

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

Reference	159
Intervention:	Betesil™ medicated plasters (betamethasone valerate 2.25mg) and fludroxycortide 4 microgram/cm² tape for the management of symptomatic hypertrophic or keloid scars in adults (Betamethasone is a glucocorticoid steroid. Fludroxycortide is a fluorinated topical corticosteroid, both steroids exert local anti-inflammatory effects)
Date of Decision:	September 2024
Date of Issue:	Marchy 2025 - time lag from initial application discussion in September 2024 to issuing the decision as the pathway was progressed
Recommendation:	Amber 1 – initiation in primary care on the recommendation of a dermatology specialist
Further Information	<ul style="list-style-type: none"> Betesil™ medicated plasters and fludroxycortide tape are accepted for use in SEL as options for the management of symptomatic hypertrophic scars or keloids in adults. Use is approved in line with the SEL pathway for the management of keloid and hypertrophic scars, included in the primary care dermatology guidelines. The use of Betesil™ medicated plasters or fludroxycortide tape in this setting is off-label*. The off-label nature should be explained to the patient/carer and informed consent gained. Betesil™ medicated plasters or fludroxycortide tape are reserved for use in people with symptomatic keloids and/or hypertrophic scars causing significant distress, where over the counter products have failed. Betesil™ plasters or fludroxycortide tape should be cut to the size of the keloid or scar and applied for at least 12 hours per day. The treatment duration of Betesil™ medicated plasters or fludroxycortide tape is for a maximum of 12 weeks and initiation should occur in primary care only on the recommendation of a dermatology specialist. The most cost-effective option of the two products should be prescribed, in line with the treatment pathway. The alternative option that can be considered at this point for people with symptomatic keloids and/or hypertrophic scars causing severe distress is topical clobetasol propionate 0.05% cream for daily application under occlusion, in line with the treatment pathway. <p>*Betesil 2.25mg plasters are licensed for the treatment of inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides. Due to its particular pharmaceutical form, Betesil™ is suitable for mild to moderate chronic plaque psoriasis localised in difficult to treat areas (e.g. knees, elbows and anterior face of the tibia). Maximum licensed treatment duration is 30 days. Summary of Product Characteristics (SPC) available here</p> <p>*Fludroxycortide tape is licensed as adjunctive therapy for chronic, localised, recalcitrant dermatoses that may respond to topical corticosteroids and particularly dry, scaling lesions. SPC available here.</p>
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> The application estimates that 700 & 460 patients per annum in SEL would receive fludroxycortide tape or Betesil™ medicated plasters respectively for hypertrophic or keloid scars. The cost of fludroxycortide tape and Betesil™ medicated plasters per 12 week course is ~ £140 and ~ £40 respectively which equates to a cost impact of ~ £100,000 to ~ £160,000 (~ £5K to £8K per 100,000 population) per year. The use of fludroxycortide tape or Betesil™ medicate plasters in this setting is expected to be more cost effective than alternative topical steroid creams providing potential cost savings.
Usage Monitoring &	Acute Trusts/community dermatology clinics: <ul style="list-style-type: none"> Monitor use and submit usage data and audit reports upon request to the Committee.

