Psoriasis: the management of psoriasis

NICE guideline Draft for consultation, May 2012

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

Psoriasis: NICE guideline DRAFT (May 2012) 1 of 45

Contents

Introdu	ıction	3
Patient	t-centred care	6
Key priorities for implementation		7
1 Gu	uidance	11
1.1	Principles of care	11
1.2	Assessment and referral	13
1.3	Topical therapy	18
1.4	Phototherapy	24
1.5	Risk of skin cancer	26
1.6	Systemic therapy	28
1.7	Systemic non-biological therapy	29
1.8	Systemic biological therapy	33
2 No	otes on the scope of this guideline	37
3 lm	plementation	38
4 Re	esearch recommendations	38
5 Ot	ther versions of this guideline	40
6 Related NICE guidance		41
7 Up	odating the guideline	42
Appen	dix A: The Guideline Development Group, National Collaborating	
Centre and NICE project team		43

Psoriasis: NICE guideline DRAFT (May 2012)

Introduction

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

Plaque psoriasis is characterised by well-delineated red, scaly plaques that vary in extent from a few patches to generalised involvement, and is the most common form of the condition (90% of patients). 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 this 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 has an 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 morbidity², with consequent reduced levels of employment and income. Factors that contribute to these include symptoms related to the skin (for example, chronic itch, bleeding, scaling and nail involvement), problems related to treatments, psoriatic arthritis, and the effects of living with a highly

Psoriasis: NICE guideline DRAFT (May 2012) 3 of 45

¹ Ibrahim G, Waxman R, Helliwell PS. The prevalence of psoriatic arthritis in people with psoriasis. Arthritis Rheum 15;61(10):1373-8 (2009)

² Kurd SK, Troxel AB, Crits-Christoph P, Gelfand JM. The risk of depression, anxiety, and suicidality in patients with psoriasis. Arch Dermatol 2010;146(8):891-895

visible, stigmatising skin disease³. Even people with minimal involvement state that psoriasis has a major effect on their life. A number of studies have also reported that people with psoriasis, particularly those with severe disease, may be at increased risk of cardiovascular disease⁴, lymphoma⁵ and non-melanoma skin cancer⁶.

A wide variety of treatments is available, some of which are expensive and/or accessed only in specialist care; all require appropriate monitoring:

- First-line therapy describes traditional topical therapies (such as corticosteroids, vitamin D and analogues, dithranol and tar preparations).
- Second-line therapy includes phototherapy (broadband or narrowband ultraviolet B [UVB] 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 (TNF) antagonists adalimumab, etanercept and infliximab, and the monoclonal antibody ustekinumab that targets interleukin (IL) IL-12 and IL-23.

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 services⁷. This guideline aims to provide clear recommendations on the management of all types of psoriasis in children, young people and adults, focusing on areas most likely to improve the management and delivery of care for a majority of people affected, where

, , ,

_

³ Richards HL, Fortune DG, Main CJ, Griffiths CEM. The contribution of perceptions of stigmatisation to disability in patients with psoriasis. J Psychosom Res 2001;50:10-15.

⁴ O Ahlehoff. Psoriasis and Cardiovascular Disease. Dan.Med.Bull. 58 (11):B4347, 2011.

⁵ J. M. Gelfand, D. B. Shin, A. L. Neimann, X. Wang, D. J. Margolis, and A. B. Troxel. The risk of lymphoma in patients with psoriasis. J.Invest.Dermatol. 126 (10):2194-2201, 2006.

⁶ P. Boffetta, G. Gridley, and B. Lindelof. Cancer risk in a population-based cohort of patients hospitalized for psoriasis in Sweden. J.Invest.Dermatol. 117 (6):1531-1537, 2001.

⁷ Eedy DJ, Griffiths CE, Chalmers RJ, Ormerod AD, Smith CH, Barker JN et al. Care of

Eedy DJ, Griffiths CE, Chalmers RJ, Ormerod AD, Smith CH, Barker JN et al. Care of patients with psoriasis: an audit of U.K. services in secondary care. British Journal of Dermatology. 2009; 160(3):557-564

practice is very varied and/or where clear consensus or guidelines on treatments are lacking.

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. In these cases informed consent should be obtained and documented. Where recommendations have been made for the use of drugs outside their licensed indications ('off-label use') these drugs are marked with a footnote in the recommendations. Before prescribing any intervention for use in children, healthcare professionals should refer to the specific summary of product characteristics and the 'British National Formulary (BNF) for Children'.

Psoriasis: NICE guideline DRAFT (May 2012) 5 of 45

Patient-centred care

This guideline offers best practice advice on the care of people with psoriasis.

Treatment and care should take into account patients' needs and preferences. People with psoriasis should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent and the Capacity Act. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

If the patient is under 16, healthcare professionals should follow the guidelines in the Department of Health's 'Seeking consent: working with children'.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Families and carers should also be given the information and support they need.

Care of young people in transition between paediatric and adult services should be planned and managed according to the best practice guidance described in the Department of Health's '<u>Transition: getting it right for young people</u>'.

Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people with psoriasis. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.

Psoriasis: NICE guideline DRAFT (May 2012) 6 of 45

Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

Assessment and referral

- Assess people with all types of psoriasis for:
 - disease severity
 - the impact of disease on physical, psychological and social wellbeing
 - psoriatic arthritis
 - the presence of comorbidities. [1.2.1.1]
- Following assessment in a non-specialist setting, offer referral for dermatology specialist advice if:
 - there is diagnostic uncertainty or
 - psoriasis is severe⁸ or extensive, for example more than 10% of BSA involvement or
 - psoriasis cannot be controlled with topical therapy or
 - acute guttate psoriasis requires phototherapy 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. [1.2.1.9]
- As soon as psoriatic arthritis is suspected, refer the person to a rheumatologist for assessment and advice about planning their care.

