General Commissioning Policy

Treatment	**Botulinum toxin type A** (Botox®, [Allergan] is the only medication specifically licensed in the UK for the prophylaxis of headaches in adult patients with chronic migraine.)
For the treatment of	**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.)
Background	This commissioning policy reflects the criteria stipulated in NICE Technology Appraisal Guidance 260, published June 2012.
Commissioning position	NHS Hull CCG will only commission the use of Botox as an option for the prophylactic treatment of chronic migraine in adults in accordance with NICE Guidance TAG 260 (Ref 1) in cases where ALL of the following criteria are fulfilled: • The patient is under the care of the specialist neurology service and has been assessed as meeting the definition for chronic migraine • The patient has chronic migraine that significantly interferes with their daily routine despite appropriate use of symptomatic medication • Symptoms have not responded to at least **three** prior pharmacological prophylaxis therapies • The condition has been appropriately managed for medication overuse. **NB**. Treatment with botulinum toxin type A 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 (which is not covered in Allergan's licence for Botox).
Effective from	September 2016
Summary of evidence / rationale	Chronic migraine is believed to affect 1.6% of adults and is a debilitating condition which significantly affects health-related quality of life. Botox has been licensed for "the prophylaxis of headaches in

Notes

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG.

	adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine)". Its precise mode of action in migraine is not known but it is assumed to block peripheral nerve signals to the central nervous system. The recommended reconstituted dose is 155–195 units, administered intramuscularly as 0.1 ml (5 units) injections to between 31 and 39 sites around the head and back of the neck, with a recommended re-treatment schedule of every 12 weeks. Botox has a well acknowledged safety profile, with a low incidence of adverse reactions of concern. The treatment has been appraised by NICE (Ref 1), which considered evidence from two phase III randomised controlled trials, PREEMPT 1 and PREEMPT 2 (Refs 2 & 3) as well as the pooled analysis of results from these trials (Ref 4). Prior to publication of the NICE Guidance the North East Treatment Advisory Group (Ref 5) and the Scottish Medicines Consortium (Ref 6) had appraised the same trial evidence and concluded that the treatment should not be recommended for the prevention of migraine because of uncertainly around its cost-effectiveness. NICE also concluded that although the treatment effects were generally in favour of Botox, the actual magnitude of treatment benefit was modest, but was nevertheless clinically meaningful in people whose chronic migraine had not responded to 3 prior treatments. As in the previous appraisals (Refs 5, 6) NICE also noted the large placebo effect, concerns over blinding being maintained in the PREEMPT trials, the lack of long term clinical trial data and numerous concerns over the manufacturer's economic modelling. However after a revised model was submitted using the NICE preferred assumptions, it was concluded that £18,900 was the most plausible ICER (incremental cost effectiveness ratio) per QALY (quality adjusted life year) and that this was considered an appropriate use of NHS resources, within certain specified criteria (reflected in the guidance above).
Date	May 2017
Review Date	May 2019
Contact for this policy	Karen Billany, Head of Acute Care, NHS Hull CCG Karen.billany@nhs.net

References:

1. NICE TAG 260 (June 2012) Migraine (chronic) - botulinum toxin type A http://guidance.nice.org.uk/ta260
2. PREEMPT 1 Aurora S K, Dodick D W, Turkel C C ,et al. Onabotulinumtoxin A for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. Cephalalgia 2010;30:793-803. http://cep.sagepub.com/content/30/7/793.abstract
3. PREEMPT 2 Diener H C, Dodick D W, Aurora S K ,et al. Onabotulinumtoxin A for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. Cephalalgia 2010;30:804-14. http://cep.sagepub.com/content/30/7/804.abstract

4. Dodick DW, Turkel CC, DeGryse RE et al. Onabotulinumtoxin A for treatment of chronic migraine: pooled results from the double-blind, randomized, placebo-controlled phases of the PREEMPT clinical program. Headache 2010;50:921-36. http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4610.2010.01678.x/pdf
5. Botulinum toxin (Botox®) for chronic migraine. NE Treatment Advisory Group. NHS Regional Drug & Therapeutics Centre. September 2011 http://www.netag.nhs.uk/files/appraisal-reports/Botox%20for%20chronic%20migraine%20-%20NETAG%20appraisal%20report%20-Sept%202011-%20WEB%20VERSION.pdf
6. Scottish Medicines Consortium advice on Botox for the Prophylaxis of headaches in adults with chronic migraine (April 2011) http://www.scottishmedicines.org.uk/SMC_Advice/Advice/692_11_botulinum_toxin_type_a_BOTOX/689_11_botulinum_toxin_type_a_Botox