

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

<b>Reference</b>	<b>095</b>
<b>Intervention:</b>	<b>Imiquimod 3.75% cream (Zyclara™) for the treatment of actinic keratosis (AK)</b> (Imiquimod is an Immune Response Modifier, it stimulates the body's immune system)
<b>Date of Decision</b>	<b>December 2018</b>
<b>Date of Issue:</b>	<b>January 2019</b>
<b>Recommendation:</b>	<b>Grey – not recommended for prescribing in South East London</b>
<b>Further Information</b>	<ul style="list-style-type: none"> <li>• Imiquimod 3.75% cream (Zyclara™) is not recommended for prescribing in South East London.</li> <li>• Two identically designed vehicle controlled studies were reviewed as part of the formulary submission.</li> <li>• The Committee acknowledged that whilst there is some evidence for the efficacy of this treatment (vs. placebo), robust comparative head to head data (vs. existing treatments, including imiquimod 5% cream) are lacking.</li> <li>• Additionally, comparative data supporting long term safety are lacking.</li> </ul> <p>* Zyclara is licensed for the topical treatment of clinically typical, non-hyperkeratotic, non-hypertrophic, visible or palpable actinic keratosis of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate</p>
<b>Shared Care/Transfer of care document required:</b>	N/A
<b>Cost Impact for agreed patient group</b>	N/A
<b>Usage Monitoring &amp; Impact Assessment</b>	Trusts – monitor non-formulary requests CCGs – monitor impact data and exception reports from GPs if inappropriate requests to prescribe are made to primary care.
<b>Evidence reviewed</b>	<p><b>References (from evidence evaluation)</b></p> <ol style="list-style-type: none"> <li>1. Summary of Product Characteristics. Zyclara 3.75% cream. Last updated Apr 2018. Accessed online via: <a href="https://www.medicines.org.uk/emc/product/2929/smpc">https://www.medicines.org.uk/emc/product/2929/smpc</a> Last accessed 15/11/18.</li> <li>2. Berker D et al. British Association of Dermatologists' guidelines for the care of patients with actinic keratosis 2017. <i>British Journal of Dermatology</i> (2017); 176: pages 20-43.</li> <li>3. Primary Care Dermatology Society Actinic Keratoses Treatment Pathway. Accessed via <a href="http://www.pcds.org.uk">http://www.pcds.org.uk</a>. Last accessed 06/11/18.</li> <li>4. Hanke CW, Beer KR, Stockfleth E et al. Imiquimod 2.5% and 3.75% for the treatment of actinic keratoses: results of two placebo-controlled studies of daily application to the face and balding scalp for two 3-week cycles. <i>J Am Acad Dermatol</i> (2010); 62: pages 573–81.</li> <li>5. Swanson N et al. Imiquimod 2.5% and 3.75% for the treatment of actinic keratoses: results of two placebo-controlled studies of daily application to the face and balding scalp for two 2-week cycles. <i>J Am Acad Dermatol</i> (2010); 62(4): pages 582-90.</li> </ol>

6. Hanke CW, Swanson N, Bruce S et al. Complete clearance is sustained for at least 12 months after treatment of actinic keratoses of the face or balding scalp via daily dosing with imiquimod 3.75% or 2.5% cream. <i>J Drugs Dermatol</i> (2011); 10:165–70 [abstract only].
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**NOTES:**

- a) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the [APC website](#).
- 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 a submission is received 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**