

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

Reference	027
Intervention:	Ketotifen tablets (1mg) and liquid (1mg in 5ml) (Zaditen®) for the symptomatic relief of food protein induced gastrointestinal allergies that has not responded to dietary manipulation alone in children aged 3 years and over and adults (ketotifen is a first generation sedating antihistamine)
Date of Decision	March 2015, updated November 2017 to include adults
Date of Issue:	April 2015, December 2017 (update)
Recommendation:	Amber 2 - Initiation and first prescription 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	<ul style="list-style-type: none"> • Ketotifen tablets are licensed for symptomatic relief of allergy such as allergic rhinitis • Intestinal mast cells are involved in the pathogenesis of food allergy related enteropathy. Ketotifen is a sedating antihistamine but unlike other antihistamines also has mast cell stabilising effects and is the preferred antihistamine for the treatment of gastrointestinal symptoms due to food allergy • There are no antihistamines specifically licensed for the treatment of gastrointestinal symptoms due to food allerg • Initiation is restricted to allergy specialists in allergy with a minimum of 1 month's initial supply. • Ongoing prescribing may be requested through the patient's GP provided there is a clinic letter detailing the individual management plan
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	Specialists have indicated there may be around 50 patients in South East London that would fit the criteria for use of ketotifen for this indication. The cost impact would be expected to be less than £5K per annum for South East London. In 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 dose of 1mg-2mg per day, the cost per patient is between £90.36 to £181 per year, this would equate to an estimated cost for adults of upto £1,810 across SEL (assuming maximum dose).

Usage Monitoring & Impact Assessment	Trusts Provide usage data up on request to the APC and audit usage as required by the APC.
	CCGs <ul style="list-style-type: none"> • Monitor E pact data • Exception reports from GPs if inappropriate transfer of prescribing to primary care is requested
Evidence reviewed	References (extracted from evidence evaluation) <ol style="list-style-type: none"> 1. Tien et al. Clinical features and treatment responses of children with eosinophilic gastroenteritis. <i>Pediatrics and Neonatology</i> (2011) 52, 272e278 2. Suzuki et al. Oral disodium cromoglycate and ketotifen for a patient with eosinophilic gastroenteritis, food allergy and protein-losing enteropathy. <i>Asian Pacific J All Immu</i> 2003;21(3) p 193-197 3. Melamed et al. Benefit of ketotifen in patients with eosinophilic gastroenteritis. <i>Am J Med</i> 1991; 90; 310-14 4. Dominguez-Ortega et al. Gastro intestinal food allergy assessment by a symptom questionnaire. <i>Allergy</i> 2013; 68 (suppl 97) 333 5. de Chambrun et al. Natural history of eosinophilic gastroenteritis. <i>Clin. Gastroenterol. Hepatol.</i> 9(11), 950–956.e1(2011) 6. Bolukbas et al. A dramatic response to ketotifen in a case of eosinophilic gastroenteritis mimicking abdominal emergency <i>Dig Dis Sci.</i> Nov/Dec 2004; 49 (11/12): p1782–1785. 7. Katsinelos et al. <i>Am J Gastroent</i> 2002 87 (4) p 1072. 8. Triantafillidis et al. Eosinophilic gastroenteritis: Current aspects on etiology, pathogenesis, diagnosis and treatment. <i>Annals of Gastroent</i> 2002; 15 (2) p 106 – 115. 9. Meyer et al. A review on the diagnosis and management of food induced gastrointestinal allergies. <i>Curr Allergy Clin Immunol</i> 2012; 25: 10-17 10. Lucendo et al. Eosinophilic Gastroenteritis. <i>Expert Rev Gastroenterol Hepatol.</i> 2012;6(5):591-601 11. Oh et al. Eosinophilic gastroenteritis: a review. <i>J Gastroenterol</i> 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**