[1.2.2.3]

- Discuss risk factors for comorbidities with people who have psoriasis of all severities. Explain that they are at higher risk of hypertension, diabetes, obesity and hyperlipidaemia than people without psoriasis. Offer preventative advice and healthy lifestyle information in line with the following NICE guidance:
 - 'Lipid modification' (NICE clinical guideline 67)

⁸ As defined on the Static Physician's Global Assessment.

Psoriasis: NICE guideline DRAFT (May 2012)

- 'Obesity' (NICE clinical guideline 43)
- 'Preventing type 2 diabetes: population and community-level
 interventions in high-risk groups and the general population' (NICE public health guidance 35)
- 'Prevention of cardiovascular disease at population level' (NICE public health guidance 25)
- 'Alcohol-use disorders: preventing the development of hazardous and harmful drinking' (NICE public health guidance 24)
- Smoking cessation services in primary care, pharmacies, local
 authorities and workplaces, particularly for manual working groups,
 pregnant women and hard to reach communities' (NICE public health
 guidance 10). [1.2.3.2]

Topical therapy

 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 'Medicines adherence' (NICE clinical guideline 76). [1.3.1.2]

Phototherapy

- 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 three or two times a week depending on patient preference. Tell people receiving narrowband UVB that a response may be achieved more quickly with treatment three times a week. Offer other second- or third-line treatment options when:
 - narrowband UVB phototherapy results in an inadequate 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

Psoriasis: NICE guideline DRAFT (May 2012) 8 of 45

- 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. [1.4.1.1]
- 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 phototherapy⁹. [1.4.1.6]

Systemic therapy

Be aware of the benefits of, contraindications to and adverse effects
associated with systemic treatments. Explain the risks and benefits to
people undergoing these treatments 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 [1.6.2.2]

Systemic non-biological therapy

- Offer systemic therapy to people with psoriasis if:
 - it cannot be controlled with topical therapy and
 - it has a significant impact on physical, psychological or social wellbeing
 and
 - one or more of the following apply:
 - psoriasis is extensive (for example, BSA of more than 10% affected or
 a 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). [1.7.1.1]

Psoriasis: NICE guideline DRAFT (May 2012) 9 of 45

⁹ See The British Association of Dermatologists 'Phototherapy Working Party Report'.

Systemic biological therapy

Consider changing to an alternative biological drug in adults with psoriasis
in whom there is an inadequate response to a first biological drug (either
following the first 3 months of treatment [primary failure], or following an
initially adequate response [secondary failure]), or if the first biological drug
cannot be tolerated or becomes contraindicated. [1.8.1.13]

Psoriasis: NICE guideline DRAFT (May 2012) 10 of 45

1 Guidance

The following guidance is based on the best available evidence. The <u>full</u> <u>guideline</u> [hyperlink to be added for final publication] gives details of the methods and the evidence used to develop the guidance.

The guidance covers adults, young people and children of all ages with all types of psoriasis. The recommendations were developed after discussion of the relevance of the evidence to children, young people and adults with psoriasis. If recommendations are age-limited or specific to disease type, they are clearly indicated as such.

1.1 Principles of care

- 1.1.1.1 Offer people with all types of psoriasis 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
 - lifestyle risk factors that are relevant
 - how to recognise a flare
 - how to use prescribed treatments safely and effectively (for example, how to apply topical treatments and how to minimise the risk of side effects through safe monitoring of medicines)
 - when and how to seek further general or specialist review
 - strategies to deal with the impact of psoriasis on physical, psychological and social wellbeing.
- 1.1.1.2 When offering treatments to a person with any type of psoriasis:
 - ensure the treatment strategy is developed to meet the individual's health goals so that the impact of their condition is minimised and use relevant assessment tools to ensure these goals are met

Psoriasis: NICE guideline DRAFT (May 2012) 11 of 45

- take into account the age and individual circumstances of the person, disease phenotype, severity and impact, co-existing psoriatic arthritis, comorbidities and previous treatment history
- discuss the risks and benefits of treatment options with the person and where possible include use of absolute risk and natural frequency.
- 1.1.1.3 Assess whether support and information needs updating or revising at every review or interaction with the person affected, in particular during transition from children's services to adult services, when new interventions become available, and when the person's disease severity or circumstances change.
- 1.1.1.4 Provide a single point of contact to help people with all types of psoriasis to 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 'Patient experience in adult NHS services' (NICE clinical guideline 138). Recommendations on shared decision making, including discussions about investigation or treatment options and risks and benefits can be found in section 1.5 of that guideline.

Psoriasis: NICE guideline DRAFT (May 2012) 12 of 45

1.2 Assessment and referral

1.2.1 Assessment tools for disease severity and impact and referral for specialist care

- 1.2.1.1 Assess people with all types of psoriasis for:
 - disease severity
 - the impact of disease on physical, psychological and social wellbeing
 - psoriatic arthritis
 - the presence of comorbidities.
- 1.2.1.2 Assess psoriasis severity and impact:
 - at first presentation
 - before referral for specialist advice and at any referral point in the treatment pathway
 - to evaluate the efficacy of interventions.
- 1.2.1.3 When assessing the disease severity, record:
 - the results of a Static Physician's Global Assessment (PGA)
 (classified as clear, nearly clear, mild, moderate, severe or very severe)¹⁰
 - the body surface area (BSA) affected
 - any involvement of nails and high-impact or difficult-to-treat sites (for example, the face, scalp, palms, soles, flexures and genitals)
 - any systemic upset (for example, in people with erythroderma or generalised pustular psoriasis).

