



CLINICAL GUIDELINE

Botulinum Toxin A (Botox) use in chronic migraine protocol

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.


Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

Version Number:	3
Does this version include changes to clinical advice:	No
Date Approved:	15 th September 2022
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Approval Group:	Institute of Neurological Sciences Medical Clinical Governance Group

Important Note:

The Intranet version of this document is the only version that is maintained. Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

	NHS Greater Glasgow and Clyde Neurology Protocol for use of Botulinum toxin A (Botox®) in chronic migraine
Background:	<p>Onabotulinum toxin A (Botox®) is the only botulinum toxin which is licensed for chronic migraine in the UK. Botox® has been accepted for use by the Scottish Medicines Consortium in patients who have failed to respond to ≥3 prophylactic treatments. In NHS GGC, it is proposed that Botox® should not be considered until patients have received an adequate trial of ≥4 prophylactic treatments.</p>
Agent and route:	<ul style="list-style-type: none"> • Intramuscular injection • Botulinum toxin products are not interchangeable therefore only onabotulinum toxin A (Botox®) should be used
Patient population applicable to:	<p>Patients will be known to the Headache service in the Institute of Neurological Sciences</p>
Authorised and Designated Areas applicable to:	<p>Institute Outpatients clinic room</p>
Indication and place in therapy:	<p>Botox® for chronic migraine will only be recommended by the Headache Team (Consultant Neurologists and General Practitioners with Specialist Interest in Headache (GPSIs) where medication overuse has been appropriately managed.</p> <p>Botox® should only be considered if patient has received an adequate trial (i.e. at least 6 weeks at therapeutic dose) of the following 4 medicines/classes of medicine (unless contraindicated or side effects):</p> <ul style="list-style-type: none"> • Beta blockers (e.g. propranolol) • Topiramate • Tricyclic antidepressant drug (e.g. amitriptyline, dosulepin) • Candesartan • If the above therapies have failed due to lack of efficacy, tolerability or are contra-indicated due to co-morbid condition then headache clinic clinician discretion to try Flunarizine (unlicensed and dispensed via hospital pharmacy) <p>Botox will be stopped after 2 courses if</p> <ul style="list-style-type: none"> • Treatment has failed to reduce the number of headache days by at least 30% or the number of severe headache days by at least 50% or • If chronic migraine becomes episodic (i.e. <15 days/month with headache for 3 consecutive months). <p>Upon initiation of treatment patients should be advised they are being trialled on the treatment and MUST bring their headache diaries to their appointments in order to assess effects, otherwise treatment will be withheld.</p> <p>Patients who fail to bring their diary following this can still be administered the treatment on one occasion, however if they fail to present their diary on a second presentation, treatment will be withheld until diaries are submitted.</p>
Dose, duration and administration:	<p>155 Units to 195 Units administered intramuscularly as 0.1 ml (5 Units) injections to 31 and up to 39 sites (see below). The recommended re-treatment schedule is every 12 weeks.</p> <p>¹ IM injection site = 0.1ml = 5 units Botox ² Dose distributed bilaterally</p>

		Recommended Dose
	Head/Neck area	Total Dosage (number of sites¹)
	Corrugator ²	10 Units (2 sites)
	Procerus	5 Units (1 site)
	Frontalis ²	20 Units (4 sites)
	Temporalis ²	40 Units (8 sites) up to 50 Units (up to 10 sites)
	Occipitalis ²	30 Units (6 sites) up to 40 units (up to 8 sites)
	Cervical Paraspinal Muscle Group ²	20 Units (4 sites)
	Trapezius ²	30 Units (6 sites) up to 50 Units (up to 10 sites)
	Total Dose Range	155 Units to 195 Units 31 to 39 sites
Strength of preparation used:	200 unit vial where available 2 x 100 unit vials if above not available.	
Licensed status:	Licensed Medicine	
Authorised prescribers:	Dr Alok Tyagi, Consultant Neurologist, NHS GGC Dr Johann Selvarajah, Consultant Neurologist, NHS GGC Dr George Gorrie, Consultant Neurologist, NHS GGC Dr Michael McKenzie, GPSI Dr Sandeep Sharma, GPSI Laura McCorkell Headache CNS Anissa Benchiheub, Clinical Nurse Specialist – Headache, NHS GGC Dr Krishna Dani, Consultant Neurologist, NHS GGC Dr Sarah Miller, Consultant Neurologist, NHS GGC	
Authorised for administration:	Dr Alok Tyagi, Consultant Neurologist, NHS GGC Dr Johann Selvarajah, Consultant Neurologist, NHS GGC Dr George Gorrie, Consultant Neurologist, NHS GGC Dr Krishna Dani, Consultant Neurologist, NHS GGC Dr Sarah Miller, Consultant Neurologist, NHS GGC Dr Sandeep Sharma, GPSI Laura McCorkell, Headache CNS Christine Rankin, Headache CNS Anissa Benchiheub, Headache CNS Marcia McAdam, Headache CNS Donna Neilson, Headache CNS Marissa Herron, Headache CNS	
Authorised for preparation in clinical area:	Yes	
Authorised for storage in clinical areas:	Yes. Store in a refrigerator	
References:	Scottish Medicines Consortium https://www.scottishmedicines.org.uk/medicines-advice/botulinum-toxin-a-botox-resubmission-69211/ Botox® Summary of Product Characteristics http://www.medicines.org.uk/emc/medicine/22562	
Updated by:	Dr Krishna Dani, Consultant Neurologist	
Checked by:	Laura Stobo, Senior Pharmacist Clinical Effectiveness	
Endorsed by:	West of Scotland Regional Headache Service, NHS GGC	
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