National Institute for Health and Clinical Excellence

Psoriasis: scope consultation

Scope Consultation Table

3 September 2010 – 1 October 2010

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Abbott Laboratories	1	2	The remit: *'The Department of Health has asked NICE: 'to produce a clinical guideline on the **diagnosis** and management of psoriasis in young people and adults'.* However, the scope then states the following: **Clinical issues that will not be covered** **a) Diagnosis.** Therefore this does not satisfy the remit put forward by the Department of Health. Diagnosis is an integral part of the management of all diseases. We believe that diagnosis is particularly important in the primary care setting as delayed diagnosis or misdiagnosis can adversely impact upon the patient. Therefore it is important to cover diagnosis, especially at the primary care level.	Thank you. Stakeholders indicated to the NCGC that there was no real issue with diagnosis of psoriasis. Stakeholders and experts in the field indicated that it was the 'evaluation of disease severity and its impact' that guidance was required for. In light of this diagnosis of psoriasis was excluded but evaluation of disease severity was included to ensure we addressed the concerns of stakeholders and expert opinion. Hence to ensure that the guideline meets user requirements the developers feel that the current approach is correct. This approach was discussed with NICE at the scoping meeting and agreed by the commissioners of the guideline. The Department of Health has approved a change to the remit. The remit for the guideline is now, the 'Management of Psoriasis"
SH	Abbott	2	4.1.1	It is not clear why the age of 15 is being used as	Thank you for your comment. In light of the stakeholders'

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	Laboratories		a	the lower limit. We believe that the group covered should be limited to 'adults' with psoriasis i.e. 18 years and older.	comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups.
SH	Abbott Laboratories	3	4.2 a	This point states that Healthcare Setting includes 'all settings in which healthcare is delivered by the NHS'. We believe that there needs to be a clear emphasis of the specific roles of HCPs within primary care and within secondary care. This would subsequently include clear and objective criteria for referral from primary to secondary care. There should be clear statements providing guidance for the requirements for the assessment and measurement of disease severity in the primary care setting. This would result in equality of care for patients.	Thank you; NICE guidelines do not make recommendations that are role specific unless there is an extremely strong evidence base. Guidelines look at the evidence for techniques and what is offered rather than who delivers the output. The GDG will be looking at the evidence for the effectiveness of different treatment modalities and we will take settings into account based on the evidence found. We will look at the evaluation of disease severity in primary care.
SH	Abbott Laboratories	4	4.3.1	Guidance on when to commence, switch and stop the different therapies would be greatly beneficial and, in our opinion, a fundamental requirement of a clinical guideline. It would be of great benefit to explicitly state that optimal sequencing strategies of the therapies will be considered by the group. A similar statement was included in the draft scope for the clinical guideline for the management of rheumatoid arthritis (4,3b – November 2006).	Thank you, where possible in the confines of the scope the GDG will consider treatment sequencing. Please note the rheumatoid arthritis guideline was given a specific remit from the department of health to look at the drug sequencing.
SH	Abbott Laboratories	5	4.4	We believe that that it is important to explicitly state that the main outcomes (especially 4.4a and 4.4b) will be incorporated within the treatment strategy using the different therapies to enable optimal decision making using objective	Thank you. The GDG will advise the technical team which outcomes are the most appropriate a priori.

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				measures.	
SH	Abbott Laboratories	6	General	The manner in which the draft scope is presented seems to suggest that emphasis on the guideline is to assess the suitability of the different therapies. We believe that the most important objective of this guideline should be to produce a treatment / management algorithm or pathway to assist HCPs to assess the disease (scoring etc) and decide on the best course of treatment. This would include guidance on specific criteria to commence, switch and stop various therapies in order to standardise patient care so as to create equality of treatment. The remit clearly states the '**management of psoriasis**'. Therefore a treatment algorithm would be an integral part of this.	Thank you for your comment. Algorithms will be produced in accordance with the NICE Guideline Manual.
SH	Abbott Laboratories	7	General	Co-morbidities (except from psoriatic arthritis and the psychological impact) are not being addressed. Co-morbidities such as, for example, cardiovascular factors and glucose intolerance, are important issues to consider. As a minimum, we believe that simple screening for these co-morbidities should be considered and that there should be a statement to the effect that referral to the appropriate specialists is indicated for patients who are affected.	Thank you. Generally NICE guidelines do not cover screening. We are unable to cover the management of associated co-morbidities within the time available but we will take these into consideration in terms of evaluation of disease severity and impact (see 4.3.1 a).
SH	British Association Of Dermatologists	1	General	Our overall impression is that this scope looks satisfactory, although it was noted that the shortly-to-be-published SIGN guideline for psoriasis covers much the same ground.	Thank you for your comment.
SH	British	2	4.1	We would like to question the exclusion of	Thank you for your comment. In light of the stakeholders'

