## Kent and Medway Policy Recommendation and Guidance Committee

## Policy Recommendation

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| **Policy:** | **PR 2016-12: Botulinum toxin for chronic anal fissures** |
| **Issue date:** | **May 2016** |
| **Review date:** | **May 2019** |

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered national and professional society guidance, the baseline position (with respect to activity, costs and expenditure), other CCG policies, evidence relating to the burden of disease and the safety, clinical- and cost-effectiveness of treatment, and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account, the PRGC recommends that:

- A single treatment of botulinum toxin type A[1] should be funded for the treatment of chronic anal fissures in adults where all other appropriate non-surgical, pharmacological treatment (e.g. diltiazem, GTN) and dietary changes have been tried and optimised and despite this treatment has failed.

See overleaf for background information and supporting rationale.

This policy recommendation will be reviewed in light of new evidence or guidance from NICE.

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

### Supporting documents

South East CSU Health Care Intervention Appraisal and Guidance (HCiAG) team (2016) *Botulinum toxin injections for chronic anal fissures – Briefing note*

*Equality Analysis Screening Tool – Botulinum toxin for chronic anal fissures* (2016)

[1] Botulinum toxin is listed as a High Cost Drug Exclusion (Payment by Results Exclusion)

## Key points and rationale

**What are anal fissures?**

An anal fissure (AF) is a tear or ulcer that develops in the squamous epithelium of the anal canal located distal to the dentate line. Most cases arise in people with constipation, when a particularly hard or large stool tears the lining causing bleeding, local itching and severe pain with bowel movements. Anal fissures that present for less than six weeks are referred to as 'acute'; those that have not healed after 6 weeks are referred to as 'chronic' anal fissures (CAFs). It is thought that CAF occur as a result of the sphincter muscle becoming so tense, that the flow of blood to the lining of the anus is reduced. Subsequently, insufficient oxygen reaches the fissure, resulting in the cells in the lining of the anus being unable to grow and hence repair.

Acute anal fissures are initially treated with an increase in the intake of oral fluids, fibre, stool softeners and analgesics. For chronic anal fissures, the only licensed treatment available in adults is 0.4% glyceryl trinitrate (GTN) ointment. Other medicines for CAF are unlicensed in the UK including: 0.2% GTN ointment, botulinum toxin injections and diltiazem cream or ointment (a calcium channel blocker). Surgical interventions may be an option when other interventions have been exhausted.

**What is it like to live with CAF?**

Only one small prospective study (N=54) was identified which assessed health related quality of life (HRQoL) in people with untreated CAF. When compared to age and gender matched norm scores, people with CAF reported significantly greater bodily pain and decreased general health perception on the Short Form-36 Health Survey (SF-36) , but improved role emotional, social functioning and role physical; the reasons for this are unclear. SF-36 scores of people with CAF were higher when compared to those of people with irritable bowel syndrome (IBS), suggesting that IBS has a greater impact on HRQoL than CAF.

**What is botulinum toxin?**

Botulinum toxin (BTX) is a powerful neurotoxic agent synthesised by the anaerobic bacterium *Clostridium botulinum*. Different strains of *C. botulinum* produce seven immunologically distinct forms of botulinum neurotoxin, labelled BTX-A to BTX-G. For CAF, BTX-A is typically administered by injection into the anal sphincter muscle. It induces a relative hypertonia, reducing resting anal canal pressure. Botulinum toxin is a High Cost Drug excluded from Tariff.

**What national and professional society guidance is available on the use of BTX to treat CAF?**

There is no NICE guidance relating to the treatment of CAF with BTX. The Royal College of Surgeons published a commissioning guide for rectal bleeding in 2013 sponsored by the Association of Coloproctology of Great Britain and Ireland, which indicates that the first line option in secondary care, if the patient has previously used GTN, is topical diltiazem 2% or injection with BTX.

**How effective and safe is treatment with BTX-A compared to other CAF treatments?**

NICE Evidence Summary for Unlicensed or Off-label Medicines (ESUOM) 14 (2013) concluded that BTX-A is less effective than surgery, no better or worse than topical GTN (mostly 0.2% ointment) or isosorbide dinitrate, and no better than placebo or lidocaine at healing anal fissure. A recent meta-analysis (2012) concluded CAF patients undergoing surgery have higher healing rates and lower recurrence rates than those receiving BTX-A. However, surgery is more likely to leave patients with anal incontinence than BTX-A.

No serious adverse events or safety concerns were associated with the use of BTX-A.

No cost effectiveness studies on the use of BTX for CAF in a UK setting were identified.

**What is the baseline position in Kent and Medway?**

The Kent and Medway Health Economy National Tariff Excluded Drugs document for 2015/16 (also known as the High Cost Drug Manual [HCDM]) states that currently only Medway CCG commissions BTX for the treatment of CAF. However, Maidstone and Tunbridge Wells NHS Trust (MTW) and Dartford and Gravesham NHS Trust (DGT) offer BTX to CAF patients; it appears that the Trusts absorb the cost of the BTX but CCGs fund the related activity. BTX is not available to CAF patients attending East Kent Hospitals Universities NHS Foundation Trust.

