

Shampoos and scalp preparations

This bulletin considers topical preparations for psoriasis of the scalp and also seborrhoeic dermatitis. Although these conditions share some features and treatments, they are distinct, and are therefore addressed separately in the bulletin. In England, Scotland and Wales, approximately £60.8 million is spent annually on the prescribing of shampoos and scalp preparations (although it is not possible to specify the proportion of this spend that relates to other indications) [NHSBSA (May-July22) and Public Health Scotland (Apr-Jun22)].

Medicines optimisation projects in this area focus on appropriate treatment choices, effective use of products, timely review and the promotion of self care where appropriate.

This bulletin should be read in conjunction with bulletin 307, Cost-effective prescribing in dermatology

Recommendations

Scalp psoriasis

- Offer a potent corticosteroid applied once daily for up to four weeks as initial treatment for people with scalp psoriasis.
- If this does not result in clearance, near clearance or satisfactory control of scalp psoriasis after four weeks consider:
 - » A different formulation of the potent corticosteroid (e.g. a shampoo or mousse) and/or
 - » Topical agents to remove adherent scale (e.g. agents containing salicylic acid, emollients and oils) before application of the potent corticosteroid.
- If the response remains unsatisfactory after a further four weeks of treatment offer:
 - » A combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily for up to four weeks or
 - » A vitamin D preparation applied once daily for up to eight weeks.*
 *Consider a topical vitamin D preparation alone only in people who are intolerant of, or cannot use topical corticosteroids at this site, or have mild to moderate scalp psoriasis. These products have a relatively lower efficacy rank, yet generally higher acquisition cost than products containing topical steroids alone. Calcipotriol scalp solution in particular is relatively expensive compared to other topical scalp treatments.
- Before changing to an alternative treatment (including escalating to a more potent corticosteroid), discuss with the person whether they have any difficulties in adhering to their treatment.
- If the treatment as above does not result in clearance, near clearance or satisfactory control of scalp psoriasis offer:
 - » A very potent corticosteroid applied up to twice daily for two weeks for adults only or
 - » A coal tar preparation applied once or twice daily or
 - » Referral to a specialist for additional support with topical applications and/or advice on other treatment options.
- If a single-component vitamin D preparation for the scalp is indicated: consider tacalcitol lotion, if suitable and acceptable for the patient, in preference to calcipotriol scalp solution which currently costs significantly more than tacalcitol lotion.

Recommendations

- Do not offer coal tar-based shampoos alone for the treatment of severe scalp psoriasis.
- Take into account patient preference, cosmetic acceptability, practical aspects of application at the site(s) and extent of psoriasis.
- Discuss the variety of formulations available and, depending on the person's preference, use lotion, solution or gel for the scalp or hair-bearing areas.
- Show people with scalp psoriasis (and their families or carers where appropriate) how to safely apply corticosteroid topical treatment.
- For adults, arrange a review four weeks after starting a new topical treatment.
- For children and young people with scalp psoriasis:
 - » Review new topical treatment **two weeks** after starting.
 - » Do not use **very potent** corticosteroids.
 - » Review those using corticosteroids of any potency at least annually.
- The licensed status, dosing and treatment duration of products used to treat scalp psoriasis can vary in children and young people compared with adults. Check in the product's prescribing information the suitability of the preparation and appropriate directions for use before they are recommended or prescribed.
- Use of combined calcipotriol monohydrate and betamethasone dipropionate in children is unlicensed and initiation should be restricted to secondary care.
- Children and young people with any type of psoriasis should be referred to a specialist at presentation.
- Be aware that paraffin and non-paraffin based skin products can be a fire hazard if they come into contact with clothing, bedding or dressings (see 'Safety' section).

Topical corticosteroids

- Use topical corticosteroids as courses rather than used continuously:
 - » Do not use very potent corticosteroids continuously at any site for longer than four weeks.
 - » Do not use **potent** corticosteroids continuously at any site for longer than **eight weeks**.
 - » Aim for a break of four weeks between courses of potent or very potent corticosteroids. Consider non-steroid topical treatments (e.g. vitamin D preparations or a coal tar preparation) to maintain disease control during this period.
- Practices should ensure that systems are in place to avoid and detect overuse of topical corticosteroids.
- Prescribe topical corticosteroids as acute prescriptions, or as a 'variable use' repeat where clinically
 appropriate (and where the practice's clinical system has this facility). If practices do use repeat
 templates for topical corticosteroids then ensure that treatment breaks are scheduled in.
- Review at least annually adults with psoriasis who are using intermittent or short-term courses of potent or very potent corticosteroids.
- Be vigilant for the signs and symptoms of topical corticosteroid withdrawal reactions. A severe form
 of withdrawal reaction has been identified involving a form of dermatitis with intense redness (or
 change in normal skin tone), stinging and burning that can spread beyond the initial treatment area.
- Advise patients to carry a steroid treatment card if receiving long term treatment (several weeks) with a potent or very potent topical corticosteroid.
- Consider the need for an NHS Steroid Emergency Card and issue if appropriate for the individual.
 Further information on both the NHS Steroid Emergency Card and on steroid treatment cards is
 available in a PrescQIPP Hot Topic Document on Implementing the NHS Steroid Emergency Card
 National Patient Safety Alert (NatPSA).

Recommendations

Seborrhoeic dermatitis in adults

- For scalp and beard areas ketoconazole 2% shampoo is recommended.
- Scales can be removed before shampooing by applying warm mineral oil (for mild crusting) or a
 keratolytic preparation (e.g. salicylic acid and coconut oil for thicker scale) for several hours before
 shampooing.
- Other medicated shampoos such as zinc pyrithione, coal tar, or salicylic acid can be used, if ketoconazole is not appropriate or acceptable to the person. Although widely used in seborrhoeic dermatitis there is little published evidence to support their efficacy.
- Encourage self care with over the counter (OTC) products for milder cases where ongoing medical review is not required.
- NHS England advise that treatments for dandruff are purchased rather than prescribed (guidance applies in England).

