

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

Reference	012
Intervention:	Diltiazem 2% cream for post-operative anal spasm in high-risk patients following clinical examination (unlicensed special product) The calcium channel blocker diltiazem is a vasodilator. It is available in an unlicensed cream formulation that has been used topically for treating anal fissure. It increases blood flow to smooth muscle and relaxes muscle tone.
Date of Decision	July 2014, updated in February 2025 following a change to the formulary arrangements for use of diltiazem 2% cream in anal fissures (see formulary recommendation 156)
Date of Issue:	September 2014. Re-issued March 2025
Recommendation:	Red – suitable for prescribing and supply by hospital only (see below)
Further Information	<ul style="list-style-type: none"> • Diltiazem 2% cream is supported for prescribing by hospitals in South East London for post operative anal spasm in high risk patients following clinical examination. • Diltiazem 2% cream is an unlicensed special product. Informed consent should be gained from the patient before treatment is started. • The full supply will be provided by the hospital. • March 2025: This formulary recommendation has been updated following a request to the Committee in February 2025 to recategorise diltiazem 2% cream from red (hospital only) to Amber 1 for use in anal fissure. A separate Formulary Recommendation (No.156) is now available for use of diltiazem 2% cream in anal fissure. The use of diltiazem cream in post-operative anal spasm in high risk patients following clinical examination remains under a red category under this formulary recommendation (No. 012).
Shared Care/Transfer of care document required:	N/A
Cost Impact for agreed patient group	It is estimated that this recommendation will be cost neutral and could result in a small saving to ICBs through a reduction in repeat prescribing.
Usage Monitoring & Impact Assessment	<p>Acute Trusts:</p> <ul style="list-style-type: none"> • Monitor use and submit usage data and audit reports upon request to the Committee <p>SEL Borough Medicines Teams:</p> <ul style="list-style-type: none"> • Monitor ePACT2 data • Exception reports from GPs if inappropriate prescribing requests are made to primary care
Evidence reviewed	<p>The evidence evaluation considered the following data:</p> <ol style="list-style-type: none"> 1. Anon (2013) Non-surgical treatments for anal fissure in adults. Drug and Therapeutics Bulletin; 51(9): 102-4 2. Nelson RL, Thomas K, Morgan J, Jones A. Non surgical therapy for anal fissure. Cochrane Database of Systematic Reviews 2012, Issue 2. Available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003431.pub3/tables#CD003431-sec2-0010 3. Sajid MS; Whitehouse PA; sains P; Baig MK (2012) Systematic review of the use of topical

	<p>diltiazem compared with glyceryltrinitrate for the nonoperative management of chronic anal fissure. <i>Colorectal Disease</i>; 15:19-26</p> <p>4. Ala S; Saeedi M; Hadianamrei R; Ghorbanian A (2012) Topical diltiazem vs. topical glyceril trinitrate in the treatment of chronic anal fissure: a prospective, randomized, double-blind trial. <i>Acta Gastroenterol Belg</i>;75(4):438-42</p> <p>5. Arthur JD, Makin CA, El-Sayed TY, Walsh CJ. A pilot comparative study of fissurectomy/diltiazem and fissurectomy/botulinum toxin in the treatment of chronic anal fissure. <i>Tech Coloproctol</i> 2008; 12: 331-6</p> <p>6. Samim M, Twigt B, Stoker L, Pronk A. Topical diltiazem cream versus botulinum toxin a for the treatment of chronic anal fissure: A double-blind randomized clinical trial. <i>Ann Surg</i> 2012; 255: 18-22</p> <p>7. BioSpace (14/5/2012): Ventrus Biosciences, Inc. Unveils Positive Results of Its Phase 3 Trial of Diltiazem http://www.biospace.com/News/ventrus-biosciences-inc-unveils-positiveresults/260088/source=TopBreaking</p> <p>8. Cevik M, Boleken ME, Koruk I, et al. A prospective, randomized, double-blind study comparing the efficacy of diltiazem, glyceryl trinitrate, and lidocaine for the treatment of anal fissure in children. <i>Pediatric Surg Int</i> 2012; 28: 411-6</p> <p>9. Jonas M, Speake W, Scholefield JH. Diltiazem heals glyceryl trinitrate-resistant chronic anal fissures: a prospective study. <i>Dis Colon Rectum</i> 2002;45:1091-5</p> <p>10. Griffin N; Acheson AG; Jonas M; Scholefield JH (2002) The role of topical diltiazem in the treatment of chronic anal fissures that have failed glyceryl trinitrate therapy. <i>Colorectal Disease</i>; 4: 430-435</p> <p>11. DasGupta R; Franklin I, Pitt J, Dawson PM (2002) Successful treatment of chronic anal fissure with diltiazem gel. <i>Colorectal Disease</i>; 4:20-22</p> <p>12. Nash GF; Kapoor K; Saeb-Parsy K; Kunanadam T; Dawson PM (2006) The long-term results of diltiazem treatment for anal fissure. <i>Int J Clin Pract</i>; 60(11):1411-1413</p> <p>13. NICE advice [ESUOM3] Chronic anal fissure: 2% topical diltiazem hydrochloride (January 2013) http://www.nice.org.uk/advice/ESUOM3</p> <p>14. Rectogesic 4mg/g rectal ointment SPC (last revised 02/2012)</p> <p>15. Clinical Knowledge Summaries: Anal fissure (last updated November 2012). Accessed online at http://cks.nice.org.uk/anal-fissure</p> <p>16. Cross KLR; Massey EJD; Fowler AL; Monson JRT (2008) The management of anal fissure: ACPGBI position statement. <i>Colorectal Disease</i>; 10(Supp 3):1-7</p> <p>17. The Royal College of Surgeons - Commissioning guide for rectal bleeding (October 2013) http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/rectal-bleeding</p> <p>18. NICE advice (ESUOM7): Chronic anal fissure: 0.2% topical glyceryl trinitrate ointment (March 2013) http://www.nice.org.uk/advice/ESUOM7/</p>
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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**