort, Niels Nilsson, Mitchell Haas, Roni L Evans, Charles H Goldsmith, Willem JJ Assendelft, Lex M Bouter, Published: 2009

**Note:** *This review is out of date, but is correct at the date of publication. The review has been withdrawn from The Cochrane Library, but readers can still access previous versions in the 'Other versions' tab. The original author team is preparing three new protocols which will serve to update and replace this review: Manual treatment and spinal rehabilitative exercise for the prevention of migraine attacks in adults, Manual treatment and spinal rehabilitative exercise for the prevention of TTH in adults, and Manual treatment and spinal rehabilitative exercise for the prevention of cervicogenic headaches in adults. For further information, please contact the PaPaS CR.*

**Main results:** Twenty-two studies with a total of 2628 patients (age 12 to 78 years) met the inclusion criteria. Five types of headache were studied: migraine, tension-type, cervicogenic, a mix of migraine and tension-type, and post-traumatic headache. Ten studies had methodological quality scores of 50 or more (out of a possible 100 points), but many limitations were identified. We were unable to pool data because of study heterogeneity. For the prophylactic treatment of migraine headache, there is evidence that spinal manipulation may be an effective treatment option with a short-term effect similar to that of a commonly used, effective drug (amitriptyline). Other possible treatment options with weaker evidence of

effectiveness are pulsating electromagnetic fields and a combination of transcutaneous electrical nerve stimulation [TENS] and electrical neurotransmitter modulation. For the prophylactic treatment of chronic tension-type headache, amitriptyline is more effective than spinal manipulation during treatment. However, spinal manipulation is superior in the short term after cessation of both treatments. Other possible treatment options with weaker evidence of effectiveness are therapeutic touch; cranial electrotherapy; a combination of TENS and electrical neurotransmitter modulation; and a regimen of auto-massage, TENS, and stretching. For episodic tension-type headache, there is evidence that adding spinal manipulation to massage is not effective. For the prophylactic treatment of cervicogenic headache, there is evidence that both neck exercise (low-intensity endurance training) and spinal manipulation are effective in the short and long term when compared to no treatment. There is also evidence that spinal manipulation is effective in the short term when compared to massage or placebo spinal manipulation, and weaker evidence when compared to spinal mobilisation. There is weaker evidence that spinal mobilisation is more effective in the short term than cold packs in the treatment of post-traumatic headache.

**Authors' conclusions:** A few non-invasive physical treatments may be effective as prophylactic treatments for chronic/recurrent headaches. Based on trial results, these treatments appear to be associated with little risk of serious adverse effects. The clinical effectiveness and cost-effectiveness of non-invasive physical treatments require further research using scientifically rigorous methods. The heterogeneity of the studies included in this review means that the results of a few additional high-quality trials in the future could easily change the conclusions of our review.

## 7. LEVEL N/A: NICE INTERVENTIONAL PROCEDURE GUIDANCE

**NICE IPG 477: Transcranial magnetic stimulation for treating and preventing migraine,** Issued: January 2014

### 1 Recommendations

Transcranial magnetic stimulation (TMS) has been evaluated for use during the aura before a migraine episode or at the start of a migraine episode, with the intention of stopping or reducing the severity of the episode ('treatment'); or at planned intervals, with the intention of reducing the frequency and/or severity of migraine episodes ('prevention').

1.1 Evidence on the efficacy of TMS for the treatment of migraine is limited in quantity and for the prevention of migraine is limited in both quality and quantity. Evidence on its safety in the short and medium term is adequate but there is uncertainty about the safety of long-term or frequent use of TMS. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Patient selection should normally be done in specialist headache clinics and the procedure should only be used under the direction of clinicians specialising in the management of headache.

1.3 Patients should be informed that TMS is not intended to provide a cure for migraine and that reduction in symptoms may be modest.

1.4 Clinicians wishing to undertake TMS for treating and preventing migraine should take the following actions.

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having TMS for the treatment and prevention of migraine).