Psoriasis of the scalp

Background

Psoriasis is an immune-mediated, chronic, systemic inflammatory condition affecting the skin and other organ systems. It typically follows a relapsing and remitting course. The prevalence of psoriasis is estimated to be around 1.3–2.2% in the UK. It can occur at any age, although is uncommon in children and the majority of cases occur before 35 years. For most people, psoriasis is managed in primary care, with specialist referral being needed at some point for up to 60% of people.^{1,2}

Plaque psoriasis is the most common form of the condition, accounting for approximately 90% of cases.¹ The scalp is frequently affected, with scalp psoriasis occurring in 75–90% of people with psoriasis.² The extent varies from fine scaling to thick erythematous crusted plaques on the entire scalp, typically crossing the hair line and affecting a small area of the adjacent facial skin.³ Psoriasis can be itchy, making the scalp feel tight and occasionally causes soreness, especially if there are cracks in the skin. Hair loss during flare-ups can occur in some cases, but the hair will normally grow back.⁴

Psoriasis of the scalp requires special consideration due to its difficult-to-treat nature and disproportionate impact on quality of life.⁵ Hair makes the scalp less accessible to topical agents, and the proximity of the sensitive skin of the face increases the risk of local adverse effects of treatment.³ Furthermore, cosmetically unpleasant effects of topical treatments can negatively impact adherence and patients' satisfaction with treatment.⁵ It is recognised that some people with psoriasis experience major psychological distress, and the extent to which people can feel socially stigmatised and excluded can be substantial.⁶ Compared to sites of the body that can easily be covered by clothes, lesions of the scalp or face are difficult to hide. Together with pruritus, this has been shown to be one of the most distressing aspects of scalp psoriasis.³

National guidance

National Institute for Health and Clinical Excellence (NICE) guidance on the management of psoriasis¹ recommends the following topical treatment for the scalp:

- Offer a potent corticosteroid applied once daily for up to four weeks as initial treatment for people with scalp psoriasis.
- If treatment with a potent corticosteroid does not result in clearance, near clearance or satisfactory control of scalp psoriasis after four weeks consider:
 - » A different formulation of the potent corticosteroid (e.g. a shampoo or mousse) and/or
 - » Topical agents to remove adherent scale (for example, agents containing salicylic acid, emollients and oils) before application of the potent corticosteroid.

- If the response to treatment with a potent corticosteroid for scalp psoriasis remains unsatisfactory after a further four weeks of treatment offer:
 - » A combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily for up to four weeks, or
 - » Vitamin D or a vitamin D analogue applied once daily for up to eight weeks (only in those who cannot use steroids or with mild to moderate scalp psoriasis).
- If continuous treatment with either a combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily or vitamin D or a vitamin D analogue applied once daily does not result in clearance, near clearance or satisfactory control of scalp psoriasis offer:
 - » A very potent corticosteroid applied up to twice daily for two weeks for adults only or
 - » A coal tar preparation applied once or twice daily or
 - » Referral to a specialist for additional support with topical applications and/or advice on other treatment options.
- Consider topical vitamin D or a vitamin D analogue alone for the treatment of scalp psoriasis only in people who:
 - » Are intolerant of or cannot use topical corticosteroids at this site or
 - » Have mild to moderate scalp psoriasis.
- Do not offer coal tar-based shampoos alone for the treatment of severe scalp psoriasis.¹

Due to the risk of side-effects, topical steroids should be used as courses rather than used continuously.

- Do not use very potent corticosteroids continuously at any site for longer than four weeks.
- Do not use potent corticosteroids continuously at any site for longer than eight weeks.
- Aim for a break of four weeks between courses of treatment with potent or very potent
 corticosteroids. Consider topical treatments that are not steroid-based (such as vitamin D analogues
 or a coal tar preparation) as needed to maintain psoriasis disease control during this period.¹
- If it is not possible to achieve satisfactory control of the patient's psoriasis within these safety parameters then referral for specialist advice is indicated (see 'Referral' section on page 9).

Information about the potency of corticosteroids contained in different preparations can be found in table 1 on page 14, and in the <u>BNF</u>.

NICE introduced the option of descaling agents after four weeks of potent corticosteroid therapy if the response is inadequate.¹ For patients with thick scaling of the scalp it may be justifiable to incorporate a descaling agent in the treatment regimen from the outset. Although not specifically suggested by NICE, the experience of the guideline development group was that removing scale on the scalp before applying active treatment improved the efficacy of the active treatment.⁶ This approach is supported by the Primary Care Dermatology Society (PCDS) which recommends that thick scale is removed before commencing topical treatments.⁷

When offering topical agents:

- Take into account patient preference, cosmetic acceptability, practical aspects of the application and the site(s) and extent of psoriasis to be treated.¹
- Discuss the variety of formulations available and, depending on the person's preference, use lotion, solution, gel or foam for the scalp or hair-bearing areas.^{1,4}
- Show people with scalp psoriasis (and their families or carers where appropriate) how to safely apply corticosteroid topical treatment.¹

Advise people using potent or very potent steroids on the scalp to take care not to let the treatment run onto their face or behind their ears. The risk of steroid atrophy is greater in such areas where the skin is thinner.⁴

Healthcare professionals may need to prescribe different topical preparations for different sites, meaning that patients may have an assortment of products to use.⁶ The prescriber should ensure that the directions on the prescription state the area of the body that the product should be applied to. This information can then be included on the pharmacy label.

Children and young people

The treatment pathway for scalp psoriasis in children and young people has some important differences to the adult pathway, including:

- Earlier review of new topical treatments two weeks after starting the treatment.
- Avoidance of very potent corticosteroids, which should not be used in children and young people.
- Review at least annually children and young people with psoriasis who are using corticosteroids of any potency to assess for the presence of steroid atrophy and other adverse effects.
- The licensed status, dosing and treatment duration of products used to treat scalp psoriasis can
 vary in children and young people compared with adults. Suitability and appropriate directions for
 use must be checked in the product's prescribing information before they are recommended or
 prescribed.¹
- Children and young people with any type of psoriasis should be referred to a specialist at presentation.¹

See <u>Attachment 1. 307 Cost-effective prescribing in dermatology</u> – Psoriasis algorithm for treatment pathway flowcharts for adults and for children and young people with scalp psoriasis.

