

## Berkshire West Area Prescribing Committee Policy Statement

<b>Drug Name</b>	Pentosan
<b>Indication under review</b>	Interstitial cystitis (IC)
<b>Policy No:</b>	APC 112
<b>Date of Issue:</b>	July 2015
<b>Review Date:</b>	July 2018
<b>Policy Statement:</b> Pentosan is not recommended for routine use in the treatment of interstitial cystitis	
<b>Traffic Light Status</b>	<b>Brown</b>
<b>Key Points considered:</b>	
<ul style="list-style-type: none"> <li>• A double-blind RCT (n=369) in adults with IC found no statistically significant difference between pentosan and placebo using the Interstitial Cystitis Symptom Index (ICSI), (covering pain, urinary urgency, frequency and nocturia). The study was underpowered, randomising only 369 of the required 645 participants.</li> <li>• A meta-analysis (4 RCTs, n=448) comparing pentosan with placebo in adults found pentosan statistically significantly improved symptoms of pain, urinary urgency and frequency compared with placebo but not for improvements in nocturia. Results from the individual RCTs were inconsistent with some finding no statistically significant difference between pentosan and placebo for these outcomes. The trials used a number of different outcome measures and did not use validated tools to measure responses. Some trials used multiple methods to assess single symptoms.</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>	
<p>Papp K, Reich K, Leonardi C, et al. Apremilast, an oral phosphodiesterase 4 inhibitor, in patients with moderate to severe psoriasis: Results from the randomized treatment withdrawal phase of a phase 3, randomized, controlled trial (ESTEEM 1) [poster]. <i>Poster presented at: 72nd Annual Meeting of the American Academy of Dermatology (AAD) 2014; March 21-25; Denver, CO, USA.</i></p> <p>Papp K, Reich K, Leonardi C, et al. Apremilast, an Oral Phosphodiesterase 4 Inhibitor, in Nail and Scalp Psoriasis: 52-Week Results From the ESTEEM 1 Study [poster]. <i>Poster presented at: 22nd Annual Meeting of the European Academy of Dermatology and Venereology (EADV) 2013; October 2-6; Istanbul, Turkey.</i></p> <p>Paul C, Cather J, Gooderham M, et al. Apremilast, an oral phosphodiesterase 4 inhibitor, in patients with moderate to severe psoriasis: 16-week results of a phase 3, randomized, controlled trial (ESTEEM 2) [poster]. <i>Poster presented at: 72nd Annual Meeting of the American Academy of Dermatology (AAD) 2014; March 21-25; Denver, CO, USA.</i></p> <p>Reich K, Papp K, Leonardi C, et al. Effects of Apremilast on Health-Related Quality of Life in Patients With Moderate to Severe Plaque Psoriasis: Results From the ESTEEM 1 Study [poster]. <i>Poster presented at: 22nd Annual Meeting of the European Academy of Dermatology and Venereology (EADV) 2013a; October 2-6; Istanbul, Turkey</i></p> <p>Cutolo M, Mease PJ, Gladman D, et al. Apremilast, an Oral Phosphodiesterase 4 Inhibitor, Is Associated With Long-Term (52-Week) Improvement In Tender and Swollen Joint Counts In Patients With Psoriatic Arthritis: Results From Three Phase 3, Randomized, Controlled Trials [poster]. <i>Poster presented at: 77th Annual Scientific Meeting of the American College of Rheumatology (ACR) and the 48th Annual Meeting of the Association of Rheumatology Health Professionals (ARHP) 2013a; October 25-30; San Diego, CA, USA.</i></p> <p>Cutolo M, Myerson GE, Fleischmann RM, et al. Long-Term (52-Week) Results of a Phase 3, Randomized, Controlled Trial of Apremilast, an Oral Phosphodiesterase 4 Inhibitor, in Patients with Psoriatic Arthritis (PALACE 2) [oral]. <i>Oral presented at: 77th Annual Scientific Meeting of the American College of Rheumatology (ACR) and the 48th Annual Meeting of the Association of Rheumatology Health Professionals (ARHP) 2013b; October 25-30; San Diego, CA, USA.</i></p> <p>Edwards CJ, Birbara C, Blanco FJ, et al. Apremilast, an oral phosphodiesterase 4 inhibitor, in patients with psoriatic arthritis including current skin involvement: Results of a Phase 3, randomized, controlled trial (PALACE 3) [oral]. <i>Oral presented at: 14th Annual European League Against Rheumatism (EULAR) 2013a; June 12-15; Madrid, Spain.</i></p> <p>Gladman D, Mease PJ, Kavanaugh A, et al. Apremilast, an Oral Phosphodiesterase 4 Inhibitor, is Associated with Long-Term (52-Week) Improvements in Enthesitis and Dactylitis in Patients with Psoriatic Arthritis: Pooled Results From Three Phase 3, Randomized, Controlled Trials [oral]. <i>Oral presented at: 77th Annual Scientific Meeting of the American College of Rheumatology (ACR) and the 48th Annual Meeting of the Association of Rheumatology Health Professionals (ARHP) 2013; October 25-30; San Diego, CA, USA.</i></p> <p>Kavanaugh A, Mease PJ, Gomez-Reino JJ, et al. <b>Longterm (52-week) Results of a Phase III Randomized, Controlled Trial of Apremilast in Patients with Psoriatic Arthritis.</b> <i>J Rheumatol.</i> 2015 Mar;42(3):479-88. doi: 10.3899/jrheum.140647. Epub 2015 Jan 15. (Original) PMID: 25593233</p>	
<b>Date taken to APC:</b>	1 <sup>st</sup> July 2015
<b>Date Ratified by MMC on Behalf of the Board:</b>	19 <sup>th</sup> August 2015

Berkshire West Area Prescribing Policies serve as a guide to clinicians. This does not overrule the clinical or budgetary responsibility of clinicians when considering treatment for individual patients.

Brown	Green	Amber	Red
These drugs have been reviewed and are not considered a cost effective use of scarce NHS resources	Medicines suitable for routine use. Primary care prescribers take full responsibility for prescribing	Medicines that should be initiated by a specialist and can be continued in primary care under a shared care agreement.	Medicines which should be prescribed by specialists only