

**South East London Integrated Medicines Optimisation Committee  
Formulary recommendation**

<b>Reference:</b>	<b>169</b>
<b>Intervention:</b>	<b>Pentoxifylline 400mg modified release (M/R) tablets for recurrent aphthous stomatitis (off-label) in adults</b> (Pentoxifylline is a peripheral vasodilator with immunomodulatory effects)
<b>Date of Decision:</b>	<b>April 2026</b>
<b>Date of Issue:</b>	<b>May 2026</b>
<b>Recommendation:</b>	<b>RED – suitable for prescribing, supply and administration by hospital only (restricted to oral medicine specialists)</b>
<b>Further Information</b>	<ul style="list-style-type: none"> <li>• Recurrent aphthous stomatitis (RAS) is a non-contagious condition causing painful, recurring mouth ulcers usually on the inner lips, cheeks, or tongue.</li> <li>• Pentoxifylline 400mg modified release (M/R) tablet is accepted for use in South East London (SEL) for the management of recurrent aphthous stomatitis (RAS) in adults.</li> <li>• Initiation and prescribing of pentoxifylline in this setting is restricted to oral medicine specialists.</li> <li>• Treatment with pentoxifylline M/R is recommended as a third-line systemic option for the management of RAS, following failure or intolerance of:             <ul style="list-style-type: none"> <li>○ topical therapies, including anaesthetics, analgesics, antimicrobial agents and corticosteroids <b>and</b></li> <li>○ at least three months of systemic colchicine</li> </ul> </li> <li>• The use of pentoxifylline 400mg M/R tablets in this setting is <b>off-label*</b>. The off-label nature should be explained to the patient/carer and informed consent gained.</li> <li>• Pentoxifylline for RAS is usually initiated at 400mg twice a day with an option to increase dosing to three times daily if clinically appropriate based on efficacy, tolerability, and individual patient factors.</li> <li>• Prior to initiation, baseline blood pressure and blood monitoring will be carried out by the oral medicine specialists.</li> <li>• Blood pressure and blood monitoring should be repeated 3 months after initiation and at each follow up appointment with the specialist oral medicine team. See the <a href="#">Summary of Product Characteristic</a> (SmPC) for further details.</li> <li>• Patients should be reviewed by the specialist oral medicine team within 3 months of starting pentoxifylline to assess efficacy, adherence, and adverse effects, then every 3 to 6 months once treatment is established.</li> <li>• Treatment with pentoxifylline should be stopped if there is no significant reduction in frequency, duration, or severity of ulcer episodes after a reasonable trial period (typically 12 weeks).</li> </ul> <p><i>*Pentoxifylline 400mg modified release tablets is licensed for peripheral vascular disease.</i></p>
<b>Shared Care/ Transfer of care required:</b>	N/A
<b>Cost Impact for agreed patient group</b>	<ul style="list-style-type: none"> <li>• It is estimated that approximately 22 patients per annum in SEL may be eligible for treatment with pentoxifylline M/R tablets for the management of RAS.</li> <li>• Assuming all patients are titrated to the maximum dose of 400mg three times a day, the estimated cost impact for SEL is ~ £5,119 per annum (~£244 per 100,000 population).</li> </ul>
<b>Usage Monitoring &amp; Impact Assessment</b>	<p><b>Acute Trusts:</b></p> <ul style="list-style-type: none"> <li>• Monitor and audit usage as agreed and report back to the Committee (against this recommendation) upon request of the Committee</li> </ul> <p><b>SEL Borough Medicines Teams:</b></p> <ul style="list-style-type: none"> <li>• Monitor exception reports from GPs if inappropriate prescribing requests are made to primary care</li> </ul>

