



# Psoriasis: assessment and management

Clinical guideline

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# Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

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This guideline is the basis of QS40.

# Overview

This guideline covers assessing and managing psoriasis in adults, young people and children. It aims to improve long-term disease control and quality of life for people with psoriasis.

#### Who is it for?

- Healthcare professionals
- · Commissioners and providers
- Children and adults with a diagnosis of psoriasis, and their families and carers

### Introduction

Psoriasis is an inflammatory skin disease that typically follows a relapsing and remitting course. The prevalence of psoriasis is estimated to be around 1.3% to 2.2% in the UK. Psoriasis can occur at any age, although is uncommon in children (0.71%) and most cases occur before 35 years. Psoriasis is associated with joint disease in a significant proportion of patients (reported in 1 study at 13.8%).

Plaque psoriasis is characterised by well-delineated red, scaly plaques that vary in extent from a few patches to generalised involvement. It is by far the most common form of the condition (about 90% of people with psoriasis). Other types of psoriasis include guttate psoriasis and pustular (localised or generalised) forms. Distinctive nail changes occur in around 50% of all those affected and are more common in people with psoriatic arthritis.

Healthcare professionals and patients using the term psoriasis are usually referring to plaque psoriasis, and unless stipulated otherwise, 'psoriasis' is used in this way in the guideline. The phrase 'difficult-to-treat sites' encompasses the face, flexures, genitalia, scalp, palms and soles and are so-called because psoriasis at these sites may have especially high impact, may result in functional impairment, requires particular care when prescribing topical therapy and can be resistant to treatment.

Psoriasis for many people results in profound functional, psychological, and social morbidity, with consequent reduced levels of employment and income. Factors that contribute to this include symptoms related to the skin (for example, chronic itch, bleeding, scaling and nail involvement), problems related to treatments, psoriatic arthritis, and the effect of living with a highly visible, stigmatising skin disease. Even people with minimal involvement state that psoriasis has a major effect on their life. Several studies have also reported that people with psoriasis, particularly those with severe disease, may be at increased risk of cardiovascular disease, lymphoma and non-melanoma skin cancer.

A wide variety of treatment options are available. Some are expensive and some are accessed only in specialist care; all require monitoring. The treatment pathway in this guideline begins with active topical therapies. The guideline development group (GDG) acknowledged that the use of emollients in psoriasis was already widespread and hence the evidence review was limited to active topical therapies for psoriasis. See the <u>BNF</u> and <u>BNF for children</u> for guidance on use of emollients.

In this guideline, first-line therapy describes traditional topical therapies (such as corticosteroids, vitamin D and vitamin D analogues, dithranol and tar preparations). Second-line therapy includes the phototherapies (broad- or narrowband ultraviolet B light and psoralen plus UVA light [PUVA]) and systemic non-biological agents such as ciclosporin, methotrexate and acitretin. Third-line therapy refers to systemic biological therapies such as the tumour necrosis factor antagonists adalimumab, etanercept and infliximab, and the monoclonal antibody ustekinumab that targets interleukin-12 (IL-12) and IL-23. NICE has published technology appraisals on the use of biological drugs, and this guideline incorporates recommendations from these appraisals where relevant (listed in alphabetical order). Biologic treatment is complicated by a poor response in a minority of people, and this guideline reviewed the literature for the use of a second biological drug.

For most people, psoriasis is managed in primary care, with specialist referral being needed at some point for up to 60% of people. Supra-specialist (level 4) tertiary care is required in the very small minority with especially complex, treatment resistant and/or rare manifestations of psoriasis. Level 4 care is defined as usually taking place entirely within an acute hospital and is carried out by consultant dermatologists and a range of other healthcare professionals with specialist skills in managing complex and/or rare skin disorders – see Quality Standards for Dermatology: providing the right care for people with skin conditions.

A recent UK audit in the adult population demonstrated wide variations in practice, and in particular, access to specialist treatments (including biological therapy), appropriate drug monitoring, specialist nurse support and psychological services (<u>Eedy et al. 2009</u>).

This guideline covers people of all ages and aims to provide clear recommendations on the management of all types of psoriasis. The term 'people' is used to encompass all ages. 'Children' refers to those up to 12 years, who become 'young people' thereafter, before merging with the adult population by 18 years of age. The GDG have focused on areas most likely to improve the management and delivery of care for most people affected, where practice is very varied and/or where clear consensus or guidelines on treatments are lacking. It is hoped that this guideline will facilitate the delivery of high-quality healthcare and improved outcomes for people with psoriasis.

# Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

# Assessment tools for disease severity and impact and when to refer for specialist care

- For people with any type of psoriasis assess:
  - disease severity
  - the impact of disease on physical, psychological and social wellbeing
  - whether they have psoriatic arthritis
  - the presence of comorbidities.
- Following assessment in a non-specialist setting, refer people for dermatology specialist advice if:
  - there is diagnostic uncertainty or
  - any type of psoriasis is severe or extensive, for example, more than 10% of the body surface area is affected or
  - any type of psoriasis cannot be controlled with topical therapy or
  - acute guttate psoriasis requires phototherapy (see recommendation 1.4.1.1) or
  - nail disease has a major functional or cosmetic impact or
  - any type of psoriasis is having a major impact on a person's physical, psychological or social wellbeing.

### Assessment and referral for psoriatic arthritis

 As soon as psoriatic arthritis is suspected, refer the person to a rheumatologist for assessment and advice about planning their care.

#### Identification of comorbidities

- Discuss risk factors for cardiovascular comorbidities with people who have any type of psoriasis (and their families or carers where appropriate). Where appropriate offer preventative advice, healthy lifestyle information and support for behavioural change tailored to meet the needs of the individual in line with the following NICE guidance:
  - Cardiovascular disease: risk assessment and reduction, including lipid modification
  - Obesity prevention
  - Type 2 diabetes prevention: population and community-level interventions
  - Cardiovascular disease prevention
  - Alcohol-use disorders: prevention
  - Stop smoking interventions and services
  - Physical activity: brief advice for adults in primary care
  - Physical activity in the workplace
  - Physical activity for children and young people.

# Topical therapy: general recommendations

Offer practical support and advice about the use and application of topical treatments.
 Advice should be provided by healthcare professionals who are trained and competent in the use of topical therapies. Support people to adhere to treatment in line with the <a href="NICE guideline on medicines adherence">NICE guideline on medicines</a> optimisation.

# Topical therapy: topical treatment of psoriasis affecting the trunk and limbs

• Offer a potent corticosteroid applied once daily plus vitamin D or a vitamin D analogue applied once daily (applied separately, 1 in the morning and the other in the evening) for up to 4 weeks as initial treatment for adults with trunk or limb psoriasis.

# Phototherapy (broad- or narrowband ultraviolet B light)

 Offer narrowband ultraviolet B (UVB) phototherapy to people with plaque or guttatepattern psoriasis that cannot be controlled with topical treatments alone. Treatment with narrowband UVB phototherapy can be given 3 or 2 times a week depending on patient preference. Tell people receiving narrowband UVB that a response may be achieved more quickly with treatment 3 times a week.

### Systemic non-biological therapy

- Offer systemic non-biological therapy to people with any type of psoriasis if:
  - it cannot be controlled with topical therapy and
  - it has a significant impact on physical, psychological or social wellbeing and
  - 1 or more of the following apply:
    - psoriasis is extensive (for example, more than 10% of body surface area affected or a <u>Psoriasis Area and Severity Index</u> (PASI) score of more than 10)
       or
    - psoriasis is localised and associated with significant functional impairment and/or high levels of distress (for example, severe nail disease or involvement at high-impact sites) or
    - phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months).

# Choice of drugs (systemic non-biological therapy)

• Offer methotrexate as the first choice of systemic agent for people with psoriasis who fulfil the criteria for systemic therapy (see previous recommendation 1.5.2.1) except in the circumstances described in recommendations 1.5.2.4 and 1.5.2.12.

In October 2012, methotrexate did not have a UK marketing authorisation for this indication in children and young people. See <u>NICE's information on prescribing</u>

medicines.

# Changing to an alternative biological drug (systemic biological therapy)

- Consider changing to an alternative biological drug in adults if:
  - the psoriasis does not respond adequately to a first biological drug as defined in NICE technology appraisal guidance on etanercept and efalizumab, infliximab, adalimumab, ustekinumab, secukinumab and ixekizumab (at 10 weeks after starting treatment for infliximab, 12 weeks for etanercept, ixekizumab and secukinumab, and 16 weeks for adalimumab and ustekinumab; primary failure) or
  - the psoriasis initially responds adequately but subsequently loses this response, (secondary failure) or
  - the first biological drug cannot be tolerated or becomes contraindicated.

### Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>NICE's information on making decisions about your</u> care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

## 1.1 Principles of care

- 1.1.1.1 Offer people with any type of psoriasis (and their families or carers), support and information tailored to suit their individual needs and circumstances, in a range of different formats so they can confidently understand:
  - their diagnosis and treatment options
  - relevant lifestyle risk factors
  - when and how to treat their condition.
  - how to use prescribed treatments safely and effectively (for example, how to apply topical treatments, how to minimise the risk of side effects through monitoring for safety of medicines)
  - when and how to seek further general or specialist review
  - strategies to deal with the impact on their physical, psychological and social wellbeing.

Also see the <u>NICE guidelines on behaviour change: individual approaches</u> and <u>behaviour change: general approaches</u>.

1.1.1.2 When offering treatments to a person with any type of psoriasis:

- ensure the treatment strategy is developed to meet the person's health goals so that the impact of their condition is minimised and use relevant assessment tools to ensure these goals are met
- take into account the age and individual circumstances of the person, disease phenotype, severity and impact, coexisting psoriatic arthritis, comorbidities and previous treatment history
- discuss the risks and benefits of treatment options with the person (and their families or carers where appropriate); where possible, use absolute risk and natural frequency (also see the <u>appendix for details of the risk-benefit</u> profiles of interventions recommended in this guideline)
- discuss the importance of adherence to treatment for optimising outcomes.

For more information, see the <u>NICE guidelines on medicines adherence</u> and medicines optimisation.

- 1.1.1.3 Assess whether support and information need updating or revising at every review or interaction with the person, in particular:
  - during transition from children's services to adult services
  - when new interventions become available
  - when the person's disease severity or circumstances (for example, in terms of comorbidities or lifestyle) change.

See also the <u>NICE guideline on transition from children's to adults' services</u> for young people using health or social care services.

- 1.1.1.4 Provide a single point of contact to help people with all types of psoriasis (and their families or carers where appropriate) access appropriate information and advice about their condition and the services available at each stage of the care pathway.
- 1.1.1.5 NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in the NICE guideline on patient experience in adult NHS

services.

#### 1.2 Assessment and referral

Severe or atypical psoriasis is an HIV indicator condition as described in <u>HIV in Europe's</u> <u>HIV indicator conditions</u>. Also see <u>recommendations 1.1.5 and 1.1.8 in the NICE guideline on HIV testing</u>.

# 1.2.1 Assessment tools for disease severity and impact and when to refer for specialist care

- 1.2.1.1 For people with any type of psoriasis assess:
  - disease severity
  - the impact of disease on physical, psychological and social wellbeing
  - · whether they have psoriatic arthritis
  - the presence of comorbidities.
- 1.2.1.2 Assess the severity and impact of any type of psoriasis:
  - at first presentation
  - before referral for specialist advice and at each referral point in the treatment pathway
  - to evaluate the efficacy of interventions.
- 1.2.1.3 When assessing the disease severity in any healthcare setting, record:
  - the results of a <u>static physician's global assessment</u> (classified as clear, nearly clear, mild, moderate, severe or very severe)
  - the patient's assessment of current disease severity, for example, using the static patient's global assessment (classified as clear, nearly clear, mild, moderate, severe or very severe)

- the body surface area affected
- any involvement of nails, high-impact and difficult-to-treat sites (for example, the face, scalp, palms, soles, flexures and genitals)
- any systemic upset such as fever and malaise, which are common in unstable forms of psoriasis such as erythroderma or generalised pustular psoriasis.
- 1.2.1.4 In specialist settings, use a validated tool to assess severity of psoriasis, for example, the <u>Psoriasis Area and Severity Index</u> (PASI; in addition to the assessments indicated in recommendation 1.2.1.3).
- 1.2.1.5 Be aware that:
  - PASI and body surface area are not validated for use in children and young people
  - erythema may be underestimated in people with darker skin types, such as skin types 5 and 6 on the <a href="Fitzpatrick scale">Fitzpatrick scale</a>.
- 1.2.1.6 Use the Nail Psoriasis Severity Index to assess nail disease in specialist settings:
  - if there is a major functional or cosmetic impact or
  - before and after treatment is initiated specifically for nail disease.
- 1.2.1.7 Assess the impact of any type of psoriasis on physical, psychological and social wellbeing by asking:
  - what aspects of their daily living are affected by the person's psoriasis
  - how the person is coping with their skin condition and any treatments they are using
  - if they need further advice or support
  - if their psoriasis has an impact on their mood
  - if their psoriasis causes them distress (be aware the patient may have levels of distress and not be clinically depressed)

• if their condition has any impact on their family or carers.

Ask children and young people age-appropriate questions.

- 1.2.1.8 In specialist settings, and if practical in non-specialist settings, use a validated tool to assess the impact of any type of psoriasis on physical, psychological and social wellbeing, for example, the:
  - <u>Dermatology Life Quality Index</u> (DLQI; see also <u>recommendation 1.5.3.3</u>) for adults or
  - <u>Children's Dermatology Life Quality Index</u> (CDLQI) for children and young people.
- 1.2.1.9 When using an assessment tool for a person with any type of psoriasis:
  - take account of their age, any disabilities (such as physical, visual or cognitive impairment), and any language or other communication difficulties, and provide help and support if needed (see <u>Dermatology Life Quality Index</u>)
  - ensure that the chosen assessment tool continues to be a sufficiently accurate measure.
- 1.2.1.10 Following assessment in a non-specialist setting, refer people for dermatology specialist advice if:
  - there is diagnostic uncertainty or
  - any type of psoriasis is severe or extensive, for example, more than 10% of the body surface area is affected or
  - any type of psoriasis cannot be controlled with topical therapy or
  - acute guttate psoriasis requires phototherapy (see recommendation 1.4.1.1) or
  - nail disease has a major functional or cosmetic impact or
  - any type of psoriasis is having a major impact on a person's physical, psychological or social wellbeing.

- 1.2.1.11 People with generalised pustular psoriasis or erythroderma should be referred immediately for same-day specialist assessment and treatment.
- 1.2.1.12 Refer children and young people with any type of psoriasis to a specialist at presentation.

#### 1.2.2 Assessment and referral for psoriatic arthritis

- 1.2.2.1 Offer annual assessment for psoriatic arthritis to people with any type of psoriasis. Assessment is especially important within the first 10 years of onset of psoriasis.
- 1.2.2.2 Use a validated tool to assess adults for psoriatic arthritis in primary care and specialist settings, for example, the Psoriasis Epidemiological Screening Tool (PEST). Be aware that the PEST does not detect axial arthritis or inflammatory back pain.
- 1.2.2.3 As soon as psoriatic arthritis is suspected, refer the person to a rheumatologist for assessment and advice about planning their care. Also see the <a href="NICE guideline on spondyloarthritis in over 16s">NICE guideline on spondyloarthritis in over 16s</a>.

#### 1.2.3 Identification of comorbidities

- 1.2.3.1 Offer adults with severe psoriasis of any type (defined as either needing treatment with phototherapy or systemic agents, or needing hospital admission in the studies underpinning this recommendation), a cardiovascular risk assessment at presentation using a validated risk estimation tool. Offer further assessment of cardiovascular risk every 5 years, or more frequently if indicated following assessment. For further information, see the <a href="NICE guideline on cardiovascular">NICE guideline on cardiovascular</a> disease: risk assessment and reduction, including lipid modification.
- 1.2.3.2 Discuss risk factors for cardiovascular comorbidities with people who have any type of psoriasis (and their families or carers where appropriate). Where appropriate offer preventative advice, healthy lifestyle information and support for behavioural change tailored to meet the needs of the individual in line with the

#### following NICE guidance:

- Cardiovascular disease: risk assessment and reduction, including lipid modification
- Obesity prevention
- Type 2 diabetes prevention: population and community-level interventions
- Cardiovascular disease prevention
- Alcohol-use disorders: prevention
- Stop smoking interventions and services
- Physical activity: brief advice for adults in primary care
- Physical activity in the workplace
- Physical activity for children and young people.
- 1.2.3.3 For people with multiple comorbidities and/or multimorbidities and any type of psoriasis needing second- or third-line therapy, ensure multidisciplinary working and communication between specialties and, if needed, interdisciplinary team working (for example, when both skin and joints are significantly affected).
- 1.2.3.4 Be aware that psoriasis of any type, especially if severe (identified by hospitalisations [including outpatient visits] for psoriasis [ICD-10 L40] or psoriatic arthritis) is a risk factor for venous thromboembolism in adults, and:
  - explain this risk to adults with any type of psoriasis
  - offer advice on how to minimise the risk (for example, during hospital admission, surgery, or periods of immobility)
  - manage the risk in line with the <u>NICE guideline on venous thromboembolism</u> in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism.
- 1.2.3.5 Assess whether people with any type of psoriasis are depressed when assessing disease severity and impact, and when escalating therapy. If appropriate offer

information, advice and support in line with the NICE guidelines on depression in adults with a chronic physical health problem and depression in children and young people.