1.5 NICE encourages further research on TMS for treating and preventing migraine. Data should be collected for all patients not entered into controlled trials. Studies should describe clearly whether its use is for treatment or prevention. They should report details of patient selection and the dose and Transcranial magnetic stimulation for treating and preventing migraine frequency of use. Outcome measures should include the number and severity of migraine episodes, and quality of life in both the short and long term. The development of any neurological disorders (such as epilepsy) in the short or longer term after starting treatment should be documented.

## 2 Indications and current treatments

2.1 Migraine is a common condition characterised by recurrent, pulsatile, unilateral or bilateral headaches that may last from hours to days and are often accompanied by nausea and sensitivity to light and sound. Migraine headache may be preceded by an aura, which can include visual or olfactory disturbances, or difficulties with speech (dysphasia). The second edition of International Classification of Headache Disorders (International Headache Society 2004) provides a classification of migraine types.

2.2 Current treatment for migraine aims to prevent or stop episodes and manage symptoms with drugs such as triptans, analgesics and anti-emetics (as recommended in Headaches: diagnosis and management of headaches in young people and adults [NICE clinical guideline 150]). Other treatments include nerve blocks, botulinum toxin type A injections (as recommended in Botulinum toxin type A for the prevention of headaches in adults with chronic migraine [NICE technology appraisal guidance 260]) or acupuncture.

## 3 The procedure

3.1 Transcranial magnetic stimulation (TMS) is a non-invasive procedure that aims to treat or prevent migraine episodes in people with acute or chronic migraine (with or without aura). TMS is given using a tabletop or handheld device that delivers a predetermined level of magnetic pulse or pulses to the head.

3.2 The device is placed on the scalp and either single (sTMS) or repeated (rTMS) magnetic pulses are delivered. The frequency, intensity, duration and interval times of pulses can be varied. Treatments can be automatically recorded by the device in an integrated headache diary, which can be used to identify headache patterns and trigger factors. Patients may continue to use regular medications, including drugs to prevent migraines. Transcranial magnetic stimulation for treating and preventing migraines.

# 8. LEVEL N/A: NICE INTERVENTIONAL PROCEDURE GUIDANCE

**NICE IPG 370: Percutaneous closure of patent foramen ovale for recurrent migraine,** Issued: December 2010

## 1 Guidance

1.1 Current evidence on the efficacy of percutaneous closure of patent foramen ovale (PFO) for recurrent migraine is inadequate in quality and quantity. The evidence on safety shows a small incidence of well-recognised but sometimes serious adverse events, including device embolisation and device prolapse (each reported in less than 1% of patients). Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake percutaneous closure of PFO for recurrent migraine should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and the possibility of serious complications. Clinicians should provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.

1.3 Patient selection for percutaneous closure of PFO for recurrent migraine should be carried out by a neurologist or other specialist in headache followed by an interventional cardiologist. Use of this procedure should be restricted to patients who are severely affected by recurrent, refractory migraine.

1.4 The procedure should be done by an interventional cardiologist and supporting team with specific training in the procedure.

1.5 The procedure should only be carried out in units where there are arrangements for emergency cardiac surgical support in the event of complications.

1.6 Data on all patients having this procedure should be submitted to the UK Central Cardiac Audit Database.

1.7 NICE encourages further research into this procedure, which should investigate the uncertainty surrounding the aetiology and natural history of natural history of migraine in patients with PFO. NICE may review this procedure on publication of further evidence.

## 9. LEVEL N/A: NICE INTERVENTIONAL PROCEDURE GUIDANCE

**NICE IPG 527: Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache,** Issued: June 2015

### 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.

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

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.

## 10. LEVEL 1: SYSTEMATIC REVIEW

**BMJ Clinical Review: Cluster Headache,** Manjit Matharu, Search date: June 2009

### ABSTRACT

**Introduction:** The revised International Headache Society (IHS) criteria for cluster headache are: attacks of severe or very severe, strictly unilateral pain, which is orbital, supraorbital, or temporal pain, lasting 15 to 180 minutes and occurring from once every other day to eight times daily.

**Methods and outcomes:** We conducted a systematic review and aimed to answer the following clinical questions:

- What are the effects of interventions to abort cluster headache?
- What are the effects of interventions to prevent cluster headache?

