PrescQIPP Community Interest Company

Wound care - Silicone scar treatments

In England and Wales £1.2 million is spent annually on silicone gels and sheets (ePACT August to October 2016). Medicines optimisation projects in this area focus on reducing inappropriate prescribing of silicone scar treatment and using cost effective choices if deemed appropriate.

Key recommendations

- There is weak evidence of the benefit of silicone gels and sheets for the treatment or prevention of hypertrophic and keloid scarring.[1]
- Prescribing of silicone sheets and gels is not recommended for routine cosmetic treatment. Examples include treatment that may be secondary to ear piercing or other body piercing procedures, or post-surgery prevention of hypertrophic and keloid scars.[1]
- Clinical Commissioning Groups (CCGs) may wish to consider prescribing in certain specified circumstances, e.g. prescribing should be restricted to hypertrophic or keloid scars that result from burns, trauma or from surgery where the scar is functionally disabling (due to significant pain or pruritis) or the scar results in facial disfigurement.
- Exceptions to treatment are where scarring impacts severely on physical function. CCGs may have specific criteria (as stated above). In these cases local procedures should be developed (such as individual funding, prior approval, formulary restriction etc.).
- Silicone gels and sheets are available to purchase if patients wish to use these products, where they do not meet the prescribing criteria.
- Patients who have a high risk of scarring should consider self care measures, i.e. avoid tattoos or piercing.[2] Cosmetic camouflage could be considered where appropriate.

Background

Keloid and hypertrophic scars are common and are caused by a proliferation of dermal tissue following skin injury.[1] Hypertrophic scars occur when the wound heals to become red, raised and itchy for a few months and then resolve to become flat and pale. A keloid is similar, but the scar continues to grow encroaching upon normal tissue and may need specific treatment.[2]

Hypertrophic scars tend to follow surgery and thermal injuries such as severe burns. Keloid scars often originate after injury such as ear piercing, insect bites and vaccination. Keloid scarring is reported to be more common in darker skin, while hypertrophic scarring is more common in fair skin.[1] There are usually no symptoms of a keloid scar; but some are tender, painful, itchy, cause a burning sensation or if very tight, they can limit movement at nearby joints. The main problem is their appearance can cause embarrassment.[2] Both types of scarring can cause functional and psychological problems for patients, and their management can be difficult. The British Association of Aesthetic Plastic Surgeons state that time is the best healer, as eventually normal scars and hypertrophic scars will mature and become pale. However plastic surgeons and dermatologists do tend to treat the more severe hypertrophic scars and keloids.[3]

Treatment options have included surgery, radiation therapy, steroid injections, pressure therapy, cryotherapy (treatment with liquid nitrogen) and laser therapy. Treatment may be difficult and not always successful.[2-5]

Clinical evidence

The use of silicone gel sheeting to prevent and treat hypertrophic scarring is still relatively new. It started in 1981 with treatment of burns scars.[1] Currently gels, sprays and sheets are available and listed in the NHS Electronic Drug Tariff under Part IXA-Wound Management Dressings as medical devices. They are designed to be placed onto or applied to healing skin (not open wounds) overnight (12-24 hours) for several months.[1,2]

Up to date published evidence is from a recent Cochrane review, which included 20 controlled clinical trials (n=873 people aged 1.5 to 81 years). The trials compared adhesive silicone gel sheeting with no treatment; non silicone dressing; other silicone products; laser therapy; triamcinolone acetonide injection; topical onion extract and pressure therapy.[1]

For prevention, silicone gel reduced the incidence of hypertrophic scarring in people prone to scarring (risk ratio (RR) 0.46, 95% confidence interval (CI) 0.21 to 0.98). For treatment, silicone gel sheeting produced a statistically significant reduction in scar thickness (mean difference (MD) -2.00, 95% CI -2.14 to -1.85) and colour amelioration (RR 3.49, 95% CI 1.97 to 6.15). The studies however were from small trials. The authors commented that the research was of poor quality and studies were highly susceptible to bias, which means that a great deal of uncertainty prevails.[1]

