

South East London Area Prescribing Committee Formulary recommendation

Reference:	096
Intervention:	Imiquimod 5% cream (Aldara™) for the treatment of superficial basal cell carcinoma in adults (Imiquimod is an Immune Response Modifier, it stimulates the body's immune system)
Date of Decision:	December 2018
Date of Issue:	January 2019
Recommendation:	Red – suitable for prescribing and supply by skin cancer specialists
Further Information:	 Imiquimod 5% cream is accepted as an option for use in SEL for the topical treatment of small, low risk superficial basal cell carcinomas (sBCCs) in adults. The evidence presented suggests that imiquimod 5% cream is non-inferior to fluorouracil cream. The other options for sBCCs are photodynamic therapy (PDT) and surgical excision. The evidence presented suggests that imiquimod 5% cream is superior to PDT for treating sBCC but inferior to surgery. Imiquimod 5% cream may be considered as a 2nd line topical option in patients who have unsuccessfully tried fluoruracil 5% cream or have a contraindication to it and where cosmetic outcomes following excision surgery might be unacceptable for the patient. For the treatment of sBCC, imiquimod 5% cream is applied for 6 weeks, 5 times per week (example: Monday to Friday) prior to normal sleeping hours, and left on the skin for approximately 8 hours. The full course of imiquimod 5% cream will be prescribed and supplied by the specialist service.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	 The evidence review estimates that for the treatment of sBCC, three packs of 12 sachets of imiquimod 5% cream would be required. This equates to £145.80 per person and is less expensive than PDT or surgery. It is, however, more expensive than fluorouracil 5% cream (one tube expected to be required, costing £32.90). The prevalence of BCC is approximately 226 per 100,000 population. If it is assumed that 25% of patients have sBCC and are suitable for topical treatment and 50% receive imiquimod 5% cream instead of fluorouracil 5% cream, the additional cost impact would be £3,150 per 100,000 population (or ~£57K across SEL).
Usage Monitoring & Impact Assessment	Acute Trusts: Monitor use and submit usage data and audit reports (against this recommendation) upon request to the APC.
	 CCGs: Monitor ePACT2 data. Exception reports from GPs if inappropriate prescribing requests are made to primary care.

Evidence reviewed References (from evidence evaluation)



- Summary of Product Characteristics. Aldara 5% Cream. Last updated Mar 2017. Accessed online via: https://www.medicines.org.uk/emc/product/823/smpc. Last accessed 15/11/18.
- Sottish Medicines Consortium. Imiquimod 5% cream (Aldara) No. 385/07 April 2008. Accessed online via: https://www.scottishmedicines.org.uk. Last accessed 10/12/2018.
- 3. NICE guidance on cancer services. Improving outcomes for people with skin tumours including melanoma (update). The management of low-risk basal cell carcinomas in the community (2010). Accessed online via: https://www.nice.org.uk/guidance/csg8. Last accessed 16/11/18.
- 4. Telfer NR et al. Guidelines for the management of basal cell carcinoma. *British Journal of Dermatology* (2008); 159: pages 35-48.
- 5. Primary Care Dermatology Society Basal Cell Carcinma Treatment Pathway. Accessed via: http://www.pcds.org.uk/clinical-guidance/basal-cell-carcinoma-an-overview. Last accessed 03/12/2018.
- 6. Geisse J et al. Imiquimod 5% cream for the treatment of superficial basal cell carcinoma: Results from two phase III, randomized, vehicle-controlled studies. *J Am Acad Dermatol* (2004); 50 (5): pages 722-733.
- 7. Arits AH et al. Photodynamic therapy versus topical imiquimod versus topical fluorouracil for treatment of superficial basal-cell carcinoma: a single blind, non-inferiority, randomised controlled trial. *Lancet Oncol* (2013); 14:647–54 [abstract only].
- 8. Bath-Hextall F et al. Surgical excision versus imiquimod 5% cream for nodular and superficial basal-cell carcinoma (SINS): a multicentre, non-inferiority, randomised controlled trial. *Lancet Oncol* (2014); 15(1): 96.
- 9. European Medicines Agency. Aldara. Accessed online via: https://www.ema.europa.eu. Last accessed 11/12/18.
- Uptodate clinical decision support tool. Epidemiology, pathogenesis, and clinical features of basal cell carcinoma. Available online at: https://www.uptodate.com/contents/epidemiology-pathogenesis-and-clinical-features-of-basal-cell-carcinoma?topicRef=5338&source=see_link (accessed 10.12.2018)

NOTES:

- a) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the <u>APC website</u>.
- 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.