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	Association Of Dermatologists			children (<15 years of age) from the scope of this psoriasis guideline. When all is said and done, children are "young people", and the management of psoriasis in children can be challenging and certainly merits guideline assistance. The majority of children with psoriasis are managed by general practitioners and general (not paediatric) dermatologists, and the management of psoriasis in children does not differ significantly from that in adults. Thus it appears illogical to exclude children. Surely, the inclusion of children within the remit of this guideline will obviate the need for a separate guideline in due course, and thereby avoid unnecessary duplication.	comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups.
SH	British Association Of Dermatologists	3	4.3.1 (b) & 4.3.2 (b)	It is intended that the *diagnosis* of psoriatic arthritis will be covered by this guideline, yet not its *management*. Perhaps either both or neither of these aspects of psoriasis should be considered, at the discretion of the guideline developers.	Stakeholders' comments and expert opinion indicated that identification of psoriatic arthritis was problematic and that guidance was required for this aspect (and not for the diagnosis of psoriasis). In the time available the developers are unable to review the evidence base for psoriatic arthritis management as well as psoriasis. Consideration will be given to the specific needs, if any, of people with psoriatic arthritis. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise the needs of patients with psoriasis who also have psoriatic arthritis and it will be specifically considered throughout the guideline. We recognise, and will take into consideration the fact that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa. However, in the time available, we are unable to produce a comprehensive guideline on ALL aspects of care for patients with psoriatic arthritis and we will not be dealing with aspects specific to the arthritis. We encourage you to suggest psoriatic arthritis to the topic

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					selection panel at NICE details of which can be found at http://www.nice.org.uk/getinvolved/topicselection/topicselection.jsp
SH	British Association Of Dermatologists	4	4.3.1 (c)	We consider that, in the evaluation of phototherapy and photochemotherapy, *access* to these therapies by patients is addressed. As mentioned in 3.2c, access to phototherapy services for a significant proportion of the UK population is currently poor, and such patients are effectively excluded from these treatments on the basis of where they live. The need for more phototherapy units, strategically-sited and with opening hours defined by local need, should be emphasised. In addition, the provision of "home phototherapy" facilities should be considered, especially for patients living in remote areas and for those unable to attend during routine opening times. There is concern that certain psoriasis patients, who could be very adequately managed by topical medication and phototherapy, are being discriminated against by the uneven provision of phototherapy facilities.	Thank you, the developers cannot prejudge the clinical and health economic evidence. Where possible the GDG will seek to make service delivery recommendations.
SH	British Association Of Dermatologists	5	4.3.1 (c)	It is felt that, in addition to the oral therapies listed, consideration should be given to the use of both hydroxyurea and mycophenolate mofetil.	Thank you for your suggestion. The list of therapies is not exhaustive. The GDG will consider which specific drugs to cover in the guideline, including hydroxyrea and mycophenolate mofetil, although given the timelines and resources, not all interventions can be considered.
SH	British Association Of Dermatologists	6	4.3.1 (c)	It is noted that this new guideline will incorporate existing NICE technology appraisal guidance on the use of biological therapy in psoriasis. However, we feel strongly that this should not prevent or restrict the guideline developers from addressing aspects of biological therapy usage in psoriasis that may not have been adequately covered by the technology appraisals.	Thank you. The combination and sequencing of treatments will be considered as outlined in the scope and the GDG will consider the drugs accordingly.