An earlier 2010 review of evidence also concluded that the few trials that do exist are associated with limited follow-up time. Keloids can emerge up to two years after an inciting traumatic event. The authors did however note that despite the obvious need for more precisely designed research, silicone gel sheeting of hypertrophic scars and keloids does benefit certain patients. This includes those with a history of hypertrophic scar or keloid formation, and or burn injury, with little risk of adverse effects to the patient. They concluded that silicone gel sheeting is also an excellent treatment option for pediatric patients, who may not be able to tolerate intra-lesional corticosteroid injection. They also concluded that silicone gel sheeting does not tend to completely resolve keloids, but it is evident that this therapy modulates keloid formation and can reduce thickness and induration.[6]

Very limited data is available on silicone gels. A very small study of 30 patients with scars, evaluated silicone gel treatment, applied twice daily for up to six months. After treatment, improvement was noted in the scars; 60% of scars were graded as normal (Grade I), 20% were graded as mildly hypertrophic (Grade II) and 20% of scars were of Grade III and IV at the end of study; side effects were few. Allergic reaction to silicone gel was seen in one case and mild desquamation was seen in two cases.[7]

ReCell Spray-On Skin system ('ReCell') is a rapid, autologous cell harvesting, processing and delivery system for treating skin loss and preventing scarring and depigmentation in adults and children with burns. A NICE medical technology appraisal stated that there is insufficient evidence on its use in clinical practice, particularly in relation to which patients might benefit most from its use, to support the case for its routine adoption in the NHS. Further research was recommended and a further review of this product will commence in 2017.[8]

Policies for funding

Due to the limited evidence base, silicone gels and sheets for preventing and treating hypertrophic and keloid scars are not recommended. However, CCGs may wish to consider prescribing in exceptional cases i.e. treatment for hypertrophic or keloid scars that result from burns, trauma or surgery and if the scar is functionally disabling (due to significant pain or pruritis) or the scar results in facial disfigurement.

Prescribing is not recommended for:

- Prevention of hypertrophic or keloid scarring in people with newly healed wounds (e.g. post-surgery).
- Treatment of established scarring in people with existing keloid or hypertrophic scars.

- Keloid scars that are on the body or are secondary to ear piercing or other body piercing procedures will not normally be funded.
- Scar revision secondary to trauma or accidents on the body for cosmetic reasons unless there is evidence of exceptions.

Commissioning bodies will need to consider exceptions to its policy. A request that is regarded as an exception is likely to be based on evidence that the patient differs from the usual group to whom the policy applies. Funding for treatment under these exceptional circumstances will be subject to local policy.

If prescribing is considered appropriate, referral to a dermatologist would be acceptable or initiation may be through tissue viability services.

Figures 1-4 provide a comparison of costs/cm^2 for the gel sheets or cost per g or ml for the gel products.

Figure 1: Cost of silicone keloid sheets 0-124cm^2 (pence/cm^2)[9]

