Guide for primary care on the off-label use of medicines in the Oral Medicine Clinics in South East London

Background

Recurrent oral ulceration, oral lichen planus, orofacial granulomatosis and immunobullous conditions are disorders seen within the specialist Oral Medicine Clinic. There is a paucity of pharmaceutical products licensed to treat these conditions. Oral Medicine has traditionally used several treatments off-label, particularly topical steroids. The following off-label regimens have been approved for use in South East London for these indications. *Please note*: In cases where continuation of treatment or repeat courses are required, the category for these medicines in SEL is Amber 2 (initiation and supply by a specialist, stabilisation for a specified time (4 weeks), then continuation in primary care under an individual management plan).

When topical steroid treatments are used, the specific formulation and hence delivery route chosen would depend on patient specific characteristics – e.g. mouthwash versions for large areas of lesions, sprays and inhalers for individual lesions. The first prescription would be issued from the clinic, and the GP might be asked to prescribe follow on or repeat courses.

Standard follow up and review in the oral medicine clinic

- In general, the treatments below are used until the oral lesions have healed and then for a further 2 days only; restarting when required for repeat attacks. This would usually be in the region of 1-2 weeks for mild or moderate lesions.
- For chronic or more severe ulceration (e.g. oral lichen planus) the required treatment course is usually 6-8 weeks.
- When a specialist follow-up is required, this will be at an appropriate interval for the severity of the condition, and will usually be between 6 weeks and 6 months following the initial appointment.
- For short courses, the full supply will be made by the clinic, and follow repeat courses may be requested through primary care.
- For longer courses, a minimum of 4 weeks will be provided by the clinic, with clear instruction to primary care with respect to course length and follow up arrangements.

Steroid mouthwashes

- Mouthwashes are useful in treating large areas of the mouth and lesions that are not accessed easily by ointments or sprays.
- Betamethasone soluble tablets are used first line. If this product is unavailable, prednisolone 5mg may be used (it is not necessary to use the soluble tablet formulation; standard tablets can be crushed and dispersed)
- Fluticasone 400 microgram nasules are the second line treatment option, if the above first line option is insufficiently effective. The mouthwash may also be mixed with 1mL nystatin solution depending on the likelihood fungal super infection.

General directions for use of mouthwashes

1. Disperse the tablet, or mix the contents of a unit dose vial with 10mL water and use as a mouth wash four times a day.
2. It should be held in mouth for 3 - 4 minutes, particularly against the sore or ulcerated areas, and then spat out.
3. Patients should be advised to avoid eating or drinking anything for 30 minutes after the mouthwash.

Approved: January 2019 **Review date:** January 2021 (or sooner if evidence base or practice changes)

South East London Area Prescribing Committee. A partnership between NHS organisations in South East London: Bexley/ Bromley/ Greenwich/ Lambeth/ Lewisham & & Southwark Clinical Commissioning Groups (CCGs) & GSTFT/KCH/SLAM/Oxleas NHS Foundation Trusts & Lewisham & Greenwich NHS Trust

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Steroid inhalers and sprays

- Metered dose inhalers (MDIs) and sprays are useful for treating anterior individual lesions e.g. on the lips, inside of the cheek or mouth.
- Beclometasone 50 or 100 micrograms MDI is the usual first line treatment choice.
- Mometasone 50 microgram nasal spray may be used as an alternative first line choice e.g. if a more targeted administration is appropriate.
- Fluticasone 50 microgram or 125 microgram MDI is the usual second line treatment choice, if a potency escalation is indicated.

General directions for use of sprays and inhalers

1. Spray one or two puffs directly on to the lesion or lesion area, three times a day.
2. Avoid eating or drinking anything 30 minutes after use.

Steroid ointments

- Ointments are useful for targeting specific lesions, or lesion areas in the anterior mouth or the tongue.
- Betametasone 0.1% (potent) and clobetasol 0.05% (very potent) ointments are the standard treatments, with the choice being dependent on the severity of the lesion(s).
- Orabase protective paste, is used as a diluent and vehicle to facilitate use in the mouth (i.e. it helps the ointment stick better to the lesion(s))
- Betametasone or clobetasol pre-mixed in orabase are available as "Pharmacy specials" for patients that are likely to struggle or are unable to follow the appropriate mixing and administration instructions at home. Where the "special" is required, prescribing will be maintained by the hospital specialist.

General directions for use of steroid ointments

1. Patients should be supplied with scripts for the steroid ointment and orabase ointment separately.
2. Patients are instructed to mix a small amount (pea sized volume) with the same volume of orabase in a small clean plastic measure using a cotton bud.
3. A small amount is to be applied to the lesion once daily.

Tacrolimus 0.03% or 0.1% ointment

- This immunosuppressant is used off-label for some oral inflammatory conditions, e.g. orofacial granulomatosis.
- Patients are advised to apply to the affected lesion once a day, at bedtime ideally.
- The usual course length is 6-8 weeks, when it will then be reviewed in clinic.

Doxycycline 100mg soluble tablets

- Often used for viral or herpetiform ulcers.
- Tablets are dissolved in 10mL water and used as a mouthwash four times a day, held in the mouth for 3 minutes before discarding.
- The standard course length is 2 weeks. For severe or recalcitrant ulceration an extended course of 6-8 weeks may be required.

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