South East London Area Prescribing Committee
Formulary recommendation

Reference	**028**
Intervention:	**Sodium Cromoglicate capsules for gastrointestinal symptoms due to food allergy in adults and children aged 2 years and over** (Sodium cromoglicate inhibits the release from mast cells of mediators of the allergic reaction)
Date of Decision:	**March 2015, updated May 2017 to include adults**
Date of Issue:	**April 2015, June 2017 (update)**
Recommendation:	**Amber 2 - Initiation and first month's supply from specialist allergy clinic. A clinic letter should be provided to the patient's GP detailing the individual management plan if requesting the GP to continue the prescribing.**
Further Information:	• Sodium Cromoglicate (Nalcrom®) capsules are licensed for use in adults and children aged 2 years and over for the treatment of food allergy in conjunction with restriction of the causative allergens. • There are no other products specifically licensed for the treatment of gastrointestinal symptoms due to food allergy • The starting dose is 100mg 4 times a day for children aged 2-14 years and 200mg 4 times a day for adults and children aged over 14 years. If satisfactory control is not achieved, the dose may be increased after 2-3 weeks to a maximum of 40mg/kg daily and then reduced according to response (the minimum required to maintain the patient free from symptoms). • The capsules should be taken before meals. Capsules may be swallowed whole or the contents dissolved in hot water and diluted with cold water before taking • Initiation is restricted to specialist adult and paediatric allergy teams with a minimum of 1 month's initial supply from the hospital. Ongoing prescribing may be requested through the patient's GP provided there is a clinic letter detailing the individual management plan • Sodium cromoglicate inhibits the release from mast cells of mediators of the allergic reaction. In gastrointestinal allergy the release of mediators can result in gastrointestinal symptoms or may allow absorption of antigenic material leading to systemic allergic reactions. There are, however, no specific randomised controlled trials detailing the efficacy of sodium cromoglicate for the treatment of gastrointestinal symptoms in food allergy.
Shared Care/Transfer of care document required:	No but clinic letter containing individualised management plan must be sent to GP.

Cost Impact for agreed patient group	Paediatric specialists indicated there may be around 50 paediatric patients in South East London that would fit the criteria for use of sodium cromoglicate for this indication. This would equate to a potential of £43K/year for South East London for patients requiring a maintenance dose of 4 capsules per day, though potential usage may vary. In May 2017, the APC considered and approved use in adults following an abbreviated request from allergy teams. It is anticipated that there will be 10 adult patients eligible for treatment across SEL per year. Based on a maintenance of 8x100mg capsules per day, the cost per patient is ~£1,200 per year, this would equate to a cost of £12K across SEL.
Usage Monitoring & Impact Assessment	**Trusts** Audit usage as required
	CCGs Epact data monitoring and exception reporting as needed of inappropriate use to Trust via medicines/formulary teams.
Evidence reviewed	**References (extracted from evidence evaluation)** 1. Pierog et al. A childhood case of eosinophilic gastritis and protein-losing enteropathy. Clinical Pediatrics 2014, Vol. 53(3) 289–292 2. Hubain et al. Eosinophilic gastritis in children: clinicalpathological correlation, disease course and response to therapy. Am J Gastroenterol 2014; 109:1277–1285 3. Suzuki et al. Oral disodium cromoglycate and ketotifen for a patient with eosinophilic gastroenteritis, food allergy and protein-losing enteropathy. Asian Pacific J All Immu 2003;21(3) p 193-197. 4. Pérez-Millán et al. Subserosal eosinophilic gastroenteritis treated efficaciously with sodium cromoglicate. Dig. Dis. Sci. 42, 342–344(1997) 5. Dominguez-Ortega et al. Gastro intestinal food allergy assessment by a symptom questionnaire. Allergy 2013; 68 (suppl 97) 333 6. Moots et al. Near fatal eosinophilic gastroenteritis responding to oral sodium chromoglycate. Gut 29(9), 1282–1285(1988) 7. de Chambrun et al. Natural history of eosinophilic gastroenteritis. Clin. Gastroenterol. Hepatol. 9(11), 950–956.e1(2011) 8. Van Dellen et al. Oral administration of cromolyn in a patient with protein-losing enteropathy, food allergy and eosinophilic gastroenteritis. Mayo Clin Proc 1994 69 5 p441– 4 9. Di Gioacchino et al. Sodium cromoglycate in the treatment of eosinophilic gastroenteritis. Allergy 1990 Apr;45(3):161-6 10. Triantafillidis et al. Eosinophilic gastroenteritis: Current aspects on etiology, pathogenesis, diagnosis and treatment. Annals of Gastroent 2002; 15 (2) p 106 – 115 11. Xie et al. World J Gastroenterol 2005: 11 19): 2851-2857 12. Meyer et al. A review on the diagnosis and management of food induced gastrointestinal allergies. Curr Alllergy Clin Immunol 2012; 25: 10-17 13. Lucendo et al. Eosinophilic Gastroenteritis. Expert Rev Gastroenterol Hepatol. 2012;6(5):591-601 14. Oh et al. Eosinophilic gastroenteritis: a review. J Gastroenterol 2008; 43:741–750

NOTES:

a. Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.

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