

**South East London Area Prescribing Committee  
Formulary recommendation**

<b>Reference</b>	<b>098</b>
<b>Intervention:</b>	<b>Aprepitant for the treatment of severe nausea and vomiting in adults with gastroparesis</b> (Aprepitant is an antiemetic agent)
<b>Date of Decision</b>	<b>January 2019</b>
<b>Date of Issue:</b>	<b>February 2019</b>
<b>Recommendation:</b>	<b>RED – suitable for prescribing and supply by hospital only</b>
<b>Further Information</b>	<ul style="list-style-type: none"> <li>• Aprepitant is accepted for use in South East London as a last line treatment option for patients with severe, refractory nausea and vomiting associated with gastroparesis (including diabetic gastroparesis).</li> <li>• The following management strategies/treatment options will have been tried or considered not suitable (due to a contraindication or intolerance) before aprepitant is considered:             <ul style="list-style-type: none"> <li>- Review of any medicines that can cause delayed gastric emptying</li> <li>- Diet and nutritional support</li> <li>- Optimising glycaemic control in people with diabetes</li> <li>- Prokinetic agents to improve gastric emptying and symptoms of gastroparesis: metoclopramide (1<sup>st</sup> line prokinetic agent), domperidone (2<sup>nd</sup> line) and erythromycin (3<sup>rd</sup> line)</li> <li>- Anti-emetic agents for nausea and vomiting symptom improvement and prevention</li> <li>- Botulinum toxin intrapyloric injection</li> </ul> </li> <li>• Prescribing and supply of aprepitant will be through the hospital. If patients demonstrate a positive response (determined on a case by case basis by the clinician) to treatment during the first month, treatment with aprepitant may be continued. Treatment should be discontinued if there is no response in the first 2 weeks.</li> <li>• In patients who respond, there will be ongoing review to ensure a continuing response to aprepitant.</li> <li>• The first month's supply will be funded by the hospital. Treatment for patients who continue after 1 month may be billed to Commissioners. A <b>B* notification form</b> will need to be completed and submitted to commissioners for each patient continuing treatment after the first month in order for the cost of the medicine to be reimbursed to the Trust.</li> <li>• This billing arrangement will be reviewed once generic versions of aprepitant are available later in 2019.</li> <li>• <b>Note:</b> at the time of writing, aprepitant is not licensed* for the treatment of gastroparesis. Informed consent to use an unlicensed preparation should be gained from the patient before treatment is started.</li> <li>• The acute trusts will report data covering 12 months to the Committee outlining:             <ul style="list-style-type: none"> <li>(i) Total number of patients treated with aprepitant over this time</li> <li>(ii) Whether use is in line with this recommendation and the rationale for any deviation.</li> <li>(iii) Patient outcomes, including:                 <ul style="list-style-type: none"> <li>- Response to treatment, including clinical outcomes (and diabetic control for people with diabetes), the number of patients stopping aprepitant therapy and the <b>reasons for discontinuation.</b></li> <li>- Baseline number of hospital admissions/year/patient due to gastroparesis pre-initiation of aprepitant and number of admissions post initiation of aprepitant.</li> <li>- Impact on inpatient stay.</li> <li>- Any safety issues identified (especially due to longer term use of aprepitant).</li> </ul> </li> </ul> </li> <li>• A pathway outlining the different steps in the management of gastroparesis is under development to support this recommendation.</li> </ul> <p style="font-size: small; margin-top: 10px;">*Aprepitant is licensed in the UK for the prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults and adolescents from the age of 12. The treatment course in this indication is for 3 days.</p>