Clinical evidence and cost-effectiveness

NICE carried out a network meta-analysis of randomised controlled trials (RCTs) to investigate the clinical efficacy of topical psoriasis treatments. A separate cost-effectiveness analysis was undertaken to identify the most cost-effective sequence of topical therapies.⁶

The network meta-analysis found the following interventions to be more effective than twice daily vehicle/placebo at inducing clearance/near clearance:

- Once and twice daily very potent corticosteroids.
- Once and twice daily potent corticosteroids.
- Once and twice daily vitamin D or vitamin D analogue.
- Once daily combined product containing calcipotriol monohydrate and betamethasone dipropionate.

No statistically significant difference in clearance/near clearance was observed with a once daily coal tar polytherapy preparation (coal tar 5%/allantoin 2%/hydrocortisone cream 0.5%) compared with twice daily placebo.

Few comparisons between active treatments reached statistical significance for treatment effect. Exceptions include the following:

- Once daily potent corticosteroids are more effective than once daily vitamin D or vitamin D analogues.
- Once daily combined products containing calcipotriol monohydrate and betamethasone dipropionate
 are more effective than once daily vitamin D or vitamin D analogue and once daily coal tar
 polytherapy.
- Once and twice daily very potent corticosteroids are more effective than once and twice daily vitamin D or vitamin D analogues and once daily coal tar polytherapy.⁶

Economic analysis identified that the most cost-effective strategy is likely to be one of starting with once daily very potent corticosteroid. However, this was considered an overly aggressive initial strategy

which could carry greater risk of steroid-related adverse events. Once daily potent corticosteroids were recommended as a more appropriate initial treatment choice.⁶

If treatment with a potent corticosteroid (+/- descaling agent) does not give a satisfactory result the next treatment recommended is another product containing a potent corticosteroid in combination with calcipotriol monohydrate. This was considered to be a safer option than moving directly to a very potent corticosteroid.

Products containing vitamin D or vitamin D analogues alone have a relatively lower efficacy rank, yet generally have a higher acquisition cost than products containing topical steroids alone (see table 1). Strategies including them were not found to be cost-effective regardless of where the vitamin D or vitamin D analogue was included in the sequence. The NICE guideline limits their role to where the patient is intolerant of or cannot use topical corticosteroids on their scalp, or where the condition is mild to moderate.⁶

For people who have still not had a satisfactory response after treatment with a combined calcipotriol monohydrate and moderate corticosteroid product (or vitamin D or a vitamin D analogue), the next step is:

- Very potent corticosteroid applied up to twice daily for two weeks for adults only or
- A coal tar preparation applied once or twice daily or
- Referral to a specialist for additional support with topical applications and/or advice on other treatment options.

Coal tar preparations are positioned as a fourth-line treatment option. Coal tar compared less favourably to other topical treatments in terms of efficacy, being only slightly more effective that placebo/vehicle scalp solution. Modelling showed their use led to more patients failing treatment in primary care and being referred onward for specialist consultations and treatments, thus making the true costs to the NHS of treatment with coal tar shampoos much higher than the acquisition cost alone. To make it clear that coal tar alone is not an appropriate therapy for severe scalp psoriasis NICE made a 'do not do' recommendation to this effect. It may be a more appropriate option where something less aggressive than twice daily very potent corticosteroids is called for.⁶ Coal tar products have a strong and unpleasant odour and may stain clothing and bedding, which can affect their acceptability.⁴

Children and young people

NICE found that evidence for treating children with psoriasis at difficult-to-treat sites was generally lacking. It was agreed that the recommendations for adults could be extrapolated to children and young people for scalp psoriasis provided that healthcare professionals also consulted the relevant <u>Summary of Product Characteristics</u> (SPC) and <u>BNF</u> sections. The age at which potent corticosteroid preparations are licensed for use varies, and the duration of treatment specified in the NICE guidance may not be appropriate. It is therefore essential to **consult the product information for individual preparations.** Furthermore, a specialist should be involved in the care of all children and young people with psoriasis and their guidance on treatment should be followed.¹

NICE note that topical calcitriol and tacalcitol preparations available in the UK are not licensed for use in children. Furthermore, topical calcipotriol preparations available in the UK vary in their licensing status for use in children and young people under 18, so the <u>SPC</u> for individual topical calcipotriol preparations must be checked.¹ Where the use of scalp products containing calcipotriol might be considered in those under 18 years of age, the BNF for Children designates them as 'specialist use only'.8

Evidence update

Since the publication of CG153, new published evidence on this subject includes two Cochrane reviews, one on topical psoriasis treatments⁹ and the other specific to scalp topical treatments.³ In general the findings of these reviews support NICE's recommendations on managing scalp psoriasis.

One potential exception is the place in therapy of the compound combination of corticosteroid plus vitamin D analogue (calcipotriol/betamethasone). Both Cochrane reviews conclude that the compound combination is significantly superior to steroid monotherapy.^{3,9} However, the authors of the most recent review note that although the difference between these treatments is statistically significant, the additional benefit is small and not clinically important. They state that, given the similar safety profile and only slim benefit of the compound combination over the steroid alone, monotherapy with generic topical steroids may be fully acceptable for short-term therapy.³ NICE consider this to be consistent with CG153.¹⁰

Evidence relating to a new formulation containing calcipotriol and betamethasone dipropionate in an aerosol foam (Enstilar®) is also available. A double-blind, multicentre RCT (n=302 patients aged ≥ 18 years with greater than mild severity plaque psoriasis) with three treatment arms compared calcipotriol/betamethasone dipropionate aerosol foam, calcipotriol foam and betamethasone dipropionate foam once daily for four weeks. With regard to effects on scalp psoriasis at week four, a statistically significant difference in the percentage of patients achieving treatment success was observed favouring calcipotriol/betamethasone dipropionate foam compared with calcipotriol foam (53% vs. 35.6%, odds ratio (OR) 1.91, 95% confidence interval (CI) 1.09,3.35, p=0.021). This was not seen with betamethasone dipropionate foam (53% vs. 47.5%, OR 1.24, 95% CI 0.71,2.16, P=0.45).¹¹ As calcipotriol/betamethasone dipropionate aerosol foam was not significantly more effective than betamethasone dipropionate foam (a potent steroid, recommended as first line treatment for scalp psoriasis in CG153) then the evidence is unlikely to affect the NICE guideline.¹⁰