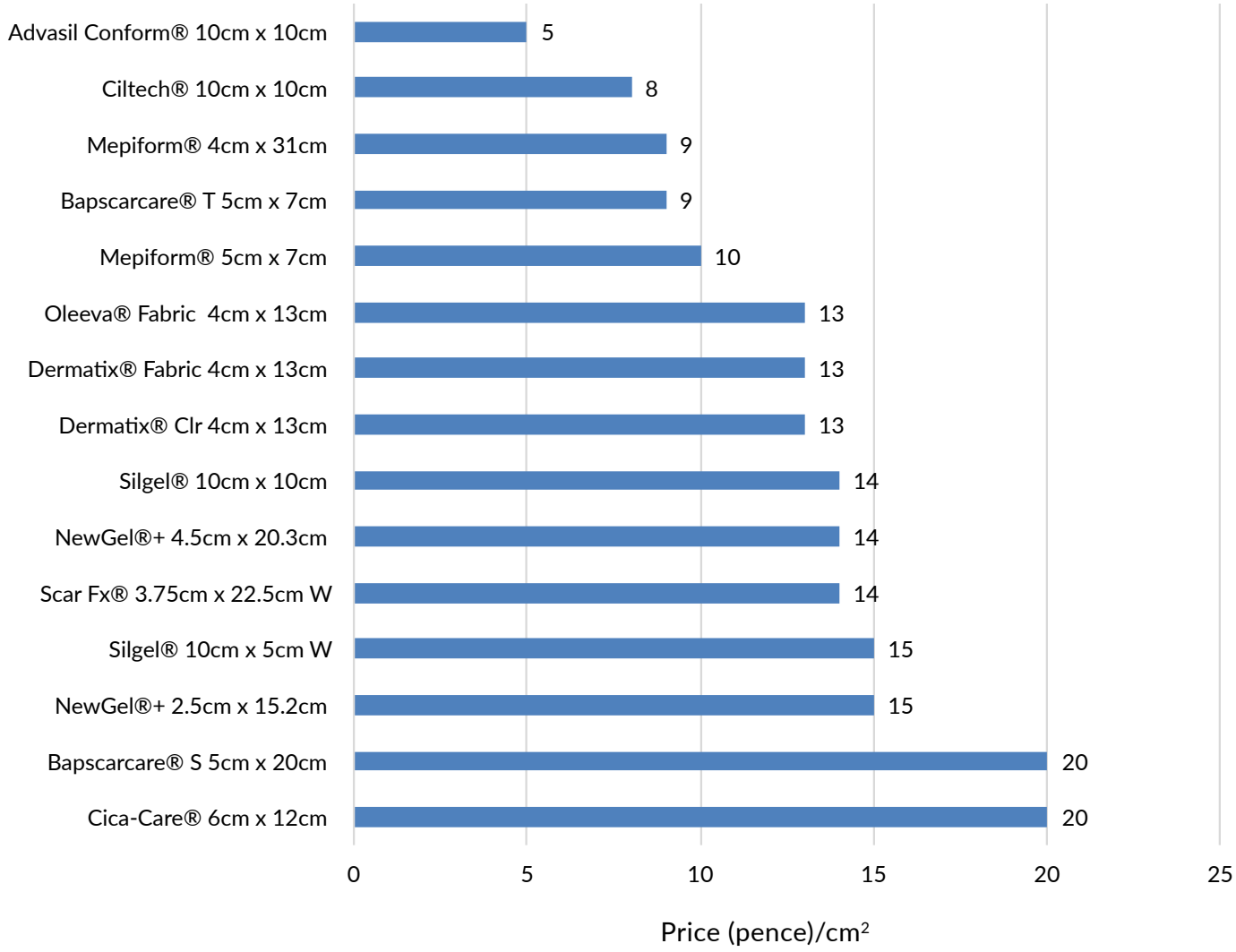


Figure 2: Cost of silicone keloid sheets 125-299cm² (pence/cm²)[9]