In 2014/15, 246 Kent and Medway patients were admitted with a primary diagnosis of anal fissure; of these 79 (32%) underwent surgery, at an estimated cost of £72,000.

The estimated cost of one treatment with BTX-A given as an outpatient procedure is £634; the estimated cost of surgery for CAF is £1,124 (both estimates are inclusive of costs of first and follow up outpatient appointments).

**What is the cost impact of implementing this policy recommendation?**
Implementation of this policy will be cost neutral for Medway CCG, who already commission BTX for CAF. It is likely that West Kent CCG, Swale CCG and Dartford, Gravesham and Swanley CCG are currently funding activity relating to BTX being administered to CAF patients at MTW and DGT; the additional cost of funding the BTX for these patients is estimated to be £25,500 per year across these CCGs. East Kent CCGs do not currently fund BTX for CAF or any associated activity; the estimated annual cost impact of implementing this PR across east Kent CCGs is £93,800. The above estimates should be treated with caution as they use assumptions from a range of sources, several of which it has not been possible to verify. These estimates do not include consideration of cost savings that may be realised from avoiding surgery, which it has not been possible to estimate.

**Why is BTX-A funded for the treatment of CAF?**

- This recommendation is consistent with The Royal College of Surgeons Commissioning Guide on rectal bleeding (2013), which indicates that:
    - topical glyceryl trinitrate (GTN) 0.4% ointment should be considered for the primary care management of CAF
    - If the patient has previously used GTN, the first line options in secondary care are topical diltiazem 2% or injection with BTX-A. Surgical options for AF include fissurectomy with injection of BTX-A and laternal internal anal sphincterotomy.
- Treatment with BTX-A is likely to be effective in ~68% of CAF patients; these patients may avoid progressing to surgery, which is associated with a higher risk of faecal incontinence compared to receiving BTX-A and is a more expensive intervention

## Change sheet

**Reason for review:**
Current policies relating to patient access to BTX injections for chronic anal fissures differ across Kent and Medway; an area wide policy is required to ensure that all patients across the area are treated equitably.

**Changes made to current policy:**
The table below highlights the changes made to the existing policy on BTX for chronic anal fissure:

| Current Kent and Medway HCDM policy | New policy recommendations (PR2016-12) |
|---|---|
| BOTULINUM TOXINS A and B:<br><br>Indication(s): — Commissioned By:<br>Chronic anal fissure — Medway CCG | A single treatment of botulinum toxin type A should be funded for the treatment of chronic anal fissures in adults where all other appropriate non-surgical, pharmacological treatment (e.g. diltiazem, GTN) and dietary changes have been tried optimised and despite this treatment has failed. |

**Rationale for PR2016-12:**

- This recommendation is consistent with The Royal College of Surgeons Commissioning Guide on rectal bleeding (2013), which indicates that:
  - topical glyceryl trinitrate (GTN) 0.4% ointment should be considered for the primary care management of CAF
  - If the patient has previously used GTN, the first line options in secondary care are topical diltiazem 2% or injection with BTX-A. Surgical options for AF include fissurectomy with injection of BTX-A and laternal internal anal sphincterotomy.
- Treatment with BTX-A is likely to be effective in ~68% of CAF patients; these patients may avoid progressing to surgery, which is associated with a higher risk of faecal incontinence compared to receiving BTX-A and is a more expensive intervention

**Estimated cost impact of implementing this policy:**
Implementation of this policy will be cost neutral for Medway CCG who already commission BTX for CAF. It is likely that West Kent CCG, Swale CCG and Dartford, Gravesham and Swanley CCG are currently funding activity relating to BTX being administered to CAF patients at MTW and DGT; the additional cost of funding the BTX for these patients is estimated to be £25,500 per year across these CCGs. East Kent CCGs do not currently fund BTX for CAF or any associated activity; the estimated annual cost impact of implementing this PR across east Kent CCGs is £93,800. The above estimates should be treated with caution as they use assumptions from a range of sources, several of which it has not been possible to verify. These estimates do not include consideration of cost savings that may be realised from avoiding surgery, which it has not been possible to estimate.

| CCGs | Estimated cost impact of implementing PR2016-12 |
|---|---|
| NHS Ashford CCG | £17,200 |
| NHS Canterbury and Coastal CCG | £28,600 |
| NHS Dartford, Gravesham and Swanley CCG | £7,700 |
| NHS Medway CCG | £0 |
| NHS South Kent Coast CCG | £28,800 |
| NHS Swale CCG | £3,400 |
| NHS Thanet CCG | £19,300 |
| NHS West Kent CCG | £14,400 |
| **Total Kent and Medway** | **£119,300** |