Calcipotriol/betamethasone dipropionate foam costs more than the equivalent gel preparation, although the cost difference is relatively small (see table 1).¹² It is therefore a rational choice for those that find it easier to use or more cosmetically acceptable, where this compound combination is indicated. The Scottish Medicines Consortium has accepted calcipotriol/betamethasone dipropionate foam for use within NHS Scotland.¹³

Adherence, patients education and practical support

Successful treatment of scalp psoriasis requires shared decision making between the healthcare professional and the patient to find the most acceptable and effective treatment to enable maximum adherence. The presence of hair not only affects the application and penetration of medications to affected areas, but also strongly influences treatment adherence. Patients commonly complain of the greasy effect of medications in this area, and difficulty removing products from their hair. 15

Lotions, solutions, gels and foams are more suitable for use on the scalp, although oily preparations can be useful in helping to remove adherent scale. Patient preference, cosmetic acceptability and practical aspects of application need to be taken into account when prescribing and reviewing topical treatment. Patients should be offered practical support and advice about the use and application of topical treatments.^{1,4}

Topical corticosteroids are often the treatment of choice in psoriasis, but concern regarding their use is highly prevalent among dermatology patients and can adversely affect treatment adherence. When educating people about the important safety precautions that apply to topical corticosteroid use, it may be reassuring to also discuss their general safety and efficacy when used appropriately. The information provided should support the person to use their treatment safely and confidently.

A number of organisations have produced resources that are freely available to support people in managing their psoriasis, including specific advice on scalp psoriasis. Resources include the following:

 The Psoriasis Association website includes information about the condition and its treatment (including a leaflet on topical corticosteroids), a helpline and forums for peer to peer support. https://www.psoriasis-association.org.uk/

- St John's Derm Academy offers videos and leaflet PDF downloads that have been produced
 jointly by the St John's Institute of Dermatology, Guy's & St Thomas' Hospital NHS Foundation
 Trust in collaboration with the British Association of Dermatologists. Resources include a video
 demonstrating techniques for treating scalp psoriasis. https://www.stjohnsdermacademy.com/patient-resources
- The Psoriasis and Psoriatic Arthritis Alliance (PAPAA) website includes information about scalp psoriasis https://www.papaa.org/learn-about-psoriasis-and-psoriatic-arthritis/further-resources/scalp-psoriasis/
- The NHS website has a section on psoriasis https://www.nhs.uk/conditions/psoriasis/
- The British Association of Dermatologists (BAD) website includes several patient information leaflets on psoriasis https://www.bad.org.uk/patient-information-leaflets
- Patient information on psoriasis is available on the Patient website at https://patient.info/skinconditions/psoriasis-leaflet

Practical tips

- Products need to be in contact with the scalp. People with long hair may find it helps to part the hair and apply treatment to the exposed area of scalp.¹⁷
- Having another person to help can make treating the scalp easier.¹⁷
- Wash hands thoroughly before and after applying treatment.¹⁷
- If thick scales are present on the scalp it can be helpful to soften them and then try to gently remove them using the steps described below before using other therapies (e.g. topical corticosteroids).¹⁷
 - » Apply emollient ointments or an oil. Simple emollient oil such as olive oil or coconut oil can be used. Note that arachis oil (ground nut oil, peanut oil) is best avoided in children under five years.⁸
 - » Leave the ointment/oil in the hair for an hour or longer (some people use them overnight under a shower cap) before washing them out with shampoo.¹⁷
 - While the scalp is still damp the scales should be softened and looser, making them easier to remove by hand. The patient (or a helper) should place a plastic, fine-toothed comb flat against the scalp and gently rotate it in a circular motion to loosen the scale carefully, and then try to comb it out of the hair.
 - » The scales should not be removed too fiercely.
 - » The hair should then be shampooed again to remove debris.⁴
- Descaling ointments with active ingredients such as salicylic acid and coal tar are also available.
 They may be used in a similar way to the description above, and should be left on the scalp for the time stated in the specific product information (e.g. one hour for Cocois ointment® and Sebco® ointment).¹⁸
 - » If scale is thick and adherent the person can be advised to leave it on overnight under occlusion (for example using a shower cap); it can then be washed off in the morning with a detergent shampoo or a coal tar shampoo. Note: this method of application is off-label.² An old towel or pillowcase can be used to protect bedding.⁷
- Paraffin and non-paraffin based skin products can be a fire hazard if they come into contact with clothing, bedding or dressings (see 'Safety' section).¹⁹

Review

For adults, NICE recommend a review appointment four weeks after starting a new topical treatment. Children should be reviewed sooner, two weeks after starting a new treatment. The purpose of the review is to:

- Evaluate tolerability, toxicity, and initial response to treatment.
- Reinforce the importance of adherence when appropriate.
- Reinforce the importance of a four week break between courses of potent/very potent corticosteroids.

The next steps in treatment can also be discussed, including further treatment options if there is little or no improvement. Before changing to an alternative treatment discuss with the person whether they have any difficulties in adhering to their treatment, which could include problems with application, cosmetic acceptability or tolerability. Where relevant, offer an alternative formulation.¹

Where the patient's psoriasis is responding to treatment the discussion should include:

- The importance of continuing treatment until a satisfactory outcome is achieved (for example clear or nearly clear) or up to the recommended maximum treatment period for corticosteroids.
- That relapse occurs in most people after treatment is stopped.
- That after the initial treatment period topical treatments can be used when needed to maintain satisfactory disease control.¹

Risk factors for cardiovascular comorbidities should be discussed with people who have any type of psoriasis, as they may be at increased risk of cardiovascular disease. Adults with severe psoriasis of any type should be offered a cardiovascular risk assessment at presentation, with reassessment at least every five years.¹ Patient information about psoriasis and the heart from is available from the Psoriasis and Psoriatic Arthritis Alliance at https://www.papaa.org/learn-about-psoriasis-and-psoriatic-arthritis/further-resources/psoriasis-and-the-heart/.

Adults with psoriasis who are using intermittent or short-term courses of potent or very potent corticosteroids should be reviewed at least annually. The review should include assessment for steroid atrophy and other adverse effects. For children, this review should take place if they are using corticosteroids of any potency.¹

Topical corticosteroids should be prescribed as acute prescriptions, or as variable repeats where clinically appropriate (and where the practice's clinical system has this facility).

