



## Berkshire West Area Prescribing Committee Policy Statement

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| <b>Drug Name</b>  | Tadalafil (Cialis®)                             |
| <b>Indication under review</b>  | Treatment of benign prostatic hyperplasia (BPH) |
| <b>Policy No:</b>   | APC 081   |
| <b>Date of Issue:</b>   | July 2014                                       |
| <b>Review Date:</b>   | July 2017                                       |
| <b>Policy Statement:</b><br>Tadalafil (Cialis®) is not recommended for routine use within Berkshire West for the treatment of benign prostatic hyperplasia (BPH)  |   |
| <b>Traffic Light Status</b>   | <b>Brown</b>                                    |
| <b>Key Points considered:</b> <ul style="list-style-type: none"> <li>• There is no evidence of significant benefit over other agents used to treat BPH</li> <li>• The cost of tadalafil is significantly higher than other established medicines used to treat BPH.</li> <li>• This policy has been produced as a guide for GPs. Evidence and information was carefully considered and consulted upon by clinicians who concluded that this treatment is not a cost effective use of scarce NHS resources. There are situations where this policy may not apply to an individual patient due to their clinical exceptionality. This policy statement does not overrule an individual GPs clinical decision making and therefore each GP would be need to make the final decision on whether treatment is a cost-effective use of their CCG budget.</li> </ul>   |   |
| <b>References:</b><br>British national formulary (February 2013) [online; accessed 20 March 2013]<br>Donatucci CF, Brock GB, Goldfischer ER et al. (2011) Tadalafil administered once daily for lower urinary tract symptoms secondary to benign prostatic hyperplasia: a 1-year, open-label extension study. <i>British Journal of Urology International</i> 107: 1110–6<br>Egerdte RB, Auerbach S, Roehrborn CG et al. (2012) Tadalafil 2.5 or 5 mg administered once daily for 12 weeks in men with both erectile dysfunction and signs and symptoms of benign prostatic hyperplasia: results of a randomized, placebo-controlled, double-blind study. <i>The Journal of Sexual Medicine</i> 9: 271–81<br>Eli Lilly and Company Ltd (2012) Cialis summary of product characteristics [online; accessed 5 March 2013]<br>Gacci M, Corona G, Salvi M et al. (2012) A systematic review and meta-analysis on the use of phosphodiesterase 5 inhibitors alone or in combination with alpha blockers for lower urinary tract symptoms due to benign prostatic hyperplasia. <i>European Urology</i> 61: 994–1003<br>HM Government (2004) NHS (General medical services contracts) (prescription of drugs etc.) regulations 2004 [online; accessed 5 March 2013]<br>National Institute for Health and Clinical Excellence (2010) Lower urinary tract symptoms: the management of lower urinary tract symptoms in men. NICE clinical guideline 97<br>National Clinical Guideline Centre (2010) Lower urinary tract symptoms: the management of lower urinary tract symptoms in men. NICE clinical guideline 97. London (UK): National Clinical Guideline Centre at The Royal College of Physicians<br>National Institute for Health and Clinical Excellence. Lower urinary tract symptoms in men. NICE Pathway [online; accessed 5 March 2013]<br>National Institute for Health and Clinical Excellence (2013) Tadalafil for the treatment of symptoms associated with benign prostatic hyperplasia (terminated appraisal). NICE technology appraisal 273<br>Oelke M, Giuliano F, Mirone V et al. (2012) Monotherapy with tadalafil or tamsulosin similarly improved lower urinary tract symptoms suggestive of benign prostatic hyperplasia in an international, randomised, parallel, placebo-controlled clinical trial. <i>European Urology</i> 61: 917–25<br>Porst H, Kim ED, Casabe AR et al. (2011) Efficacy and safety of tadalafil once daily in the treatment of men with lower urinary tract symptoms suggestive of benign prostatic hyperplasia: results of an international randomized, double-blind, placebo-controlled trial. <i>European Urology</i> 60: 1105–13<br>Roehrborn CG, McVary KT, Elion-Mboussa A et al. (2008) Tadalafil administered once daily for lower urinary tract symptoms secondary to benign prostatic hyperplasia: a dose finding study. <i>The Journal of Urology</i> 180: 1228–34 |   |
| <b>Date taken to APC:</b>   | 2 <sup>nd</sup> July 2014                       |
| <b>Date Ratified by MMC on Behalf of the Board:</b>   | 10 <sup>th</sup> July 2014                      |