### 1.3 Topical therapy

The treatment pathway in this guideline begins with active topical therapies. The guideline development group acknowledged that the use of emollients in psoriasis was already widespread and hence the evidence review was limited to active topical therapies for psoriasis. Refer to the <u>BNF</u> and <u>BNF for children</u> for guidance on use of emollients.

#### 1.3.1 General recommendations

- 1.3.1.1 Offer people with psoriasis topical therapy as first-line treatment.
- 1.3.1.2 Offer second- or third-line treatment options (phototherapy or systemic therapy) at the same time when topical therapy alone is unlikely to adequately control psoriasis, such as:
  - extensive disease (for example, more than 10% of body surface area affected) or
  - at least 'moderate' on the static Physician's Global Assessment or
  - where topical therapy is ineffective, such as nail disease.

See also recommendations 1.2.1.9; 1.4.1.1; 1.5.2.1; 1.5.3.4; 1.5.3.6; 1.5.3.8 and 1.5.3.10.

- 1.3.1.3 Offer practical support and advice about the use and application of topical treatments. Advice should be provided by healthcare professionals who are trained and competent in the use of topical therapies. Support people to adhere to treatment in line with the <a href="NICE guideline on medicines optimisation">NICE guideline on medicines optimisation</a>.
- 1.3.1.4 When offering topical agents:

- take into account patient preference, cosmetic acceptability, practical aspects of application and the site(s) and extent of psoriasis to be treated
- discuss the variety of formulations available and, depending on the person's preference, use:
  - cream, lotion or gel for widespread psoriasis
  - lotion, solution or gel for the scalp or hair-bearing areas
  - ointment to treat areas with thick adherent scale
- be aware that topical treatment alone may not provide satisfactory disease control, especially in people with psoriasis that is extensive (for example, more than 10% of body surface area affected) or at least 'moderate' on the static Physician's Global Assessment.
- 1.3.1.5 If a person of any age with psoriasis requiring topical therapy has a physical disability, or cognitive or visual impairment offer advice and practical support that take into account the person's individual needs.
- 1.3.1.6 Arrange a review appointment 4 weeks after starting a new topical treatment in adults, and 2 weeks after starting a new topical treatment in children, to:
  - evaluate tolerability, toxicity, and initial response to treatment (including measures of severity and impact described in recommendations 1.2.1.3, 1.2.1.6 and 1.2.1.7)
  - reinforce the importance of adherence when appropriate
  - reinforce the importance of a 4 week break between courses of potent/very potent corticosteroids (see recommendation 1.3.1.10).
    - If there is little or no improvement at this review, discuss the next treatment option with the person.
- 1.3.1.7 Discuss with people whose psoriasis is responding to topical treatment (and their families or carers where appropriate):
  - 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 (see the sections on topical treatment of psoriasis affecting the trunk and limbs, scalp and face, flexures and genitals)

- 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.
- 1.3.1.8 Offer people with psoriasis a supply of their topical treatment to keep at home for the self-management of their condition.
- 1.3.1.9 In people whose psoriasis has not responded satisfactorily to a topical treatment strategy, before changing to an alternative treatment:
  - discuss with the person whether they have any difficulties with application, cosmetic acceptability or tolerability and where relevant offer an alternative formulation
  - consider other possible reasons for non-adherence in line with the <u>NICE</u> guideline on medicines adherence.
  - Also see the <u>NICE guideline on medicines optimisation</u>.

#### How to use corticosteroids safely

Also see <u>recommendations 1.3.4.2 and 1.3.4.4 for details on safe use of steroids at facial, flexural and genital sites.</u>

- 1.3.1.10 Be aware that continuous use of potent or very potent corticosteroids may cause:
  - irreversible skin atrophy and striae
  - psoriasis to become unstable
  - systemic side effects when applied continuously to extensive psoriasis (for example, more than 10% of body surface area affected).

Explain the risks of these side effects to people undergoing treatment (and their families or carers where appropriate) and discuss how to avoid them.

- 1.3.1.11 Aim for a break of 4 weeks between courses of treatment with potent or very potent corticosteroids. Consider topical treatments that are not steroid based (such as vitamin D or vitamin D analogues or coal tar) as needed to maintain psoriasis disease control during this period.
- 1.3.1.12 When offering a corticosteroid for topical treatment select the potency and formulation based on the person's need.
- 1.3.1.13 Do not use very potent corticosteroids continuously at any site for longer than 4 weeks.
- 1.3.1.14 Do not use potent corticosteroids continuously at any site for longer than 8 weeks.
- 1.3.1.15 Do not use very potent corticosteroids in children and young people.
- 1.3.1.16 Offer a review at least annually to adults with psoriasis who are using intermittent or short-term courses of a potent or very potent corticosteroid (either as monotherapy or in combined preparations) to assess for the presence of steroid atrophy and other adverse effects. Also see recommendations 1.3.1.12 and 1.3.1.13 for details on safe duration of steroid use.
- 1.3.1.17 Offer a review at least annually to children and young people with psoriasis who are using corticosteroids of any potency (either as monotherapy or in combined preparations) to assess for the presence of steroid atrophy and other adverse effects.

#### 1.3.2 Topical treatment of psoriasis affecting the trunk and limbs

1.3.2.1 Offer a potent corticosteroid applied once daily plus vitamin D or a vitamin D analogue applied once daily (applied separately, 1 in the morning and the other in the evening) for up to 4 weeks as initial treatment for adults with trunk or limb

psoriasis.

- 1.3.2.2 If once-daily application of a potent corticosteroid plus once-daily application of vitamin D or a vitamin D analogue does not result in clearance, near clearance or satisfactory control of trunk or limb psoriasis in adults after a maximum of 8 weeks, offer vitamin D or a vitamin D analogue alone applied twice daily. Also see <a href="recommendation 1.3.1.8">recommendation 1.3.1.8</a> for additional considerations before changing to the next treatment option.
- 1.3.2.3 If twice-daily application of vitamin D or a vitamin D analogue does not result in clearance, near clearance or satisfactory control of trunk or limb psoriasis in adults after 8 to 12 weeks, offer either:
  - a potent corticosteroid applied twice daily for up to 4 weeks or
  - a coal tar preparation applied once or twice daily.

Also see <u>recommendation 1.3.1.8</u> for additional considerations before changing to the next treatment option.

- 1.3.2.4 If a twice-daily potent corticosteroid or coal tar preparation cannot be used or a once-daily preparation would improve adherence in adults offer a combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily for up to 4 weeks.
- 1.3.2.5 Offer treatment with very potent corticosteroids in adults with trunk or limb psoriasis only:
  - in specialist settings under careful supervision
  - when other topical treatment strategies have failed
  - for a maximum period of 4 weeks.
- 1.3.2.6 Consider short-contact dithranol for treatment-resistant psoriasis of the trunk or limbs and either:
  - give educational support for self-use or
  - ensure treatment is given in a specialist setting.

- 1.3.2.7 For children and young people with trunk or limb psoriasis consider either:
  - calcipotriol applied once daily (only for those over 6 years of age) or
  - a potent corticosteroid applied once daily (only for those over 1 year of age).

In August 2017, there were different topical calcipotriol preparations available in the UK, which vary in their licensing status for use in children and young people under 18. Additionally, potent topical corticosteroid preparations available in the UK vary in the age from which they are licensed for use in children. Please refer to the BNF for children for information on appropriate dosing and duration of treatment. Refer to the summary of product characteristics for specific information on individual topical calcipotriol and corticosteroid preparations. See also NICE's information on prescribing medicines.

#### 1.3.3 Topical treatment of psoriasis affecting the scalp

In children and young people, the specified duration of therapy in recommendations 1.3.3.1, 1.3.3.3, 1.3.3.4 and 1.3.3.5 may not be appropriate. Please refer to the <u>BNF for children</u> for information on appropriate dosing and duration of treatment.

In August 2017, there were several potent topical corticosteroid preparations available in the UK, and the age from which they are licensed for use in children varies. Refer to the summary of product characteristics for information on individual potent topical corticosteroid preparations. See also NICE's information on prescribing medicines.