Referral

- For psoriasis in general, NICE advise referral for dermatology specialist advice if any of the following apply:¹
 - » There is diagnostic uncertainty.
 - » Any type of psoriasis is severe or extensive, for example more than 10% of the body surface area is affected.
 - » Psoriasis cannot be controlled with topical therapy.
 - » Acute guttate psoriasis requires phototherapy.
 - » Nail disease has a major functional or cosmetic impact.
 - » The condition is having a major impact on a person's physical, psychological or social wellbeing.
- People with generalised pustular psoriasis or erythroderma should be referred immediately for sameday specialist assessment and treatment.¹
- Refer children and young people with any type of psoriasis to a specialist at presentation.¹
- Advise people to seek urgent medical advice if they experience unexplained joint pain or swelling.² If
 psoriatic arthritis is suspected refer the person to a rheumatologist.¹

Safety

When used correctly, topical corticosteroids rarely cause serious adverse effects. The likelihood of side effects is related to age, duration of treatment, site of use, extent of the area of skin being treated, potency of the topical corticosteroid and use of occlusion. Local adverse effects are more common and include:

- Acne vulgaris
- Folliculitis
- Skin atrophy (thinning)
- Telangiectasia
- Transient burning or stinging
- Permanent striae (stretch marks)
- Allergic contact dermatitis
- Exacerbation of rosacea, perioral dermatitis, or tinea infections
- Skin depigmentation usually reversible
- Excessive hair growth at the site of application (hypertrichosis)
- Vasodilation²⁰

Systemic adverse effects are rare²⁰ and are more likely when potent or very potent topical corticosteroids are applied continuously and extensively (for example to more than 10% of body surface area) or under occlusion.^{1,20} They include adrenal suppression, Cushing's syndrome, visual disturbances and growth retardation in children. The Clinical Knowledge Summary (CKS) on topical corticosteroids recommends monitoring the height of children who are using large amounts of topical corticosteroid. Consider referral to an ophthalmologist for people presenting with visual symptoms, which could possibly be caused by cataracts, glaucoma, or rare diseases such as central serous chorioretinopathy.²⁰

Continuous use of potent or very potent corticosteroids could cause psoriasis to become unstable. There is also concern about potential risks of rapid relapse or rebound on treatment cessation.⁶ Systemic or very potent topical corticosteroids are generally avoided or given only under specialist supervision in psoriasis because of these concerns.¹⁸

The Medicines and Healthcare Products Regulatory Agency (MHRA) have issued new advice regarding the potential for withdrawal reactions with topical corticosteroids. In addition to recognising the potential for rebound flares after stopping long term continuous or inappropriate topical corticosteroids, a severe form of withdrawal reaction has also been identified. It involves a form of dermatitis with intense redness (or a spectrum of colour changes or change in normal skin tone), stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated.²¹ Healthcare professionals should be vigilant for the signs and symptoms of topical corticosteroid withdrawal reactions and review the <u>position statement</u> from the National Eczema Society and British Association of Dermatologists.¹⁸

Patients should be advised to carry a steroid treatment card if they are receiving long term treatment (several weeks) with a potent or very potent topical corticosteroid.²⁰

In accordance with a National Patient Safety Alert issued by NHS England and NHS Improvement's national patient safety team, the need for an NHS Steroid Emergency Card should also be considered.²² They should be issued to all patients with adrenal insufficiency or steroid dependence as they are at risk of an adrenal crisis during intercurrent illnesses or an invasive procedure/surgery if not managed appropriately. This is relevant to some people receiving topical corticosteroids for psoriasis, depending on a number of factors including potency of corticosteroid, quantity used and length of treatment. Further information is available in a PrescQIPP Hot Topic Document on Implementing the NHS Steroid Emergency Card National Patient Safety Alert (NatPSA).

Topical vitamin D or vitamin D analogues can cause local adverse effects including skin burning, dermatitis, erythema, itching, local skin reactions, and paraesthesia. Local adverse effects often reduce with time, but people should be advised to stop treatment if there is significant skin irritation.² Tacalcitol and calcitriol may be less irritating than calcipotriol.¹⁸ Systemic adverse effects are rare and have generally been reported in people using excessive amounts, in people who have kidney disease or impaired calcium metabolism, and in people with generalised pustular or erythrodermic psoriasis. Photosensitivity has also been reported.²

In terms of tolerability, a Cochrane review of topical treatments for scalp psoriasis found corticosteroids and compound combinations (corticosteroid plus vitamin D analogue) caused fewer withdrawals due to adverse events than vitamin D or vitamin D analogues used alone. The most common side effects of scalp treatments were irritation, itching and skin pain at the site of application.³

Warn people who use oil-based topical products (e.g. ointments, creams, lotions) to keep away from fire or other naked flames (e.g. candles, cigarettes). If oil-based products come into contact with dressings, clothing and bedding, the fabric can be easily ignited.²⁰ Regulatory bodies have highlighted the danger of fire and serious injury for patients using paraffin-based and non-paraffin based emollients on their skin.¹⁹ Emollients are of particular concern as they tend to be used in larger quantities and applied frequently. Emollients are often part of psoriasis treatment regimens and patients should be advised how to use them (and other oil-based topical treatments) safely. See PrescQIPP Bulletin 228: Emollients, paraffin content and fire risk for further information.

