NICE National Institute for Health and Care Excellence

NICE guideline

Headaches in over 12s: diagnosis and management

Clinical guideline
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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

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.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

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.

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This guideline is the basis of QS42.

This guideline should be read in conjunction with NG193.

Overview

This guideline covers advice on the diagnosis and management of tension-type headache, migraine (including migraine with aura and menstrual-related migraine), cluster headache and medication overuse headache in young people (aged 12 years and older) and adults. It aims to improve the recognition and management of headaches, with more targeted treatment to improve the quality of life for people with headaches, and to reduce unnecessary investigations.

MHRA advice on antiepileptic drugs in pregnancy: In May 2021, we amended our recommendation on topiramate for migraine prophylaxis to include discussion of the potential benefits and risks, and the importance of effective contraception for women and girls of childbearing potential when taking topiramate.

Who is it for?

- Healthcare professionals who provide care for young people and adults with headaches
- Young people (12 years and older) and adults with headaches, and their families and carers. Particular consideration is given to the needs of girls and women of reproductive age

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Key priorities for implementation

The following recommendations were identified as priorities for implementation in 2012. In 2015, the evidence was reviewed for the key priority recommendation on prophylactic treatment, but no change was made to the recommended action. No changes were made to the other key priority recommendations.

Tension-type headache, migraine and cluster headache

- Diagnose tension-type headache, migraine or cluster headache according to the headache features in table 1. Chronic migraine and chronic tension-type headache commonly overlap. If there are any features of migraine, diagnose chronic migraine.

  See recommendations 1.2.2, 1.2.3 and 1.2.4 for more information on diagnosis of migraine with aura. **[2012]**

Medication overuse headache

- 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 or more **or**
  - paracetamol, aspirin or an NSAID, either alone or any combination, on 15 days per month or more. **[2012]**

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Management

All headache disorders

- Do not refer people diagnosed with tension-type headache, migraine, cluster headache or medication overuse headache for neuroimaging solely for reassurance. **[2012]**

Information and support for people with headache disorders

- 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. **[2012]**

Migraine with or without aura

Acute treatment

- 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 to 17 years consider a nasal triptan in preference to an oral triptan. **[2012]**

  In November 2015, this was an off-label use of triptans (except nasal sumatriptan) for under 18s. See NICE's information on prescribing medicines.

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- For people in whom oral preparations (or nasal preparations in young people aged 12 to 17 years) for the acute treatment of migraine are ineffective or not tolerated:
  - consider a non-oral preparation of metoclopramide or prochlorperazine **and**
  - if non-oral metoclopramide or prochlorperazine is used, consider adding a non-oral NSAID or triptan if these have not been tried. **[2012]**

    Note the special warnings and precautions for use in the summaries of product characteristics for metoclopramide and prochlorperazine, and discuss the benefits and risks with the person (or their parents or carers, as appropriate).

    In November 2015, only a buccal preparation of prochlorperazine was licensed for this indication (prochlorperazine was licensed for the relief of nausea and vomiting); nasal sumatriptan was the only triptan licensed for this indication in under 18s. This was an off-label use of metoclopramide in children and young people. See NICE's information on prescribing medicines.

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Prophylactic treatment

- For the prophylaxis of migraine, offer topiramate or propranolol after a full discussion of the benefits and risks of each option. Include in the discussion:
  - the potential benefit in reducing migraine recurrence and severity
  - the risk of fetal malformations with topiramate
  - the risk of reduced effectiveness of hormonal contraceptives with topiramate
  - the importance of effective contraception for women and girls of childbearing potential who are taking topiramate (for example, by using medroxyprogesterone acetate depot injection, an intrauterine method or combined hormonal contraceptive with a barrier method).

    Follow the MHRA safety advice on antiepileptic drugs in pregnancy. **[2015, amended 2021]**

    In November 2015, this was an off-label use of topiramate in children and young people. See NICE's information on prescribing medicines.