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SH	British Association Of Dermatologists	7	4.3.1 (c)	Doubt was raised as to the necessity of a *detailed* assessment of conventional and established topical therapies, such as coal tar products, dithranol and vitamin D analogues.	Thank you, we have noted your comment. The clinical questions will be finalized and prioritized by the GDG.
SH	British Association Of Dermatologists	8	4.3.1 (d)	The section on self-management has been given a separate sub-heading, yet it is not entirely clear as to what is considered relevant to this heading that is not included elsewhere.	Thank you, the developers felt it prudent having listened to views at the SH workshop to leave this as a generic heading so as to be as inclusive as possible when searching the literature. The GDG can then make a decision on aspects of self management that may require specific recommendations that would not be covered elsewhere in the guideline.
SH	British Association Of Dermatologists	9	4.3.1 (e)	We welcome the fact the management of the psychological impact of psoriasis will be considered, although this draft scoping document does not go into detail. We hope that the guideline will address the relative lack of NHS resource for psychological intervention for non-malignant disease.	Thank you the developers cannot prejudge the clinical or health economic evidence base and we will not specifically comment about lack of resource within the guideline. However, if a clear recommendation is possible about the benefit of specific psychological treatments this will be made.
SH	British Association Of Dermatologists	10	General	We feel this guideline should address the requirements for in-patient care for patients with severe and debilitating psoriasis. Dedicated dermatology beds are the ideal, but patients admitted to "general" wards should, we believe, receive daily care from appropriately trained nursing staff.	Thank you. Although we sympathise with your point we think it unlikely that we will find evidence specifying where a patient should be treated. In general the Guideline will focus on what should be done rather than where and by whom. The GDG will be looking at the evidence for the effectiveness of different treatment modalities and we will take settings into account based on the evidence found.
SH	British Society for Paediatric and Adolescent Rheumatology	1	3.2	Presence of psoriatic arthritis is cited as a common cause for referral to secondary care but the scope then excludes it's management	Thank you, consideration will be given to the specific needs, if any, of people with psoriatic arthritis. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa; but in the time available, we will not be dealing with aspects specific to the arthritis. We encourage you to suggest psoriatic arthritis to the topic selection panel at NICE details of which can be found at http://www.nice.org.uk/getinvolved/topicselection/topicselection.jsp

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SH	British Society for Paediatric and Adolescent Rheumatology	2	4.1.1 b)	Patients with Psoriatic Arthritis don't just need "consideration" being given to their specific needs. They should be directly included within this guideline.	Thank you for your comment. Consideration will be given to the specific needs, if any, of people with psoriatic arthritis. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise the needs of patients with psoriasis who also have psoriatic arthritis and it will be specifically considered throughout the guideline. We recognise, and will take into consideration the fact that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa. However, in the time available, we are unable to produce a comprehensive guideline on ALL aspects of care for patients with psoriatic arthritis and we will not be dealing with aspects specific to the arthritis. We encourage you to suggest psoriatic arthritis to the topic selection panel at NICE details of which can be found at http://www.nice.org.uk/getinvolved/topicselection/topicselection.jsp
SH	British Society for Paediatric and Adolescent Rheumatology	3	4.1.2	Children below the age of 15 are excluded from this scope. This is directly discriminatory on the basis of age, and the cut-off of 15 seems entirely arbitrary. NICE was tasked by government 'to produce a clinical guideline on the diagnosis and management of psoriasis in young people and adults'. Children are "young people"	Thank you for your comment. In light of the stakeholders' comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups.
SH	British Society for Paediatric and Adolescent Rheumatology	4	4.3.1 a)	Why have a section on the identification of Psoriatic Arthritis if you don't then go on to consider its treatment?	Stakeholders' comments and expert opinion indicated that identification of psoriatic arthritis was problematic and that guidance was required for this aspect (and not for the diagnosis of psoriasis). In the time available the developers are unable to review the evidence base for psoriatic arthritis management as well as psoriasis. Consideration will be given to the specific needs, if any, of people with psoriatic arthritis. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise the needs of patients with psoriasis who also have psoriatic arthritis and it will be specifically considered throughout the guideline. We recognise, and will take

