NICE RECOMMENDATION:

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.

HMMC Recommendation, following further clarification of NICE TA260 with specialists:

The treatment will be commissioned in line with a patient specific notification form.

The service providing the treatment is required to ensure that:

1. The patient’s headaches are not attributed to any other disorder.
2. The practitioner providing the injection has been trained by a certified trainer in giving the I.M injection in the appropriate areas of head and neck.
3. A process is in place to differentiate headache episodes from migraine. Patients should be required to keep a headache diary and given a leaflet outlining the sort of information they need to keep a record of on a daily basis. International Headache Society (HIS) criteria (Appendix 1, number 1a-e) for determining the days that qualify as migraine days are to be used to differentiate a migraine from a normal headache.
4. That patients referred to the service have had at least three prophylactic treatments from different drug groups as outlined in the guidance from the local neurologist (Appendix 1, number 4). Where this is not the case, appropriate advice should be given to the referring GP and the patient. The injection should not be administered at this stage. Patients must be encouraged to keep a headache diary prior to re-referral to specialist.
5. Analgesia overuse headaches are assessed, as outlined in Appendix 1, number 2, and managed appropriately, by the practitioner. In addition to headache and type, patients must be asked to note in the diary whether they took analgesics or triptans that day.
6. Patients should not be overusing analgesics for 2 months prior to consideration for botulinum toxin type A to ensure that analgesic overuse is not the cause of the migraine becoming chronic.
7. Stopping criteria outlined in NICE TA 260 are adhered to. Stopping criteria can be monitored by the service using the patient’s headache diary.
8. Providers must submit audit of treatment in line with these commissioning arrangements and allow the service and outcomes to be audited.

Where the provider is outside neurology services, commissioners must ensure that the service specification includes the guidance provided in the documents from the RCGP web-site and DH guidelines on Care Closer to Home.


References:

Appendix 1: Specific items to be included in Service Specification

Number 1: International Headache Society’s (IHS) guidelines for diagnosing migraine headaches – Migraine without Aura

- At least five headaches fulfilling criteria b through d.
- Headaches lasting 4-72 hours (untreated or unsuccessfully treated).
- Headache has at least two of the following characteristics:
  - Unilateral location
  - Pulsating quality
  - Moderate or severe pain intensity
  - Aggravation by or causing avoidance of, routine physical activity (e.g. walking or climbing stairs).
- During headache, at least one of the following characteristics:
  - Nausea and/or vomiting
  - Photophobia and/or phonophobia
- Headache cannot be attributed to another disorder.

Number 2: Current diagnostic guidance from the International Headache Society for medication overuse headache (MOH)

Diagnostic criteria
A. Headache* present on ≥15 days/month fulfilling criteria C and D.
B. Regular overuse for ≥3 months of one or more drugs that can be taken for acute and/or symptomatic treatment of headache.
C. Headache has developed or markedly worsened during medication overuse.
D. Headache resolves or reverts to its previous pattern within 2 months after discontinuation of overused medication.

Subtypes of MOH
2.1 Ergotamine-overuse headache
Ergotamine intake on ≥10 days/month on a regular basis for >3 months
2.2 Triptan-overuse headache
Triptan intake (any formulation) on ≥10 days/month on a regular basis for >3 months
2.3 Analgesic-overuse headache
Intake of simple analgesics on ≥15 days/month on a regular basis for >3 months
2.4 Opioid-overuse headache
Opioid intake on ≥10 days/month on a regular basis for >3 months
2.5 Combination analgesic-overuse headache
Intake of combination analgesic medications on ≥10 days/month on a regular basis for >3 months
2.6 MOH attributed to the combination of acute medications
Intake of any combination of ergotamine, triptans, analgesics, and/or opioids on ≥10 days/month on a regular basis for >3 months without overuse of any single class alone.
2.7 Headache attributed to other medication overuse
Regular overuse for >3 months of a medication other than those described earlier
2.8 Probable MOH
A. Headache fulfilling criteria A, C, and D for MOH
B. Medication overuse fulfilling criterion B for any one of the subtypes 2.1–2.7
C. One or other of the following:
  - Overused medication has not yet been withdrawn, and/or
  - Medication overuse has ceased within the last 2 months, but headache has not so far resolved or reverted to its previous pattern

Subtypes typically implicated are those containing simple analgesics combined with opioids, butalbital, and/or caffeine. Note butalbital is classified as a schedule III CD in the UK and is not currently available in any UK combination products.

The specific subform(s) 2.1–2.5 should be diagnosed if criterion B is fulfilled in respect of any one or more single class(es) of these medications.

The definition of overuse in terms of treatment days per week will vary with the nature of the medication.
Number 3: **Competency for administering Botulinum Toxin (from Dr Phil Wilkinson)**
- The individual must have attended a certified training course in order to be qualified to administer this treatment.

Number 4: **Prophylactic treatment dose and length of treatment (advised by Dr Phil Wilkinson)**
There are no generally accepted numbers other than to say that failure includes both failure to tolerate (a common reason for discontinuation) as well as failure of efficacy. Therefore, contra-indications should be taken into account e.g. propranolol in asthmatics; amitriptyline in someone on a monoamine oxidase inhibitor etc. There should be enough scope for each patient to try at least 3 migraine preventing medications first.

Assuming there are no tolerance issues, the following are standard (total daily) doses and durations for each of the common first and second line migraine preventative medications:

- Amitriptyline to at least 50 mg for at least 2 months
- Propranolol to at least 160 mg for at least 2 months
- Pizotifen to at least 1.5 mg for at least 2 months
- Topiramate to at least 100 mg for at least 2 months
- Sodium valproate to at least 1,000 mg for at least 2 months.

These are, of course, not the lowest effective doses as some patients can respond to as little as 10 mg of amitriptyline or 40 mg of propranolol.

General policy would be to start low and titrate up according to response to at least the doses above (sometimes even higher) and continue for at least 2 months (often longer) before considering the drug to have failed. Discontinuation may however occur at some point during the titration.

Produced on behalf of NHS Hertfordshire: Rasila Shah, Lead Pharmacist, Acute Commissioning.