Psoriasis: NICE guideline DRAFT (May 2012) 13 of 45

¹⁰ See S. R. Feldman and G. G. Krueger. Psoriasis assessment tools in clinical trials. Ann.Rheum.Dis. 64 (Suppl 2):ii65-ii68, 2005.

- 1.2.1.4 In specialist settings, use a validated tool to assess severity, for example the Psoriasis Activity and Severity Index (PASI)¹¹ in adults and for young children use the PGA. Be aware that:
 - PASI and BSA are not validated for use in children
 - erythema may be underestimated in people with darker skin types, such as skin types V and VI on the Fitzpatrick scale¹².
- 1.2.1.5 Assess the impact of all types of psoriasis on physical. psychological and social wellbeing by asking:
 - what aspects of daily living are affected by the person's psoriasis
 - how the person is coping with their skin condition and any treatments they are using, and if they need further advice or support
 - if their psoriasis has a big impact on their mood.

In children and young people also ask about the impact on the family and ask age-appropriate questions.

- 1.2.1.6 In specialist settings and if practical in non-specialist settings, use a validated tool to assess the impact of all types of psoriasis on physical, psychological and social wellbeing, for example the:
 - Dermatology Life Quality Index (DLQI)¹³ for adults or
 - Children's Dermatology Life Quality Index (CDLQI)¹⁴ for children and young people.
- 1.2.1.7 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

¹¹ See Psoriasis Activity and Severity Index.

¹² Fitzpatrick scale: type I: always burns, never tans; type II: usually burns, tans with difficulty, type III: sometimes mild burn, gradually tans; type IV: rarely burns, tans with ease; type V: very rarely burns, tans very easily; type VI: never burns, tans very easily.

13 See Dermatology Life Quality Index.

¹⁴ See Children's Dermatology Life Quality Index.

support in line with 'Depression in adults with a chronic physical health problem' (NICE clinical guideline 91) for adults and 'Depression in children and young people' (NICE clinical guideline 28) for children and young people.

- Use the Nail Psoriasis Severity Index¹⁵ to assess nail disease in 1.2.1.8 specialist settings:
 - if there is a major functional or cosmetic impact or
 - before and after treatment is initiated specifically for nail disease.
- 1.2.1.9 Following assessment in a non-specialist setting, offer referral for dermatology specialist advice if:
 - there is diagnostic uncertainty or
 - psoriasis is severe 16 or extensive, for example more than 10% of BSA involvement or
 - psoriasis cannot be controlled with topical therapy or
 - acute guttate psoriasis requires phototherapy 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.
- 1.2.1.10 People with unstable psoriasis, for example generalised pustular psoriasis or erythroderma, should be referred immediately for same-day specialist assessment and treatment.
- 1.2.1.11 When using an assessment tool for a person with any type of psoriasis take into account their age, any disabilities (such as physical, visual or cognitive impairment), and any language or other communication difficulties, and provide help and support if

See Rich P, Scher RK, Nail Psoriasis Severity Index: A useful tool for evaluation of nail psoriasis. JAAD 2003 (49) 206-212.
 As defined on the Static Physician's Global Assessment.

- needed. Ensure that the chosen assessment tool continues to be a sufficiently accurate measure.
- 1.2.1.12 Offer specialist referral to children with psoriasis 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)¹⁷. 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.

1.2.3 Identification of comorbidities

1.2.3.1 Offer a cardiovascular risk assessment using a validated risk estimation tool to adults with severe psoriasis at presentation, and offer further assessments every 5 years, or more frequently if indicated following risk assessment. For further information see 'Lipid modification' (NICE clinical guideline 67).

Psoriasis: NICE guideline DRAFT (May 2012) 16 of 45

¹⁷ See: G. H. Ibrahim, M. H. Buch, C. Lawson, R. Waxman, and P. S. Helliwell. Evaluation of an existing screening tool for psoriatic arthritis in people with psoriasis and the development of a new instrument: the Psoriasis Epidemiology Screening Tool (PEST) questionnaire. Clin.Exp.Rheumatol. 27 (3):469-474, 2009.

- 1.2.3.2 Discuss risk factors for comorbidities with people who have psoriasis of all severities. Explain that they are at higher risk of hypertension, diabetes, obesity and hyperlipidaemia than people without psoriasis. Offer preventative advice and healthy lifestyle information in line with the following NICE guidance:
 - 'Lipid modification' (NICE clinical guideline 67)
 - 'Obesity' (NICE clinical guideline 43)
 - 'Preventing type 2 diabetes: population and community-level interventions in high-risk groups and the general population' (NICE public health guidance 35)
 - 'Prevention of cardiovascular disease at population level' (NICE public health guidance 25)
 - 'Alcohol-use disorders: preventing the development of hazardous and harmful drinking' (NICE public health guidance 24)
 - Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities' (NICE public health guidance 10).
- 1.2.3.3 For people with multiple comorbidities 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)¹⁸.

Psoriasis: NICE guideline DRAFT (May 2012) 17 of 45

¹⁸ For further information see '<u>The National Service Framework for long-term conditions</u>'.

- 1.2.3.4 Be aware that psoriasis is a risk factor for venous thromboembolism, especially in people with severe psoriasis and:
 - explain this risk to people with 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 '<u>Venous thromboembolism: reducing</u>
 <u>the risk'</u> (NICE clinical guideline 92).

