South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation

Reference	**057**
Intervention:	**Botulinum toxin type A injection for the treatment of refractory gastroparesis in adults** (Botulinum toxin is a protein complex derived from the bacterium *Clostridium botulinum*)
Date of Decision	**November 2016, updated December 2020**
Date of Issue:	**December 2016 , reissued January 2021 – use expanded to cover refractory non-diabetic gastroparesis in adults**
Recommendation:	**RED – suitable for prescribing and supply by hospital only**
Further Information	· Botulinum toxin type A injection is accepted for use in SEL as a 3rd line option for the treatment of refractory gastroparesis in adults if the following criteria are met: · First line management options fail, including: optimisation of glycaemic control (for people with diabetes), fluid and electrolyte replacement, nutritional support, and review of medicines that can cause symptoms of delayed gastric emptying AND · Patients are refractory to or not suitable (due to a contraindication or intolerance) for 2nd line treatment with prokinetics (metoclopramide, domperidone and erythromycin) All of these must have been tried/considered before botulinum toxin type A injection. For people with diabetic gastroparesis, this is in line with the NICE treatment pathway for gastroparesis in type 1 diabetes and type 2 diabetes. · A local treatment pathway is available for the pharmacological management of gastroparesis. This outlines the place in therapy of botulinum toxin type A injection. · Botulinum toxin type A is administered via intrapyloric injection in this indication. A dose of 50 units per quadrant of the pylorus will be delivered, up to a total dose of 200 units. · Treatment effectiveness will be measured using the gastroparesis cardinal symptom index questionnaire and individual patient clinical status, including HbA1c. · Where the first injection is not considered effective, a further injection can be considered. If there is no response to the second injection, no further botulinum toxin type A injections will be administered to the patient. · Where treatment is considered effective, treatment with botulinum toxin type A injection may be repeated at a minimum of 4 monthly intervals. · Botulinum toxin type A injection is a tariff excluded, CCG commissioned medicine for this indication and will be classified as a B* medicine locally. · Only the most cost effective brand of botulinum toxin type A injection will be commissioned for use, taking into consideration any negotiated prices. · **Note:** At the time of writing there are no brands of botulinum toxin type A injection licensed for the treatment of diabetic gastroparesis and administration via the intrapyloric route is not licensed. Patients should be made aware of this before treatment is started.
Shared Care/ Transfer of care required:	N/A

Cost Impact for agreed patient group	· If it is estimated there may be up to 10 people with diabetic gastroparesis per Trust per year eligible for treatment with botulinum toxin. this equates to 30 people across SEL per year. · Assuming treatment is with the most cost effective brand (currently Xeomin®), the cost of treatment with 200 units every 4 months per patient per year (3 injections/ patient/year/) would be £576 (including VAT). · This would result in a total cost across SEL of approximately £17,000 per year. · For the expansion of this recommendation to include non-diabetic gastroparesis, it is estimated there will be an additional 8 patients per year for SEL across all 3 acute trusts. This will result in an additional cost of ~£4,600 across SEL (or <£250 per 100,000 population). · This does not include activity related costs from the appointments needed to administer the injections. However, there is a possibility that some of the overall spend could be offset by a reduction in admissions and a reduced need for surgery.
Usage Monitoring & Impact Assessment	**Acute Trusts:** · Monitor /audit use upon request and report back to IMOC when required to ensure use is in line with this recommendation.
	SEL CCG borough Medicines Optimisation teams: · Monitor monthly tariff excluded high cost drugs invoicing submitted by Trusts to the CSU to ensure billing of most cost effective product.
Evidence reviewed	**References (from evidence review)** 1. Type 1 diabetes in adults – full guideline, NG17, National Institute for Health and Care Excellence August 2015. 2. Camilleri M, Parkman H, Shafi A et al. Clinical Guideline: Management of Gastroparesis. American Journal of Gastroenterology 2012 108 (18) p18-37. 3. Type 2 diabetes in adults - full guideline NG28. National Institute for Health and Care Excellence December 2015. 4. Gastroelectrical stimulation for gastroparesis IPG489. National Institute for Health and Care Excellence 2014 5. Summary of Product Characteristics: Botox 100 units. Available online here <accessed on 05/02/2016> 6. Reddymasu S, Singh S, Sankula R et al. Endoscopic pyloric injection of botulinum toxin-A for the treatment of postvagotomy gastroparesis. American Journal of the Medical Sciences 2009 337 3 p161-164 7. Friedenberg F, Palit A, Parkman H et al. Botulinum Toxin A for the Treatment of Delayed Gastric Emptying. American Journal of Gastroenterology 2008 103 p416-423 8. Arts J, Holvoet L, Caenpeel P et al. Clinical trial: a randomized-controlled cross-over study of intrapyloric injection of botulinum toxin in gastroparesis. Alimentary Pharmacology and Therapeutics 2007 26 p1251-1258 9. Bai Y, Xu M, Yang X et al. A systematic review on intrapyloric botulinum toxin injection for gastroparesis. Digestion 2010 81 p27-34 10. Lacy B, Crowell M, Schettler-Duncan A. The treatment of diabetic gastroparesis with botulinum toxin injection in the pylorus. Diabetes Care 2004 27 10 p2341-2347 11. Coleski R, Anderson M, Hasler W. Factors associated with symptom response to pyloric injection of botulinum toxin in a large series of gastroparesis patients. Digestive Diseases and Sciences 2009 54 p2634-2642 12. Ukleja A, Tandon K, Shah K. Endoscopic botox injections in therapy of refractory gastroparesis. World Journal of Gastrointestinal Endoscopy 2015 7 (8) p790-798

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.
b) This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS