

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

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| Reference | 156 |
| Intervention: | Diltiazem 2% cream for anal fissure (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 recategorisation from Red to Amber 1 in anal fissure |
| Date of Issue: | September 2014. Re-issued March 2025 |
| Recommendation: | Amber 1 – initiation in primary care on the recommendation of the specialist team |
| Further Information | <ul style="list-style-type: none"> Diltiazem 2% cream is accepted for use in SEL as a 2nd line option for the treatment of anal fissure in adults under the following criteria: <ul style="list-style-type: none"> Rectal 0.4% glyceryl trinitrate (GTN) ointment remains the first line treatment option. Patients may be considered for diltiazem 2% cream if there is no improvement of symptoms following a 6 – 8 week treatment course with rectal 0.4% GTN ointment or where intolerable side effects prevent the rectal 0.4% GTN ointment course to be completed (e.g. headaches) Treatment initiation and review will follow the primary and secondary care general surgery guidelines developed by the SEL Acute Provider Collaborative (APC). In line with the SEL APC primary and secondary care general surgery guidelines the treatment duration course with diltiazem 2% cream for the management of anal fissure is 2 weeks Stopping criteria: Non-healing fissure after 2 weeks of treatment, or intolerable adverse effects One tube of diltiazem 2% cream should be prescribed to fulfil the two week treatment course Diltiazem 2% cream is an unlicensed product. Informed consent should be gained from the patient before treatment is started. <p>March 2025: The original formulary recommendation has been re-issued 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. The use of diltiazem cream in post-operative anal spasm in high risk patients following clinical examination remains under a red category and further information can be found in Formulary Recommendation 012.</p> |
| Shared Care/ Transfer of care required: | N/A |
| Cost Impact for agreed patient group | <ul style="list-style-type: none"> The abridged formulary request to the supporting the re-categorisation of diltiazem 2% cream from Red to Amber 1 estimated 450 patients per annum may be initiated on diltiazem 2% cream in primary care for the management of anal fissure. The overall medicines cost impact is expected to be negligible. Based on the supply of one tube of diltiazem 2% cream for a treatment course, this equates to ~ £6,070 (~£300 per 100,000 population) per year. Savings are also expected from reduced referrals to secondary care for the prescribing and supply of diltiazem 2% cream. |
| 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 |

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| <p>Evidence reviewed</p> | <p>References (from evidence evaluation)</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. 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 diltiazem compared with glyceryltrinitrate for the nonoperative management of chronic anal fissure. Colorectal Disease; 15:19-26 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. Acta Gastroenterol Belg;75(4):438-42 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. Tech Coloproctol 2008; 12: 331-6 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. Ann Surg 2012; 255: 18-22 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 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. Pediatric Surg Int 2012; 28: 411-6 9. Jonas M, Speake W, Scholefield JH. Diltiazem heals glyceryl trinitrate-resistant chronic anal fissures: a prospective study. Dis Colon Rectum 2002;45:1091-5 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. Colorectal Disease; 4: 430-435 11. DasGupta R; Franklin I, Pitt J, Dawson PM (2002) Successful treatment of chronic anal fissure with diltiazem gel. Colorectal Disease; 4:20-22 12. Nash GF; Kapoor K; Saeb-Parsy K; Kunanadam T; Dawson PM (2006) The long-term results of diltiazem treatment for anal fissure. Int J Clin Pract; 60(11):1411-1413 13. NICE advice [ESUOM3] Chronic anal fissure: 2% topical diltiazem hydrochloride (January 2013) http://www.nice.org.uk/advice/ESUOM3 14. Rectogesic 4mg/g rectal ointment SPC (last revised 02/2012) 15. Clinical Knowledge Summaries: Anal fissure (last updated November 2012). Accessed online at http://cks.nice.org.uk/anal-fissure 16. Cross KLR; Massey EJD; Fowler AL; Monson JRT (2008) The management of anal fissure: ACPGBI position statement. Colorectal Disease; 10(Supp 3):1-7 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 18. NICE advice (ESUOM7): Chronic anal fissure: 0.2% topical glyceryl trinitrate ointment (March 2013) http://www.nice.org.uk/advice/ESUOM7/ |
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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**