

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

<b>Reference:</b>	<b>114</b>
<b>Intervention:</b>	<b>Imiquimod 5% cream (Aldara®) for the topical treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (AK) on the face or scalp in immunocompetent adult patients</b> (When applied to the skin imiquimod 5% cream helps the body's own immune system to produce natural substances which help fight actinic keratosis)
<b>Date of Decision:</b>	<b>January 2020</b>
<b>Date of Issue:</b>	<b>February 2020</b>
<b>Recommendation:</b>	<b>GREEN – can be prescribed within agreed criteria for use in primary or secondary care</b>
<b>Further Information:</b>	<ul style="list-style-type: none"> <li>Imiquimod 5% cream is supported for use in SEL as an option for the topical management of actinic keratosis (AK) in line with its licensed indication* and the SEL pathway for the management of AK which forms part of the <a href="#">primary care dermatology guidelines</a>.</li> <li>In line with the local AK pathway, imiquimod 5% cream may be considered in AK with field change as a 2<sup>nd</sup> line option in patients who are intolerant to 5-fluorouracil cream (Efudix®).</li> <li>Imiquimod 5% cream should be applied 3 times per week (for example: Monday, Wednesday and Friday) for four weeks prior to normal sleeping hours, and left on the skin for approximately 8 hours.</li> <li>After a 4-week treatment-free period, clearance of AKs should be assessed. If any lesions persist, treatment should be repeated for another four weeks.</li> <li><b>Patients should be counselled on the appropriate use of this topical preparation.</b></li> </ul> <p>Please refer to the <a href="#">SEL primary care dermatology guidelines and supporting key messages</a> for further information.</p> <p>*With respect to AK, imiquimod 5% cream is licensed for the topical treatment of clinically typical, non-hyperkeratotic, non-hypertrophic AKs on the face or scalp in immunocompetent adult patients when size or number of lesions limit the efficacy and/or acceptability of cryotherapy and other topical treatment options are contraindicated or less appropriate.</p>
<b>Shared Care/ Transfer of care required:</b>	N/A
<b>Cost Impact for agreed patient group</b>	<ul style="list-style-type: none"> <li>Addition of imiquimod 5% is likely to be at least cost neutral as the single course is cheaper than all current treatment options except fluorouracil 5% cream. It may require repeat treatment, but if 50% of patients require a repeat course the price is equivalent to diclofenac cream which is likely to be the most common treatment used currently.</li> </ul>
<b>Usage Monitoring &amp; Impact Assessment</b>	<p><b>Trusts/Community dermatology clinics</b></p> <ul style="list-style-type: none"> <li>Monitor and submit usage and audit data on request to the APC (community clinics to submit through their borough based leads).</li> </ul> <p><b>Borough based teams:</b></p> <ul style="list-style-type: none"> <li>Monitor primary care prescribing data.</li> <li>Audit locally (including locally commissioned dermatology services) to ensure use in line with this recommendation and the local pathway.</li> <li>Exception reports from GPs if inappropriate prescribing requests are made to primary care.</li> </ul>

<p><b>Evidence reviewed</b></p>	<p><b>References (from evidence evaluation prepared December 2018)</b></p> <ol style="list-style-type: none"> <li>1. 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>2. Marks R, Rennie G, Selwood T. Malignant transformation of solar keratoses to squamous cell carcinoma. <i>Lancet</i> (1988); 331 (8589): pages 795–797</li> <li>3. NHS Health. Skin cancer (non-melanoma) Treatment. Accessed online via <a href="#">here</a> (16/11/18)</li> <li>4. Primary Care Dermatology Society Actinic Keratoses Treatment Pathway. Accessed <a href="#">here</a> (06.11.18).</li> <li>5. Hadley D, Derry S, Moore R. Imiquimod for Actinic Keratosis: Systematic Review and Meta-Analysis. <i>Journal of Investigative Dermatology</i> 20016 p1251-1255</li> <li>6. Summary of Product Characteristics. Aldara 5% Cream. Last updated Mar 2017. Accessed online via: <a href="https://www.medicines.org.uk/emc/product/823/smpc">https://www.medicines.org.uk/emc/product/823/smpc</a>. Last accessed 15/11/18.</li> <li>7. Scottish Medicines Consortium. Imiquimod 5% cream (Aldara) No. 385/07 April 2008. Accessed online via: <a href="https://www.scottishmedicines.org.uk">https://www.scottishmedicines.org.uk</a>. Last accessed 10/12/2018.</li> <li>8. Summary of Product Characteristics. Efudix Cream. Last updated Aug 2018. Accessed online via: <a href="https://www.medicines.org.uk/emc/product/9260/smpc">https://www.medicines.org.uk/emc/product/9260/smpc</a>. Last accessed 15/11/18.</li> <li>9. Jorizzo J et al. Vehicle-controlled, double-blind, randomised study of imiquimod 5% cream applied 3 days per week in one or two courses of treatment for actinic keratoses on the head. <i>J Am Acad Dermatol</i> (2007); 57(2): pages 265-268.</li> <li>10. Alomar A, Bichel J, McRae S. Vehicle-controlled, randomized, double-blind study to assess safety and efficacy of imiquimod 5% cream applied once daily 3 days per week in one or two courses of treatment of actinic keratoses on the head. <i>Br J Dermatol</i> (2007); 157: pages 133–141.</li> <li>11. Stockfelth et al. Low incidence of new actinic keratoses after topical 5% imiquimod cream treatment: a long-term follow up study. <i>Arch Dermatol</i> (2004); 140: pages 1542</li> <li>12. Lee et al. Long-term clinical outcomes following treatment of actinic keratosis with imiquimod 5% cream. <i>Dermatolog Surg</i> (2005); 31: pages 659-64.</li> <li>13. Krawtschenko N et al. A randomised study of topical 5% imiquimod vs. topical 5-fluorouracil vs. cryotherapy in immunocompetent patients with actinic keratoses: a comparison of clinical and histological outcomes including 1-year follow-up. <i>British Journal of Dermatology</i> (2007); 157: pages 34-40.</li> <li>14. 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>15. 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> <li>16. 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].</li> </ol>
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**NOTES:**

- a) Area Prescribing Committee recommendations 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 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.**