- 1.3.3.1 Offer a potent corticosteroid applied once daily for up to 4 weeks as initial treatment for people with scalp psoriasis.
- 1.3.3.2 Show people with scalp psoriasis (and their families or carers where appropriate) how to safely apply corticosteroid topical treatment.
- 1.3.3.3 If treatment with a potent corticosteroid does not result in clearance, near clearance or satisfactory control of scalp psoriasis after 4 weeks consider:

- a different formulation of the potent corticosteroid (for example, 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.
- 1.3.3.4 If the response to treatment with a potent corticosteroid for scalp psoriasis remains unsatisfactory after a further 4 weeks of treatment (also see <a href="recommendation 1.3.1.8">recommendation 1.3.1.8</a> for additional considerations before changing to the next treatment option), offer:
  - a combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily for up to 4 weeks or
  - vitamin D or a vitamin D analogue applied once daily (only in those who cannot use steroids and with mild to moderate scalp psoriasis).

In October 2012, the combined product containing calcipotriol monohydrate and betamethasone dipropionate did not have a UK marketing authorisation for this indication in children and young people.

In August 2017, topical calcitriol and tacalcitol preparations available in the UK were not licensed for use in children. Topical calcipotriol preparations available in the UK vary in their licensing status for use in children and young people under 18. Refer to the summary of product characteristics for specific information on individual topical calcipotriol preparations. See <a href="NICE's">NICE's</a> information on prescribing medicines.

- 1.3.3.5 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 for up to 8 weeks does not result in clearance, near clearance or satisfactory control of scalp psoriasis offer:
  - a very potent corticosteroid applied up to twice daily for 2 weeks for adults only or
  - coal tar applied once or twice daily or

 referral to a specialist for additional support with topical applications and/or advice on other treatment options.

In October 2012, the combined product containing calcipotriol monohydrate and betamethasone dipropionate did not have a UK marketing authorisation for this indication in children and young people. See <a href="NICE's information on prescribing medicines">NICE's information on prescribing medicines</a>.

- 1.3.3.6 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.

Refer to the <u>BNF for children</u> for information on appropriate dosing and duration of treatment.

In August 2017, topical calcitriol and tacalcitol preparations available in the UK were not licensed for use in children. Topical calcipotriol preparations available in the UK vary in their licensing status for use in children and young people under 18. Refer to the summary of product characteristics for specific information on individual topical calcipotriol preparations. See <a href="MICE's information on prescribing medicines">MICE's information on prescribing medicines</a>.

1.3.3.7 Do not offer coal tar-based shampoos alone for the treatment of severe scalp psoriasis.

# 1.3.4 Topical treatment of psoriasis affecting the face, flexures and genitals

1.3.4.1 Offer a short-term mild or moderate potency corticosteroid applied once or twice daily (for a maximum of 2 weeks) to people with psoriasis of the face, flexures or genitals.

In October 2012, moderate potency corticosteroids did not have a UK marketing

authorisation for this indication. See NICE's information on prescribing medicines.

In children and young people, the specified duration of therapy may not be appropriate. Please refer to the <u>BNF for children</u> for information on appropriate dosing and duration of treatment.

- 1.3.4.2 Be aware that the face, flexures and genitals are particularly vulnerable to steroid atrophy and that corticosteroids should only be used for short-term treatment of psoriasis (1 to 2 weeks per month). Explain the risks to people undergoing this treatment (and their families or carers where appropriate) and how to minimise them.
- 1.3.4.3 For adults with psoriasis of the face, flexures or genitals if the response to short-term moderate potency corticosteroids is unsatisfactory, or they require continuous treatment to maintain control and there is serious risk of local corticosteroid-induced side effects, offer a calcineurin inhibitor applied twice daily for up to 4 weeks. Calcineurin inhibitors should be initiated by healthcare professionals with expertise in treating psoriasis.

In October 2012, topical calcineurin inhibitors did not have a UK marketing authorisation for this indication. See NICE's information on prescribing medicines.

- 1.3.4.4 Do not use potent or very potent corticosteroids on the face, flexures or genitals.
- 1.3.4.5 When prescribing topical agents at facial, flexural and genital sites take into account that they may cause irritation and inform people undergoing treatment (and their families and carers where appropriate) of these risks and how to minimise them. See also recommendation 1.3.4.2.

# 1.4 Phototherapy (broad- or narrowband UVB light and (PUVA)

1.4.1.1 Offer narrowband ultraviolet B (UVB) phototherapy to people with plaque or guttate-pattern psoriasis that cannot be controlled with topical treatments alone. Treatment with narrowband UVB phototherapy can be given 3 or 2 times a week

depending on patient preference. Tell people receiving narrowband UVB that a response may be achieved more quickly with treatment 3 times a week.

- 1.4.1.2 Offer alternative second- or third-line treatment when:
  - narrowband UVB phototherapy results in an unsatisfactory response or is poorly tolerated or
  - there is a rapid relapse following completion of treatment (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months) or
  - accessing treatment is difficult for logistical reasons (for example, travel, distance, time off work or immobility) or
  - the person is at especially high risk of skin cancer.
- 1.4.1.3 Consider psoralen (oral or topical) with local ultraviolet A (PUVA) irradiation to treat palmoplantar pustulosis.
  - In October 2012, psoralen did not have a UK marketing authorisation for this or any indication. See <u>NICE's information on prescribing medicines</u>.
- 1.4.1.4 When considering PUVA for psoriasis (plaque type or localised palmoplantar pustulosis) discuss with the person:
  - other treatment options
  - that any exposure is associated with an increased risk of skin cancer (squamous cell carcinoma)
  - that subsequent use of ciclosporin may increase the risk of skin cancer,
     particularly if they have already received more than 150 PUVA treatments
  - that risk of skin cancer is related to the number of PUVA treatments.
- 1.4.1.5 Do not routinely offer co-therapy with acitretin when administering PUVA. See the MHRA Drug Safety Update on oral retinoid medicines: revised and simplified pregnancy prevention educational materials for healthcare professionals and women (June 2019). Also see the summary of product characteristics for further information on this issue.

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- 1.4.1.6 Consider topical adjunctive therapy in people receiving phototherapy with broadband or narrowband UVB who:
  - have plaques at sites that are resistant or show an inadequate response (for example, the lower leg) to phototherapy alone, or at difficult-to-treat or highneed, covered sites (for example, flexures and the scalp), and/or
  - do not wish to take systemic drugs or in whom systemic drugs are contraindicated.
- 1.4.1.7 Do not routinely use phototherapy (narrowband UVB, broadband UVB or PUVA) as maintenance therapy.
- 1.4.1.8 Ensure that all phototherapy equipment is safety checked and maintained in line with local and national policy. Also see the <u>British Association of Dermatologists</u> service guidance and standards for phototherapy and guidelines on the measurement of ultraviolet radiation levels in ultraviolet phototherapy.
- 1.4.1.9 Healthcare professionals who are giving phototherapy should be trained and competent in its use and should ensure an appropriate clinical governance framework is in place to promote adherence to the indications for and contraindications to treatment, dosimetry and national policy on safety standards for phototherapy. Also see the <u>British Association of Dermatologists service</u> guidance and standards for phototherapy and guidelines on the measurement of ultraviolet radiation levels in ultraviolet phototherapy.

#### 1.4.2 Risk of skin cancer and how to minimise risk

- 1.4.2.1 Do not use PUVA in people with psoriasis of any type and a genetic predisposition to skin cancer for example, xeroderma pigmentosum or familial melanoma.
- 1.4.2.2 Do not use PUVA when other appropriate treatments are available in:
  - people with a personal history of skin cancer or
  - people who have already received 150 PUVA treatments or

- children.
- 1.4.2.3 Use PUVA with caution or consider other treatment options in:
  - people at risk of skin cancer (melanoma and non-melanoma type) see <u>NICE</u> cancer service guidance on improving outcomes for people with skin tumours including melanoma
  - people with lighter skin types, such as skin types 1 or 2 on the <u>Fitzpatrick</u> scale
  - people who are likely to require ciclosporin or long-term methotrexate
  - young people.
- 1.4.2.4 Offer lifetime skin cancer surveillance to people treated with PUVA who have:
  - had more than 150 PUVA treatments or
  - developed skin cancer.
- 1.4.2.5 Ensure that a permanent record of the person's cumulative number of UV treatments is kept (for example, in a national record).

### 1.5 Systemic therapy

#### 1.5.1 General recommendations

- 1.5.1.1 Responsibility for use of systemic therapy should be in specialist settings only.

