South East London Area Prescribing Committee
Formulary recommendation

Reference	**082**
Intervention:	**Doxycycline 40mg modified release capsules (Efracea™) for the treatment of papulopustular facial rosacea in adults** (Doxycycline is a tetracycline based antibiotic)
Date of Decision:	**May 2018**
Date of Issue:	**May 2018**
Recommendation	**GREEN – can be prescribed within agreed criteria for use in primary or secondary care**
Further Information:	• Doxycycline 40mg (formulated as modified release [M/R] capsules, Efracea™) is approved in SEL to reduce papulopustular lesions in adult patients with facial rosacea. This is the licensed indication for the product. In line with the SEL Pustulopapular Rosacea treatment pathway, doxycycline 40mg M/R is reserved as a **2nd line antibiotic** where there is intolerance (e.g. abdominal pain, nausea) to the first line oral antibiotic choice (either oxytetracyline or doxycycline 100mg). Please refer to the Pustulopapular Rosacea treatment pathway and Recommendation 083 for further information on treatment steps prior to oral antibiotic agents. **Practical information** (refer also to SPC and patient information leaflet for further information): • Patients should be evaluated after 6 weeks and, if no effect is seen, consideration should be given to stopping treatment. • Where treatment is successful it may be continued for up to 16 weeks. In clinical trials, lesions tended to reappear at 4 weeks follow-up after discontinuation. Therefore it is recommended that patients should be assessed 4 weeks after stopping treatment. • Patients should be advised to take the capsule in the morning, on an empty stomach, preferably at least one hour prior to or two hours after their meal. • The capsule should be taken with adequate amounts of water in order to reduce the risk of oesophageal irritation and ulceration. • Doxycycline 40mg M/R should not be used in patients with ocular manifestations of rosacea (such as ocular rosacea and/or blepharitis/meibomianitis) as there are limited efficacy and safety data in this population. If these manifestations appear during the course of the treatment, doxycycline 40mg M/R should be discontinued and the patient should be referred to an ophthalmologist.
Shared Care/Transfer of care document required:	N/A
Cost Impact for agreed patient group	• It is estimated that approximately 30 patients might be suitable for treatment with doxycycline 40mg M/R in SEL. • Treatment costs £21.71 for 56 tablets (1 month supply). Assuming a treatment course of 16 weeks in all patients at the licensed dose of 40mg daily and one treatment course a year, this would result in a cost of ~£2,600 across SEL (excluding VAT). • As doxycycline 40mg M/R may be initiated in primary care, this has the potential to release savings through reduced referrals to dermatology.

Usage Monitoring & Impact Assessment	**Trusts:** • Monitor usage and report back to APC when requested. • Audit to ensure use in line with this recommendation and local pathway. **CCGs:** • Monitor primary care prescribing data. • Audit locally to ensure use in line with this recommendation and local pathway. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation):** 1. NICE Evidence summary ESNM68: Inflammatory lesions of papulopustular rosacea: ivermectin 10 mg/g cream. Published date: January 2016 2. Summary of product characteristics (SmPC) for Efracea 40mg Modified Release Hard Capsules Galderma (UK) Ltd. Accessed via www.medicines.org.uk. 3. Webster, G. (Nov 2010). An open label community based 12 week assessment of effectiveness and safety of mono therapy with doxycycline 40mg (30mg immediate release and 10mg delayed release beads). Cutis. 86 (5i), 7-15. 4. Del Rosso, J. (Nov 2010). Effectiveness and safety of doxycycline 40mg (30mg immediate release and 10mg delayed release beads) once daily as add on therapy to existing topical regimens for the treatment of papulopustular rosacea results from a community based trial. Cutis. 86 (5i), 16-25. 5. Zuuren, E & Fedorowicz. (2015). Interventions for rosacea: abridged updated Cochrane systematic review including GRADE assessments. British Journal of Dermatology. 173, 651-662.

NOTES:

a) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the APC webpages.

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.**