Note that some scalp preparations contain flammable alcohol and therefore carry warnings that people should keep their body away from fire or flames after applying the product.¹⁸ Other sources of heat such as hair dryers should also be avoided after application.²³

Seborrhoeic dermatitis (including cradle cap and dandruff)

Background

Seborrhoeic dermatitis is a common inflammatory skin condition occurring in areas rich in sebaceous glands (such as the scalp, nasolabial folds, eyebrows, and chest). It is characterised by relatively well defined patches of erythema associated with flaking of the skin. In darker skin affected areas may appear hypo or hyperpigmented compared to surrounding skin. Mild itching can occur, particularly where the scalp is affected.²⁴ The scaling in seborrhoeic dermatitis is more diffuse and less well-defined than the thicker, silvery white, sharply demarked plaques usually associated with psoriasis.² In adults seborrhoeic dermatitis is a chronic condition that tends to flare and remit spontaneously, and often recurs after treatment.²⁵

In infants seborrhoeic dermatitis can affect the skin folds, nappy area and scalp.²⁵ The scalp is most commonly affected area (sometimes referred to as 'cradle cap'). It typically presents as erythematous patches with scale which may be white or yellow, oily or dry. It usually resolves spontaneously by four months of age, although it can persist for 8-12 months or longer.²⁴

The cause of seborrhoeic dermatitis is not fully understood and appears to be multifactorial. Malassezia yeasts are thought to have an important role in the inflammatory reaction.²⁵

Dandruff is an uninflamed form of seborrhoeic dermatitis.²⁴

Management

Infantile seborrhoeic dermatitis of the scalp (cradle cap)

Treatments for cradle cap are included in guidance from NHS England on the prescribing of medicines that are available to purchase OTC. It states that cradle cap is harmless and doesn't usually itch or cause discomfort. It usually appears in babies in the first two months of their lives, and clears up without treatment within weeks to a few months. Prescriptions for treatment of cradle cap should not routinely

be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment. The exception to this is if the condition is causing distress to the infant and is not improving.²⁶

Where treatment is indicated, CKS recommend the following:

- Advise the parent/carer to massage a topical emollient onto the scalp to loosen scales, brush gently with a soft brush and wash off with mild shampoo.
- If this is not effective consider prescribing a topical imidazole cream (clotrimazole 1% or miconazole 2%).
- If symptoms persist longer than four weeks with treatment, seek specialist advice.
- Referral should also be considered where seborrhoeic dermatitis is severe or widespread (due to the risk of underlying immunodeficiency), or where there is diagnostic uncertainty.²⁴

For choice of emollient to massage into the scalp the BNF suggests coconut oil, olive oil or a bland emollient such as emulsifying ointment.⁸ Note that some experts no longer recommend olive oil due to concerns about damage to the skin barrier²⁷ and possible promotion of Malassezia yeast growth.²⁸

A factsheet for parents/carers is available from the National Eczema Society at https://eczema.org/wp-content/uploads/Seborrhoeic-dermatitis-and-cradle-cap-in-infants-Sep-19-1.pdf

Adults

Seborrhoeic dermatitis is generally managed with treatment that reduces the level of skin yeast. Topical corticosteroids can be used for short periods if irritation is a problem.²⁹ People should also be advised to stop using soap and shaving cream on the face if they cause irritation. Non-greasy emollient soap substitutes should be used.²⁴ Lots of 'leave-on' emollients are suitable for use as a soap substitute - see PrescQIPP Bulletin 244 Prescribing of bath and shower preparations for dry and pruritic skin conditions for further information.

For the scalp and beard areas ketoconazole 2% shampoo is widely recommended in various resources²⁴ including in clinical guidance on seborrhoeic dermatitis from the PCDS.³⁰ It has been demonstrated to improve seborrhoeic dermatitis symptoms compared with placebo.^{25,31} Selenium sulphide shampoo is listed as a treatment option but this has now been discontinued by the UK manufacturer for commercial reasons.^{24,32}

Scales can be removed before shampooing by applying warm mineral oil (for mild crusting) or a keratolytic preparation (for example salicylic acid and coconut oil for thicker scale) for several hours before shampooing.²⁴

Other medicated shampoos such as zinc pyrithione, coal tar,^{24,25} or salicylic acid can be used,²⁴ if ketoconazole is not appropriate or acceptable to the person. Although widely used in seborrhoeic dermatitis there is little published evidence to support their efficacy.^{24,25}

Evidence supports the short-term use of topical corticosteroids where needed. They have been shown to be effective compared with placebo in achieving clearance in seborrhoeic dermatitis of the face or scalp.³³ If the person has severe itching of the scalp:

- Consider co-prescribing a short course (maximum four weeks of treatment) of a topical corticosteroid scalp application.²⁴
- Products such as such as betamethasone valerate 0.1% or mometasone furoate 0.1% once a day can be used, but note that these are potent corticosteroids and therefore they are **not** suitable for use on the face/beard.²⁴
- Topical corticosteroids should be issued on an acute prescription with clear instructions on safe and effective use, as discussed above.

Once a diagnosis of seborrhoeic dermatitis has been established many people will be able to manage the condition without routine follow up. With the exception of topical corticosteroids, most treatments can be purchased over the counter (OTC) for self care with advice from a pharmacist when needed. The PrescQIPP Over the counter items - GP guide to self care provides examples of OTC preparations available. People should see their doctor for review if treatment response is poor, if symptoms worsen or if there are signs of infection.²⁴

Dandruff is an uninflamed form of seborrhoeic dermatitis²⁴ characterised by mild scaling of the scalp without itching.²⁶ NHS England have published guidance advising that medicines available to buy OTC should not be prescribed for certain conditions, including dandruff. Patients should be encouraged to manage mild dandruff with long term OTC treatments. There are some general exceptions including where there is greater clinical complexity, or where the person's ability to self care is significantly compromised, the details of which can be found in the <u>full guidance document</u>.²⁶ This guidance does not apply in Wales, where similar proposals have been rejected.³⁴

Patient information on seborrhoeic dermatitis, dandruff and cradle cap is available from:

- The British Association of Dermatologists <u>Seborrhoeic dermatitis</u>
- The National Eczema Association Seborrhoeic dermatitis
- The NHS website https://www.nhs.uk/conditions/cradle-cap/
- Patient website https://patient.info/skin-conditions/seborrhoeic-dermatitis-leaflet, https://patient.info/skin-conditions/seborrhoeic-dermatitis-leaflet, https://patient.info/skin-conditions/seborrhoeic-dermatitis-leaflet, https://patient.info/skin-conditions/seborrhoeic-dermatitis-leaflet, https://patient.info/skin-conditions/seborrhoeic-dermatitis-leaflet, <a href="https://patient.info/skin-conditions/seborrhoeic-dermatitis-leaflet/seborrhoeic-dermatitis-dermatitis-dermatitis-de

Information about managing seborrhoeic dermatitis affecting areas other than the scalp (in infants and adults) is available at https://cks.nice.org.uk/topics/seborrhoeic-dermatitis/

Resources to promote and support self care for a range of conditions, including cradle cap and dandruff, are available in the self care section of the PrescQIPP website at https://www.prescqipp.info/our-resources/webkits/self-care/

Costs

Table 1 provides information about shampoo and scalp preparations for psoriasis of the scalp and seborrhoeic dermatitis. It includes information about which of these indications each product is licensed for, the age groups they are licensed for, whether they are available OTC, as well as the cost.