    People with depression and migraine could be at an increased risk of using propranolol for self-harm. Use caution when prescribing propranolol, in line with the Healthcare Safety Investigation Branch's report on the under-recognised risk of harm from propranolol.

Cluster headache

Acute treatment

- Offer oxygen and/or a subcutaneous or nasal triptan for the acute treatment of cluster headache. **[2012]**

  In November 2015, this was an off-label use of subcutaneous triptans in under 18s. Nasal triptans did not have a UK marketing authorisation for this indication. See NICE's information on prescribing medicines.

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- 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. **[2012]**
- 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. [2012]

  In November 2015, this was an off-label use of subcutaneous triptans in under 18s. Nasal triptans did not have a UK marketing authorisation for this indication. See NICE's information on prescribing medicines.

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Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

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

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- symptoms and signs of acute narrow angle glaucoma
- a substantial change in the characteristics of their headache. **[2012]**

  For information on referral for suspected tumours of the brain or central nervous system, see the NICE guideline on suspected cancer.

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. **[2012]**

1.1.3 Consider using a headache diary to aid the diagnosis of primary headaches. **[2012]**

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. **[2012]**

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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 table 1. Chronic migraine and chronic tension-type headache commonly overlap. If there are any features of migraine, diagnose chronic migraine.

See recommendations 1.2.2, 1.2.3 and 1.2.4 for more information on diagnosis of migraine with aura. **[2012]**

Table 1 Headache features according to headache type

Headache feature	Tension-type headache	Migraine (with or without aura)	Cluster headache
Pain location (can be in the head, face or neck)	Bilateral	Unilateral or bilateral	Unilateral (around the eye, above the eye and along the side of the head/face)
Pain quality	Pressing/ tightening (non-pulsating)	Pulsating (throbbing or banging in young people aged 12 to 17 years)	Variable (can be sharp, boring, burning, throbbing or tightening)
Pain intensity	Mild or moderate	Moderate or severe	Severe or very severe
Effect on activities	Not aggravated by routine activities of daily living	Aggravated by, or causes avoidance of, routine activities of daily living	Restlessness or agitation

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Headache feature	Tension-type headache	Migraine (with or without aura)	Cluster headache
Other symptoms	None	Unusual sensitivity to light and/or sound or nausea and/or vomiting Symptoms of aura can occur with or without headache and: • are fully reversible • develop over at least 5 minutes • last 5 to 60 minutes Typical aura symptoms include visual symptoms such as flickering lights, spots or lines and/or partial loss of vision; sensory symptoms such as numbness and/or pins and needles; and/or speech disturbance	On the same side as the headache: • red and/or watery eye • nasal congestion and/or runny nose • swollen eyelid • forehead and facial sweating • constricted pupil and/or drooping eyelid
Duration of headache	30 minutes to continuous	4 to 72 hours in adults 1 to 72 hours in young people aged 12 to 17 years	15 to 180 minutes

Episodic tension-type headaches occur on fewer than 15 days per month. Chronic tension-type headaches occur on 15 or more days per month for more than 3 months.

Episodic migraines (with or without aura) occur on fewer than 15 days per month. Chronic migraines (with or without aura) occur on 15 or more days per month for more than 3 months.

Episodic cluster headaches occur from once every other day to 8 times a day with a pain-free period of more than 1 month. Chronic cluster headaches occur from once every other

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day to 8 times a day with a continuous pain-free period of less than 1 month in a 12-month period.

NICE has developed technology appraisal guidance on botulinum toxin type A for the prevention of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine).

Migraine with aura

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 to 60 minutes. **[2012]**

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. **[2012]**

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**

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- decreased level of consciousness. **[2012]**

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. **[2012]**

1.2.6 Diagnose menstrual-related migraine using a headache diary (see recommendation 1.1.4) for at least 2 menstrual cycles. **[2012]**

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 or more **or**
- paracetamol, aspirin or an NSAID, either alone or in any combination, on 15 days per month or more. **[2012]**

  For guidance on safe prescribing of opioids and managing withdrawal, see NICE's guideline on medicines associated with dependence or withdrawal symptoms.