We searched: Medline, Embase, The Cochrane Library, and other important databases up to June 2009 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review).We included harms alerts from relevant organisations, such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

**Results:** We found 23 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions.

**Conclusions:** In this systematic review, we present information relating to the effectiveness and safety of the following interventions: baclofen (oral); botulinum toxin (intramuscular); capsaicin (intranasal); chlorpromazine; civamide (intranasal); clonidine (transdermal); corticosteroids; ergotamine and dihydroergotamine (oral or intranasal); gabapentin (oral); greater occipital nerve injections (betamethasone plus xylocaine); high-dose and high-flow-rate oxygen; hyperbaric oxygen; leuprolide;

lidocaine (intranasal); lithium (oral); melatonin; methysergide (oral); octreotide (subcutaneous); pizotifen (oral); sodium valproate (oral); sumatriptan (oral, subcutaneous, and intranasal); topiramate (oral); tricyclic antidepressants (TCAs); verapamil; and zolmitriptan (oral and intranasal).

## 11. LEVEL 1: SYSTEMATIC REVIEW

**BMJ Clinical Review: Headache (chronic tension-type),** Anita Krishnan and Nicholas Silver, Search date: March 2007

### ABSTRACT

**Introduction:** Chronic tension-type headache (CTTH) is a disorder that evolves from episodic tension-type headache, with daily or very frequent episodes of headache lasting minutes to days. It affects 4.1% of the general population in the USA, and is more prevalent in women (up to 65% of cases).

**Methods and outcomes:** We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of drug treatments for chronic tension-type headache? What are the effects of non-drug treatments for chronic tension-type headache? We searched: Medline, Embase, The Cochrane Library, and other important databases up to March 2007 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review).We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

**Results:** We found 50 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review, we present information relating to the effectiveness and safety of the following interventions: acupuncture; amitriptyline; analgesics; anticonvulsant drugs; benzodiazepines; botulinum toxin; chiropractic and osteopathic manipulations; cognitive behavioural therapy (CBT); Indian head massage; mirtazapine; relaxation and electromyographic biofeedback; selective serotonin reuptake inhibitor antidepressants (SSRIs); and tricyclic antidepressants (other than amitriptyline).

## 12. LEVEL N/A: NICE CLINICAL KNOWLEDGE SUMMARY

**NICE CKS: Cluster Headache**

### Summary

- Cluster headache is the most common of a group of conditions called trigeminal autonomic cephalalgias.
- Cluster headache is characterized by recurrent attacks of one-sided pain, in or around the eye or temporal region, and associated with signs of autonomic dysfunction on the same side.
    - Attacks of pain usually last for 45–90 minutes and are almost always described as the most severe pain known. They tend to recur at the same time each day, often waking the person shortly after falling asleep.
    - Symptoms and signs of autonomic dysfunction include: rhinorrhoea; lacrimation; facial sweating or flushing; constriction of the pupil; swelling of periorbital tissue and conjunctiva with apparent drooping of the eyelid; and a sense of fullness in the ear.
    - Most people have episodic cluster headache when recurrent attacks of pain occur in cluster periods lasting between 1 week and 1 year. Cluster periods are separated by periods of remission lasting at least 1 month and may recur predictably during certain times of the year.
- The cause of cluster headache is not fully understood. It has been suggested that a disturbance in the hypothalamus causes reflex activation of the autonomic system and vasodilation of the ophthalmic, anterior cerebral, and middle cerebral arteries during attacks.
- All people with suspected cluster headache should be urgently referred to a specialist.
- While awaiting referral:
    - A triptan is recommended, to be taken when required for treatment of acute attacks.
    - 100% oxygen therapy should be arranged for treatment of acute attacks that occur at home.
    - A trial of indometacin should be considered to exclude paroxysmal hemicrania if this can not be clearly distinguished from cluster headache.

    - The person should be advised to avoid drinking alcohol or inhaling volatile fumes from substances such as solvents or oil based products, as these may trigger an attack during an active period of cluster headaches.
- Specialists recommend preventive treatment for most people with cluster headache, such as Verapamil which is often used as a first-line treatment.