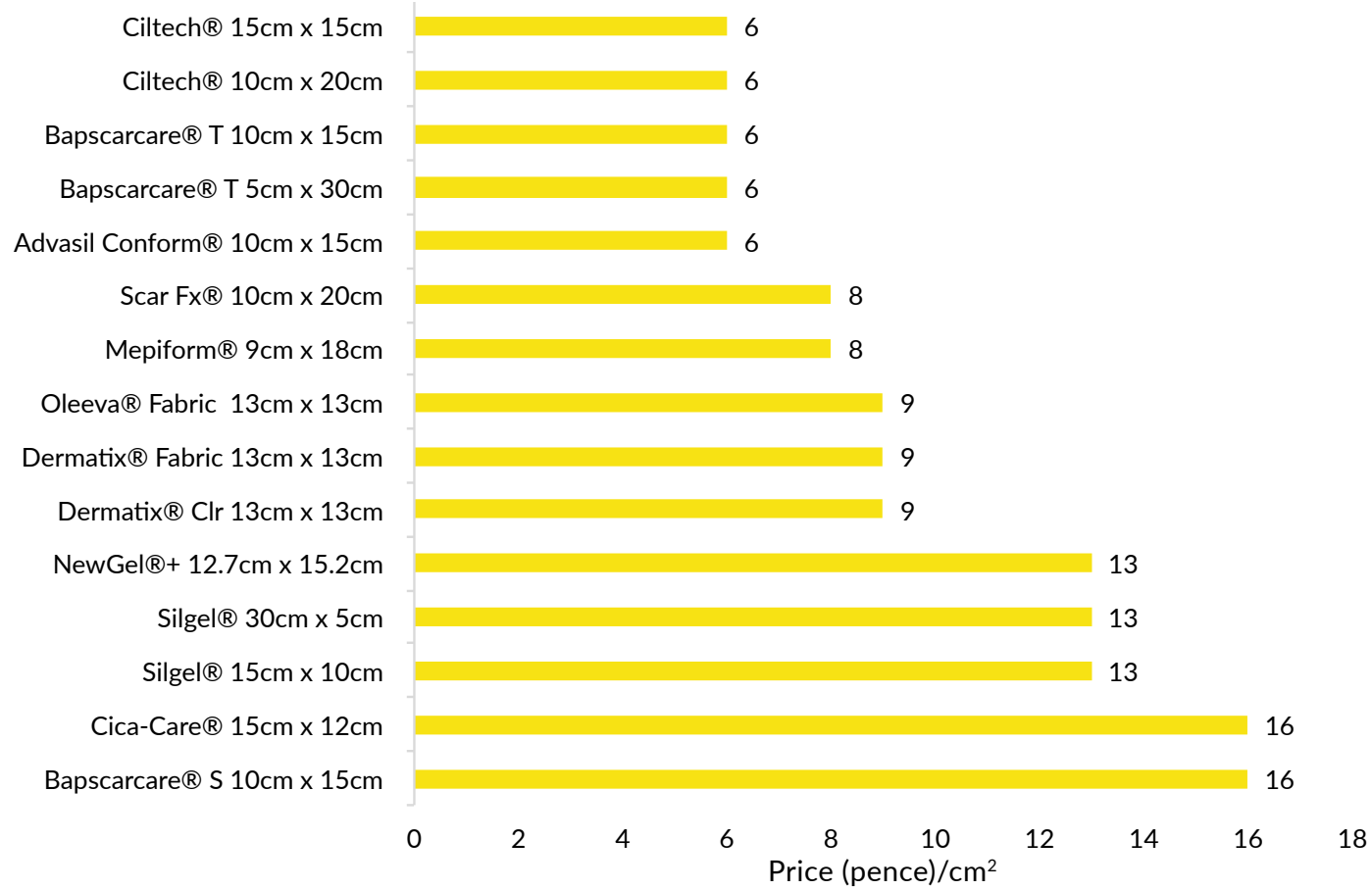


Figure 3: Cost of silicone keloid sheets >300cm² (pence/cm²)[9]