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

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- as a basis for discussion with the person about their headache disorder and its impact. **[2012]**

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. **[2012]**

1.3.3 Do not refer people diagnosed with tension-type headache, migraine, cluster headache or medication overuse headache for neuroimaging solely for reassurance. **[2012]**

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. **[2012]**

1.3.5 Give the person written and oral information about headache disorders, including information about support organisations. **[2012]**

1.3.6 Explain the risk of medication overuse headache to people who are using acute treatments for their headache disorder. **[2012]**

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.

Because of the association with Reye's syndrome, preparations

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containing aspirin should not be offered to under 16s. **[2012]**

1.3.8 Do not offer opioids for the acute treatment of tension-type headache. **[2012]**

Prophylactic treatment

1.3.9 Consider a course of up to 10 sessions of acupuncture over 5 to 8 weeks for the prophylactic treatment of chronic tension-type headache. **[2012]**

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 to 17 years consider a nasal triptan in preference to an oral triptan. **[2012]**

In November 2015, this was an off-label use of triptans (except nasal sumatriptan) in under 18s. See NICE's information on prescribing medicines.

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. **[2012]**

In November 2015, this was an off-label use of triptans in under 18s. See NICE's information on prescribing medicines. Because of the association with Reye's syndrome, preparations containing aspirin should not be offered to under 16s.

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. **[2012]**

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In November 2015, this was an off-label use of triptans in under 18s. See NICE's information on prescribing medicines.

1.3.13 Consider an anti-emetic in addition to other acute treatment for migraine even in the absence of nausea and vomiting. **[2012]**

1.3.14 Do not offer ergots or opioids for the acute treatment of migraine. **[2012]**

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

- consider a non-oral preparation of metoclopramide or prochlorperazine **and**
- if non-oral metoclopramide or prochlorperazine is used, consider adding a non-oral NSAID or triptan if they have not been tried. **[2012, amended 2021]**

  Note the special warnings and precautions for use in the summaries of product characteristics for metoclopramide and prochlorperazine, and discuss the benefits and risks with the person (or their parents or carers, as appropriate).

  In November 2015, only a buccal preparation of prochlorperazine was licensed for this indication (prochlorperazine was licensed for the relief of nausea and vomiting); nasal sumatriptan was the only triptan licensed for this indication in under 18s. This was an off-label use of metoclopramide in children and young people. See NICE's information on prescribing medicines.

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. **[2012]**

1.3.17 For the prophylaxis of migraine, offer topiramate or propranolol after a full discussion of the benefits and risks of each option. Include in the discussion:

- the potential benefit in reducing migraine recurrence and severity

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- the risk of fetal malformations with topiramate
- the risk of reduced effectiveness of hormonal contraceptives with topiramate
- the importance of effective contraception for women and girls of childbearing potential who are taking topiramate (for example, by using medroxyprogesterone acetate depot injection, an intrauterine method or combined hormonal contraception with a barrier method).

  Follow the MHRA safety advice on antiepileptic drugs in pregnancy. **[2015, amended 2021]**

  In November 2015, this was an off-label use of topiramate in children and young people. See NICE's information on prescribing medicines.

  People with depression and migraine could be at an increased risk of using propranolol for self-harm. Use caution when prescribing propranolol, in line with the Healthcare Safety Investigation Branch's report on the under-recognised risk of harm from propranolol.

1.3.18 Consider amitriptyline for the prophylactic treatment of migraine according to the person's preference, comorbidities and risk of adverse events.

In November 2015, this was an off-label use of amitriptyline. See NICE's information on prescribing medicines. **[2015]**

For guidance on safe prescribing of antidepressants (such as amitriptyline) and managing withdrawal, see NICE's guideline on medicines associated with dependence or withdrawal symptoms.