## 13. LEVEL N/A: NICE CLINICAL KNOWLEDGE SUMMARY
**NICE CKS: Medication Overuse**

**Summary**

- Medication-overuse headache (MOH) is a chronic headache (occurring on more than 15 days each month) that develops or worsens with frequent use of any drug treatment for pain in people with tension-type headache (TTH) or migraine.
    - Typically, it develops with drug treatment of episodic migraine or TTH, but may occur in people with migraine or TTH who take analgesics for other painful conditions.
    - The symptoms of MOH resemble chronic TTH or chronic migraine; people overusing triptans are more likely to have migraine-like symptoms.
- MOH resolves following withdrawal of symptomatic treatment.
- It is thought that in people predisposed to migraine or TTH, frequent symptomatic treatment of any type of pain, including headache disorders, causes progressive down-regulation of receptors inhibiting pain. This increases sensitivity to pain, increasing the tendency to develop headache.
- Diagnostic criteria for MOH are:
    - Headache is present on 15 days or more each month.
    - Symptomatic treatment for headache has been overused regularly for more than 3 months. Overuse is considered to be occurring when ergotamine, triptans, opioids, or combined analgesic medications are taken on 10 days or more each month; simple analgesics are taken on 15 days or more each month; or any combination of ergotamine, triptans, or opioids is taken on 15 days or more each month without overuse of any single drug alone.
    - Headache develops, or is markedly worsened, during medication overuse.
- Withdrawal of symptomatic treatments is necessary to exclude MOH as a cause of, or contributing factor to, chronic headache. Withdrawal of symptomatic treatment will result in:
    - Complete resolution of the headache, if MOH is the only cause of the headache.
    - Improvement of the headache, if medication overuse is a contributing factor to chronic migraine or TTH.
    - No improvement of the headache, if medication overuse is not a significant factor.
- Management of MOH involves:
    - Advising the person to stop taking all overused headache medications for at least one month.
    - Providing close follow up and support.
    - Considering prescribing an anti-emetic if the person is not able to manage withdrawal because of withdrawal symptoms.
    - Considering prophylactic treatment for the underlying primary headache disorder.
    - Reviewing the person 4–8 weeks from the start of withdrawal of overused medication to review the diagnosis of MOH and assess the need for further management of an underlying primary headache disorder.