  Certain aspects of supervision and monitoring may be delegated to other healthcare professionals and completed in non-specialist settings, in which case, such arrangements should be formalised.
- 1.5.1.2 When offering systemic therapy, tailor the choice of agent and dosing schedule to the needs of the individual and include consideration of:
  - the person's age

- disease phenotype, pattern of activity and previous treatment history
- disease severity and impact
- the presence of psoriatic arthritis (in consultation with a rheumatologist)
- conception plans
- comorbidities
- the person's views.
- 1.5.1.3 Be aware of the benefits of, contraindications to and adverse effects associated with systemic treatments. Explain the risks and benefits to people undergoing this treatment (and their families or carers where appropriate), using absolute risks and natural frequencies when possible. Support and advice should be provided by healthcare professionals who are trained and competent in the use of systemic therapies.
- 1.5.1.4 When reviewing response to systemic therapy, take into account:
  - disease severity compared with baseline (for example, <u>PASI</u> baseline to endpoint score)
  - control of psoriatic arthritis disease activity (in consultation with a rheumatologist if necessary)
  - the impact of the disease on the person's physical, psychological and social wellbeing
  - the benefits versus the risks of continued treatment
  - the views of the person undergoing treatment (and their family or carers where appropriate).
- 1.5.1.5 Monitor people using systemic treatment for all types of psoriasis in accordance with national and local drug guidelines and policy. Take appropriate action in the event of laboratory abnormalities or adverse events.
- 1.5.1.6 Offer adjunctive topical therapy to people with psoriasis using systemic therapy

to optimise treatment outcomes.

1.5.1.7 Offer people with psoriasis who are starting treatment with a systemic non-biological or biological drug the opportunity to participate in long-term safety registries (for example, the British Association of Dermatologists Biologic Interventions Register).

#### 1.5.2 Systemic non-biological therapy

- 1.5.2.1 Offer systemic non-biological therapy to people with any type of psoriasis if:
  - it cannot be controlled with topical therapy and
  - it has a significant impact on physical, psychological or social wellbeing and
  - 1 or more of the following apply:
    - psoriasis is extensive (for example, more than 10% of body surface area affected or a <u>PASI</u> score of more than 10) or
    - psoriasis is localised and associated with significant functional impairment and/or high levels of distress (for example, severe nail disease or involvement at high-impact sites) or
    - phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months).

#### **Choice of drugs**

1.5.2.2 Offer methotrexate as the first choice of systemic agent for people with psoriasis who fulfil the criteria for systemic therapy (see previous recommendation 1.5.2.1) except in the circumstances described in recommendations 1.5.2.4 and 1.5.2.12.

In October 2012, methotrexate did not have a UK marketing authorisation for this indication in children and young people. See <u>NICE's information on prescribing medicines</u>.

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- 1.5.2.3 In people with both active psoriatic arthritis and any type of psoriasis that fulfils the criteria for systemic therapy (see recommendation 1.5.2.1) consider the choice of systemic agent in consultation with a rheumatologist.
- 1.5.2.4 Offer ciclosporin as the first choice of systemic agent for people who fulfil the criteria for systemic therapy (see recommendation 1.5.2.1) and who:
  - need rapid or short-term disease control (for example, a psoriasis flare) or
  - have palmoplantar pustulosis or
  - are considering conception (both men and women) and systemic therapy cannot be avoided.

In October 2012, ciclosporin did not have a UK marketing authorisation for this indication in children and young people under 16 years of age. See NICE's information on prescribing medicines.

- 1.5.2.5 Consider changing from methotrexate to ciclosporin (or vice versa) when response to the first-choice systemic treatment is inadequate.
- 1.5.2.6 Consider acitretin for adults, and in exceptional cases only for children and young people, in the following circumstances:
  - if methotrexate and ciclosporin are not appropriate or have failed or
  - for people with pustular forms of psoriasis.

See the MHRA Drug Safety Update on oral retinoid medicines: revised and simplified pregnancy prevention educational materials for healthcare professionals and women (June 2019). Also see the summary of product characteristics for further information on this issue.

#### **Apremilast**

See also NICE's technology appraisal guidance on <u>apremilast for treating moderate to</u> <u>severe plaque psoriasis</u> and <u>apremilast for treating active psoriatic arthritis</u>.

#### **Drug regimens**

- 1.5.2.7 Use incremental dosing of methotrexate (for example, starting with an initial dose of 5 mg to 10 mg once a week) and gradually increase up to an effective dose and a maximum of 25 mg a week. Assess the treatment response after 3 months at the target dose of methotrexate and stop treatment if the response is inadequate (for example, a decrease of less than 75% in PASI score or a decrease of less than 50% in PASI score and 5 points in DLQI score).
- 1.5.2.8 Use the lowest possible therapeutic dose of methotrexate to maintain remission.
- 1.5.2.9 Use 2.5 to 3 mg/kg a day of ciclosporin. Escalate to 5 mg/kg a day after 4 weeks only when there is no response to the lower dose or when rapid disease control is necessary (for example, in severe unstable disease). Assess the treatment response after 3 months at the optimum dose of ciclosporin and stop treatment if the response is inadequate (for example, less than a 75% decrease in PASI score, or less than a 50% decrease in PASI score and less than 5 points in DLQI score).

In October 2012, ciclosporin did not have a UK marketing authorisation for this indication in children and young people under 16 years of age. See <u>NICE's</u> <u>information on prescribing medicines</u>.

- 1.5.2.10 Use the lowest possible therapeutic dose of ciclosporin to maintain remission for up to 1 year. Consider other treatment options when disease relapses rapidly on stopping ciclosporin therapy (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months of stopping treatment). Do not use ciclosporin continuously for more than 1 year unless disease is severe or unstable and other treatment options, including systemic biological therapy, cannot be used.
- 1.5.2.11 Use incremental dosing of acitretin to minimise mucocutaneous side effects and achieve a target dose of 25 mg daily in adults. Consider dose escalation to a maximum of 50 mg daily when no other treatment options are available. Assess the treatment response after 4 months at the optimum dose of acitretin and stop treatment if the response is inadequate, for example:
  - in plaque-type psoriasis, less than a 75% decrease in <u>PASI</u> score or less than a 50% decrease in PASI score and less than 5 points in DLQI score

• in pustular forms of psoriasis, not achieving clear or nearly clear on the static Physician's Global Assessment.

See the MHRA Drug Safety Update on oral retinoid medicines: revised and simplified pregnancy prevention educational materials for healthcare professionals and women (June 2019). Also see the summary of product characteristics for further information on this issue.

#### Methotrexate and risk of hepatotoxicity

1.5.2.12 When considering the risks and benefits of treating any type of psoriasis with methotrexate, be aware that methotrexate can cause a clinically significant rise in transaminases and that long-term therapy may be associated with liver fibrosis (see recommendations 1.5.2.13 to 1.5.2.16).

#### Methotrexate and monitoring for hepatotoxicity

- 1.5.2.13 Before and during methotrexate treatment, offer the person with any type of psoriasis an evaluation for potential risk of hepatotoxicity. Use standard liver function tests and serial serum procollagen III levels to monitor for abnormalities during treatment with methotrexate, taking into account pre-existing risk factors (for example, obesity, diabetes and alcohol use), baseline results and trends over time.
- 1.5.2.14 When using serum procollagen III levels to exclude liver fibrosis or cirrhosis, be aware that the:
  - test cannot be used in children and young people
  - results may be unreliable in people with psoriatic arthritis
  - estimated positive predictive value is 23% to 95% and the estimated negative predictive value is 89% to 100%.
- 1.5.2.15 Provide advice on modifiable risk factors for liver disease prior to and during therapy, including alcohol intake and weight reduction if appropriate in line with

the <u>NICE guidelines on alcohol-use disorders: prevention</u> and <u>obesity prevention</u>. For further advice on how to support attitude and behavioural change, see the NICE guideline on behaviour change.

1.5.2.16 Seek timely specialist advice and consider referral to a clinician with expertise in liver disease if the results of liver tests are abnormal.

#### 1.5.3 Systemic biological therapy

The guideline development group did not review evidence for any aspect of the use of a first biological agent because guidance on this is already available in existing NICE technology appraisal guidance on etanercept and efalizumab, infliximab, adalimumab, ustekinumab, secukinumab and ixekizumab.

- 1.5.3.1 Biological agents for psoriasis should be initiated and supervised only by specialist physicians experienced in the diagnosis and treatment of psoriasis.
- 1.5.3.2 If a person has both psoriasis and psoriatic arthritis, take into account both conditions before initiating or making changes to biological therapy and manage their treatment in consultation with a rheumatologist (see also the NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis, ustekinumab for treating active psoriatic arthritis, certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs and golimumab for the treatment of psoriatic arthritis, and the NICE guideline on spondyloarthritis in over 16s).

Also see the MHRA Drug Safety Updates on tumour necrosis factor alpha inhibitors – risk of tuberculosis (April 2014) and ustekinumab (Stelara): risk of exfoliative dermatitis (January 2015).

1.5.3.3 When using the <u>DLQI</u>, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI and make any adjustments they consider appropriate.

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#### Adalimumab in adults

For guidance on treating psoriasis with adalimumab, see <u>NICE's technology appraisal on adalimumab for the treatment of adults with psoriasis</u>. Also see the <u>MHRA Drug Safety</u> Update on tumour necrosis factor alpha inhibitors – risk of tuberculosis (April 2014).

