

BOTULINUM TOXIN TYPE A injection for achalasia, gastric motility disorder and gastroparesis

The Pan Mersey Area Prescribing Committee recommends Botulinum Toxin Type A injection by specialists for the treatment of achalasia, non-specific gastric motility disorder and functional or post-operative gastroparesis in adults.

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Botulinum toxin type A is recommended as a treatment option in patients with the conditions listed above who are:

- (1) at high risk of aspiration, AND
- (2) unfit for surgery, AND
- (3) at risk from complications from pneumatic dilatation treatment (perforated oesophagus) OR
- (4) peri / post operatively for delayed gastric emptying after oesophagectomy

Standard therapy for these conditions is either pneumatic balloon dilatation or per-oral endoscopic myotomy. A further treatment for achalasia is Heller's surgical myotomy. These treatment options are invasive with significant morbidity, adverse events and mortality in certain patient groups.

Botulinum toxin type A treatment is off label for these indications. This treatment is less invasive than surgery and is well tolerated with an immediate reduction of symptoms. It is usually painless and can be used for temporary relief in people who are not able to have other treatments.

Using an endoscope, the dose of 100 units of botulinum toxin is injected into the ring of muscle at the oesophageal junction or the pylorus, as a day case procedure. It is normally effective for a few months and, occasionally several years, but often has to be repeated when the effects diminish¹. Some patients will be able to subsequently have permanent treatment when they can tolerate it.

The European guidelines for achalasia² recommend that botulinum toxin therapy can be considered an effective and safe therapy for short-term symptom relief in oesophageal achalasia. This is a conditional recommendation with a moderate certainty of evidence. It can also be considered an effective and safe therapy for short-term symptom relief in oesophageal achalasia, and it should be reserved for patients who are unfit for more invasive treatments, or in whom a more definite treatment needs to be deferred.

The American College of Gastroenterology guidelines³ also recommend that botulinum toxin injection is reserved for those people who cannot undergo the definitive therapies.

There is also evidence to suggest intrapyloric botulinum toxin injection reduces symptomatic gastroparesis⁴.

The MHRA has warned healthcare professionals about the rare but serious risk of toxin spread when using all types of botulinum toxin.⁵

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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Effectiveness

Botulinum toxin type A blocks the transmission of overactive nerve impulses to the targeted tissue by selectively preventing the release of the transmitter acetylcholine at the nerve ending, temporarily preventing transmission. The European Guidelines for achalasia and the American College of Gastroenterology guidelines support the use of botulinum toxin type A to treat achalasia.

Safety

Botulinum toxin type A is contraindicated in:

- Hypersensitivity to the active substance or any of the excipients.
- Infection at the proposed injection site(s).

The MHRA has issued a warning regarding the rare but serious risk of toxin spread with all botulinum toxin products.⁴

Cost^{6,7}

Botulinum toxin type A drug cost per 100U vial is £129. Tariffs per treatment episode are estimated to be £542. Total cost per treatment is therefore estimated to be £671. Treatment is cost effective when compared with surgery.

It is expected that there will be 50-60 patients per year across the Cheshire & Mersey Network.

Patient factors

- Treatment is a day case procedure in the endoscopy unit.
- Patients should be warned about the signs and symptoms of toxin spread, such as muscle weakness and breathing difficulties, and advised to seek medical attention if they experience such symptoms.
- Rarely symptoms of vomiting may be exacerbated in a small proportion of patients and they will be advised accordingly

Prescribing information

Where more than one botulinum toxin type A product is available, the least costly should be used, taking into account drug acquisition cost, anticipated administration costs, and licensed indications.

A dose of botulinum toxin type A 100 Units is injected into the gastro-oesophageal junction or pylorus at four quadrants to help with the emptying of oesophageal/stomach contents distally.

Dose regimen- 100 units per treatment episode.

Implementation notes

Botulinum toxin type A should be prescribed and administered by specialists experienced in the administration of injections to the gastro-oesophageal junction or pylorus. Treatment and monitoring should be retained by the specialist.

References

1. NHS website for England: Achalasia Last reviewed December 2020 [Achalasia - NHS](#)
2. Oude Nijhuis RAB et al. [European guidelines on achalasia: United European Gastroenterology and European Society of Neurogastroenterology and Motility recommendations](#). United European Gastroenterology Journal 2020, Vol. 8(1) 13–33
3. Vaezi MF et al. ACG clinical guidelines: diagnosis and management of achalasia. Official journal of the American College of Gastroenterology| ACG. 2020 Sep 1;115(9):1393-411.
4. Bromer MQ et al. Endoscopic pyloric injection of botulinum toxin A for the treatment of refractory gastroparesis. Gastrointestinal endoscopy. 2005 Jun 1;61(7):833-9.
5. MHRA. Drug Safety Update December 2014. Accessed 30/02/21 [Botulinum toxin products: rare but serious risks](#)
6. National Tariff Payment System. Accessed 30/02/21 [2020/21 National Tariff workbook](#)
7. NHS Business Services Authority. Drug Tariff. Accessed 30/02/21 [NICE BNF](#)