1.3 Topical therapy

1.3.1 General recommendations

- 1.3.1.1 Offer people with psoriasis topical therapy as first-line treatment and escalate to second-line treatment (that is, phototherapy or systemic non-biological therapy) or third-line treatment (systemic biological therapy) if psoriasis is extensive and/or severe.
- 1.3.1.2 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 'Medicines adherence' (NICE clinical guideline 76).
- 1.3.1.3 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.

Explain the risks of these side effects to people undergoing treatment and discuss how to avoid them.

1.3.1.4 When offering a corticosteroid for topical treatment choose a low-cost preparation.

Psoriasis: NICE guideline DRAFT (May 2012) 18 of 45

- 1.3.1.5 Do not use potent or very potent corticosteroids on the face or flexures, including genital sites.
- 1.3.1.6 Do not use very potent corticosteroids continuously at any site for longer than 4 weeks.
- 1.3.1.7 Do not use potent corticosteroids continuously at any site for longer than 8 weeks.
- 1.3.1.8 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 use:
 - cream or lotion 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 severe psoriasis.

- 1.3.1.9 If a person with psoriasis has a physical disability or visual impairment and needs topical therapy, offer advice and practical support that take into account the person's individual needs.
- 1.3.1.10 Arrange a review appointment at 4 weeks after starting a new topical treatment strategy to evaluate tolerability, toxicity and initial response to treatment.

Psoriasis: NICE guideline DRAFT (May 2012) 19 of 45

- 1.3.1.11 Discuss with people whose psoriasis is responding to topical treatment:
 - 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 sections 1.3.2 to 1.3.4)
 - that relapse occurs in most people after treatment is stopped
 - that topical treatments can be used as and when required to maintain satisfactory disease control.
- 1.3.1.12 Offer people with psoriasis a supply of their topical treatment to keep at home for the self-management of their condition.
- 1.3.1.13 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 'Medicines adherence' (NICE clinical guideline 76).

1.3.2 Trunk and limb psoriasis

- 1.3.2.1 Offer a potent corticosteroid applied once daily plus vitamin D or a vitamin D analogue applied once daily (applied separately, for example one agent applied in the morning and the other in the evening) for a maximum period of 8 weeks as initial treatment for psoriasis of the trunk or limbs in adults.
- 1.3.2.2 If once-daily application of a potent corticosteroid plus vitamin D or a vitamin D analogue does not result in clearance, near clearance or satisfactory control of psoriasis of the trunk or limbs in adults after 8 weeks, offer vitamin D or a vitamin D analogue alone applied twice daily.

Psoriasis: NICE guideline DRAFT (May 2012) 20 of 45

- 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 by 8–12 weeks offer either:
 - a potent corticosteroid applied twice daily for up to 8 weeks or
 - a coal tar preparation applied once or twice daily.
- 1.3.2.4 If a twice-daily potent corticosteroid or coal tar preparation cannot be used and a once-daily preparation would improve adherence, offer a combined product containing calcipotriol monohydrate and betamethasone dipropionate applied once daily for up to 8 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 day-care setting.
- 1.3.2.7 Offer a review at least annually to people with trunk or limb psoriasis who are using 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.

Psoriasis: NICE guideline DRAFT (May 2012) 21 of 45

- 1.3.2.8 For children and young people with trunk or limb psoriasis consider either:
 - · calcipotriol applied once daily or
 - a potent corticosteroid¹⁹ applied once daily.

Review treatment 2 weeks after starting treatment.

1.3.3 Scalp psoriasis

- 1.3.3.1 Offer a potent corticosteroid²⁰ applied once daily for a maximum period of 8 weeks as initial treatment for people with scalp psoriasis. Choose a low-cost preparation.
- 1.3.3.2 Show people with scalp psoriasis how to safely apply corticosteroid topical treatment.
- 1.3.3.3 If treatment with a potent corticosteroid²¹ 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 further application of the potent corticosteroid.

Psoriasis: NICE guideline DRAFT (May 2012) 22 of 45

_

¹⁹ At the time of publication (May 2012), potent corticosteroids had UK marketing authorisation for this indication in children only for application limited to 5 days and not for children under 1 year of age. Informed consent should be obtained and documented.
²⁰ At the time of publication (May 2012), potent corticosteroids had UK marketing

²⁰ At the time of publication (May 2012), potent corticosteroids had UK marketing authorisation for this indication in adults, but in children licensed use was limited to 5 days and not for children under 1 year of age. Informed consent should be obtained and documented.

At the time of publication (May 2012), potent corticosteroids had UK marketing authorisation for this indication in adults, but in children licensed use was limited to 5 days and not for children under 1 year of age. Informed consent should be obtained and documented.

If the response remains unsatisfactory after a further 4 weeks of treatment offer:

- a combined product containing calcipotriol monohydrate and betamethasone dipropionate²² applied once daily for up to 8 weeks or
- vitamin D or a vitamin D analogue²³ applied once daily.
- 1.3.3.4 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 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
 (up to a maximum of 4 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 alternative treatment options.
- 1.3.3.5 Consider topical vitamin D or a vitamin D analogue²⁴ alone for the treatment of scalp psoriasis only in people who:
 - are intolerant to or cannot use topical corticosteroids at this site
 or
 - have mild-to-moderate scalp psoriasis.
- 1.3.3.6 Do not offer coal tar-based shampoos alone for the treatment of plaque-type scalp psoriasis.

Psoriasis: NICE guideline DRAFT (May 2012) 23 of 45

_

²² At the time of publication (May 2012), combined product containing calcipotriol monohydrate and betamethasone dipropionate did not have UK marketing authorisation for this indication in children. Informed consent should be obtained and documented.