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					into consideration the fact that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa. However, in the time available, we are unable to produce a comprehensive guideline on ALL aspects of care for patients with psoriatic arthritis and we will not be dealing with aspects specific to the arthritis. We encourage you to suggest psoriatic arthritis to the topic selection panel at NICE details of which can be found at http://www.nice.org.uk/getinvolved/topicselection/topicselection.jsp
SH	British Society for Paediatric and Adolescent Rheumatology	5	4.3.2	Treatments for psoriasis and psoriatic arthritis frequently overlap. Particularly in the sphere of systemic therapy. The guideline must acknowledge this and look at ways to combine therapies.	Thank you, consideration will be given to the specific needs, if any, of people with psoriatic arthritis. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa; but we will not be dealing with aspects specific to the arthritis. The guideline will acknowledge the overlap of treatment for psoriasis and psoriatic arthritis and look at ways to combine therapies.
SH	British Society for Paediatric and Adolescent Rheumatology	6	General	The scope, as it is currently drafted, will only produce a partial guideline. To exclude children below the age of 15 and to exclude the treatment of Psoriatic Arthritis misses the opportunity to produce a truly comprehensive guideline. The extra work would not be excessive and the stakeholder groups to do this (BSPAR, RCPCH etc) are readily available to be involved.	Thank you for your comment. In light of the stakeholders' comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups. Consideration will be given to the specific needs, if any, of people with psoriatic arthritis. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise the needs of patients with psoriasis who also have psoriatic arthritis and it will be specifically considered throughout the guideline. We recognise, and will take into consideration the fact that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa. However, in the time available, we are unable to produce a comprehensive guideline on ALL aspects of care for patients with psoriatic arthritis and we will not be dealing with aspects specific to the arthritis. We encourage you to suggest psoriatic arthritis to the topic selection panel at NICE details of which can be found at

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SH	Department of Health	1	General	The Department of Health has no substantive comments to make, regarding this consultation	Thank you for your comment.

SH	Dermal Laboratories	1	4.3.1 c)	Emollients should be included within the scope of this NICE guideline as they have an important role to play in the management of psoriasis. They should be included in the 'topical therapy – self-administered by the patient' section.
				Consideration should be given to the following points to support the inclusion of emollients within the guideline:-
				• Therapeutic role
				  ○ Emollients help in psoriasis by moisturising and softening scaly skin thereby reducing scale and irritation.
				  ○ Emollients can be helpful even if patients are receiving systemic therapy.
				• Professional bodies recommendations/support
				  ○ The use of emollients in psoriasis is recommended by the PCDS/BAD, The Psoriasis Association and they are also included in the draft SIGN Psoriasis Guideline.
				  ○ Similarly, in the fairly recent Cochrane Review of Topical Treatments for Chronic Plaque
					Thanks you for your comment. Emollients are not explicitly excluded from the scope; the list of topical therapies is not exhaustive. The GDG will consider which specific drugs to cover in the guideline, including emollients, although given the timelines and resources, not all interventions can be considered.

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				Psoriasis emollients are considered to have a supportive role as an addition to topical treatments, to normalise hyperproliferation, differentiation, and to exert anti-inflammatory effects.
				• Choice of emollient
				  ○ Not all emollients are the same. They differ in consistency, degree of emolliency, excipients and cosmetic acceptability.
				  ○ The most effective emollient is the one the patient will use. If a patient likes the emollient then they will use it, improving concordance with treatment.
				  ○ It is also important to avoid soaps and bubble baths etc. as they can irritate the skin, a soap substitute emollient should be used instead.
				• Socioeconomic inequalities
				  ○ Emollients are widely prescribed for psoriasis in primary care and this is confirmed in the feedback from the draft scope meeting whereby under prioritisation of pharmacological treatments, emollients and vitamin D preparations were claimed to be the most used in primary care. Therefore, if emollients are not included in the guideline and not	