1.3.19 Do not offer gabapentin for the prophylactic treatment of migraine. **[2015]**

1.3.20 If both topiramate and propranolol are unsuitable or ineffective, consider a course of up to 10 sessions of acupuncture over 5 to 8 weeks according to the person's preference, comorbidities and risk of adverse events. **[2012, amended 2015]**

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1.3.21 For people who are already having treatment with another form of prophylaxis and whose migraine is well controlled, continue the current treatment as required. **[2012, amended 2015]**

1.3.22 Review the need for continuing migraine prophylaxis 6 months after the start of prophylactic treatment. **[2012]**

1.3.23 Advise people with migraine that riboflavin (400 mg once a day) may be effective in reducing migraine frequency and intensity for some people. **[2012]**

In November 2015, this was an off-label use of riboflavin, but this is available as a food supplement.

Combined hormonal contraceptive use by women and girls with migraine

1.3.24 Do not routinely offer combined hormonal contraceptives for contraception to women and girls who have migraine with aura. **[2012]**

Menstrual-related migraine

1.3.25 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. **[2012]**

In November 2015, this was an off-label use of frovatriptan and zolmitriptan. See NICE's information on prescribing medicines.

Treatment of migraine during pregnancy

1.3.26 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. **[2012]**

In November 2015, this was an off-label use of triptans (except nasal sumatriptan) in under 18s. See NICE's information on prescribing

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medicines.

1.3.27 Seek specialist advice if prophylactic treatment for migraine is needed during pregnancy. **[2012]**

Cluster headache

Acute treatment

1.3.28 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. **[2012]**

1.3.29 Offer oxygen and/or a subcutaneous or nasal triptan for the acute treatment of cluster headache. **[2012]**

In November 2015, this was an off-label use of subcutaneous triptans in under 18s. Nasal triptans did not have a UK marketing authorisation for this indication. See NICE's information on prescribing medicines.

1.3.30 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. **[2012]**

1.3.31 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. **[2012]**

In November 2015, this was an off-label use of subcutaneous triptans in under 18s. Nasal triptans did not have a UK marketing authorisation for this indication. See NICE's information on prescribing medicines.

1.3.32 Do not offer paracetamol, NSAIDS, opioids, ergots or oral triptans for the acute treatment of cluster headache. **[2012]**

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Prophylactic treatment

1.3.33 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. **[2012]**

In November 2015, this was an off-label use of verapamil. See NICE's information on prescribing medicines.

1.3.34 Seek specialist advice for cluster headache that does not respond to verapamil. **[2012]**

In November 2015, this was an off-label use of verapamil. See NICE's information on prescribing medicines.

1.3.35 Seek specialist advice if treatment for cluster headache is needed during pregnancy. **[2012]**

Medication overuse headache

For guidance on managing withdrawal of opioids, see NICE's guideline on medicines associated with dependence or withdrawal symptoms.

1.3.36 Explain to people with medication overuse headache that it is treated by withdrawing overused medication. **[2012]**

1.3.37 Advise people to stop taking all overused acute headache medications for at least 1 month and to stop abruptly rather than gradually. **[2012]**

1.3.38 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. **[2012]**

1.3.39 Consider prophylactic treatment for the underlying primary headache disorder in addition to withdrawal of overused medication for people with medication overuse headache. **[2012]**

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1.3.40 Do not routinely offer inpatient withdrawal for medication overuse headache. **[2012]**

1.3.41 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. **[2012]**

1.3.42 Review the diagnosis of medication overuse headache and further management 4 to 8 weeks after the start of withdrawal of overused medication. **[2012]**

Terms used in this guideline

Acute narrow-angle glaucoma

An uncommon eye condition that results from blockage of the drainage of fluid from the eye. Symptoms of acute glaucoma may include headache with a painful red eye and misty vision or haloes, and in some cases nausea. Acute glaucoma may be differentiated from cluster headache by the presence of a semi-dilated pupil compared with the presence of a constricted pupil in cluster headache.