²³ At the time of publication (May 2012), calcitriol and tacalcitol did not have UK marketing authorisation for this indication in children. Calcipotriol should be used in children. Informed consent should be obtained and documented.

At the time of publication (May 2012), calcitriol and tacalcitol did not have UK marketing authorisation for this indication in children. Calcipotriol should be used in children. Informed consent should be obtained and documented.

1.3.3.7 Do not use very potent corticosteroids for scalp psoriasis in children.

1.3.4 Psoriasis of the face, flexures and genitals

- 1.3.4.1 Offer a short-term mild or moderate potency corticosteroid²⁵ applied once or twice daily (for a maximum of 2 weeks) to people with psoriasis of the face, flexures or genitals.
- 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 (1–2 weeks per month). Explain the risks to people undergoing this treatment and how to minimise them.
- 1.3.4.3 For people with psoriasis of the face, flexures or genitals who show an unsatisfactory response to, or require ongoing continuous treatment with, short-term moderate potency corticosteroids to maintain control, offer a calcineurin inhibitor²⁶ applied twice daily for 4 weeks. Calcineurin inhibitors should be initiated by healthcare professionals with expertise in treating psoriasis.
- 1.3.4.4 Do not use very potent corticosteroids in children.
- 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 of these risks and how to minimise them.

1.4 Phototherapy

1.4.1.1 Offer narrowband ultraviolet B (UVB) phototherapy to people with plaque or guttate-pattern psoriasis that cannot be controlled with

Psoriasis: NICE guideline DRAFT (May 2012) 24 of 45

²⁵ At the time of publication (May 2012), moderate potency corticosteroids did not have UK marketing authorisation for this indication in adults or children. Informed consent should be obtained and documented.

26 At the time of publication (May 2012), calcineurin inhibitors did not have UK marketing

authorisation for this indication. Informed consent should be obtained and documented.

topical treatments alone. Treatment with narrowband UVB phototherapy can be given three or two times a week depending on patient preference. Tell people receiving narrowband UVB that a response may be achieved more quickly with treatment three times a week.

- 1.4.1.2 Offer other second- or third-line treatment options when:
 - narrowband UVB phototherapy results in an inadequate 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 psoralen²⁷ (oral or topical) with local ultraviolet A (UVA) irradiation to treat palmoplantar pustulosis.
- 1.4.1.4 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 high-need, covered sites (for example, flexures and the scalp)
 - do not wish to take systemic drugs or in whom systemic drugs are contraindicated.
- 1.4.1.5 Do not routinely use phototherapy (narrowband UVB, broadband UVB or psoralen plus ultraviolet A [PUVA]) as maintenance therapy.

Psoriasis: NICE guideline DRAFT (May 2012)

²⁷ At the time of publication (May 2012), psoralens did not have UK marketing authorisation for this indication in children. Informed consent should be obtained and documented.

- 1.4.1.6 Ensure that all phototherapy equipment is safety-checked and maintained in line with local and national policy²⁸.
- 1.4.1.7 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 phototherapy²⁹.
- 1.4.1.8 Do not routinely offer co-therapy with acitretin when administering PUVA.

1.5 Risk of skin cancer

- 1.5.1.1 Do not use PUVA in people with psoriasis and a genetic predisposition to skin cancer, for example xeroderma pigmentosum or familial melanoma.
- 1.5.1.2 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.

²⁹ See The British Association of Dermatologists 'Phototherapy Working Party Report'.

Psoriasis: NICE guideline DRAFT (May 2012)

²⁸ See The British Association of Dermatologists 'Phototherapy Working Party Report'.

- 1.5.1.3 Use PUVA with caution and consider other treatment options in:
 - people at risk of skin cancer (melanoma and non-melanoma type) (see '<u>Improving outcomes for people with skin tumours</u> including melanoma' [NICE cancer service guidance])
 - people with lighter skin types, such as skin types I or II on the
 Fitzpatrick scale³⁰
 - people who are likely to require ciclosporin or long-term methotrexate
 - · young people.
- 1.5.1.4 When considering PUVA for psoriasis (plaque 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 UV exposures.
- 1.5.1.5 Offer lifetime skin cancer surveillance to people treated with PUVA who have:
 - had more than 150 PUVA treatments or
 - developed skin cancer.
- 1.5.1.6 Document (for example, in a national record) the cumulative number of UV exposures.

Psoriasis: NICE guideline DRAFT (May 2012) 27 of 45

_

³⁰ Fitzpatrick scale: type I: always burns, never tans; type II: usually burns, tans with difficulty, type III: sometimes mild burn, gradually tans; type IV: rarely burns, tans with ease; type V: very rarely burns, tans very easily; type VI: never burns, tans very easily.

1.6 Systemic therapy

1.6.1.1 Only use systemic therapy in specialist settings.

1.6.2 Discussion and monitoring

- 1.6.2.1 When offering systemic therapy, tailor the choice of agent and dosing schedule to the needs of the person 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.
- 1.6.2.2 Be aware of the benefits of, contraindications to and adverse effects associated with systemic treatments. Explain the risks and benefits to people with psoriasis undergoing these treatments 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.
- 1.6.2.3 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.
- 1.6.2.4 Offer adjunctive topical therapy to optimise treatment outcomes.
- 1.6.2.5 Offer people with psoriasis who are starting treatment with a systemic non-biological or biological drug the opportunity to

Psoriasis: NICE guideline DRAFT (May 2012) 28 of 45

participate in long-term safety registries (for example the <u>British</u> <u>Association of Dermatologists Biologic Interventions Register</u>).

1.7 Systemic non-biological therapy

- 1.7.1.1 Offer systemic therapy to people with psoriasis if:
 - it cannot be controlled with topical therapy and
 - it has a significant impact on physical, psychological or social wellbeing and
 - one or more of the following apply:
 - psoriasis is extensive (for example, BSA of more than 10% affected or a 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).
- 1.7.1.2 Offer methotrexate³¹ as the first choice of systemic agent for people with psoriasis that fulfils the criteria for systemic therapy (see recommendation 1.7.1.1) except in the circumstances described in recommendations 1.7.1.4 and 1.7.1.5.
- 1.7.1.3 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 1.7.4.1 to 1.7.4.5).

Psoriasis: NICE guideline DRAFT (May 2012) 29 of 45

³¹ At the time of publication (May 2012), methotrexate did not have an official dose recommendation for this indication in children and the summary of product characteristics states that there is no experience in young children.

- 1.7.1.4 In people with both active psoriatic arthritis and psoriasis that fulfils the criteria for systemic therapy (see recommendation 1.7.1.1) consider the choice of systemic agent in consultation with a rheumatologist. For further information see 'Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis' (NICE technology appraisal guidance 199).
- 1.7.1.5 Offer ciclosporin³² as the first choice of systemic agent for people with psoriasis that fulfils the criteria for systemic therapy (see recommendation 1.7.1.1) 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.
- 1.7.1.6 Consider changing from methotrexate to ciclosporin (or viceversa) when response to the first-choice systemic treatment is inadequate.
- 1.7.1.7 Consider acitretin for adults, and in exceptional cases only for children³³, in the following circumstances:
 - if methotrexate and ciclosporin are not appropriate or have failed
 or
 - for people with pustular forms of psoriasis.

30 of 45

Psoriasis: NICE guideline DRAFT (May 2012)

_

³² At the time of publication (May 2012), ciclosporin did not have an official dose recommendation for this indication in children, but there was no specific contraindication for use in the age group.

At the time of publication (May 2012), acitretin only had UK marketing authorisation for this indication in children if the benefits outweigh the risks as it is contraindicated. Informed consent should be obtained and documented.

1.7.2 Drug regimens

- 1.7.2.1 Use incremental dosing of methotrexate (for example, starting with an initial dose of 5–10 mg once a week) in adults and gradually increase the dose up to the target dose 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).
- 1.7.2.2 Use the lowest possible therapeutic dose of methotrexate to maintain remission.
- 1.7.2.3 Use 2.5–3 mg/kg a day of ciclosporin³⁴ for adults and children. 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).
- 1.7.2.4 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 cannot be used.

Psoriasis: NICE guideline DRAFT (May 2012) 31 of 45

³⁴ At the time of publication (May 2012), ciclosporin did not have an official dose recommendation for this indication in children, but there was no specific contraindication for use in the age group.

1.7.2.5 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.

1.7.3 Reviewing treatment response

- 1.7.3.1 When reviewing response to systemic therapy, take into account:
 - disease severity compared with baseline (for example, PASI 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 and, in children, their family.

1.7.4 Methotrexate and monitoring for hepatotoxicity

- 1.7.4.1 Before and during methotrexate treatment, evaluate for potential hepatotoxicity.
- 1.7.4.2 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.
- 1.7.4.3 When using serum procollagen III levels to exclude liver fibrosis or cirrhosis, be aware that the:
 - test cannot be used in children
 - results may be unreliable in people with psoriatic arthritis
 - positive predictive value is 23–95% and the negative predictive value is 89–100%.

Psoriasis: NICE guideline DRAFT (May 2012) 32 of 45

- 1.7.4.4 Provide advice on modifiable risk factors for liver disease prior to and during therapy including alcohol intake and weight reduction if appropriate. For more information see 'Alcohol-use disorders: physical complications' (NICE clinical guideline 100), 'Alcohol-use disorders: preventing the development of hazardous and harmful drinking' (NICE public health guidance 24) and 'Obesity' (NICE clinical guideline 43).
- 1.7.4.5 Seek timely specialist advice and consider referral to a clinician with expertise in liver disease if the results of liver tests are abnormal.

1.8 Systemic biological therapy

- 1.8.1.1 Adalimumab is recommended as a treatment option for adults with plaque psoriasis for whom anti-tumour necrosis factor (TNF) treatment is being considered and when the following criteria are both met.
 - The disease is severe as defined by a total PASI of 10 or more and a DLQI of more than 10.
 - The psoriasis has not responded to standard systemic therapies including ciclosporin, methotrexate and PUVA; or the person is intolerant of, or has a contraindication to, these treatments.
- 1.8.1.2 Adalimumab should be discontinued in people whose psoriasis has not responded adequately at 16 weeks. An adequate response is defined as either:
 - a 75% reduction in the PASI score (PASI 75) from when treatment started or
 - a 50% reduction in the PASI score (PASI 50) and a five-point reduction in DLQI from start of treatment.
- 1.8.1.3 When using the DLQI, healthcare professionals should ensure that when reaching conclusions on the severity of plaque psoriasis they take into account a person's disabilities (such as

Psoriasis: NICE guideline DRAFT (May 2012) 33 of 45

physical impairments) and linguistic or other communication difficulties. In such cases, healthcare professionals should ensure that their use of the DLQI continues to be a sufficiently accurate measure. The same approach should apply in the context of a decision about whether to continue the use of adalimumab in accordance with recommendation 1.8.1.5.

[These recommendations are from 'Adalimumab for the treatment of adults with psoriasis' (NICE technology appraisal guidance 146).]

- 1.8.1.4 Etanercept, within its licensed indications, administered at a dose not exceeding 25 mg twice weekly is recommended for the treatment of adults with plaque psoriasis only when the following criteria are met.
 - The disease is severe as defined by a total PASI of 10 or more and a DLQI of more than 10.
 - The psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA; or the person is intolerant to, or has a contraindication to, these treatments.
- 1.8.1.5 Etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Further treatment cycles are not recommended in these patients. An adequate response is defined as either:
 - a 75% reduction in the PASI score from when treatment started (PASI 75) or
 - a 50% reduction in the PASI score (PASI 50) and a five-point reduction in DLQI from when treatment started.
- 1.8.1.6 It is recommended that the use of etanercept for psoriasis should be initiated and supervised only by specialist physicians experienced in the diagnosis and treatment of psoriasis. If a

Psoriasis: NICE guideline DRAFT (May 2012) 34 of 45

person has both psoriasis and psoriatic arthritis their treatment should be managed by collaboration between a rheumatologist and a dermatologist.

[These recommendations are from '<u>Etanercept and efalizumab for</u> the treatment of adults with psoriasis' (NICE technology appraisal guidance 103).]

- 1.8.1.7 Infliximab, within its licensed indications, is recommended as a treatment option for adults with plaque psoriasis only when the following criteria are met.
 - The disease is very severe as defined by a total PASI of 20 or more and a DLQI of more than 18.
 - The psoriasis has failed to respond to standard systemic therapies such as ciclosporin, methotrexate or PUVA, or the person is intolerant to or has a contraindication to these treatments.
- 1.8.1.8 Infliximab treatment should be continued beyond 10 weeks only in people whose psoriasis has shown an adequate response to treatment within 10 weeks. An adequate response is defined as either:
 - a 75% reduction in the PASI score from when treatment started (PASI 75) or
 - a 50% reduction in the PASI score (PASI 50) and a five-point reduction in the DLQI from when treatment started.
- 1.8.1.9 When using the DLQI healthcare professionals should take care to ensure that they take account of a patient's disabilities (such as physical impairments) or linguistic or other communication difficulties, in reaching conclusions on the severity of plaque psoriasis. In such cases healthcare professionals should ensure that their use of the DLQI continues to be a sufficiently accurate measure. The same approach should apply in the context of a

Psoriasis: NICE guideline DRAFT (May 2012) 35 of 45

decision about whether to continue the use of the drug in accordance with recommendation 1.8.1.8.

[These recommendations are from 'Infliximab for the treatment of adults with psoriasis' (NICE technology appraisal guidance 134).]

- 1.8.1.10 Ustekinumab is recommended as a treatment option for adults with plaque psoriasis when the following criteria are met.
 - The disease is severe, as defined by a total PASI score of 10 or more and a DLQI score of more than 10.
 - The psoriasis has not responded to standard systemic therapies, including ciclosporin, methotrexate and PUVA, or the person is intolerant of or has a contraindication to these treatments.
 - The manufacturer provides the 90 mg dose (two 45 mg vials) for people who weigh more than 100 kg at the same total cost as for a single 45 mg vial.
- 1.8.1.11 Ustekinumab treatment should be stopped in people whose psoriasis has not responded adequately by 16 weeks after starting treatment. An adequate response is defined as either:
 - a 75% reduction in the PASI score (PASI 75) from when treatment started or
 - a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in the DLQI score from when treatment started.
- 1.8.1.12 When using the DLQI, 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.

[These recommendations are from '<u>Ustekinumab for the treatment</u> of adults with moderate to severe psoriasis' (NICE technology appraisal guidance 180).]

Psoriasis: NICE guideline DRAFT (May 2012) 36 of 45

- 1.8.1.13 Consider changing to an alternative biological drug in adults with psoriasis in whom there is an inadequate response to a first biological drug (either following the first 3 months of treatment [primary failure], or following an initially adequate response [secondary failure]), or if the first biological drug cannot be tolerated or becomes contraindicated.
- 1.8.1.14 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.
- 1.8.1.15 If a person has both psoriasis and psoriatic arthritis, take into account both conditions before making changes to biological therapy and manage their treatment in consultation with a rheumatologist. For further information see 'Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis' (NICE technology appraisal guidance 199).

2 Notes on the scope of this guideline

NICE guidelines are developed in accordance with a <u>scope</u> that defines what the guideline will and will not cover.

How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations.

There is more information about <u>how NICE clinical guidelines are developed</u> on the NICE website. A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' is <u>available</u>.

Psoriasis: NICE guideline DRAFT (May 2012) 37 of 45

3 Implementation

NICE has developed <u>tools to help organisations implement this guidance</u>. Note: these details will apply when the guideline is published.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

4.1 Assessment of disease severity and impact

What validated tools can be used in people (including children and young people) to assess disease severity and impact in non-specialist and specialist healthcare settings to facilitate assessment, appropriate referral, treatment planning and measurement of outcomes?

Why this is important

Assessment of disease severity and impact is fundamental to delivering high-quality healthcare and measuring outcomes. The evidence review indicates that the existing tools have important limitations, and have not been validated in relevant healthcare settings. 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 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).

4.2 Identification of comorbidities

Does treating psoriasis modify the risk of cardiovascular disease and are there any demographic, phenotypic or other biomarkers that identify those most likely to benefit?

Psoriasis: NICE guideline DRAFT (May 2012) 38 of 45

Why this is important

Psoriasis is a common disease, and the evidence review indicates that in all people affected there is a clinically relevant increase in cardiovascular disease. If treatment of the psoriasis also improved cardiovascular morbidity or mortality, this would be of major importance to patients, and also justify early and/or more aggressive treatment of psoriasis.

4.3 Methotrexate and risk of hepatotoxicity

What is the impact of methotrexate compared with other approaches to care 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.

4.4 Biological therapy

In people with psoriasis, does early intervention to achieve and maintain complete disease remission alter the long-term prognosis in terms of psoriasis severity, comorbidities, or treatment-related adverse effects, and are there any clinical or other 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 done to evaluate whether early intervention alters prognosis. Consequently, patients with more severe disease sequence

Psoriasis: NICE guideline DRAFT (May 2012) 39 of 45

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 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 deliver much more cost-effective treatment strategies.

4.5 Self-management

Do structured psoriasis-focussed educational 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 focussed educational programme that effectively improves outcomes for patients would be of clinical benefit and likely deliver healthcare savings.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Psoriasis: the management of psoriasis' contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre and is available from <u>our website</u>. Note: these details will apply to the published full guideline.

Psoriasis: NICE guideline DRAFT (May 2012) 40 of 45

5.2 NICE pathway

The recommendations from this guideline have been incorporated into a <u>NICE</u> <u>pathway</u>. Note: these details will apply when the guideline is published.

5.3 'Understanding NICE guidance'

A summary for patients and carers ('<u>Understanding NICE guidance</u>') is available.

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N[XXXX]). Note: these details will apply when the guideline is published.

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about psoriasis.

6 Related NICE guidance

Published

- <u>Patient experience in adult NHS services.</u> NICE clinical guideline 138 (2012)
- Preventing type 2 diabetes: population and community-level interventions
 in high-risk groups and the general population. NICE public health
 quidance 35 (2011)
- <u>Etanercept, infliximab and adalimumab for the treatment of psoriatic</u>
 <u>arthritis.</u> NICE technology appraisal 199 (2010)
- Prevention of cardiovascular disease at population level. NICE public health guidance 25 (2010)
- Alcohol-use disorders: preventing the development of hazardous and harmful drinking. NICE public health guidance 24 (2010)
- Alcohol-use disorders. NICE clinical guideline 100 (2010)
- Venous thromboembolism: reducing the risk. NICE clinical guideline 92
 (2010)
- Improving outcomes for people with skin tumours including melanoma.
 NICE cancer service guidance (2010)

Psoriasis: NICE guideline DRAFT (May 2012) 41 of 45

- Ustekinumab for the treatment of adults with moderate to severe psoriasis.
 NICE technology appraisal guidance 180 (2009)
- <u>Depression in adults with a chronic physical health problem.</u> NICE clinical guideline 91 (2009)
- Medicines adherence. NICE clinical guideline 76 (2009)
- Adalimumab for the treatment of adults with psoriasis. NICE technology appraisal guidance 146 (2008)
- <u>Infliximab for the treatment of adults with psoriasis</u>. NICE technology appraisal guidance 134 (2008)
- <u>Lipid modification.</u> NICE clinical guideline 67 (2008)
- Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities. NICE public health guidance 10 (2008)
- Etanercept and efalizumab for the treatment of adults with psoriasis. NICE technology appraisal guidance 103 (2006)
- Obesity. NICE clinical guideline 43 (2006)
- <u>Depression in children and young people</u>. NICE clinical guideline 28 (2005)

Under development

NICE is developing the following guidance:

Preventing type 2 diabetes: risk identification and interventions for individuals at high risk NICE public health guidance (publication expected July 2012)

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Psoriasis: NICE guideline DRAFT (May 2012) 42 of 45

Appendix A: The Guideline Development Group, National Collaborating Centre and NICE project team

Guideline Development Group

Catherine Smith (Chair)

Consultant Dermatologist and Senior Lecturer, St John's Institute of Dermatology, Guys and St Thomas' NHS Foundation Trust, London

David Chandler

Patient member

Paul Hepple

GP, Edinburgh

Karina Jackson

Nurse Consultant, St John's Institute of Dermatology, Guys and St Thomas' NHS Foundation Trust, London

Ruth Murphy

Adult and Paediatric Consultant Dermatologist, Nottingham University Hospitals NHS Trust

Jillian Peters

Dermatology Nurse Practitioner, NHS Suffolk

Natasha Smeaton

GP, London

Claire Strudwicke

Patient member

Roderick Tucker

Community Pharmacist, East Yorkshire

Richard Warren

Senior Clinical Lecturer and Honorary Consultant Dermatologist, University of Manchester and Salford Royal NHS Foundation Trust

Psoriasis: NICE guideline DRAFT (May 2012) 43 of 45

Christine Bundy

Consultant Health Psychologist, Central Manchester University Hospitals NHS Foundation Trust (expert advisor)

James Ferguson

Consultant Dermatologist, Ninewells Hospital and Medical School, Dundee (expert advisor – phototherapy)

Neil McHugh

Consultant Rheumatologist, Royal National Hospital for Rheumatic Diseases, Bath (expert advisor)

National Clinical Guideline Centre

Jill Cobb

Information Scientist

Bernard Higgins

Clinical Director

Jill Parnham

Operations Director

Nancy Pursey

Senior Project Manager (until May 2012)

Silvia Rabar

Project Manager (until January 2011)

Eleanor Samarasekera

Research Fellow

Laura Sawyer

Senior Health Economist

Katrina Sparrow

Senior Research Fellow

Psoriasis: NICE guideline DRAFT (May 2012) 44 of 45

NICE project team

Philip Alderson

Associate Director

Sarah Dunsdon

Guideline Commissioning Manager

Natalie Boileau

Guideline Coordinator

Judith Thornton

Technical Lead

Prashanth Kandaswarmy

Health Economist

Catharine Baden-Daintree

Editor

Psoriasis: NICE guideline DRAFT (May 2012) 45 of 45