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				considered to be part of psoriasis management, healthcare professionals may be reluctant to prescribe them. o Although emollients are available to purchase over the counter, the cost is often prohibitive especially in view of the large quantities required to manage this long term, chronic condition.	
SH	Dermal Laboratories	2	4.3.1 c)	Coal tar based products should be included within the 'topical therapy – self-administered by the patient' section and not wholly restricted to topical therapy administered in specialist settings. Coal tar preparations are widely used in the management of psoriasis of the skin and scalp with coal tar based shampoos (with or without a keratolytic) often used as a first line therapy for scalp psoriasis. Coal tar preparations are available as shampoos, lotions, creams, gels, ointments and bath emulsions which are designed for self-application by the patient in a primary care environment and not just within a specialist setting.	Thank you for your comment. In the topical therapy paragraph (4.3.1.c) we have now removed the "topical therapy administered in specialist setting" sub-heading.
SH	Dermal Laboratories	3	3.1 d)	Specific body areas affected by psoriasis, such as the scalp, should be considered individually and included with the 'variant' forms of psoriasis. As treatment of psoriasis will vary according to the area of the body affected, guidance on managing the condition in specific body areas	Thank you, we have based the scope around types of treatment rather than parts of the body. Whether we need to make separate recommendations for different body areas for any of these treatment modalities will be at the discretion of the GDG.

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				should be given. In the case of scalp psoriasis, patient advice, the use of preparations bespoke to treating the scalp, such as shampoos and scalp applications, and referral criteria will be unique to the management of this condition and not applicable to managing chronic plaque psoriasis affecting other areas of the body.	
SH	GSTT	1	general	Focus should not be on topical. Disappointingly there has been very little progress in this area. Guidelines were published in BMJ in early 1990s and in essence they still stand	Thank you, we have noted your comment.
SH	GSTT	2	general	I endorse focus on co-morbidities - a key part of clinical evaluation is to identify those at risk of cardiovascular disease etc. Are there any clinical or other indicators that identify patients with psoriasis who are at especially high risk of cvd/cancer (including prior treatments)?	Thank you for your comment and suggestion. We will take co-morbidities into consideration in terms of evaluation of disease and impact (see 4.3.1 a) and cross refer, when relevant, to existing NICE guidance (eg: obesity).
SH	GSTT	3	general	Given the increasing reliance on systemic immunosuppression and potentially cytotoxic therapy, there is a real need for guidance about what to do in situations such as travel and vaccination. This should be included.	Thank you for your comment. Travel and vaccinations are outside of the remit of this scope. Guidance on this matter has been published by the Department of Health (for example: The Green Book: Immunisation against Infectious Disease. 2007. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917).
SH	GSTT	4	general	The issue of psoriasis and ethnicity has not been covered elsewhere. This is a real issue given phenotypic variation across races, varying prevalence of co-morbidities that have a profound effect on clinical management.	Thank you, the GDG will be alert to looking at ethnicity differences as we look at the evidence.

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SH	Janssen	1	3.2 h	This paragraph highlights the issue of inequitable access to therapy among severe psoriasis patients. It will be important that the psoriasis clinical guideline addresses the processes in primary care, secondary care and tertiary care settings that will lead to patients receiving the level of care that their condition requires.	Thank you for your comment. The GDG will be looking at the evidence for the effectiveness of different treatment modalities and we will take settings into account based on the evidence found. We will look at the evaluation of disease severity in primary care.
SH	Janssen	2	4.3.1 a	Evaluation of disease activity and impact is already relatively routine among patients receiving biologics. Routine evaluation in all moderate to severe patients will help ensure that the risk-benefit balance of treatment in these patients can also be appropriately managed.	Thank you for your comment.
SH	Janssen	3	4.4	We are supportive of the list of main outcomes proposed in the scoping document. For example, even though hospitalisations among the psoriasis population in general may be low, in the severe patient population hospital stays can be an important aspect of health care resource utilisation.	Thank you for your comment.
SH	Janssen	6	6	We note the proposal that the Guideline Development Group include two Dermatologists, one of whom has a special interest in phototherapy. We consider that it would be necessary for a Dermatology biologic lead to sit on the GDG since, like phototherapy, the levels of availability and expertise in the use of biologics varies across the country. There are a relatively small number of dermatologists who have the relevant clinical experience and are routinely treating patients with biologic therapy.	Thank you. We will ensure there is adequate expertise on the Guideline Development Group to consider all the aspects of care that are covered in the guideline.
SH	LEO Pharma	1	General	LEO Pharma welcome the development of the NICE Psoriasis Clinical Guideline. Psoriasis affects approximately 2% of the UK population	Thank you for your comment.