Cluster headache bout

The duration over which recurrent cluster headaches occur, usually lasting weeks or months. Headaches occur from 1 every other day to 8 times per day.

Giant cell arteritis

Also known as temporal arteritis, giant cell arteritis is characterised by the inflammation of the walls of medium and large arteries. Branches of the carotid artery and the ophthalmic artery are preferentially involved, giving rise to symptoms of headache, visual disturbances and jaw claudication.

NSAID

Non-steroidal anti-inflammatory drug.

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Positive diagnosis

A diagnosis based on the typical clinical picture that does not require any further investigations to exclude alternative explanations for a patient's symptoms.

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Context

Headaches are one of the most common neurological problems presented to GPs and neurologists. They are painful and debilitating for individuals, an important cause of absence from work or school and a substantial burden on society.

Headache disorders are classified as primary or secondary. The aetiology of primary headaches is not well understood and they are classified according to their clinical pattern. The most common primary headache disorders are tension-type headache, migraine and cluster headache. Secondary headaches are attributed to underlying disorders and include, for example, headaches associated with medication overuse, giant cell arteritis, raised intracranial pressure and infection. Medication overuse headache most commonly occurs in those taking medication for a primary headache disorder. The major health and social burden of headaches is caused by primary headache disorders and medication overuse headache.

This guideline makes recommendations on the diagnosis and management of the most common primary headache disorders in young people (aged 12 years and older) and adults. Many people with headache do not have an accurate diagnosis of headache type. Healthcare professionals can find the diagnosis of headache difficult, and both people with headache and their healthcare professionals can be concerned about possible underlying causes. Improved recognition of primary headaches will help the generalist clinician to manage headaches more effectively, allow better targeting of treatment and potentially improve quality of life and reduce unnecessary investigations for people with headache.

In 2015, we reviewed the evidence on the prophylactic treatment of headaches and updated or added new recommendations.

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Recommendations for research

In 2012, the guideline committee made the following recommendations for research.

1 Amitriptyline to prevent recurrent migraine

Is amitriptyline a clinically and cost effective prophylactic treatment for recurrent migraine?

Why this is important

Effective prevention has the potential to make a major impact on the burden of disability caused by recurrent migraine. There are few pharmacological agents that have been proven to prevent recurrent migraine.

Amitriptyline is widely used, off-label, to treat chronic painful disorders, including migraine. The updated evidence review (2015) found evidence comparing amitriptyline with topiramate, but not with placebo, and there was uncertainty about the effectiveness of amitriptyline as a prophylactic treatment. A double-blind randomised controlled trial (RCT) is needed to assess the clinical and cost effectiveness of amitriptyline compared with placebo. The definition of migraine used should be that in the International classification of headache disorders 2 or this guideline. Outcomes should include change in patient-reported headache days, responder rate and incidence of serious adverse events.

2 Pizotifen to prevent recurrent migraine

Is pizotifen a clinically and cost effective prophylactic treatment for recurrent migraine?

Why this is important

There are few data to inform guidance on the prevention of migraine in children and young people.

Pizotifen is a popular treatment for migraine prevention in the UK, especially in children and young people. It has been in use since the 1970s and appears to be well tolerated. Inadequate evidence was found in the review for this guideline for the effectiveness of

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pizotifen in the prophylaxis of migraine. A double-blind RCT either head-to-head with best available treatment, or placebo controlled, is needed to assess the clinical and cost effectiveness of pizotifen in young people aged under 18 and adults. The trial should enrol people aged under 18 and adults. The definition of migraine used should be that in the International classification of headache disorders 2 or this guideline. Outcomes should include change in patient-reported migraine days, responder rate and incidence of serious adverse events. If pizotifen is shown to be effective, it will widen the range of therapeutic options, in particular for young people in whom recommended medications are ineffective or not tolerated.

3 Topiramate to prevent recurrent cluster headache

Is topiramate a clinically and cost effective prophylactic treatment for recurrent cluster headache?