#### **Etanercept in adults**

For guidance on treating psoriasis with etanercept, see <u>NICE's technology appraisal on</u> etanercept and efalizumab for the treatment of adults with psoriasis. Also see the <u>MHRA Drug Safety Update on tumour necrosis factor alpha inhibitors – risk of tuberculosis</u> (April 2014).

#### Infliximab in adults

For guidance on treating psoriasis with infliximab, see <u>NICE's technology appraisal on infliximab for the treatment of adults with psoriasis</u>. Also see the <u>MHRA Drug Safety</u> Update on tumour necrosis factor alpha inhibitors – risk of tuberculosis (April 2014).

#### Ixekizumab in adults

For guidance on treating psoriasis with ixekizumab, see <u>NICE's technology appraisal on ixekizumab for treating moderate to severe plaque psoriasis</u>.

#### Secukinumab in adults

For guidance on treating psoriasis with secukinumab, see <u>NICE's technology appraisal on</u> secukinumab for treating moderate to severe plaque psoriasis.

#### Ustekinumab in adults

For guidance on treating psoriasis with ustekinumab, see <a href="NICE's technology appraisal">NICE's technology appraisal</a> guidance on ustekinumab for the treatment of adults with moderate to severe psoriasis. Also see the <a href="MHRA Drug Safety Update on ustekinumab">MHRA Drug Safety Update on ustekinumab</a> (Stelara): risk of exfoliative <a href="decreation: dermatitis">dermatitis</a> (January 2015).

#### Adalimumab, etanercept and ustekinumab in children and young people

For guidance on treating psoriasis with adalimumab, etanercept and ustekinumab, see NICE's technology appraisal guidance on adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people. Also see the MHRA Drug Safety Updates on tumour necrosis factor alpha inhibitors – risk of tuberculosis (April 2014) and ustekinumab (Stelara): risk of exfoliative dermatitis (January 2015).

#### Changing to an alternative biological drug

- 1.5.3.4 Consider changing to an alternative biological drug in adults if:
  - the psoriasis does not respond adequately to a first biological drug as
     defined in NICE technology appraisal guidance on etanercept and efalizumab,
     infliximab, adalimumab, ustekinumab, secukinumab and ixekizumab (at
     10 weeks after starting treatment for infliximab, 12 weeks for etanercept,
     ixekizumab and secukinumab, and 16 weeks for adalimumab and
     ustekinumab; primary failure) or
  - the psoriasis initially responds adequately but subsequently loses this response (secondary failure) or
  - the first biological drug cannot be tolerated or becomes contraindicated.
- 1.5.3.5 For adults in whom there is an inadequate response to a second biological drug, seek supra-specialist advice from a clinician with expertise in biological therapy.

# Terms used in this guideline

This section defines terms that have been used in a particular way for this guideline.

#### Fitzpatrick scale

The scale has 6 main skin types based on the colour of the skin and its reaction to sun exposure:

type 1: always burns, never tans

- type 2: usually burns, tans minimally
- type 3: sometimes burns mildly, tans uniformly
- type 4: burns minimally, tans easily
- type 5: very rarely burns, tans very easily
- type 6: never burns, tans very easily.

# Recommendations for research

The guideline development group has made the following recommendations for research.

# 1 Assessment of disease severity and impact

In children, young people and adults with psoriasis, can tools be developed and/or existing ones further refined and validated to:

- assess disease severity and impact in both non-specialist and specialist healthcare settings, to facilitate assessment, appropriate referral, treatment planning and measurement of outcomes
- measure burden and cumulative effect of disease activity, severity and impact for people with both psoriasis and psoriatic arthritis?

## Why this is important

Assessment of disease severity and impact is fundamental to delivering high-quality health care and measuring outcomes. The evidence review indicates that the existing tools have important limitations, and have not been validated in relevant healthcare settings or in children or young people. Future research should ensure that tools are developed that capture information on site of involvement as well as extent and the impact of previous treatments. Tools should capture all aspects of impact on life including physical, psychological and social wellbeing and factors that may influence this impact, such as distress and beliefs about psoriasis. Tools that can be used by patients (as well as healthcare professionals) to assess disease severity and that encompass new technologies should be evaluated to facilitate, when appropriate, modern healthcare delivery models (for example, remote monitoring of disease activity).

In addition, understanding the true burden and effect of disease activity, severity and impact for both psoriasis and psoriatic arthritis has not previously been comprehensively studied. Capturing this information and distilling out significant factors for focused investigation will lead to better understanding of the needs of this particular group of people and the impact of treatments that benefit both disease compartments (skin and joints).

# 2 Methotrexate and risk of hepatotoxicity

What is the impact of methotrexate compared with other approaches to care (for example, other systemic non-biological or biological treatments) on risk of significant liver disease in people with psoriasis and do risk factors such as obesity, alcohol use or diabetes alter this risk?

# Why this is important

The evidence review indicates that people with psoriasis may be at risk of liver disease, and there is great uncertainty about the contributing role of methotrexate. Clinician and patient concerns about this side effect are a common cause of treatment discontinuation. However, existing studies are poorly controlled for important confounders and many are very old. Methotrexate is a low-cost intervention that is effective in an important proportion of patients. Research in this area will properly delineate the size of risk and how to minimise it. Future research should be adequately powered to detect clinically relevant liver disease, use relevant tools to do so, and properly control for relevant confounders.

# 3 Rapid escalation to systemic treatments

In people with psoriasis, does early intervention with systemic treatments improve the long-term prognosis of psoriasis severity, comorbidities (including psoriatic arthritis), or treatment-related adverse effects, and are there any clinical (for example, demographic or phenotypic) or laboratory (for example, genetic or immune) biomarkers that can be used to identify those most likely to benefit from this treatment approach?

#### Why this is important

At present the treatment pathway for people with psoriasis follows clinical need as no studies have been conducted to evaluate whether early intervention with systemic treatments alters prognosis. Consequently, patients with more severe disease sequence through all therapies in the treatment pathway, with a proportion requiring high-cost biological interventions to maintain disease control. The evidence indicates that there are very few treatment options for people with chronic disease, all of them are associated with side effects, many are co-dependent (for example, escalated risk of skin cancer in people treated with the phototherapy and ciclosporin sequence), and loss of response to biological therapies is a significant clinical issue. If early intervention with systemic

treatments was shown to alter the prognosis, particularly if there were markers that could stratify those likely to benefit, this would be of major importance to patients, and likely to deliver much more cost-effective treatment strategies.

# 4 Self-management

Do structured psoriasis-focused self-management programmes improve patient confidence, wellbeing and disease control compared with standard care?

# Why this is important

Virtually all patients self-manage their condition to a greater or lesser extent, and this involves complex topical applications as well as systemic therapies to be used over many years in response to fluctuating disease severity. The evidence indicates that in contrast to many chronic disorders, there are no validated programmes to help patients achieve effective self-management. Establishing a focused programme that effectively improves outcomes for patients would be of clinical benefit and likely deliver healthcare savings.

# 5 Topical therapy

In people of all ages with psoriasis:

- 1. How should topical therapies be used to maintain disease control i) safely; ii) effectively and iii) what are the health economic implications?
- 2. What are the risks of 'real life' long-term corticosteroid use, are there particular people at risk and what strategies can be used to modify or avoid risks?

# Why this is important

Currently, topical therapies, in some form or another, are prescribed to virtually everyone with psoriasis, often as first line psoriasis treatment and they are also frequently used adjunctively with other interventions. There is a wide array of potential topical agents available and further research specifically targeting therapeutic strategies together with sequencing of topical agents for maintaining disease control in the long term continues to deserve focused attention. In addition, exploration of the risks associated with long-term corticosteroid use and strategies aimed at modifying risk would be a critical element of

this research to fill the current gap i	this research to fill the current gap in the literature.					

# Appendix: Information to facilitate discussion of risks and benefits of treatments for people with psoriasis

Data is provided for the proportions of people achieving remission, withdrawing due to adverse events and experiencing specific adverse events (as prioritised by the guideline development group [GDG]) for interventions that have been recommended in this guideline. Data are based on pooled estimates where possible and from trials with populations and dosing appropriate to the intervention. For full details of the duration of treatment and dosing schedules please refer to the main text of the guideline.

Text is labelled with an asterisk when the GDG had very low confidence in the absolute estimates, for example, due to confounding and inadequate sample size.

For a landscape version of the following table, please refer to the <u>full guideline</u>.