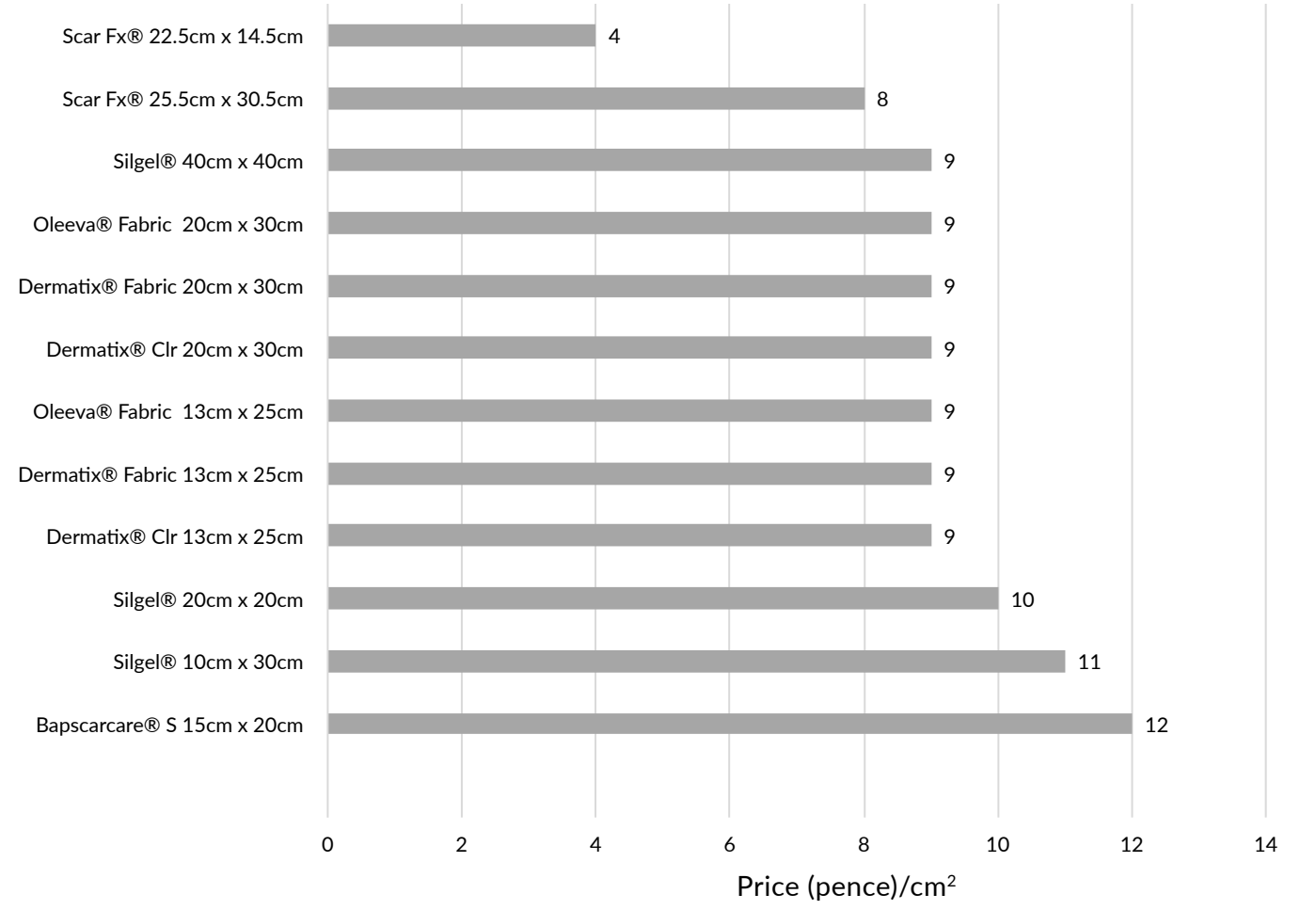
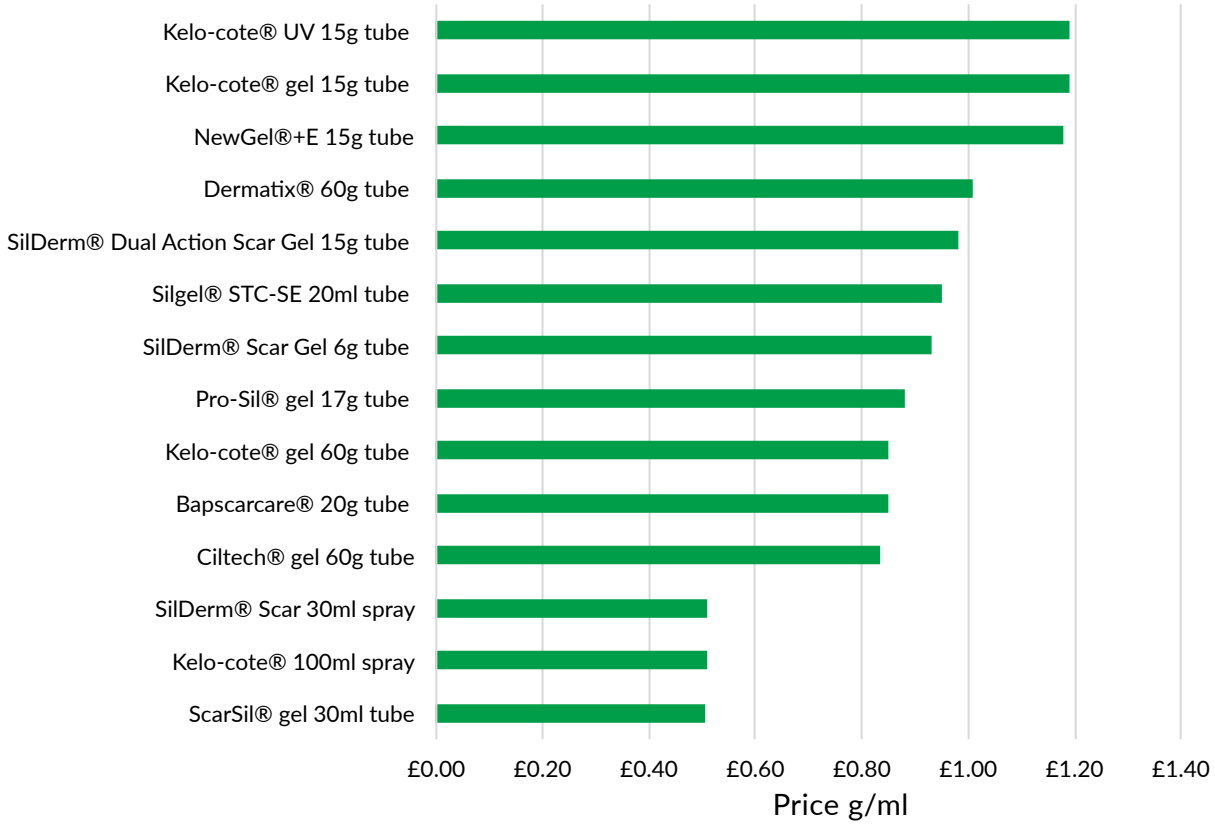