Table 1. Shampoo and scalp preparations for psoriasis of the scalp and seborrhoeic dermatitis

Information included is from the relevant <u>Summary of Product Characteristics (SPC)</u> unless otherwise indicated. It is important to check the SPC when prescribing for children as even where a product is licensed there may be additional precautions, such as a shorter recommended duration of use than for adults.

The price per ml/g quoted for OTC products is based on NHS list price (not retail price).

Products are listed in order of ascending price within each product category.

For products available OTC see also PrescQIPP Over the counter items - GP guide to self care.

	Active ingredient(s) and strength	Indications (see SPC)					
Brand name		Scalp psoriasis	Seborrhoeic dermatitis	Available OTC? ¹⁸	Licensed for children? (see SPC) ⁸	Price per largest available original pack ³⁵ (unless otherwise stated)	Price per ml/g
			Potent corticost	eroids		,	
Betacap® Scalp Application ³⁶	Betamethasone 0.1% (as valerate)	✓	✓	No	≥1 year	£3.75 for 100ml	£0.04
Betnovate® Scalp Application ²³	Betamethasone 0.122% (as valerate)	✓	✓	No	≥1 year	£4.99 for 100ml	£0.05
Locoid® Scalp Lotion ³⁷	Hydrocortisone butyrate 0.1%	✓	Inflammatory skin disorders not caused by micro- organisms, e.g. dermatitis	No	>3 months	£6.83 for 100ml	£0.07
Diprosone® Lotion ³⁸	Betamethasone 0.05% (as dipropionate)	✓	Dermatitis of all types affecting the scalp	No	Licensed for use in children, but no age range specified	£7.80 for 100ml	£0.08
Diprosalic® Scalp Application ³⁹	Betamethasone 0.05% (as dipropionate) Salicylic acid 2%	✓	Inflammatory dermatoses that are normally responsive to topical corticosteroid	No	Licensed for use in children, but no age range specified.	£10.10 for 100ml	£0.10
Bettamousse® cutaneous foam ⁴⁰	Betamethasone 0.1% (as valerate)	√	Steroid responsive dermatoses of the scalp	No	>6 years	£10.50 for 100g	£0.10

		Indications (see SPC)					
Brand name	Active ingredient(s) and strength	Scalp psoriasis	Seborrhoeic dermatitis	Available OTC? ¹⁸	Licensed for children? (see SPC) ⁸	Price per largest available original pack ³⁵ (unless otherwise stated)	Price per ml/g
Elocon® Scalp Lotion ⁴¹	Mometasone furoate 0.1%	✓	✓	No	>2 years	£4.36 for 30ml	£0.15
Synalar® Gel ⁴²	Fluocinolone acetonide 0.025%	✓	✓	No	>1 year	£10.02 for 60g	£0.17
			Very potent cortico	steroids			
Etrivex® Shampoo ⁴³	Clobetasol propionate 0.05%	✓	No	No	Not recommended <18 years Contraindicated <2 years	£9.15 for 125ml	£0.07
Dermovate® Scalp Application ⁴⁴	Clobetasol propionate 0.05%	✓	Steroid responsive dermatoses of the scalp, such as recalcitrant dermatoses	No	>1 year	£10.42 for 100ml	£0.10
			Vitamin D analo	gue			
Curatoderm® 4 micrograms/g Lotion ⁴⁵	Tacalcitol 4 micrograms/g	√	No	No	Not recommended <18 years See BNF for Children for information about unlicensed use in some age groups	£12.73 for 30ml	£0.42
Calcipotriol 50micrograms/ml scalp solution (generic) ⁴⁶	Calcipotriol 50micrograms/ml	√	No	No	Not recommended <18 years See BNF for Children for information about unlicensed use in 6 -17 years (specialist use only)	£148.59 for 120ml ¹²	£1.24
Vitamin D analogue & potent corticosteroid							
Calcipotriol/ Betamethasone 50 micrograms/g + 0.5	Calcipotriol (as monohydrate) 50 micrograms/g	√	No	No	Safety and efficacy in <18 years not established See BNF for Children for	£32.62 for 60g ¹²	£0.54
milligrams/g gel (generic) ⁴⁷	Betamethasone (as dipropionate) 0.5 mg/g				information about unlicensed use in 12 -17 years (specialist use only)	J	

	Active ingredient(s) and strength	Indications (see SPC)					
Brand name		Scalp psoriasis	Seborrhoeic dermatitis	Available OTC? ¹⁸	Licensed for children? (see SPC) ⁸	Price per largest available original pack ³⁵ (unless otherwise stated)	Price per ml/g
Dovobet® gel ⁴⁸	Betamethasone (as dipropionate) 0.5 milligram/g Calcipotriol (as monohydrate) 50 micrograms/g	✓	No	No	Safety and efficacy in <18 years not established See BNF for Children for information about unlicensed use in 12 -17 years (specialist use only)	£69.11 for 120g	£0.58
Enstilar® Cutaneous Foam ⁴⁹	Betamethasone (as dipropionate) 0.5 milligrams/g Calcipotriol (as monohydrate) 50 micrograms/g	√	No	No	Safety and efficacy in <18 years not established See BNF for Children for information about unlicensed use in 12 -17 years (specialist use only)	£79.36 for 120g	£0.66
	<u> </u>		Coal tar		,,		
Capasal® Therapeutic Shampoo ⁵⁰	Distilled coal tar 1% Salicylic acid 0.5% Coconut oil 1%	√	√	Yes	No age range specified	£4.69 for 250ml	£0.02
Psoriderm® Scalp Lotion shampoo ⁵¹	Distilled coal tar 2.5%	✓	No	Yes	No age range specified	£4.74 for 250ml	£0.02
Polytar® Scalp Shampoo ⁵²	Coal tar solution 4%	✓	✓	Yes	Not recommended <12 years	£3.46 for 150ml	£0.02
Alphosyl® '2 in 1' Shampoo ⁵³	Alcoholic extract of coal tar 5%	✓	✓	Yes	Use with caution under 12 years - see SPC	£6.46 for 250ml	£0.03
Neutrogena® T/Gel Therapeutic Shampoo ⁵⁴	Solubilised coal tar extract 20mg/ml (equivalent to 5mg/ ml coal tar)	√	✓	Yes	Not recommended <12 years	£6.61 for 250ml	£0.03

