Kent and Medway Policy Recommendation and Guidance Committee

Policy Recommendation

Policy:	**PR 2022-15: Botulinum toxin A injection for ventral hernia repair and abdominal wall reconstruction in adults**
Issue date:	**May 2022**

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered relevant guidance, the baseline position, the evidence base, other CCG policies, the views of local specialists and the potential impact of a change in policy. All decisions were made with reference to the Ethical Framework. Taking these into account, the PRGC recommends:

Botulinum toxin A administered as a pre-operative ultrasound guided injection into the lateral abdominal wall of adults (≥18 years) requiring elective complex ventral hernia repair will be funded where:

- Major abdominal surgery, separation of muscular components and mesh repair is required, **and**
- The case has been reviewed by a multidisciplinary team, **and**
- The abdominal wall defect is >10cm in diameter **or** loss of domain is >20%, **and**
- It is considered by the surgeon that botulinum toxin A is required to achieve fascial closure that would otherwise not be possible, **and**
- Botulinum toxin A is administered by a suitably trained individual and appropriate arrangements are in place for clinical governance, consent and audit.

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 its IFR process.

Supporting documents

Health Policy Support Unit (HPSU) (2022) *Botulinum toxin A injection for ventral hernia repair and abdominal wall reconstruction in adults – Scoping report*

Equality Analysis Screening Tool – Botulinum toxin A injection for ventral hernia repair and abdominal wall reconstruction in adults (2022)

Key points

What is a hernia?

A hernia occurs when an internal part of the body pushes through a weakness in the surrounding muscle or tissue wall and may present as a swelling or a lump. Individuals with hernia may also experience pain or discomfort that can limit daily activities. Hernias of the abdomen involve misplacement of the lower digestive system. They are described as ventral when they occur along the vertical midline of the abdominal wall. They can occur as a primary hernia, or incisional hernia. An incisional hernia occurs through a previously made incision, normally a scar left from a previous operation. In addition to hernia, other abdominal wall defects may occur that require surgical repair. In adults, an open abdomen (intentionally leaving the abdomen unclosed after surgery) may be necessary in the short-term to manage trauma, compartmental pressure in the abdomen or sepsis.

How is a hernia managed?

The primary aim of ventral hernia repair is enclosing the digestive organs within the abdominal cavity and complete closure of the fascia (the thin sheath of fibrous tissue enclosing the abdominal muscle). A mesh may be used to reinforce the repair in a bid to prevent recurrence.

Fascial closure may not be possible in the case of large hernias or hernias with loss of domain (in which the abdominal cavity is unable to fully accommodate the abdominal contents) without advanced techniques such as abdominal wall reconstruction, which involves redistribution of the muscles across the abdomen, commonly referred to as the component separation technique (CST). Botulinum toxin A (BTA) has been proposed as an alternative method of supporting fascial closure.

What is botulinum toxin A (BTA)?

BTA is a powerful neurotoxic agent synthesised by the anaerobic bacterium *Clostridium botulinum*. It blocks the release of nerve transmitters and pain-modulating substances to induce flaccid paralysis of muscle, with the maximum effect reached in 3 weeks and lasting up to 3-6 months after injection.

BTA is licensed for a number of neurological, bladder and skin disorders, but its use in hernia repair would be off-label. BTA was a High Cost Drug under the 2021/22 tariff. However, under the 2022/23 tariff botulinum toxin is no longer tariff-excluded. Therefore, the cost of the drug does not need to be considered separately from the procedure of hernia repair.

It is proposed that the flaccid paralysis of the lateral abdominal wall muscles imparted by BTA serves 4 purposes:

- Stretching the abdominal muscles and reducing the size of the hernia gap by reduction of herniated intestine into the abdominal cavity.
- Reducing the muscle tension after surgery, which may reduce the risk of hernia recurrence.
- Closure without excessive tension and thereby avoiding complications, such as respiratory distress.
- An extended period of effect that protects the repair line from lateral tension forces for several months.

In association with ventral hernia repair, BTA is injected 4 to 6 weeks before surgery. Ultrasound is used to guide placement of the BTA injections into abdominal muscle. There are normally 6 to 10 injections (3 to 5 each side).

What does guidance say?

There is no guidance on BTA injected into the abdominal wall by NICE, SIGN, the Royal College of Surgeons, the Royal College of Anaesthetists or the British Hernia Society.