Why this is important

Cluster headache is an excruciatingly painful and highly disabling disorder. The management of cluster headache includes the use of preventive treatments to stop the attacks as quickly and safely as possible. There is a significant unmet clinical need for effective preventive treatments in cluster headache and few data to inform guidance on prophylaxis of cluster headache. Although numerous agents including verapamil, topiramate, lithium, methysergide and gabapentin are used in routine clinical practice, this is largely based on clinical experience as very few RCTs have been performed.

Several open-label studies have reported on the efficacy of topiramate in the preventive treatment of cluster headache. There is therefore a need for a high-quality RCT of topiramate in the prevention of cluster headaches.

4 Psychological interventions to manage chronic headache disorders

Does a psychological intervention such as cognitive behavioural therapy (CBT) improve headache outcomes and quality of life for people with chronic headache disorders?

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Why this is important

Psychological interventions such as CBT are widely recommended for people with chronic painful disorders. An effective psychological intervention based on cognitive behavioural principles for people with chronic headache disorders has the potential to substantially improve their quality of life. There are few data to support the use of these interventions to manage chronic headache disorders.

A pragmatic RCT is needed to assess the impact of a psychological intervention compared with an active control. Mood disorders are commonly comorbid with headache disorders, but the trial needs to address the impact of a psychological intervention on headache alone, using appropriate headache outcomes such as change in patient-reported headache days and headache-specific quality of life.

5 Pharmacological treatments for headache prophylaxis to aid withdrawal treatment in medication overuse headache

Does a course of steroid treatment or pharmacological treatments used for headache prophylaxis help people with medication overuse headaches withdraw from medication?

Why this is important

Medication overuse headache is a common disorder. Current best advice is for abrupt withdrawal without any supportive pharmacological treatment. Many people with medication overuse headache find it difficult to withdraw abruptly because in the short term their headaches can become much worse. The use of steroids may aid withdrawal and for those who have an underlying headache disorder such as migraine or tension-type headache, appropriate prophylaxis may assist in treating the headache.

Double-blind RCTs are needed in people with suspected medication overuse headache who have an identifiable primary headache disorder. There should be two separate trials, one to investigate withdrawal of medication with placebo versus withdrawal of medication with steroid treatment, and the other to investigate withdrawal of medication with placebo versus withdrawal of medication with appropriate pharmacological prophylaxis. Outcomes should include change in acute medication use, proportion of patients who no longer have suspected medication overuse headache, change in patient-reported headache days and

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headache-specific quality of life.

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Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE topic page on neurological conditions.

For full details of the evidence and the guideline committee's discussions, see the full guideline. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

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Update information

December 2021: We changed the strength of recommendation 1.3.15 from 'offer' to 'consider' to better reflect the balance between the benefits and harms associated with the use of metoclopramide and prochlorperazine. See the surveillance report for details.

May 2021: We amended recommendation 1.3.17 on the use of topiramate for migraine prophylaxis to include discussion of the potential benefits and risks of topiramate and the importance of effective contraception for women and girls of childbearing potential.

November 2015: We updated or made new recommendations on the prophylactic treatment of migraine. These recommendations are marked **[2015]**.

We also made some changes to recommendation wording without an evidence review. These recommendations are marked as **[2012, amended 2015]**. These changes are:

- Recommendations have been changed when standard practice or treatment options have changed since 2012.
- Gabapentin has been removed from a recommendation, because it is no longer used for the treatment the recommendation covers.
- Recommendations have been edited to align with changes in other recommendations or new recommendations that have been added.

Recommendations are marked as **[2012]** when the evidence was last reviewed in 2012.

Minor changes since publication

May 2022: We added links to NICE's guideline on medicines associated with dependence or withdrawal symptoms in sections 1.2 and 1.3.

February 2020: A note was added to recommendation 1.3.17 on the potential risk of propranolol overdose in people with migraine who also have depression.

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