NHS
Kent and Medway
Clinical Commissioning Group

Kent and Medway Policy Recommendation and Guidance Committee

Policy Recommendation

Policy:	**PR 2021-22: Botulinum neurotoxin (BoNT) for the management of cervical dystonias and hemifacial spasms in adults**
Issue date:	**December 2021**

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered the baseline position, the evidence base, other CCG policies, the views of local specialists and the potential impact of implanting a system wide policy for botulinum neurotoxin A (BoNT) for hemifacial spasms and cervical dystonias. All decisions were made with reference to the Ethical Framework.

Taking these into account, the PRGC recommends:

- Botulinum neurotoxin A is routinely funded for the treatment of adults for hemifacial spasms and cervical dystonias on the local NHS.

This policy recommendation will be reviewed when new information becomes available that is likely to have a material effect on the current recommendation.

Kent and Medway Clinical Commissioning Group will always consider appropriate individual funding requests (IFRs) through their IFR process.

Supporting documents

NEL HPSU (2021) *Botulinum neurotoxin for treating cervical dystonias and hemifacial spasms – Scoping report*

Equality Analysis Screening Tool – Botulinum neurotoxin for treating cervical dystonias and hemifacial spasms (2021)

Key points

What are Hemifacial Spams and Cervical Dystonias?

Cervical dystonia (CD) is a chronic disorder that affects the muscles of the neck and often the shoulders. It is the most common form of adult-onset focal dystonia. Most cases of CD are idiopathic. Nevertheless, the finding of a family history of dystonia (12% of cases) or of any movement disorder (44% of cases) suggests a genetic susceptibility. Secondary causes of CD include tardive and acute dystonia due to dopamine receptor blocking agents, neck trauma (central and peripheral trauma are less frequent), metabolic disorders such as Wilson's disease and pantothenate-kinase- associated neurodegeneration or Parkinson's disease.

Approved by: JPC, KMMOC, Clinical Cabinet
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Hemifacial spasms (HFS) is a chronic condition characterised by involuntary paroxysmal contractions of muscles innervated by the facial nerve. Bilateral involvement is rare. The involuntary contraction affects orbicularis oculi in the upper face, and orbicularis oris, platysma, and other superficial muscles of the lower area of one half of the face. Although HFS is not dangerous, it usually causes significant cosmetic and functional disability. Its severity ranges from slight unilateral blinking, with no involvement of the lower half of the face, to intense spasm of the lower half of the face and neck with one eye closed, and progressive facial weakness.

How are hemifacial spasms (HFS) and cervical dystonia (CD) managed?

The therapeutic strategy to manage CD likely requires multiple pharmacological/surgical interventions to target dystonia, pain, depression and anxiety in order to achieve a major decrease in the burden of disease. First line treatment for CD is BoNT. The two treatments routinely used to manage HFS are microvascular decompression of the facial nerve at the pons and intramuscular injections of BoNT.

What is botulinum neurotoxin A (BoNT) (Botox; Xeomin; Dysport)

BoNT is well-established as an effective and safe treatment for CD. BoNT is a powerful, natural chemical that can cause severe paralysis (an inability to move in the part of the body where it is injected) in animals and humans. It can also be used to treat many conditions, in particular, those with involuntary muscle contractions, such as cervical dystonia. BoNT is delivered by injections into the muscles that contract to produce most of the disorder symptoms. Botox is the preferred brand of choice for CD and HFS. However, Xeomin is the more cost effective brand available on formulary. Dysport is the least cost effective brand available on formulary and pharmacy groups have confirmed there is very little usage.

What does NICE recommend?

There is no NICE recommendation for cervical dystonias and hemifacial spasms specifically. However, NICE has guidance for Suspected Neurological Conditions which makes reference to cervical dystonias. Recommendation 42 – Cervical dystonia in the NICE guidance recommend referral to a neurologist for patients with Postural abnormalities of the head and neck that could be due to cervical dystonia.

What does other national guidance say?

The European federation of Neurological Science practice guideline for BoNT use in CD provides recommendations and good practice points which state botulinum A (or type B if there is resistance to type A) can be regarded as first-line treatment for primary cranial (excluding oromandibular) or CD and BoNT injections are safe and efficacious when repeated treatments are performed over many years (good practice point), but doctors and patients should be aware that excessive cumulative doses may be dangerous, particularly in children.

Association of British Neurologists provided statements for treatment of dystonia with BoNT. These included (but is not limited to):

1) BoNT injections are the main treatment approach for patients with CD.
2) Adults, who require BoNT injections, have access to specialised BoNT services within 2 months of diagnosis.
3) The BoNT service will be located within reasonable travelling distance from the patient's home address.
4) Each treatment centre should audit outcome and safety.

What is the baseline position in Kent and Medway?

Kent and Medway currently have services operating in two Trusts - Maidstone and Tunbridge Wells NHS Foundation Trust (Maidstone Hospital) and Dartford and Gravesham NHS Trust (Darent Valley

Hospital). Currently, patients are being sent to tertiary centres in London for treatment. These services are now becoming saturated and patients are being repatriated back to local hospitals with no commissioning currently in place for their treatment.