Figure 4: Cost of gel/spray products (£ per g/ml)[9]



Pricing varies considerably; from £3.15 (Bapscarcare® S 5cm by 7cm) up to £144.00 for the largest sheet (Silgel® 40cm by 40cm). Gels vary from £5.58 for a 6g tube of Silderm® scar gel up to £60.53 for a 60g tube of Dermatix®. The number of silicone sheets or volume of gel, depends on the extent and tenacity of the keloid scar.[8]

Self care

Prevention is better than cure for keloid scarring. Patients at risk (e.g. past keloid in patient or family member, or have dark skin) should avoid trauma such as tattoos or body piercing, particularly if these would go through one of the high-risk areas of skin, such as the ear lobes. Cosmetic surgery should be avoided. Acne sufferers should treat their acne vigorously to limit the risk of scarring.[2]
Patients who wish to try treatment with silicone therapies (but do not fall into the criteria for prescribing) should purchase these products.

If appropriate on local pathways, cosmetic camouflage may be considered. The Skin Camouflage Service can provide patients living with scarring, a way of regaining self-confidence and independence. (www.changingfaces.org.uk/skin-camouflage) The Service finds products that provide the best colour match for each patient and then teaches them how to apply the products effectively.

Savings

In England and Wales, £1.2 million is spent annually on silicone gels and sheets (ePACT August to October 2016). **A potential 40% reduction in prescribing through using appropriate and cost effective prescribing could result in savings of over £474,000. This equates to £775 per 100,000 patients.** Cost effective preparations based on cost/cm^2 are:

- 0-124cm^2: Advasil Conform® 10cm x 10cm Wound Dress Silicone Gel Sheet
- 125-299cm^2: Ciltech® 10cm x 20cm or 15cm x 15cm Wound Dress Silicone Gel Sheet
- >300cm^2: ScarFx®

If a gel or spray is required, ScarSil® Gel, Kelo-cote® spray and SiDerm® scar spray are the most cost effective choices based on cost/g.

Conclusion

Silicone sheets or gels might help to reduce the height or colour of scars but the supportive evidence is weak and limited by potential bias.[1,2] Use is not recommended, however CCGs may consider specific circumstances where they may be prescribed. If patients wish to use silicone gels or sheets, but do not fall into criteria for prescribing, they should be asked to self-manage and purchase these.

Reference

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Additional PrescQIPP resources

Briefing **Data pack**

Available at: https://www.prescqipp.info/resources/category/354-wound-care-silicone-scar-treatment

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Contact help@prescqipp.info with any queries or comments related to the content of this document.

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