South East London Area Prescribing Committee
Formulary recommendation

Reference	**094**
Intervention:	**Omalizumab for the treatment of inducible urticarias (symptomatic dermographism, cholinergic, delayed pressure, cold and solar) in adults** (Omalizumab is a monoclonal antibody which works by blocking immunoglobulin E, a substance which plays a role in the development of urticarias)
Date of Decision	**November 2018**
Date of Issue:	**December 2018**
Recommendation:	**RED – Prescribing and supply by hospital only**
Further Information	• Omalizumab is accepted for use in South East London for the treatment of the following inducible urticarias in adults: - Symptomatic dermographism - Cholinergic urticaria - Delayed pressure urticaria - Cold urticaria - Solar urticaria • Treatment should be initiated in line with the criteria outlined in the South East London urticaria treatment pathway, including a Dermatology Life Quality Index (DLQI) score ≥15. • Omalizumab is administered once a month and will be started at a dose of 150mg monthly, with the option to increase to 300mg monthly if necessary. • Omalizumab should be stopped at or before the fourth dose if condition has not responded or the DLQI does not reduce below 10. • The maximum treatment course is 6 doses (6 months). Omalizumab should be stopped at the end of a course of treatment and should only be restarted if the condition relapses. • It should be noted that omalizumab is not licensed for use in inducible urticarias. Informed consent should be gained from the patient before treatment is started. • As part of the local commissioning arrangements, a B* notification form will need to be completed and submitted to commissioners for each patient treated with omalizumab in this setting. • Lead clinicians should collate and aim to publish outcome data on their experience with omalizumab in this setting to contribute to the evidence base in this area.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• The tertiary dermatology centre estimates that 10 people per annum might be suitable for treatment under their service. These numbers are not restricted to SEL. • Based on Individual Funding Request (IFR) application numbers for SEL, if it is assumed 10% (or 1 patient) is from SEL and they are treated for 6 months at a dose of 150mg monthly, this would result in a cost impact of ~£1,844 per annum. If the dose is 300mg per month, the cost impact will be ~£3,700 (inclusive of VAT and based on the list price). • If treatment is given for 9 months in any given 12 month period, the cost impact would be between ~£2,770 and £5,500 (based on a dose of 150mg-300mg monthly).

Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor use and report back to APC when required. • Audit use upon request to ensure use is in line with this recommendation and the pathway.
	CCGs: • Monitor monthly tariff excluded high cost drugs invoicing submitted by Trusts to the CSU • Monitor exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation prepared January 2018)** 1. Maurer M, Metz M, Brehler R et al. Omalizumab treatment in patients with chronic inducible urticarial: A systematic review of published evidence. Journal of Allergy and Clinical Immunology 2017 (early online) dx.doi.org/10.1016/j.jaci.2017.06.032 2. Bernstein J, Lang D, Khan D et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol 2014;133:1270-7 3. Trevisonno J, Balram B, Netchiporouk E et al. Physical urticaria: review on classification, triggers and management with special focus on prevalence including a meta-analysis. Postgrad Med 2015;127: 565-70. 4. Sanchez J, Amaya E, Acevedo A et al. Prevalence of Inducible Urticaria in Patients with Chronic Spontaneous Urticaria: Associated Risk Factors. Journal of Allergy and Clinical Immunology Practice 2017 (2) p464-470 5. Chronic Urticaria. Medscape online reference. Available online here (accessed 04/12/2017) 6. M. Magerl , S. Altrichter , E. Borzova et al. The definition, diagnostic testing, and management of chronic inducible urticarias – The EAACI/GA2 LEN/EDF/ UNEV consensus recommendations 2016 update and revision. European Journal of Allergy and Immunology 2016 71 p780-802 7. Powell R, Leech S, Til S. BSACI guideline for the management of chronic urticaria and angioedema. Clinical & Experimental Allergy 2015, 45, p547–565 8. Xolair (omalizumab) Summary of Product Characteristics. Available online here (accessed 04/12/2017) 9. Omalizumab for previously treated chronic spontaneous urticaria (technology appraisal 339) 2015. Available online here (accessed 04/12/2017) 10. Mauerer M, Schutz Z, Weller K et al. Omalizumab is effective in symptomatic dermographism – results of a randomized placebo-controlled trial. Journal of Allergy and Clinical Immunology 2017 140 3 p870 to 872. 11. Metz M, Schuetz A, Weller K et al. Omalizumab is effective in cold urticarial – results of a randomised placebo controlled trial. Journal of Allergy and Clinical Immunology 2017 140 (3) p864-866 12. Metz M, Ohanyan T, Church M et al. Omalizumab is an effective and rapidly acting therapy in diffilcut to treat chronic urticaria: a retrospective clinical analysis. J Dermatol Sci 2014 73 p57-62 13. Ghazanfar M, Thomsen C, Thomsen S. Effectiveness and safety of omalizumab in chronic spontaneous or inducible urticarial: evaluation in 154 patients. British Journal of Dermatology 2016 175 p404-406. 14. Aubin F, Audran M, Jeanmougin M et al. Omalizumab in patients with severe and refractory solar urticaria: A phase II multicentre study. Journal of the American Academy of Dermatology 2016 74 (3) p574-575.

NOTES:

a) Area Prescribing Committee recommendations 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.