<table>
<thead>
<tr>
<th><strong>Treatment</strong></th>
<th><strong>Botulinum Toxin Type A</strong></th>
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<tr>
<td>For</td>
<td>for the prevention of headaches in adults with Chronic Migraine</td>
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**Background**

Botulinum Toxin Type A is a purified neurotoxin complex, which is derived from the bacterium *Clostridium Botulinum*. It has neuromuscular transmitter blocking effects. It has UK marketing authorisation 'for the prophylaxis of headaches in adults with chronic migraine'.

Chronic migraine is described as a headache on more than 15 days per month, of which 8 are migrainous. It has a prevalence of approximately 2%. The World Health Organisation has rated migraine amongst the top 20 most disabling lifetime conditions worldwide. Indeed many patients attending headache clinics have daily disabling headaches preventing them from working and participating in social activities.

The majority of patients with migraine (episodic or chronic) can be diagnosed and treated effectively in primary care. Of the patients referred to GP with Special Interest (GPSI) or neurology services for their headaches, a small group of headache sufferers will remain refractory to standard treatments. It is for this small group of patients that Botulinum Toxin Type A may be beneficial. Locally it is estimated that there may be circa 20-30 patients eligible for treatment.

In the key studies both Botulinum Toxin Type A and placebo had a statistically significant effect. The benefit seemed at best to be a reduction of headache days from 20 to 12 per month, (placebo would reduce headache days from 20 to 14 per month. Thus the net improvement compared to placebo is 2 headache days. Whether this is clinically significant or not is an important factor. There remains uncertainty about how long injections need to be undertaken in order to maintain the response. The reduction in headache days should be balanced against the discomfort from the series of injections at each treatment session.

**Commissioning position**

This treatment is routinely commissioned following diagnosis and referral by an NHS Consultant in Neurology or GP with Special Interest in Headache and who meet the criteria set out below.

Botulinum Toxin Type A is recommended as a treatment 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 are with migraine):

- That has not responded to at least three prior pharmacological prophylactic therapies **AND**
- Whose condition is appropriately managed for medication overuse.

Treatment with Botulinum Toxin Type A that is recommended according to the criteria above should be stopped in those 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.

The drug is administered via intramuscular injections to between 31 and 39 sites around the head and the back of the neck. The recommended treatment cycle is every 12 weeks.
**Patient Group(s)**

**Chronic Migraine**

- Patient diagnosed by a neurologist or an accredited GP headache specialist with experience in diagnosing and treating patients with chronic migraine
- No analgesic overuse (<10 days per month of analgesic or Triptan use)
- Tried at least 3 preventative medications for at least 12 weeks at maximum tolerated doses
- Relevant co-morbidities influencing headache, e.g. cervical pain, depression, should be adequately treated prior to use of Botulinum Toxin Type A

There is anecdotal evidence that there is a low likelihood of response to a fourth prophylactic medicine when three others have not provided pain relief.

Prior to treatment with Botulinum Toxin Type A, a run-in 2 month headache diary should be completed documenting the number of days affected by headache and severity score. On the day of treatment, the following scores should be evaluated:

a. Headache Impact Test (HIT-score)

b. Migraine Disability Assessment Scale (MIDAS)

c. Headache days per month

A headache diary will be continued for the duration of treatment. Three months after injection the above scales will be re-assessed and a second course of injections given. If, after a further three months, there is no significant improvement then treatment will be discontinued.

After one year consideration should be made with regard to stopping the treatment.

**Audit Requirements**

An annual audit is required detailing the following:

1. Number of patients treated
2. Number of responders
3. Number of non-responders
4. Of responders continuing treatment:
   a. Improvement in HIT
   b. Improvement in MIDAS
   c. Improvement in headache days
      Compared with baseline
5. Adverse events

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<tr>
<th><strong>Effective from</strong></th>
<th>October 2012</th>
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<tr>
<td><strong>Summary of evidence/rationale</strong></td>
<td>See NICE Technology Appraisal Guidance (TA260)</td>
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<tr>
<td><strong>Review Date</strong></td>
<td>NICE planned review date of June 2015</td>
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| **Policy review by** | Commissioner: Consultant in Public Health  
Provider: Consultant in Neurology and GPSI neurology service |
| **Policy contact** | NHS Bradford and Airedale Clinical Commissioning Groups |
REFERENCES
NICE technology appraisal guidance 260 (June 2012)
Botulinum toxin type A for the prevention of headaches in adults with chronic migraine
www.guidance.nice.org.uk/ta260

RESOURCES
Migraine diary
http://diary.migrainetrust.org/

FUTURE WORK
The Commissioner will work with local clinicians to consider the forthcoming NICE guidance on headache when published.

COSTINGS 2012/13
The net price of a 200 unit vial is £276.40 (excluding VAT; 'British national formulary' [BNF] edition 63). The manufacturer estimates that the administration cost is £73 per treatment, based on a total treatment time of less than 30 minutes. The total cost for treatment and administration of treatment per 12 week cycle, assuming no vial sharing, is therefore expected to be £349.40. Drug costs may vary in different settings because of negotiated procurement discounts; where this is the case the Commissioner expects the Provider to operate on the basis of a pass through payment.

Drug administration costs are not expected to exceed £73 per patient per treatment.