Table 1 Topical therapies (short term): vitamin D or vitamin D analogues

Population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)		Numbers experiencing serious or named adverse events
Chronic plaque psoriasis of trunk and limbs	Intervention:  Once daily: 220/1000  Twice daily: 487/1000  Placebo: Once daily: 76/ 1000  Twice daily: 122/1000	Once or twice daily: 23/	Intervention: Skin atrophy  Twice daily: 1.9/ 1000  Placebo: Skin atrophy  Twice daily: 3.2/1000
Children with chronic plaque psoriasis of trunk and limbs  Note: the guideline development group (GDG) had very low confidence in the absolute estimates, for example, due to confounding and inadequate sample size	Intervention:  • Twice daily: 605/1000  Placebo:  • Twice daily: 441/1000	Not available Placebo: Not available	Intervention: Not available Placebo: Not available

Population (psoriasis phenotype)	remissions (clear,	experiencing withdrawal due to	Numbers experiencing serious or named adverse events
	Intervention:		
Scaln psoriasis	• Once daily: 387/1000	• Once daily: 81/ 1000	Intervention: Not available
Scalp psoriasis	Placebo:  • Once daily: 219/1000	Placebo:  • Once daily: 52/1000	Placebo: Not available

Table 2 Topical therapies (short term): potent corticosteroids

Population (psoriasis phenotype)		Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
Chronic plaque psoriasis of trunk and limbs	Intervention:  • Once or twice daily: 394/1000  Placebo:  • Once or twice daily: 77/1000	Intervention:  Once daily: 10/1000  Twice daily: 25/1000  Placebo: Once daily: 79/1000  Twice daily: 0/1000	Intervention: Skin atrophy  • Once or twice daily: 5.5/1000  Placebo: Skin atrophy  • Once or twice daily: 0/1000

Population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
	Intervention:	Intervention:	
	Once or twice daily: 632/1000	Once or twice daily: 9.5/1000	Intervention: Not available
Scalp psoriasis	Placebo:	Placebo:	Placebo: Not available
	Once or twice daily: 223/1000	Once or twice daily: 41/1000	

Note: No active comparator. An active comparator will only be included if no placebo comparison is available; the standard intervention will be chosen if multiple active comparators are available.

Table 3 Topical therapies (short term): vitamin D or analogue and potent steroid, applied 1 in the morning and 1 in the evening

Population (psoriasis phenotype)	(clear poorly clear or DASIZE)	withdrawal due to drug	Numbers experiencing serious or named adverse events
Chronic plaque psoriasis of trunk and limbs	Intervention:  • 611/1000  No placebo Active comparator, calcipotriol:  • Twice daily: 469/1000	Intervention:  • 13/1000  Active comparator, calcipotriol:  • Twice daily: 26/1000	Intervention: Not available Active comparator: Not available

Table 4 Topical therapies (short term): combined vitamin D or analogue and potent steroid

Population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
Chronic plaque psoriasis of trunk and limbs	Intervention:  Once daily: 494/1000  No placebo Active comparator:  vitamin D once daily: 193/1000	<ul> <li>Once daily: 7.5/1000</li> <li>Active comparator:</li> <li>Vitamin D once or twice daily: 27/1000</li> </ul>	Intervention: Skin atrophy  Once daily: 4.2/ 1000  Active comparator: Skin atrophy  Vitamin D twice daily: 1.8/ 1000
Scalp psoriasis  Note: No active comparator. An active comparator will only be included if no placebo comparison is available; the standard intervention will be chosen if multiple active comparators are available.	Intervention:  Once daily: 800/1000  Placebo: Once daily: 500/1000	Note: the guideline development group (GDG) had very low confidence in the	Intervention: Not available Placebo: Not available

Table 5 Topical therapies (short term): very potent corticosteroids

Population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
Chronic plaque psoriasis of trunk and limbs	Intervention:  • Once or twice daily: 625/1000  Placebo:  • Once or twice daily: 13/1000	Intervention:  • Once or twice daily: 4.6/1000  Placebo:  • Once or twice daily: 6.0/1000	Intervention: Skin atrophy  • Once or twice daily: 23/1000  Placebo: Skin atrophy  • Once or twice daily: 0/1000
Scalp psoriasis	Intervention:  • Once or twice daily: 646/1000  Placebo:  • Once or twice daily: 80/1000	Intervention:  • Once or twice daily: 0/1000  Placebo:  • Once or twice daily: 5.9/1000	Intervention: Skin atrophy  • Once or twice daily: 0/1000  Placebo: Skin atrophy  • Once or twice daily: 11/1000

Note: No active comparator. An active comparator will only be included if no placebo comparison is available; the standard intervention will be chosen if multiple active comparators are available.

Table 6 Topical therapies (short term): tazarotene

Population (psoriasis phenotype)	(clear pearly clear or PASI75)	withdrawal due to drug	Numbers experiencing serious or named adverse events
Chronic plaque psoriasis of trunk and limbs	Intervention:  • Once daily: 58/ 1000  Placebo:  • Once daily: 20/ 1000	Intervention:  • Once daily: 107/ 1000  Placebo:  • Once daily: 44/ 1000	Intervention: Skin atrophy  • Once daily: 0/ 1000  Placebo: Skin atrophy  • Once daily: 0/ 1000

Note: No active comparator. An active comparator will only be included if no placebo comparison is available; the standard intervention will be chosen if multiple active comparators are available.

Table 7 Topical therapies (short term): short-contact dithranol

Population (psoriasis phenotype)		Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
Chronic plaque psoriasis of trunk and limbs	Intervention:  • Once daily: 430/ 1000  No placebo Active comparator, calcipotriol:  • Twice daily: 588/ 1000	Intervention:  • Once daily: 82/ 1000  Active comparator, calcipotriol:  • Twice daily: 39/ 1000	Intervention: Not available Active comparator: Not available

Note: two-third of studies reported home-use of dithranol and in one-third of studies, the setting was unclear.

Table 8 Topical therapies (short term): coal tar

Population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
Chronic plaque psoriasis of trunk and limbs	Intervention:  • Once or twice daily: 111/ 1000 to 519/1000 depending on formulation and follow-up  No placebo Active comparator, calcipotriol:  • Twice daily: 214/1000 to 723/1000 depending on follow-up	Intervention:  • Once or twice daily: 0 to 56/1000 depending on formulation and follow-up  Active comparator, calcipotriol:  • Twice daily: 0 to 40/1000 depending on follow-up	Intervention: Not available Active comparator: Not available

Note: the guideline development group (GDG) had very low confidence in the absolute estimates, for example, due to confounding and inadequate sample size.

Table 9 Topical therapies (short term): tacrolimus

Population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
	Intervention:	Intervention:	
Psoriasis of the	• Twice daily: 652/ 1000	• Twice daily: 0/ 1000	Intervention: Not available
face and flexures	Placebo:	Placebo:	Placebo: Not available
	• Twice daily: 309/ 1000	• Twice daily: 25/ 1000	avaliable

1) The guideline development group (GDG) had very low confidence in the absolute estimates, for example, due to confounding and inadequate sample size.

2) No active comparator. An active comparator will only be included if no placebo comparison is available; the standard intervention will be chosen if multiple active comparators are available.

Table 10 Topical therapies (short term): pimecrolimus

Population (psoriasis phenotype)	(clear nearly clear or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
			Intervention:
	Intervention:	Intervention:	Skin atrophy
Psoriasis of	• Twice daily: 714/1000	• Twice daily: 0/1000	• Twice daily: 0/1000
the flexures	Placebo:	Placebo:	Placebo:
	• Twice daily: 207/1000	• Twice daily: 0/1000	Skin atrophy
	, ,		• Twice daily: 0/1000

- 1) The guideline development group (GDG) had very low confidence in the absolute estimates, for example, due to confounding and inadequate sample size.
- 2) No active comparator. An active comparator will only be included if no placebo comparison is available; the standard intervention will be chosen if multiple active comparators are available.

