NCGC National Clinical Guideline Centre

Psoriasis

Appendices

Clinical Guideline <…>

Methods, evidence and recommendations

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Foreword

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Appendix A: Scope

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Psoriasis: the management of psoriasis

1.1 Short title

Psoriasis

2 The remit

The Department of Health has asked NICE: 'to produce a clinical guideline on the management of psoriasis'.

3 Clinical need for the guideline

3.1 Epidemiology

a) Psoriasis is a chronic inflammatory skin disease that typically follows a relapsing and remitting course. It is associated with joint disease in a significant minority of people.

b) There are no validated diagnostic criteria for psoriasis, so it is difficult to obtain an accurate figure for its prevalence. It is estimated to be around 1–2%, with the greatest prevalence being in white people. Men and women are equally affected. It can occur at any age, but the majority of cases occur before the age of 35 years.

c) Chronic plaque psoriasis is by far the most common variant and is characterised by well delineated red, scaly plaques. The extent of involvement is highly variable, ranging from a few localised patches at extensor sites, to generalised involvement. Distinctive nail

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changes occur in around 50% of those affected and are more common in those with arthritis.

d) Other variants include:

- guttate psoriasis (a rash of small pink spots)
- flexural or 'inverse' forms (affecting skin in the body folds)
- sebopsoriasis (particularly affecting the face and central chest)
- erythrodermic psoriasis (redness and scaling over the whole body)
- pustular psoriasis (small pus-filled spots, known as palmar plantar pustulosis if it affects just the hands and feet, or as generalised pustular psoriasis if it is more widely spread).

Occasionally combinations of the different types develop simultaneously or sequentially over time in the same person.

e) The chronic, incurable nature of psoriasis means that associated morbidity is significant. People with psoriasis, like those with other major medical disorders, have reduced levels of employment and income as well as a decreased quality of life. The impact on quality of life is similar in primary care and hospital settings, and encompasses functional, psychological, and social dimensions.

f) Factors that contribute to morbidity include symptoms specifically related to the skin (for example, chronic itch, bleeding, scaling and nail involvement), problems related to treatments (mess, odour, inconvenience and time), arthritis, and the effect of living with a highly visible, disfiguring skin disease (difficulties with relationships, difficulties with securing employment and poor self esteem). Even people with minimal involvement (less than the equivalent of three palm areas) state that psoriasis has a major effect on their life.

g) The combined costs of long-term therapy and social costs of the disease have a major impact on healthcare systems and on society in general.

h) About one in four people with psoriasis experience major psychological distress, and the extent to which they feel socially stigmatised and excluded is substantial. Doctors, including dermatologists, often fail to appreciate the extent of this disability and even when it is correctly identified, fewer than a third of people with psoriasis receive appropriate psychological interventions.

i) People with severe disease have a more than twofold increase in mortality from cardiovascular disease although it is not clear whether this increase directly relates to the psoriasis itself, or to the increased prevalence of traditional cardiovascular risk factors in people with psoriasis. These include obesity, type 2 diabetes mellitus, metabolic syndrome, excess alcohol intake or alcoholism, hyperlipidaemia (which may be partly iatrogenic, from the effects of antipsoriatic treatments such as ciclosporin and acitretin) and smoking (where long duration of smoking is associated with severe psoriasis in women).

j) Community- and hospital-based studies suggest that people with psoriasis, particularly those with severe disease, may be at increased risk of lymphoma and non-melanoma skin cancer. The relative influence of known confounders such as concomitant therapy with immunosuppressants and phototherapy, smoking, and alcohol is not clear.

k) The significant reduction in quality of life and psychosocial disability suffered by people with psoriasis underlines the need for prompt, effective treatment, and long-term disease control.

3.2 Current practice

a) Traditional topical therapies (such as corticosteroids, vitamin D3 analogues, dithranol and tar preparations) are used to treat mild to moderate disease. Adherence to topical therapy regimens is often poor, but can be improved by giving attention to cosmetic

acceptability, local side effect profiles, formulation, and practicalities of application.

b) People with moderate to severe psoriasis (approximately one in four people with the condition) may need second-line therapies because of the extent and/or severity of the disease. These include phototherapy (broad- or narrow-band ultraviolet [UV] B light, with or without supervised application of complex topical therapies such as dithranol or crude coal tar), photochemotherapy (psoralen plus UVA light, this combination is known as PUVA), and systemic agents such as ciclosporin, methotrexate, acitretin and fumarates.

c) All of these interventions can be associated with long-term toxicity and some people with psoriasis have treatment-resistant disease. Also, phototherapy is not available to many because of geographical, logistical or other constraints.

d) Over the past 5 years, a number of biological therapies that use molecules designed to block specific molecular steps important in the development of psoriasis have been licensed for use in moderate to severe psoriasis. These include TNF antagonists (adalimumab, etanercept and infliximab) and ustekinumab (anti-IL12-23 monoclonal antibody). These agents are approved for use by NICE, subject to certain disease severity criteria.

e) Recent guidelines from the British Association of Dermatologists, NICE guidance and the UK marketing authorisation for these drugs, recommend that biological therapies should generally be reserved for people in whom standard treatments have failed or cannot be used. But there remain important exceptional circumstances in which biological therapy should be used earlier in the disease course.

f) For most people psoriasis is managed in primary care, with specialist referral being needed at some point for up to 30% of people.

