

**South East London Area Prescribing Committee  
Formulary recommendation**

<b>Reference</b>	<b>012</b>
<b>Intervention:</b>	<p><b>Diltiazem 2% cream for anal fissure and and post-operative anal spasm in high risk patients following clinical examination (unlicensed special product)</b></p> <p>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.</p>
<b>Date of Decision</b>	<b>July 2014</b>
<b>Date of Issue:</b>	<b>September 2014</b>
<b>Recommendation:</b>	<b>Red – suitable for prescribing and supply by hospital only (see below)</b>
<b>Further Information</b>	<ul style="list-style-type: none"> <li>• Diltiazem 2% cream is supported for prescribing by hospitals in South East London for:             <ul style="list-style-type: none"> <li>(i) Treatment of anal fissure that has either not responded to 8 weeks of GTN ointment that has been prescribed by the patient’s GP or where intolerable side effects prevent the topical GTN course to be completed (e.g. headaches).</li> <li>(ii) First line treatment of anal fissure diagnosed by the hospital, where the patient has been referred to secondary care for management</li> <li>(iii) Post operative anal spasm in high risk patients following clinical examination</li> </ul> </li> <li>• <b>Stopping criteria:</b> Non-healing fissure after 6 weeks of treatment, or intolerable adverse effects.</li> <li>• The full supply will be provided by the hospital and any funding arrangements required should be agreed with lead commissioning CCGs.</li> </ul>
<b>Shared Care/Transfer of care document required:</b>	N/A
<b>Cost Impact for agreed patient group</b>	It is estimated that this recommendation will be cost neutral and could result in a small saving to CCGs through a reduction in repeat prescribing.
<b>Usage Monitoring &amp; Impact Assessment</b>	Trusts – audit usage as required
	CCGs – monitor impact data

<b>Evidence reviewed</b>	<p><b>The evidence evaluation considered the following data:</b></p> <ol style="list-style-type: none"> <li>1. Anon (2013) Non-surgical treatments for anal fissure in adults. Drug and Therapeutics Bulletin; 51(9): 102-4 2.</li> <li>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: <a href="http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003431.pub3/tables#CD003431-sec2-0010">http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003431.pub3/tables#CD003431-sec2-0010</a></li> <li>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</li> <li>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</li> <li>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</li> <li>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</li> <li>7. BioSpace (14/5/2012): Ventrus Biosciences, Inc. Unveils Positive Results of Its Phase 3 Trial of Diltiazem <a href="http://www.biospace.com/News/ventrus-biosciences-inc-unveils-positiveresults/260088/source=TopBreaking">http://www.biospace.com/News/ventrus-biosciences-inc-unveils-positiveresults/260088/source=TopBreaking</a></li> <li>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</li> <li>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</li> <li>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</li> <li>11. DasGupta R; Franklin I, Pitt J, Dawson PM (2002) Successful treatment of chronic anal fissure with diltiazem gel. Colorectal Disease; 4:20-22</li> <li>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</li> <li>13. NICE advice [ESUOM3] Chronic anal fissure: 2% topical diltiazem hydrochloride (January 2013) <a href="http://www.nice.org.uk/advice/ESUOM3">http://www.nice.org.uk/advice/ESUOM3</a></li> <li>14. Rectogesic 4mg/g rectal ointment SPC (last revised 02/2012)</li> <li>15. Clinical Knowledge Summaries: Anal fissure (last updated November 2012). Accessed online at <a href="http://cks.nice.org.uk/anal-fissure">http://cks.nice.org.uk/anal-fissure</a></li> <li>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</li> <li>17. The Royal College of Surgeons - Commissioning guide for rectal bleeding (October 2013) <a href="http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/rectal-bleeding">http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/rectal-bleeding</a></li> <li>18. NICE advice (ESUOM7): Chronic anal fissure: 0.2% topical glyceryl trinitrate ointment (March 2013) <a href="http://www.nice.org.uk/advice/ESUOM7/">http://www.nice.org.uk/advice/ESUOM7/</a></li> </ol>
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**NOTES:**

- a) Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.
- 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