Evidence reviewed	References (from evidence review)
	<ol style="list-style-type: none"> <li>1. Recurrent aphthous stomatitis. BMJ Best Practice [online] available <a href="#">here</a>: [Last accessed 07/06/2025]</li> <li>2. Recurrent aphthous stomatitis. University Dental Hospital of Manchester Oral Medicine [online] available at: <a href="https://mft.nhs.uk/app/uploads/sites/3/2018/09/UDH-182.pdf">https://mft.nhs.uk/app/uploads/sites/3/2018/09/UDH-182.pdf</a> [Last accessed 07/06/2025]</li> <li>3. South East London Joint Medicines Formulary. [online] Available <a href="#">here</a> [Last accessed 07/06/2025]</li> <li>4. Aphthous ulcer. National Institute for Health and Care Excellence [online] available <a href="#">here</a> [Last accessed 07/06/2025]</li> <li>5. Colchicine. Summary of Product Characteristics [online] available at <a href="#">here</a> [Last accessed 07/06/2025]</li> <li>6. Thalidomide. Summary of Product Characteristics [online] available <a href="#">here</a> [Last accessed 07/06/2025]</li> <li>7. Pentoxifylline. Summary of Product Characteristics [online] available <a href="#">here</a> [Last accessed 07/06/2025]</li> <li>8. Pentoxifylline. British National Formulary [online] available at <a href="#">here</a> [Last accessed 07/06/2025]</li> <li>9. Thornhill et al. (2007). A Randomized, Double-blind, Placebo-Controlled Trial of Pentoxifylline for the Treatment of Recurrent Aphthous Stomatitis. Archives of Dermatology, 143(4). Doi: <a href="https://doi.org/10.1001/archderm.143.4.463">https://doi.org/10.1001/archderm.143.4.463</a>. [Last accessed 07/06/2025]</li> <li>10. Generali, J. and Cada, D.J. (2007). Pentoxifylline: Aphthous Stomatitis. Hospital Pharmacy, 42(12), pp.1117–1121. Doi: <a href="https://doi.org/10.1310/hpj4212-1117">https://doi.org/10.1310/hpj4212-1117</a>. [Last accessed 07/06/2025]</li> <li>11. Mimura et al (2009). Systemic treatment in severe cases of recurrent aphthous stomatitis: an open trial. Clinics, 64(3), pp.193–198. Doi: <a href="https://doi.org/10.1590/s1807_59322009000300008">https://doi.org/10.1590/s1807_59322009000300008</a>. [Last accessed 07/06/2025]</li> <li>12. Chandrasekhar et al (1999). Oxyptentifylline in the management of recurrent aphthous oral ulcers: an open clinical trial. Oral surgery, oral medicine, oral pathology, oral radiology, and endodontics, [online] 87(5), pp.564–7. Doi: <a href="https://doi.org/10.1016/s1079-2104(99)70134-4">https://doi.org/10.1016/s1079-2104(99)70134-4</a>. [Last accessed 07/06/2025]</li> <li>13. Pizarro et al. (1997). Pentoxifylline in recurrent aphthous stomatitis. Journal of the American Academy of Dermatology, [online] 36(2), pp.284–284. Doi: <a href="https://doi.org/10.1016/s0190_9622(97)70313-x">https://doi.org/10.1016/s0190_9622(97)70313-x</a>. [Last accessed 07/06/2025]</li> <li>14. Pizarro et al (1995). Treatment of recurrent aphthous stomatitis with pentoxifylline. British Journal of Dermatology, 133(4), pp.659–660. Doi: <a href="https://doi.org/10.1111/j.1365_2133.1995.tb02728">https://doi.org/10.1111/j.1365_2133.1995.tb02728</a> [Last accessed 07/06/2025]</li> <li>15. Wahba-Yahav et al. (1995). Severe idiopathic recurrent aphthous stomatitis: treatment with pentoxifylline. Acta dermato-venereologica, [online] 75(2), p.157. Doi: <a href="https://doi.org/10.2340/0001555575157">https://doi.org/10.2340/0001555575157</a>. [Last accessed 07/06/2025]</li> <li>16. Slayter KL, Marrie TJ. Treatment of recurrent aphthous ulcers in an HIV patient - An emerging use for pentoxifylline. Can J Infect Dis. 1998;9(3):189-190. doi:10.1155/1998/569317 [Last accessed 07/06/2025]</li> <li>17. National Health Service England and Wales Electronic Drug Tariff. [online] Available <a href="#">here</a> [Last accessed: 20 March 2026]</li> </ol>

**NOTES:**

- a) SEL IMOC recommendations and minutes are available publicly via the [website](#).
- b) This SEL IMOC 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**