The provider Trusts which currently have an active service treat each clinical indication in two different departments; cervical dystonias are currently managed and treated within neurology and hemifacial spasm are managed and treated in ophthalmology. Maidstone and Tunbridge Wells NHS Trust (MTW) and East Kent Hospitals University NHS Foundation Trust (EKHUFT) currently have the hemifacial spasms service managed and functioning within the ophthalmology department. Funding is believed to be provided by the directorate. The cervical dystonia service for MTW and EKHUFT is functioning within their neurology departments. Dartford, Gravesham and Swanley NHS Trust are interested in commissioning these services within the neurology department. MTW provides ophthalmology services for Medway, therefore Medway patients requiring BoNT are seen through the Maidstone BoNT clinics. Each provider Trust is managing these conditions in slightly different ways which makes inequity of services inevitable.

What is the evidence base for BoNT for treating CD and HFS?

Evidence for cervical dystonia: Five randomised controlled trials (RCTs) were used in the Cochrane review and results showed the mean cervical dystonia-specific improvement without BoNTA was 12.00 when assessed with Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) with a total score ranging 0-85, (higher is worse) at 4 weeks. The estimated mean difference comparing experimental intervention changed outcome on average compared with the control (MD) provided a result of 8.09 higher. The study conclusion was BoNTA likely improves cervical dystonia-specific signs and symptoms. Evidence for primary efficacy outcome as the change from baseline showed treatment with BoNTA resulted in an improvement at 4 weeks on the TWSTRS total score compared to placebo. Three RCTs with 429 participants assessed cervical dystoniaspecific pain with TWSTRS pain subscale (range 0-20, result is directly proportional to pain so higher is worse) at 4 weeks. Participants reported that treatment with BoNTA resulted in more pain relief than placebo. Adverse events were measured across eight RCTs over 4 weeks and any adverse event experienced by participants during any point during follow-up was documented. Results showed treatment with BoNTA is 1.23 times more likely to experience adverse events compared to placebo. The number needed to treat for an additional harmful outcome (NNTH) with a single BoNTA treatment was 9 (95% CI 6 to 21). In summary, just fewer than ten patients need to be treated with BoNT before one patient experiences an adverse event.

Evidence for hemifacial spasms: A systematic Cochrane review found no placebo-controlled trials for BoNTA for treating HFS. It is important to note that the effectiveness of BoNTA for the treatment of HFS is difficult to question; the strength of open-label data makes it ethically difficult to randomise participants to placebo or BoNTA, in trials designed to examine efficacy. Nonetheless, a number of observational studies of interventions enrolled a total of several thousand participants. In all these studies, BoNTA was considered highly effective, with a success rate of 76% to 100%. The mean duration of improvement ranged between 2.6 and four months.

Change sheet

Reason for review:

To develop an ICS approved policy and funding for the use of BoNT to treat CD and HFS in Kent and Medway.

Change from baseline:

Development of system wide policy.

Rationale for PR2021-22:

The PRGC noted the following:

- There is currently no NICE guidance on the use of BoNT for HFS and CD.
- The clinical benefit of BoNT for treating HFS and CD has been demonstrated in observational studies and RCTs, respectively.

- BoNT units are not interchangeable from one product to another. Doses recommended in Allergan Units may be different from other BoNT preparations:
- The initial dose for a patient without prior use of Botox® should be at a lower dose, with subsequent dosing adjusted based on individual response. Limiting the total dose injected into the sternocleidomastoid muscle to 100 Units or less may decrease the occurrence of dysphagia. The maximum dose recommended according to the FDA-label is 50 U per injection site with a total dose of 400 U for adult patients.
- BoNT products have rare but serious risks of adverse effects. The MHRA advised that all patients receiving any product containing botulinum toxin should be warned of the signs and symptoms of toxin spread, such as muscle weakness and breathing difficulties. They should be advised to seek medical attention immediately if they experience breathing difficulties, choking, or any new or worsening swallowing difficulties, as such side effects may be lifethreatening.
- There was strong, consistent support for funding BoNT for treating HFS and CD from local specialists.
- According to local specialists, BoNT should only be administered by a suitably trained specialist. It should also be noted nurse led clinic(s) are unlikely to be appropriate for cervical dystonias and may not be appropriate for hemifacial spasms due to the risks associated with the administration.
- The policy recommendation may increase CCG expenditure as the service officially adopts these recommendations across the four ICPs. However, the estimated overall cost is based on administration and drug costs only. It was not possible to estimate the potential economic impact expected as the patient population to use these service(s) was based on estimation and extrapolated to reflect the population for other ICPs. Therefore, the costs illustrated should be used with caution.

Estimated impact of implementing PR2021-22:

The cost impact of funding Botox for the treatment of hemifacial spasms and cervical dystonias is subject to a number of assumptions, not all of which can be verified and should consequently be treated with caution.

Official patient numbers for three of the Trusts were difficult to obtain. Patient numbers were provided for DGS and were estimated to be approximately an average of 5 patients a year having BoNT injections approximately every 3 months. This figure was extrapolated across the Kent and Medway populations for each ICP and provided a total ICS patient count of 35. The Botox formulation is the brand of choice across the ICS so the cost of this brand was used to calculate a total cost. All four doses of BoNT would be administered in outpatient clinics. Consequently, the total cost (drug cost and administration cost) for the ICS was estimated to be £107, 905. No definitive estimate was provided for HFS as approximate patient number was not provided.