The International Endohernia Society (IEHS) has published guidelines relevant to this topic informed by a systematic literature review of studies published up to 2017. Part A of the guidance (Bittner et al, 2019, Part A) states that in large hernia repairs, additional measures – including BTA – must be considered to facilitate defect closure. Part B of the guidance (Bittner et al, 2019, Part B) states that BTA prior to ventral hernia repair facilitates a decrease in transverse hernia diameter, a significant reduction of lateral abdominal wall muscle thickness and a significant elongation of lateral abdominal muscles. It also states that in the majority of patients with large ventral hernia, BTA administration alone enables direct fascial closure without additional component separation techniques. However, Part B of the IEHS guidance also states that due to the low quality of evidence available, no recommendations regarding the use of BTA as an adjunctive intervention in ventral hernia repair can be made.

What is the evidence base for BTA in the abdominal wall?

- A systematic literature review identified 3 prospective single-arm observational studies (total sample size of 87 patients) reporting the results of BTA on abdominal wall muscle length. All 3 studies reported an increase in muscle length after BTA administration, from 2.4 to 4.2 cm on each side. Two of these studies reported on the effect of BTA on hernia size. Both studies reported that the size of the hernia had decreased after BTA injection.
- The review also identified 3 comparative studies:
    - The first comparative study was not randomised and assessed BTA plus limited abdominal reconstruction (Rives-Stoppa repair) versus CST in large ventral hernia repair. Complete fascial closure was possible in all patients in the BTA+Rives-Stoppa group but not in 2 of the 40 patients in the CST group. There was a lower rate of surgical site infection in the BTA+Rives-Stoppa group. Due to a low level of statistical evidence, no conclusions can be made regarding the impact of BTA on fascial closure or hernia recurrence.
    - The second comparative study reported on patients who had received BTA (n=145) versus no BTA (n=75) prior to abdominal wall repair in a prospectively collected database. Patients received preoperative BTA injection if there was a clinical suspicion that fascial closure would be unlikely, even with CST. The BTA group had a higher fascial closure rate (92% versus 81%; p= 0.036; no CI) and a lower rate of surgical site infection (12% versus 26%; p= 0.019; no CI). However, the BTA group had a higher rate of CST and some differences in wound management, both of which are associated with a higher chance of fascial closure and are therefore confounding factors. Due to the confounding factors no conclusions can be made regarding the impact of BTA on hernia recurrence.
    - The third comparative study was a pilot double-blind placebo-controlled trial of small sample size (n=46) administering BTA or placebo (saline). The patients had experienced trauma and temporary closure of the abdomen. The primary endpoint of primary fascial closure was similar whether patients received BTA or placebo (a hazard ratio of 1; 95% confidence interval 0.5 to 1.8; no p-value reported).
- None of these studies reported complications secondary to BTA administration.
- No studies recruited paediatric patients. No studies of cost-effectiveness were identified. No studies compared BTA to other methods of supporting fascial closure were identified.

What is the baseline position in Kent and Medway?

- Kent and Medway CCG does not have a policy on the use of BTA in hernia repair or abdominal wall reconstruction.
- BTA is not currently being used in hernia repair or abdominal wall reconstruction at local acute trusts, with the exception of Medway NHS Foundation Trust (it is unclear whether the CCG is funding the cost of the additional activity to administer the injection).

Change sheet

Reason for review:
Currently, there is no policy in Kent and Medway regarding botulinum toxin A (BTA) in hernia repair surgery. Surgeons at Medway NHS Foundation Trust have requested the use of BTA as preparation for ventral hernia repair.

Change from baseline:

- Kent and Medway CCG does not have a policy on the use of BTA in hernia repair or abdominal wall reconstruction and BTA is not currently being used for this indication at local acute trusts, with the exception of Medway NHS Foundation Trust (it is unclear whether the CCG is funding the cost of the additional activity to administer the injection).
- According to PR2022-15, BTA is funded in adults for hernia repair/ abdominal wall reconstruction in certain specified circumstances

Rationale for PR2022-15:

- Although there is no guidance developed by NICE or UK professional societies to inform policy decision-making and limited high-quality evidence on surgical outcome such as fascial closure and hernia recurrence, most local specialists strongly support the use of BTA in ventral hernia repair/ abdominal wall reconstruction, noting that failure to provide BTA to selected patients locally may lead to poorer hernia repairs and consequent reduced quality of life as well as higher risk of recurrence.
- Some local specialists favoured restricting BTA use to abdominal wall defects >5 cm, others to abdominal wall defects >15 cm. PRGC noted that the evidence base for BTA use was greatest in defect sizes >10 cm. See the accompanying report for more information.

Estimated impact of implementing PR2022-15:
The estimated cost impact of implementing PR2022-15 is ~£153,000 per year. This estimate includes the tariff for administration under ultrasound guidance to 95 patients per year. This estimate should be treated with caution as it is based on a number of unverifiable assumptions. See the accompanying report for more information.