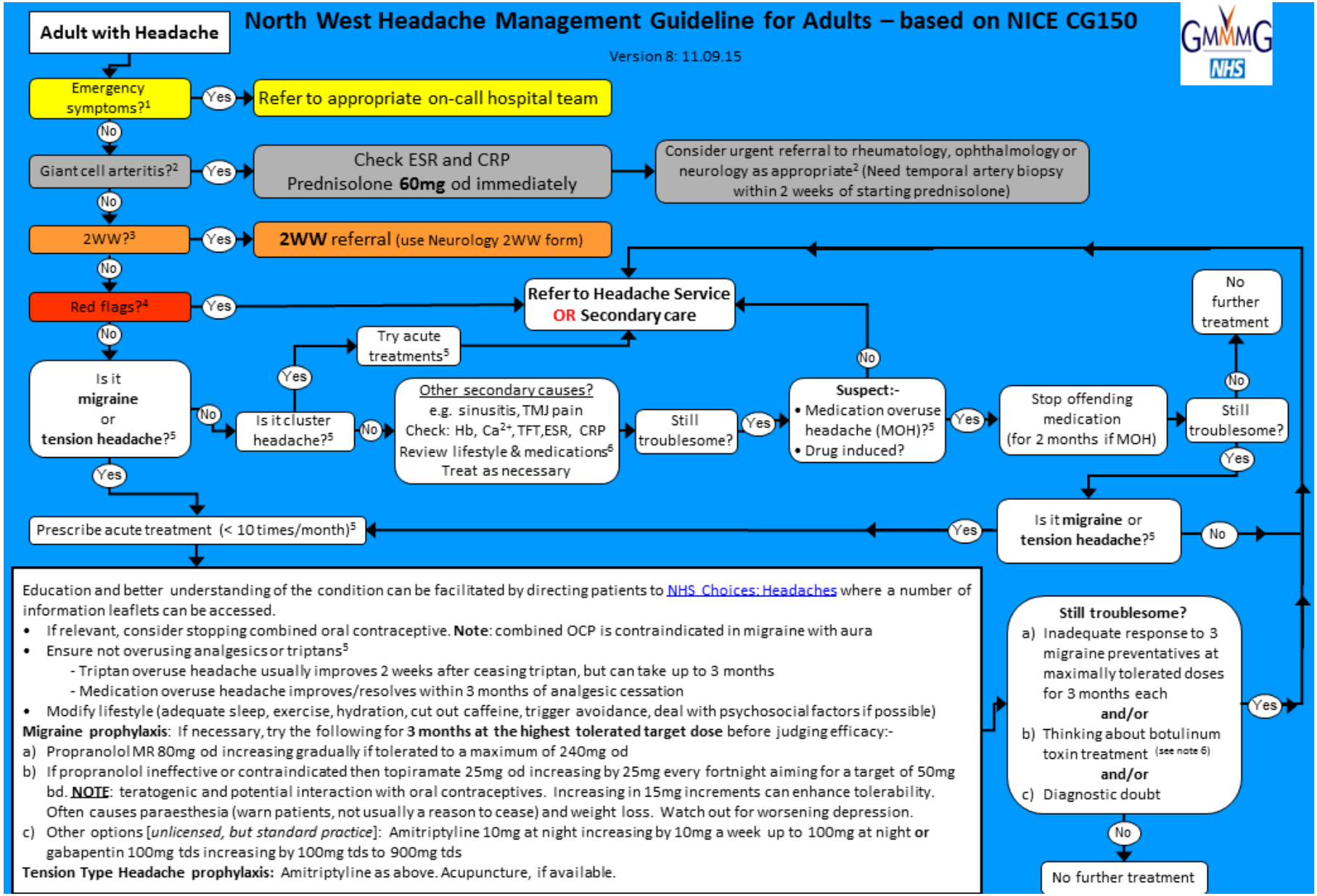
## 14. LEVEL N/A: NICE CLINICAL KNOWLEDGE SUMMARY
**NICE CKS: Migraine**

**Summary**

- Migraine is a primary episodic headache disorder. It is characterized by episodic severe headaches with associated symptoms such as photophobia, phonophobia, and nausea and vomiting. The most common subtypes of migraine are migraine without aura and migraine with aura.

- Migraine is a complex condition, and the exact pathophysiological cause is not fully understood. It has a significant genetic component, with about half of people with migraine having a first-degree relative with the condition.
- The prevalence of migraine differs between the sexes, being about three times more common in women (18%, mean onset of age 18 years) than men (6%, mean onset of age 14 years).
- In adults, migraine without aura is diagnosed when at least five attacks fulfil the following criteria:
    - Headache lasts 4–72 hours.
    - At least two of the following characteristics are present: unilateral location, moderate or severe pain intensity, pulsating quality, aggravation by routine physical activity.
    - At least one of the following is present: nausea or vomiting, photophobia or phonophobia.
- In adults, migraine with aura (reported by about one third of people with migraine) is diagnosed when:
    - There are two or more attacks with one or more symptoms of aura including visual or sensory symptoms, or dysphasic speech disturbance.
    - Each individual symptom of aura lasts less than 60 minutes.
- Other conditions may present with signs and symptoms similar to migraine. These may be an alternative form of primary headache disorder (such a cluster headache or tension-type headache), or a secondary cause, which may be serious and life-threatening.
- A headache diary may be useful to identify potential triggers (such as stress, specific foods, dehydration, missed meals), which can be managed as appropriate.
- First-line treatment of acute migraine consists of combination therapy with an oral triptan and analgesia (paracetamol or a nonsteroidal anti-inflammatory drug). An anti-emetic (prochlorperazine, domperidone, or metoclopramide) may be added even in the absence of nausea or vomiting. Monotherapy, if preferred, consists of an oral triptan, NSAID, aspirin, or paracetamol.
- When two or more triptans have been trialled unsuccessfully, or treatment is successful but attacks are frequent, preventive treatment is often used. First-line preventive treatment consists of topiramate or propranolol. If both of these have been trialled unsuccessfully or are inappropriate, gabapentin or acupuncture can be tried.
- Hospitalisation or urgent referral is only necessary if a serious cause of headache is suspected, or if the person is in severe, uncontrolled status migrainosus (migraine lasting for more than 72 hours).