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				and as highlighted in the draft scope, people living with psoriasis need prompt effective treatment and long term disease control due to the significant reduction in quality of life and psychosocial disability they suffer as a result of their psoriasis.	
SH	LEO Pharma	2	3.1 c	We believe the diagnosis and management of scalp psoriasis should also be covered by this clinical guideline. Approximately 50 – 80% of people with psoriasis will have some scalp involvement. Scalp psoriasis, as with plaque psoriasis, has a great impact on quality of life. Effective treatment of scalp psoriasis is known to have a positive impact on patient-wellbeing (Papp) In addition, it is important to note that although there have been a number of reviews and guidelines published both locally and nationally, fewer have been produced on scalp psoriasis than on plaque psoriasis and is an area that is potentially neglected. <u>Reference</u> Papp K et al. J Eur Acad Dermatol Venereol 2007; 21:1151-1160	Thank you, we have based the scope around types of treatment rather than parts of the body. Whether we need to make separate recommendations for different body areas for any of these treatment modalities will be at the discretion of the GDG.
SH	LEO Pharma	3	3.2 a	We agree that adherence to topical therapy regimens is often poor and that more needs to be done to achieve greater adherence. Involving patients in their care and treatment not	Thank you for your comment. We cannot pre judge the evidence base. Paragraph 4.3.1.d of the scope includes self management.

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				only improves health outcomes, it can help improve a patient's acceptability of their treatment, which could be an effective way of improving adherence. We would therefore, recommend including 'patient education' as a factor to improve adherence. The need to educate and support patients in order for them to care for themselves (self care) is well recognised throughout the NHS and has been cited in a number of key publications (Expert Patients Programme announced in 'Saving Lives: Our Healthier Nation; the NHS Plan; Revision to the Operating Framework for the NHS in England 2010/11). The Dermatological Care Working Group concluded that 'expert patients' who become 'sharers in their care' are best placed to improve self management via their understanding of their condition and the appropriate use of treatment. The benefits of self care and expert patients can also lead to cost savings of around £1800 per person per year. <u>Reference</u> Dermatological Care Working Group. Assessment of best practice for dermatology service in primary care. London: Ash Communications; April 2001) Self Care Reduces Costs and Improves Health – The Evidence	
SH	LEO Pharma	4	3.2	We believe this point is misleading as not all	Thank you, we do not feel that the wording as it currently stands is

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			b	patients with moderate to severe psoriasis need second line therapies such as phototherapy, photochemotherapy or systemic agents such as ciclosporin, methotrexate, acitretin and fumarates. A proportion of these patients can be managed in primary care using effective topical therapies. Furthermore, disease severity should not be the only factor considered for referral to secondary care. As outlined in the 2009 BAD (British Association of Dermatologists) Management of Psoriasis guideline and section 3.2.g of this draft scope, there are a range of indications for consultant referral.	misleading. We have inserted the word 'may' before 'need'.
SH	LEO Pharma	5	3.2 g	We would hope that with the 'growing interest in dermatology' amongst health care professionals (PCDS) there will be a reduction in the number of referrals from primary to secondary care for 'further counselling or education, including demonstration of topical treatment'. We believe that such counselling and education can and should be given by GPs, nurses and pharmacists in the primary care setting. Reference PCDS (Primary Care Dermatology Society) - http://www.pcds.org.uk/	Thank you for your comment.
SH	LEO Pharma	6	3.2 j	A number of studies have been conducted to look at patients' attitude to their treatments. A substantial proportion of patients are currently	Thank you for your comment.