<b>Shared Care/ Transfer of care required:</b>	N/A
<b>Cost Impact for agreed patient group</b>	<ul style="list-style-type: none"> <li>• The local acute Trusts estimate that 30 people in SEL might be suitable for treatment with aprepitant in this setting</li> <li>• If using higher 120mg daily dose for 15 days initially (i.e. 2 weeks), before switching to a maintenance dose of 80mg daily, the estimated annual cost per patient is approx. £6,000. If it is assumed that continued use would be required in 25% of patients, and 75% would resolve after an average of 3 months of treatment this would equate to an annual cost of approximately £78,000.</li> <li>• There may be savings from reduced admissions and reduced inpatient stay. These are difficult to quantify but will be included as part of the data reported back to the Committee.</li> <li>• Availability of generic versions of aprepitant will reduce the cost impact.</li> </ul>
<b>Usage Monitoring &amp; Impact Assessment</b>	<p><b>Acute Trusts:</b></p> <ul style="list-style-type: none"> <li>• Monitor and audit usage of aprepitant as agreed and report back to the Committee in 12 months (data to be collated and presented no later than <b>April 2020</b>).</li> </ul> <p><b>CCGs:</b></p> <ul style="list-style-type: none"> <li>• Monitor ePACT2 data and monthly high cost drugs invoicing submitted to the CSU.</li> <li>• Monitor exception reports from GPs if inappropriate transfer of prescribing to primary care is requested.</li> </ul>
<b>Evidence reviewed</b>	<p><b>References (from evidence evaluation)</b></p> <ol style="list-style-type: none"> <li>1. Camilleri, M. (2007). Clinical Practice. Diabetic Gastroparesis. . The New England Journal of Medicine. 356, 829-829.</li> <li>2. Camilleri, M; Parkman, H et al. (2013). Clinical Guideline: Management of Gastroparesis. The American Journal of Gastroenterology. 108, 18-37.</li> <li>3. National Institute for Health and Care Excellence. (2016). Type 1 diabetes in adults: diagnosis and management. Available: <a href="https://www.nice.org.uk/guidance/ng17/chapter/1-Recommendations#managing-complications">https://www.nice.org.uk/guidance/ng17/chapter/1-Recommendations#managing-complications</a>. Last accessed 04/06/2018</li> <li>4. Merck Sharp &amp; Dohme Limited. (2016). EMEND 80 mg Hard Capsules. Available: <a href="https://www.medicines.org.uk/emc/product/8228#PHARMACOLOGICAL_PROPS">https://www.medicines.org.uk/emc/product/8228#PHARMACOLOGICAL_PROPS</a> Last accessed 04/06/2018.</li> <li>5. Jacob, D; Busciglio, I; Burton, D et al. (2017). Effects of NK1 receptors on gastro motor functions and satiation in healthy humans: results from a controlled trial with the NK1 antagonist aprepitant. American Journal of Physiology - Gastrointestinal and Liver Physiology. 313, G505-G510.</li> <li>6. Fountoulakis, N; Dunn, J; Thomas, S; Karalliedde, J. (2017). Successful management of refractory diabetic gastroparesis with long-term aprepitant treatment. Diabetic Medicine. 34, 1483-1486.</li> <li>7. Chong, K; Dhatariya, K. (2009). A case of severe, refractory diabetic gastroparesis managed by prolonged use of aprepitant. Nature Reviews: Endocrinology. 5, 285-288.</li> <li>8. Fahler, J; Wall, G; Leman, B. (2012). Gastroparesis-associated refractory nausea treated with aprepitant. The Annals of Pharmacotherapy. 46, e38. [ABSTRACT ONLY].</li> <li>9. Pasricha, P; Yates, K; Sarosiek, I et al. (2018). Aprepitant has mixed effects of nausea and reduces other symptoms in patients with gastroparesis and related disorders. Gastroenterology 2018 154 (1), 65-76.</li> <li>10. Madsen, J; Fuglsang, S. (2008). A randomised, placebo-controlled, crossover, double-blind trial of the NK1 receptor antagonist aprepitant on gastrointestinal motor function in healthy humans. Alimentary Pharmacology and therapeutics. 27, 609-615.</li> </ol>

**NOTES:**

- a) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the [APC website](#).
- b) This Area Prescribing Committee 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.**