# Appendix 2 – North West Headache Management Guidelines for Adults



NW Headache Final V11 16-6-15. Approved by GMMMG June 2015. Review date: June 2017

## 1) Emergency Symptoms/signs

Thunderclap onset
Accelerated/Malignant hypertension
Acute onset with papilloedema
Acute onset with focal neurological signs
Head trauma with raised ICP headache
Photophobia + nuchal rigidity + fever +/-rash
Reduced consciousness
Acute red eye: ?acute angle closure glaucoma

**New** onset headache in:
- 3rd trimester pregnancy/early postpartum
- Significant head injury – especially elderly patients, alcohol dependency, people on anticoagulants

## 2) Giant Cell arteritis

Incidence 2/10,000 per year
- Consider with presentations of new headache in >50 year olds
- Many headaches respond to high dose steroids NB do not use response as the sole diagnostic factor.
- ESR can be normal in 10% - check CRP as well
- Symptoms may include: jaw/tongue claudication, visual disturbance, temporal artery: prominent, tender, diminished pulse; other cranial nerve palsies, limb claudication

**Urgent referral to**:
- Rheumatology if diagnosis clear
- Neurology if headache or possibly GCA
- Ophthalmology if amaurosis fugax / visual loss / diplopia **NOT** migrainous auras

## 3) 2WW - suspected cancer referral

- **Headache with features of raised intracranial pressure:-**
  - Actively wakes a patient from sleep, but not migraine or cluster
  - **Precipitated** by Valsalva manoeuvres i.e. cough, straining at stool
  - Papilloedema
  - Other symptoms of raised ICP headache including
    - Headache present upon waking and easing once up (analgesic overuse can cause this pattern) and worse when recumbent
    - Pulse synchronous tinnitus
    - Episodes of transient visual loss when changing posture e.g. upon standing
    - Vomiting - significance should be judged in context as nausea and vomiting are features of migraine
- **Headache with new onset seizures**
- **Headache with persistent new or progressive neurological deficit**
- **A relevant history of malignancy which might have metastasised to the brain**
- **Vomiting without other obvious cause (i.e. not just due to migraine)**

## 4) Red Flags (for secondary headaches)

- Headache rapidly increasing in severity and frequency despite appropriate treatment
- Undifferentiated headache (not migraine / tension headache) of recent origin and present for >8 weeks
- Recurrent headaches triggered by exertion
- Orthostatic Headache (headache that occurs in the upright position, suggesting low CSF pressure)
- New onset headache in:-
  - >50 years old (consider giant cell arteritis)
  - Immunosuppressed / HIV

## 5) Migraine

- Throbbing pain lasting hours - 3 days
- Sensitivity to stimuli: light and sound, sometimes smells
- Nausea
- Aggravated by physical activity (prefers to lie/sit still)

Aura, if present, that evolves slowly (in contrast to TIA/stroke) and lasts minutes - 60min

**'Chronic Migraine'**
≥15 headache days/month of which ≥8 are migraine

**Acute treatments:**
Aspirin dispersible 900mg or NSAID, taken with metoclopramide or domperidone **NB** Note MHRA warning
MHRA (2014): Domperidone: risks of cardiac side effects
MHRA (2013) Metoclopramide: risk of neurological adverse effects
A triptan but <10 days per month (best <6/month)
Don't use opiates as they tend to lead to increase nausea and lead to an overuse headache

## Tension Type Headache

Band-like ache, mostly featureless
Can have mild photo OR phonophobia but NO nausea
Many believe this is simply a milder form of migraine i.e. same biology and thus similar treatments can be effective

## Cluster Headache

More common in men
Most severe pain ever lasting 30-120 minutes
Unilateral, side-locked
Agitation, pacing **NB** migraineurs prefer to keep still
Unilateral Cranial Autonomic features:-
tearing, red conjunctiva, ptosis, miosis, nasal stuffiness

**Acute treatments:**
Sumatriptan injection 6mg s.c. - contra-indicated for IHD and stroke
Hi-flow oxygen through a non-rebreathe bag and mask
Prednisolone 60mg od for 1 week can abort a bout of attacks

## Triptan Overuse Headache

Can be migrainous and/or tension type
Triptan intake: ≥10 days/month for ≥3 months
**Treatment**: Stop triptan for 2-3 months

## Analgesic Overuse Headache

Can be migrainous and/or tension type
Analgesic intake ≥15 days/month (opiates ≥10 days)
For ≥3 consecutive months
**Treatment**: stop analgesic for 3 months

## 6) Botulinum Toxin for Chronic Migraine: (NICE TA260)

Between 31 and 39 injections i.m. around scalp and neck every 12 weeks
Minimum treatment criteria:
- Chronic migraine i.e. ≥15 headache days/month of which ≥8 are migraine for a minimum of 3 consecutive months
- Tried 3 different migraine preventatives at maximally tolerated doses for 3 months each **not** including pizotifen
- Not overusing triptans, opiates or other analgesics

# Appendix 3 – Diagnostic and Procedure Codes

**Headache Disorders**
**GM017**

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

| **GM017 - Headache Disorders** | |
|---|---|
| Treatments that are not covered by the North West Headache Management Guideline for Adults that may be commissioned: | |
| Electroacupuncture | A70.5 |
| Acupuncture NEC | A70.6 |
| In a secondary position to another procedure code - Treatments that are not covered by the North West Headache Management Guideline for Adults that may be commissioned: | |
| Acupuncture of organ NOC | Y33.1 |
| Treatments that are not covered by the North West Headache Management Guideline for Adults that may be commissioned. Can be in primary or secondary position: | |
| Botox - Torsion dystonias and other involuntary movements drugs - Band 1 | X85.1 |
| With the following ICD-10 diagnosis code(s): | |
| Status migrainosus | G43.2 |
| Complicated migraine | G43.3 |
| Cluster headache syndrome | G44.0 |
| Drug-induced headache, not elsewhere classified | G44.4 |
| Premenstrual tension syndrome (code used for, but not restricted to, menstrual migraine) | N94.3 |
| Can be used to monitor the care and treatment given to headache disorders, but might be considered too broad for the policy: | |
| Migraine without aura [common migraine] | G43.0 |
| Migraine with aura [classical migraine] | G43.1 |
| Other migraine | G43.8 |
| Migraine, unspecified | G43.9 |
| Tension-type headache | G44.2 |
| OPCS-4 codes that might be used: | |
| Insertion of neurostimulator electrodes into peripheral nerve (According to NICE: Not commissioned as they are considered unproven therapies based on the current evidence) | A70.4 |
| Temporary operations (only when supplementary to A70.4) | Y70.5 |
| First stage of staged operations NOC (only when supplementary to A70.4) | Y70.3 |
| Approach to organ under fluoroscopic control - only when supplementary to A70.4, if fluoroscopic control has been used | Y53.4 |
| Head NEC - only when supplementary to A70.4 | Z92.1 |

| | |
|---|---|
| Other specified manipulation of spine - Not commissioned as they are considered unproven therapies based on the current evidence | V50.1 |
| Other specified manipulation of spine - Not commissioned as they are considered unproven therapies based on the current evidence | V50.8 |
| Unspecified manipulation of spine - Not commissioned as they are considered unproven therapies based on the current evidence | V50.9 |
| Application of transcutaneous electrical nerve stimulator - Not commissioned as they are considered unproven therapies based on the current evidence | A70.7 |
| Introduction of neurostimulator into cranial nerve - Not commissioned as they are considered unproven therapies based on the current evidence | A33.1 |
| Vagus nerve (x) - Only when supplementary to A33.1 | Z04.4 |
| Percutaneous transluminal closure of patent oval foramen with prosthesis - Not commissioned as they are considered unproven therapies based on the current evidence | K16.5 |
| Insertion of neurostimulator electrodes into the cranial nerve (According to NICE: Not commissioned as they are considered unproven therapies based on the current evidence ) | A33.4 |
| Specified cranial nerve NEC - Only when supplementary to A33.4 | Z04.8 |