g) Commonly cited triggers for referral include

- diagnostic uncertainty
- request for further counselling or education, including demonstration of topical treatment
- symptoms not responding to appropriately-used topical therapy
- psoriasis at sites that are difficult to treat (scalp, face, palms, soles or genital area)
- adverse reactions to topical therapies
- need for systemic therapy, phototherapy, day treatment, or inpatient admission
- disability preventing work or causing excessive time off work
- presence of psoriatic arthritis and acute unstable psoriasis, for which urgent referral may be justified.

h) People on systemic therapy receive ongoing supervision in secondary care, sometimes with shared care arrangements for drug monitoring in primary care. Tertiary centres with access to multidisciplinary teams with experience in multiple drug therapies provide specialist care for the minority of people with severe, recalcitrant disease. A recent UK audit demonstrated wide variations in practice, and in particular in access to specialist treatments (including biological agents), appropriate drug monitoring and psychological services.

i) Psoriasis is a common, chronic disease, associated with profound psychosocial morbidity and important comorbidities. Effective treatments are available. Some treatments are expensive, all require appropriate monitoring and some may be accessed only in specialist care settings.

j) Evidence indicates that a substantial proportion of people with psoriasis are currently dissatisfied with their treatment. There is a clear need for a guideline on the management of psoriasis to improve patient satisfaction and outcomes.

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4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health, but it was decided to cover only management and to exclude diagnosis. This was because it is a clinical diagnosis that, in the majority of cases, is straightforward and there are no routinely used diagnostic tests. Following initial discussions, we have decided to focus on areas of particularly diverse, uncertain or unsafe practice (see section 4.3).

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Children and adults with a diagnosis of psoriasis.

b) Consideration will be given to the specific needs, if any, of people with psoriatic arthritis.

4.1.2 Groups that will not be covered

a) Children and adults who do not have a diagnosis of psoriasis.

4.2 Healthcare setting

a) All settings in which healthcare for psoriasis is delivered by the NHS.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Evaluation of disease severity and impact on people with psoriasis.

b) Identification of psoriatic arthritis.

c) Management of psoriasis including, for example:

- topical therapy:
  - corticosteroids
  - vitamin D analogues
  - coal tar (with or without phototherapy)
  - dithranol (with or without phototherapy)
- phototherapy (narrow band UVB)
- photochemotherapy (psoralen and UVA)
- systemic therapy:
  - ciclosporin
  - methotrexate
  - acitretin.

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

d) Self-management.

e) Management of the psychological impact of psoriasis.

f) Combination and sequencing of treatments.

4.3.2 Clinical issues that will not be covered

a) Diagnosis.

b) Management of psoriatic arthritis.

c) Complementary and alternative treatments.

d) Fumaric acid esters[1].

[1] Fumaric acid esters are not licensed for any indication within the UK and therefore we are not able to consider this treatment within the guideline.

4.4 *Main outcomes*

The following outcome measures might be looked at, depending on each individual clinical question:

a) Health related quality of life, for example CDLQI (Children's Dermatology Life Quality Index), DLQI (Dermatology Life Quality Index) and/or EQ-5D (European Quality of Life-5 Dimensions).

b) Scales of objective disease severity, for example Physician's Global Assessment and/or Psoriasis Area Severity Index (PASI).

c) Length of hospital stay.

d) Time to recurrence.

e) Maintenance of remission/relapse rate.

f) Treatment adherence.

g) Withdrawal rates.

h) Adverse events.

4.5 *Economic aspects*

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.6 *Status*

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in January 2011.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be incorporated

This guideline will incorporate the following NICE guidance:

- Ustekinumab for the treatment of adults with moderate to severe psoriasis. NICE technology appraisal guidance 180 (2009). Available from www.nice.org.uk/guidance/TA180
- Adalimumab for the treatment of adults with psoriasis. NICE technology appraisal guidance 146 (2008). Available from www.nice.org.uk/guidance/TA146
- Infliximab for the treatment of adults with psoriasis. NICE technology appraisal guidance 134 (2008). Available from www.nice.org.uk/guidance/TA134
- Etanercept and efalizumab for the treatment of adults with psoriasis. NICE technology appraisal guidance 103 (2006). Available from www.nice.org.uk/guidance/TA103

5.1.2 Other related NICE guidance

- Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis. NICE technology appraisal guidance 199 (2010). Available from www.nice.org.uk/guidance/TA199
- Alcohol-use disorders: physical complications. NICE clinical guideline 100 (2010). Available from www.nice.org.uk/guidance/CG100
- Alcohol-use disorders – preventing harmful drinking. NICE public health guidance 24 (2010). Available from www.nice.org.uk/guidance/PH24
- Medicines adherence. NICE clinical guideline 76 (2009). Available from www.nice.org.uk/guidance/CG76

- Smoking cessation services. NICE public health guidance 10 (2008). Available from www.nice.org.uk/guidance/PH10
- Grenz rays therapy for inflammatory skin conditions. NICE interventional procedure guidance 236 (2007). Available from www.nice.org.uk/guidance/IPG236
- Obesity. NICE clinical guideline 43 (2006). Available from www.nice.org.uk/guidance/CG43

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- ABT-874 for the treatment of moderate to severe chronic plaque psoriasis. NICE technology appraisal guidance. Publication expected December 2011. (This appraisal may be incorporated into the psoriasis guideline, subject to the review process with consultees and commentators.)

6 Further information

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).