Impact Assessment	SEL Borough Medicines Teams: <ul style="list-style-type: none"> • Monitor ePACT2 data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	References (from evidence evaluation) <ol style="list-style-type: none"> 1. Keloids and hypertrophic scars, Uptodate. Available online at: https://www.uptodate.com/contents/keloids-and-hypertrophic-scars (Accessed 02/09/2024). 2. Scars – hypertrophic and keloid. Primary Care Dermatological Society. Available online at: https://www.pcids.org.uk/clinical-guidance/scars (Accessed 02/09/2024). 3. Ogawa R, Akaishi S, Kuribayashi S et al. Keloids and Hypertrophic Scars Can Now Be Cured Completely: Recent Progress in Our Understanding of the Pathogenesis of Keloids and Hypertrophic Scars and the Most Promising Current Therapeutic Strategy. J Nippon Med Sch 2016 83 (2) p46-53. 4. Niessen F, Spauwen P, Schalkwijk J et al. On the nature of hypertrophic scars and keloids: a review. Plast Reconstr Surg 1999; 104 (5) p1435-58. 5. Bonavita M, Soresina M, Boccanera D et al. Efficacy And Tolerability Of A New Pharmaceutical Form Of Betamethasone Valerate In The Prevention Of Hypertrophic Scars Following Anterior Trunk Plastic Surgery: A Preliminary Exploratory Study. European Journal Of Inflammation 2014 12 (3) p459-465. 6. Keloid. BMJ Best Practice. Available online at: https://bestpractice.bmj.com/topics/en-gb/629/treatment-algorithm (Accessed 02/09/2024). 7. Scars and Keloids. The British Association of Aesthetic and Plastic Surgeons. Available online at: https://baaps.org.uk/patients/procedures/16/scars_and_keloids (Accessed 02/09/2024). 8. Ogawa R, Akita S, Aramaki-Hattori N et al. Diagnosis and Treatment of Keloids and Hypertrophic Scars—Japan Scar Workshop Consensus Document 2018. Burns & Trauma 2019 7 39. 9. Goutos I, Ogawa R. Steroid tape: a promising adjunct to scar management. Scars, Burns and Healing 2017 3 p1-9. 10. Weiner M. Fluandrenolone tape. A new preparation for occlusive therapy. Journal of Investigative Dermatology 1966 47 p63-66. 11. Fludrocortide tape, Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/2694/smpc (Accessed 03/09/2024). 12. Betesil, Summary of Product Characteristics. Available online at: https://mhraproducts4853.blob.core.windows.net/docs/296475b97fdb5731636912c6878aa98c9d60ca1b (Accessed 03/09/2024). 13. Ly S, Amici J. Role of betamethasone valerate 2.25 mg medicated plaster in the treatment of psoriasis and other dermatological pathologies: a review. Drugs in Context 2018 7 212539. 14. Goldblatt S. The use of Cordran tape in dermatology. Ohio State Med J 1969 65 p1118-1121, as cited in: Goutos I, Ogawa R. Steroid tape: a promising adjunct to scar management. Scars, Burns and Healing 2017 3 p1-9 15. Ratzler M. A clinical trial of fluandrenolone tape. British J Clin Prac 1970 24 p185-189, as cited in: Goutos I, Ogawa R. Steroid tape: a promising adjunct to scar management. Scars, Burns and Healing 2017 3 p1-9. 16. Ogawa R, Akashi S. Effectiveness of corticosteroid tape/plaster for keloids and hypertrophic scars – comparative study of fludrocortide and depomedrone tape/plasters. Scar Management 2016 10 p55-60 (Japanese), as cited in: Goutos I, Ogawa R. Steroid tape: a promising adjunct to scar management. Scars, Burns and Healing 2017 3 p1-9. 17. Bonavita M, Soresina M, Boccanera D et al. Efficacy and tolerability of a new pharmaceutical form of betamethasone valerate in the prevention of hypertrophic scars following anterior trunk plastic surgery: a preliminary exploratory study. European Journal of Inflammation 2014 12 (3) p459-465. 18. Naldi L, Yawalkar N, Kaszuba A et al. Efficacy and safety of the betamethasone 0.1% plaster in mild to moderate chronic plaque psoriasis: a randomised, parallel group, active controlled, phase III study. Am J Clin Dermatol. 2011 12 (3) p191-201. 19. Betamethasone valerate 2.25mg medicated plaster (Betesil), SMC 2010 622/10. Available online at: https://scottishmedicines.org.uk/medicines-advice/betamethasone-valerate-225mg-medicated-plaster-betesil-fullsubmission-62210/ (Accessed 06/09/2024)

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**