

**South East London Integrated Medicines Optimisation Committee
Formulary recommendation**

Reference:	158
Intervention:	Actikerall™ cutaneous solution for the topical management of recalcitrant warts in adults and children aged 5 years old and over (off-label). Each 1 g [= 1.05 ml] of Actikerall™ cutaneous solution contains 5 mg of fluorouracil and 100 mg of salicylic acid. (Fluorouracil belongs to a group of medicines known as antimetabolites, which inhibit the growth of cells (cytostatic agent). Salicylic acid is a preparation used to soften hard skin.)
Date of Decision:	September 2024
Date of Issue:	March 2025
Recommendation:	Amber 1 – initiation in primary care on the recommendation of a dermatology specialist
Further Information	<ul style="list-style-type: none"> • Actikerall™ cutaneous solution is accepted for use in adults and children aged 5 years old and over in SEL for the treatment of recalcitrant, highly symptomatic warts, in line the SEL treatment pathway for the management of viral warts which is included in the primary care dermatology guidelines. • Use of Actikerall™ cutaneous solution in this setting is off-label*. The off-label nature should be explained to the patient/carer/parent/guardian and informed consent gained. • Treatment with Actikerall™ in this setting is accepted for use as a 2nd line option in line with the viral warts pathway under the following criteria: <ul style="list-style-type: none"> - People who have recalcitrant and very symptomatic viral hand, plantar (verrucae) or peri-ungual warts where there is a specific need to treat (e.g., painful, interfering with activities of daily living) and alternative topical treatments have been ineffective or inappropriate (e.g. peri-ungual warts because of risk of damage to nail matrix/scarring), or where there is a particular concern about spread e.g. patient is immunosuppressed. - Adult patients who are very symptomatic: Actikerall™ may be considered after all available over the counter (OTC) topical treatments have been trialed for 6 months, including salicylic acid 40% plasters, in line with the viral warts treatment pathway. - Children and young people who are very symptomatic: Actikerall™ may be considered after all available OTC topical treatments, including topical salicylic acid 26%, in line with the viral warts treatment pathway. - Initiation in primary care only after the recommendation of a dermatology specialist • Actikerall™ should be applied once daily for up to 12 weeks; the film occlusion should not be removed until the wart is pared/ filed weekly. • Further information on Actikerall™ cutaneous solution can be found in the summary of product characteristics (SPC). <p>*Actikerall™ is licensed for use in the topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients.</p>
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> • The application to the committee estimated 120 patients across SEL per year (78 adult and 42 paediatric patients) will be eligible for treatment with Actikerall™ in this setting. • The cost of Actikerall™ is ~ £38.80 per person using one 25mL bottle of which one is required to complete the full 12 week course. This equates to ~ £5,000 (~£250 per 100,000 population) per year. • Actikerall™ is intended to be used where all other treatment options have failed, and is therefore an additional treatment option and thus, an additional cost. However, the application highlights the potential for savings in reduced attendance for cryotherapy which is a third line treatment option in this setting.

Usage Monitoring & Impact Assessment	<p>Acute Trusts/community dermatology clinics:</p> <ul style="list-style-type: none"> • Monitor use and submit usage data and audit reports upon request to the Committee. <p>SEL Borough Medicines Teams:</p> <ul style="list-style-type: none"> • Monitor ePACT2 data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	<p>References (from evidence evaluation)</p> <ol style="list-style-type: none"> 1. Bavinck J et al. Treatments for common and plantar warts. British Medical Journal (2011); 342: d3119. 2. NICE Clinical Knowledge Summaries. Warts and verrucae Available online at Warts and verrucae Health topics A to Z CKS NICE (Accessed: 10/09/2024) 3. Up to date (online resource). Cutaneous warts (common, plantar, and flat warts). Available online at http://www.uptodate.org/ (Accessed: 02/09/2024) 4. Sterling, J.C., Gibbs, S., Haque Hussain, S.S., Mohd Mustapa, M.F. and Handfield-Jones, S.E. (2014), British Association of Dermatologists' guidelines for the management of cutaneous warts 2014. Br J Dermatol, 171: 696-712. https://doi.org/10.1111/bjd.13310 5. Kwok CS et al. Topical Treatments for cutaneous warts (Review). Cochrane Database of Systematic Reviews (2012); Issue 9. Art. No.: CD001781. DOI:10.1002/14651858.CD001781.pub3 6. Warts. Primary Care Dermatology Society. Available online at https://www.pcds.org.uk/clinical-guidance/warts (Accessed: 02/09/2024) 7. Leon S et al. A highly effective topical compound medication for the treatment of cutaneous warts. Practical Dermatology (2017). Available online at http://practicaldermatology.com/ (Accessed: 02/09/2024) 8. Actikerall 5mg/g + 100mg/g Cutaneous Solution, Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/4621 (Accessed: 02/09/2024) 9. Actikerall to treat warts. Great Ormond Street Hospital for Children. Available online at https://www.gosh.nhs.uk/conditions-and-treatments/medicines-information/actikerall-treat-warts/ (Accessed: 02/09/2024) 10. Zschocke, I., Hartmann, A., Schlöbe, A., Cummerow, R. and Augustin, M. (2004), Wirksamkeit und Nutzen eines 5-FU-/Salicylsäure-haltigen Präparates in der Therapie vulgärer und plantarer Warzen – systematische Literaturübersicht und Metaanalyse. Journal der Deutschen Dermatologischen Gesellschaft, 2: 187-193. https://doi.org/10.1046/j.1439-0353.2004.04703.x 11. Kim DY, Park H, Cho S, Yoon HS. Effectiveness of New 5-Fluorouracil/Salicylic Acid Application Method for Periungual Warts: A Descriptive Study. Ann Dermatol. 2020 Aug;32(4):345-347. 12. Starace M, Waśkiel-Burnat A, Bruni F, Alessandrini A, Dika E, Piraccini MB, Iorizzo M. Combination of topical fluorouracil and salicylic acid as a therapeutic option for recalcitrant warts of the nail unit. J Eur Acad Dermatol Venereol. 2023 Mar;37(3):e410-e411. doi: 10.1111/jdv.18591. Epub 2022 Oct 10. PMID: 36164812. 13. Acar EM, Uyar B, Elmas ÖF, Özyurt K, Atasoy M, Türsen Ü, Lotti T. Therapeutic efficacy and safety of three different modalities in pediatric patients with plantar warts. Dermatol Ther. 2021 Sep;34(5):e15073. doi: 10.1111/dth.15073. Epub 2021 Aug 5. PMID: 34328650.

NOTES:

- a) SEL IMOC recommendations and minutes are available publicly via the [website](#).
- b) This SEL IMOC 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**