#### Table 11 Phototherapy (short term)

Intervention and population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)		Numbers experiencing serious or named adverse events
NBUVB versus PUVA Plaque psoriasis	Intervention:  • Twice weekly: 647/1000  No placebo Active comparator, oral PUVA:  • Twice weekly: 915/1000	Intervention:  • Twice weekly: 38/1000  No placebo Active comparator, oral PUVA:  • Twice weekly: 47/1000	Intervention: Not available Active comparator: Not available
PUVA (oral)  Palmoplantar pustulosis  Note: No active comparator. An active comparator will only be included if no placebo comparison is available; the standard intervention will be chosen if multiple active comparators are available.	Intervention:  • 3 to 4 times weekly: 941/1000  Placebo, no treatment:  • 500/1000	Intervention:  • 3 to 4 times weekly: 29/1000  Placebo, no treatment:  • 0/1000	Intervention: Burn  • 3 to 4 times weekly: 147/1000  Placebo, no treatment: • 0/1000

Intervention and population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)		Numbers experiencing serious or named adverse events
PUVA (cream) Palmoplantar pustulosis	Intervention:  • 3 times weekly: 952/1000  No placebo Active comparator, NBUVB:  • 3 times weekly: 429/1000	Intervention:  • 3 times weekly: 45/1000  No placebo Active comparator, NBUVB:  • 3 times weekly: 0/1000	Intervention: Not available Active comparator: Not available
NBUVB plus vitamin D or analogues Plaque psoriasis	Intervention:  • 3 times weekly UV + twice daily topical: 900/1000  No placebo Active comparator, NBUVB alone:  • 3 times weekly: 611/1000	Intervention:  • 3 times weekly UV + twice daily topical: 50/1000  No placebo Active comparator, NBUVB alone:  • 3 times weekly: 28/1000	Intervention: Burn  • 3 times weekly UV + twice daily topical: 200/1000  No placebo Active comparator, NBUVB alone: Burn  • 3 times weekly: 111/1000

Intervention and population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	experiencing withdrawal due to	Numbers experiencing serious or named adverse events
BBUVB plus vitamin D or analogues Plaque psoriasis	Intervention:  • Up to 3 times weekly UV + twice daily topical: 449/1000 8 weeks  No placebo Active comparator, BBUVB alone:  • up to 3 times weekly: 208/1000	Intervention:  • Up to 3 times weekly UV + twice daily topical: 41/1000  No placebo Active comparator, BBUVB alone:  • up to 3 times weekly: 19/1000	Intervention: Not available Active comparator: Not available

Intervention and population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	experiencing withdrawal due to	Numbers experiencing serious or named adverse events
Liquor carbonic distillate (equivalent 2.3% coal tar) plus NBUVB Plaque psoriasis	Intervention:  • Clear (3 times weekly UV + twice daily topical): 583/1000  No placebo Active comparator, NBUVB alone:  • 3 times weekly: 500/1000	Intervention:  • 3 times weekly UV + twice daily topical: 0/1000  No placebo Active comparator, NBUVB alone:  • 3 times weekly: 0/1000	Intervention: Burn  • 3 times weekly UV + twice daily topical: 167/1000  No placebo Active comparator, NBUVB alone: Burn  • 3 times weekly: 167/1000

Intervention and population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	experiencing withdrawal due to	Numbers experiencing serious or named adverse events
Dithranol plus BBUVB Psoriasis	Intervention:  • 3 times weekly UV + twice daily topical: 625/1000  No placebo Active comparator, BBUVB alone:  • 3 times weekly: 458/1000	Intervention: Not available Active comparator: Not available	Intervention: Not available Active comparator: Not available

Abbreviations: BBUVB, broadband UVB; NBUVB, narrowband UVB; PUVA, psoralen plus UVA; UVA, ultraviolet A; UVB, ultraviolet B.

Note: for all the interventions except NBUVB versus PUVA, the guideline development group (GDG) had very low confidence in the absolute estimates, for example, due to confounding and inadequate sample size.

Table 12 Systemic, non-biologic therapies (short-term)

Intervention and population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
Methotrexate; incremental dosing (plus folic acid) Chronic plaque psoriasis	Intervention:  • 415/1000  Placebo:  • 188/1000	Intervention:  • 55/1000*  Placebo:  • 20/1000*	Intervention: Elevated liver enzymes (>1.5 to 2.5 ULN): 91/1000* Placebo: Elevated liver enzymes (>1.5 to 2.5 ULN): 75/1000*
Ciclosporin Chronic plaque psoriasis	Intervention:  • 2.5 to 3 mg: 232/ 1000  • 5 mg: 600/1000  Placebo:  • 44/1000	Intervention:  • 0/1000*  Placebo:  • 0/1000*	Intervention: Hypertension:  391/1000  Decrease in GFR >15%:  3 mg/kg: 333/1000  5 mg/kg: 500/1000*  Placebo: Hypertension:  333/1000  Decrease in GFR >15%:  0/1000*

Intervention and population (psoriasis phenotype)	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
			Intervention:
	Intervention:		Hypertension:
Ciclosporin	• 652/1000	Intervention: Not available	• 37/1000*
Palmoplantar pustulosis	Placebo:	Placebo: Not	Placebo:
pastalosis	• 200/1000	available	Hypertension
			• 0/1000*

Intervention and population (psoriasis phenotype)  Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity	Numbers experiencing serious or named adverse events
(negricular phonotypo) remissions (clear, nearly		

Abbreviations: GFR, glomerular filtration rate; ULN, upper limit of normal.

Note: The guideline development group (GDG) had very low confidence in the absolute estimates, for example, due to confounding and inadequate sample size.

Table 13 Systemic, biologic therapies (short-term)

Intervention and population (psoriasis phenotype)	Prior biologics received	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity or serious adverse events
Infliximab Adults with severe plaque psoriasis and prior biologic exposure	Unclear	Intervention:	Intervention: Not available Placebo: Not available
Etanercept Adults with severe plaque psoriasis and prior biologic exposure*	Included etanercept, infliximab, and adalimumab (proportions unclear)*	Intervention:  • 370/ 1000*  Placebo: Not available* Active comparator, ustekinumab:  • 556/ 1000*	Intervention: Not available* Placebo: Not available* Active comparator: Not available*
Ustekinumab Adults with severe plaque psoriasis and prior biologic exposure	Included etanercept, infliximab, and adalimumab (proportions unclear)	Intervention:	Intervention: Not available Placebo: Not available

Intervention and population (psoriasis phenotype)	Prior biologics received	Numbers achieving remissions (clear, nearly clear, or PASI75)	Numbers experiencing withdrawal due to drug toxicity or serious adverse events
Adalimumab Adults with severe plaque psoriasis*	Etanercept (32.1%), alefacept (23.1%), ustekinumab (23.1%), efalizumab (21.8%), infliximab (20.5%) and other (17.9%)*	Intervention:  • 654/ 1000*  Placebo: Not available* Active comparator, no prior biologic:  • 744/1000*	Intervention: Not available* Placebo: Not available* Active comparator: Not available*

Note: For the interventions infliximab and ustekinumab, there were no active comparators. An active comparator will only be included if no placebo comparison is available; the standard intervention will be chosen if multiple active comparators are available.

#### Table 14 Long-term risks

Intervention and outcome(s)	Population – psoriasis phenotype	Number experiencing event
Psoralen plus ultraviolet A (PUVA; oral) Skin cancer – squamous cell carcinoma (SCC)	Plaque (84%), guttate (12%) and erythrodermic (4%) psoriasis	Relative risk compared with the general population:  PUVA exposure <100; relative risk (RR) <100  PUVA exposure 100 to 159; RR 100 to 159; RR 100 to 336  PUVA exposure 160 to 336; RR 160 to 336  PUVA exposure ≥337; RR ≥337  Absolute increase in risk:  PUVA exposure <100; SCCs 18; 1.7% increase in 10-year risk  PUVA exposure 100 to 159; SCCs 15; 2.7% increase in 10-year risk
		<ul> <li>increase in 10-year risk</li> <li>PUVA exposure 160 to 336; SCCs 68; 8.8% increase in 10-year risk</li> <li>PUVA exposure ≥337; SCCs 34; 12.7% increase</li> </ul>
Narrowband UVB (NBUVB)		in 10-year risk
Skin cancer	Insufficient data available	Insufficient data available
Methotrexate Liver fibrosis, bone marrow suppression and pneumonitis	No long-term data available	No long-term data available

Intervention and outcome(s)	Population – psoriasis phenotype	Number experiencing event
Ciclosporin Hypertension, renal impairment, gout and hyperuricaemia	No long-term data available	No long-term data available
Acitretin Hyperlipidaemia, hepatotoxicity, skeletal adverse events and cheilitis	No long-term data available	No long-term data available

# Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the <u>NICE</u> topic page on skin conditions.

For full details of the evidence and the guideline committee's discussions, see the <u>full</u> <u>guideline</u>. You can also find information about <u>how the guideline was developed</u>, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

# **Update information**

**September 2017:** We revised the guideline throughout to link to other NICE guidance (including technology appraisals) and some relevant non-NICE guidelines, as well as including new MHRA safety advice and updated licensing information.

#### Minor updates since publication

October 2021: We added links to <u>HIV in Europe's HIV indicator conditions</u> and <u>our guideline on HIV testing</u> to section 1.2 on assessment and referral. See the <u>surveillance</u> report on HIV indicator conditions for more information.

**August 2019:** Links to the MHRA safety advice on the risk of using retinoids in pregnancy have been updated to the June 2019 version. Links also updated throughout to the Dermatology Life Quality Index pages at Cardiff University's website.

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# Accreditation