	Active ingredient(s) and strength	Indications (see SPC)					
Brand name		Scalp psoriasis	Seborrhoeic dermatitis	Available OTC? ¹⁸	Licensed for children? (see SPC) ⁸	Price per largest available original pack ³⁵ (unless otherwise stated)	Price per ml/g
Exorex® Lotion ⁵⁵	Coal tar solution 5%	√	No	Yes	Instructions for use differ for those over 12 years and under 12 years old – see SPC	£16.24 for 250ml	£0.06
Cocois® ointment ⁵⁶	Coal tar solution 12% Precipitated sulphur 4% Salicylic acid 2%	✓	✓	Yes	Not recommended <6 years Under medical supervision only for 6 years – 12 years	£11.69 for 100g	£0.12
Sebco® ointment ⁵⁷	Coal tar solution 12% Sulfur 4% Salicylic acid 2%	✓	✓	Yes	Not recommended <6 years Under medical supervision only for 6 years – 12 years	£14.88 for 100g	£0.15
			Antifungal/antis	eptic			
Dermax® Therapeutic Shampoo ⁵⁸	Benzalkonium chloride 0.5%	No	Licensed for seborrhoeic scalp conditions, where there is scaling and dandruff	Yes	No lower age range specified	£5.69 for 250ml	£0.02
Nizoral® 2% Shampoo ⁵⁹	Ketoconazole 2%	No	✓	No	>12 years	£3.59 for 120ml	£0.03
Dandrazol® 2% Shampoo ⁶⁰	Ketoconazole 2%	No	√	No	>12 years	£5.20 for 120ml	£0.04
Ketoconazole 2% Shampoo (generic) ⁶¹	Ketoconazole 2%	No	✓	No	>12 years	£6.93 for 120ml ¹²	£0.06

		Indications (see SPC)					
Brand name	Active ingredient(s) and strength	Scalp psoriasis	Seborrhoeic dermatitis	Available OTC? ¹⁸	Licensed for children? (see SPC) ⁸	Price per largest available original pack ³⁵ (unless otherwise stated)	Price per ml/g
Dandrazol® Anti- Dandruff Shampoo ⁶²	Ketoconazole 2%	No	OTC licence is only for prevention and treatment of dandruff	Yes	>12 years	£6.19 for 100ml	£0.06
Nizoral® Dandruff Shampoo ⁶³	ketoconazole 2%	No	✓	Yes	>12 years ⁶⁴	£6.28 for 100ml	£0.06
Nizoral® Antidandruff Shampoo ⁶⁵	ketoconazole 2%	No	✓	Yes	>12 years ⁶⁶	£4.08 for 60ml	£0.07

Prescribing review and potential savings

In England, Scotland and Wales, approximately £60.8million is spent annually on the prescribing of shampoo and scalp products (it is not possible to specify the spend that relates to other indications) [NHSBSA (May-Jun22) and Public Health Scotland (Apr-Jun22)].

Products containing topical corticosteroids should be used for a limited period of time. Ensure that systems are in place to avoid overprescribing of these products and appropriate review. This may not always lead to cost savings, as alternative treatments may have a similar or greater cost. However it is important from a quality and risk perspective.

Ensure that combined products containing calcipotriol monohydrate and betamethasone dipropionate are prescribed appropriately. They are a third line treatment option that should be used as a four week course. They are relatively expensive compared to the first and second line treatment options.

Deprescribing in 30% of clinically appropriate patients could **release savings of £10.1 million in England**, £564,280 in Wales and £1.5 million in Scotland [NHSBSA (May-July22) and Public Health Scotland (Apr-Jun22)]. This equates to £17,178 per 100,000 population.

Calcipotriol scalp solution is expensive relative to other topical treatments for scalp psoriasis. Where a single-component vitamin D analogue scalp preparation is indicated, consider if tacalcitol lotion (which is 2.9 times cheaper) is suitable. An 80% shift in prescribing from calcipotriol scalp solution to tacalcitol lotion represents savings in the order of £3 million in England, £136,269 in Wales and £408,239 in Scotland [NHSBSA (May-July22) and Public Health Scotland (Apr-Jun22)]. This equates to £5,038 per 100,000 population.

Approximately £10.2 million is spent annually across England, Wales and Scotland on therapeutic shampoos for seborrhoeic dermatitis containing coal tar, ketoconazole and benzalkonium chloride (although it is not possible to specify the proportion of this spend that relates to other indications). Deprescribing in 20% of clinically appropriate patients (i.e. where OTC self care is suitable) could release savings of £2 million in England, Wales and Scotland [NHSBSA (May-July22) and Public Health Scotland (Apr-Jun22)]. This equates to £2,876 per 100,000 population.

Summary

- Scalp psoriasis can be difficult to treat and distressing for the patient. Corticosteroids are the
 mainstay of topical treatment but for safety reasons their use must be intermittent. Non-steroid
 alternatives are therefore important for people that don't achieve clearance after a course of
 topical corticosteroid. Appropriate review and patient education are essential to safe and successful
 treatment.
- Seborrhoeic dermatitis is another condition that affects the scalp. Many of the available treatments
 are available OTC, which can be a good option for those able to manage the condition without
 routine follow up. Dandruff is an uninflamed form of seborrhoeic dermatitis characterised by
 mild scaling of the scalp without itching, that should generally be managed as self care with OTC
 treatments when appropriate.

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Additional PrescQIPP resources

Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-312-sham-		
Implementation tools	poos-and-scalp-preparations/		
Data pack	https://data.prescqipp.info/?pdata.u/#/views/B312_Shampoosandscalppreparations/FrontPage?:iid=1		

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