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

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| **Reference** | **095** |
| **Intervention:** | **Imiquimod 3.75% cream (Zyclara™) for the treatment of actinic keratosis (AK)**<br>(Imiquimod is an Immune Response Modifier, it stimulates the body's immune system) |
| **Date of Decision** | **December 2018** |
| **Date of Issue:** | **January 2019** |
| **Recommendation:** | **Grey – not recommended for prescribing in South East London** |
| **Further Information** | • Imiquimod 3.75% cream (Zyclara™) is not recommended for prescribing in South East London.<br>• Two identically designed vehicle controlled studies were reviewed as part of the formulary submission.<br>• 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.<br>• Additionally, comparative data supporting long term safety are lacking.<br><br>* 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 |
| **Shared Care/Transfer of care document required:** | N/A |
| **Cost Impact for agreed patient group** | N/A |
| **Usage Monitoring & Impact Assessment** | Trusts – monitor non-formulary requests<br><br>CCGs – monitor epact data and exception reports from GPs if inappropriate requests to prescribe are made to primary care. |
| **Evidence reviewed** | **References (from evidence evaluation)**<br>1. Summary of Product Characteristics. Zyclara 3.75% cream. Last updated Apr 2018. Accessed online via: https://www.medicines.org.uk/emc/product/2929/smpc Last accessed 15/11/18.<br>2. Berker D et al. British Association of Dermatologists' guidelines for the care of patients with actinic keratosis 2017. *British Journal of Dermatology (2017);* 176: pages 20-43.<br>3. Primary Care Dermatology Society Actinic Keratoses Treatment Pathway. Accessed via http://www.pcds.org.uk. Last accessed 06/11/18.<br>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. *J Am Acad Dermatol* (2010); 62: pages 573–81.<br>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. *J Am Acad Dermatol (2010)*; 62(4): pages 582-90. |

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| | 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. *J Drugs Dermatol* (2011); 10:165–70 [abstract only]. |

**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**