# Appendix 4 – Version History

**Headache Disorders**
**GM017**

The latest version of this policy can be found here GM Headache Disorders policy

| Version | Date | Summary of Changes |
|---|---|---|
| 0.1 | 03/09/2015 | Initial draft |
| 0.2 | 18/11/2015 | The GM EUR Steering Group meeting on the 18 November 2015 agreed the following changes to the policy:<br>• An extract from NICE CG150 added to the Mandatory Commissioning Section of the policy<br>• Implantation of a sphenopalatine ganglion stimulation device moved to not routinely commissioned in the Commissioning Criteria Section.<br>• Second paragraph under Mandatory Criteria reworded from: '*The individual has migraine that impacts on their quality of life and* ***both topiramate and propranolol are*** *unsuitable or ineffective, for this group a course of up to 10 sessions of acupuncture over 5–8 weeks can be tried.* ***If effective, application can be made via the IFR route for ongoing treatment.'*** to: '*The individual has migraine that impacts on their quality of life and* ***all standard therapies as outlined in CG 150 (see extract below) have been tried and are either*** *unsuitable or ineffective, for this group a course of up to 10 sessions of acupuncture over 5–8 weeks can be tried****, application for the initial course is on prior approval via the IFR route application for ongoing treatment is via the IFR route.'***<br>• Acupuncture for Migraine (outside of a commissioned pathway for headaches) removed from the not routinely commissioned section.<br>• Commissioning Recommendation Section updated to reflect the above changes.<br>• Funding Mechanism added.<br>Subject to the above changes being made the GM EUR Steering Group agreed that the policy could go out for a period of clinical engagement. |
| | 15/03/2016 | Policy updated to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services. |
| 1.0 | 16/03/2016 | GM EUR Steering Group reviewed the draft policy on 16th March 2016 following feedback received during Clinical Engagement and the following changes were approved:<br>• <u>Section 4. Criteria for Commissioning</u><br>o Mandatory Criteria section rewritten to include the following sections: *"Management of Headache in Adults is commissioned in line with the North West Headache Management Guideline for Adults – based on NICE CG150.*<br>***Treatments not covered by the North West Headache Management Guideline for Adults that may be commissioned are:***<br>*<u>Acupuncture</u> if the patient falls into the following category:….*<br>***The following interventions are <u>NOT</u> commissioned as they are considered unproven therapies based on the current evidence:..."***<br>o The following added under 'Policy Exclusions': *"Treatment of headache in line with NICE CG 150 as part of locally agreed contracts and / or pathways of care are excluded from this policy e.g. North West Headache Management Guideline for Adults – based on NICE CG150.* |

| | | |
|---|---|---|
| | | *Treatment in line with this guideline is not restricted in any way by this policy."*<br>• Under Appendix 1 – Evidence Review and 'The Evidence', amendments made to the extract of guidance under number 2:<br>o 1.2.7 – Bullet points 1 and 2 merged as should of read as one<br>o 1.3.1 – Bullet points 4 and 5 merged as should of read as one<br>o 1.3.17 – "if needed" added to the end of paragraph as was left out from original text.<br>• Appendix 2 - North West Headache Management Guideline for Adults.<br>• Appendix 3 – Diagnostic and Procedure Codes added.<br>• Wording for date of review amended to read *"One year from the date of approval by Greater Manchester Association Governing Group thereafter at a date agreed by the Greater Manchester EUR Steering Group (unless stated this will be every 2 years)"* on 'Policy Statement' and section '13. Date of Review'.<br>Following the above changes the GM EUR Steering Group approved the policy to go through the governance process. |
| | 07/03/2017 | Approved by Greater Manchester Association Governing Group |
| | 08/03/2017 | Policy transferred to new template format. |