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				dissatisfied with their treatment and the resulting lack of impact it has on their disease. Studies suggest this figure could be around 40% of patients (Brown et al, Krueger et al) with up to 50% of patients not fully complying with their treatment (Richards). <u>References</u> Richards Adherence to treatment in patients with psoriasis JEADV 2006; 20: 370–379 Brown et al. J Am Acad Dermatol 2006;55:607-13 Krueger et al. Arch Dermatol. 2001;137:280-284	
SH	LEO Pharma	7	4.3.1 c	In order for the 'topical therapy' list to be representative of current clinical practice we would recommend the addition of 'commercially available' combination vitamin D analogue and corticosteroid preparation to the list of topical therapies. 'Commercially available' combination vitamin D analogue and corticosteroid is an accepted treatment in the NHS for people with psoriasis and was included in the 2009 Cochrane Review of topical treatments for chronic plaque psoriasis. The 'commercially available' combination vitamin D analogue and corticosteroid is recommended in preference to patient's or prescriber's combining the individual agents themselves. The individual agents are potentially incompatible due to chemical instability (vitamin D analogs such as calcipotriol are only stable in alkaline mediums	Thank you for your comment. The developers are happy with the scope as it currently stands The GDG will determine whether combination of those individual treatments specified in the Scope is appropriate.

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				and corticosteroids such as betamethasone dipropionate are only stable in acid mediums. References Mason AR, Mason J, Cork M, Dooley G, Edwards G. Topical treatments for chronic plaque psoriasis. Cochrane Database of Systematic Reviews 2009, Issue 2. Art. No.: CD005028. DOI: 10.1002/14651858.CD005028.pub2	
SH	LEO Pharma	8	4.4	We would recommend that 'reduction in referral rates', 'reduction in outpatient costs', 'IGA (Investigator Global Assessment' and patient reported outcomes (e.g. SKINDEX) be included as outcomes measures.	Thank you, the developers are happy with the outcomes listed in the scope that have been derived from a wide variety of stakeholders views. The list of outcomes is not exhaustive. Although not specified as a primary outcome, items such as reduction in outpatient costs would form part of any Health Economic analysis.
SH	MSD Limited	1	4.3.1 a	"Evaluation of disease severity and impact" could be expanded to include psoriatic patients with co-morbidities, such as patients with nail psoriasis, diabetes, metabolic syndrome, CHD, cancer and depression.	Thank you. We are unable to cover the management of associated co-morbidities within the time available but we will take these into consideration in terms of evaluation of disease severity and impact.
SH	MSD Limited	2	4.3.1	Section could be expanded to include clinical management of psoriatic patients with co-morbid conditions	Stakeholders' comments and expert opinion indicated that identification of psoriatic arthritis was problematic and that guidance was required for this aspect (and not for the diagnosis of psoriasis). In the time available the developers are unable to review the evidence base for psoriatic arthritis management as well as psoriasis. Consideration will be given to the specific needs, if any, of people with psoriatic arthritis. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise the needs of patients with psoriasis who also have psoriatic arthritis and it will be specifically considered throughout the guideline. We recognise, and will take

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					into consideration the fact that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa. However, in the time available, we are unable to produce a comprehensive guideline on ALL aspects of care for patients with psoriatic arthritis and we will not be dealing with aspects specific to the arthritis. We encourage you to suggest psoriatic arthritis to the topic selection panel at NICE details of which can be found at http://www.nice.org.uk/getinvolved/topicselection/topicselection.jsp
SH	MSD Limited	3	4.3	Section could include discussion of loss of efficacy; concurrent prescription of low dose methotrexate & TNF to overcome the loss of efficacy	Thank you, the GDG will decide which drug combinations to review. We will cross refer to the relevant Technology Appraisals as specified in the Scope.
SH	MSD Limited	4	3.2 d	The first two sentences of this section suggests that ustekinumab is licensed for psoriatic arthritis. The distinction between PsA & PsO should be made more clear.	Thank you for your comment. The wording: "and psoriatic arthritis" has now been deleted for clarity, since the document aims to set out the scope primarily as it relates to psoriasis.
SH	MSD Limited	5	4.3.1	Section could be expanded to include management of nail psoriasis	Thank you – we have based the scope around types of treatment rather than parts of the body. Whether we need to make separate recommendations for different body areas for any of these treatment modalities will be at the discretion of the GDG.
SH	MSD Limited	6	3.2 e	The most recent published guidance (BAD) and draft guidance (SIGN) suggests that TNFs, including IFX should be used in a moderate patient population. The NICE guidance recommends use of only adalimumab & etanercept in moderate patients. Thus, the comment that the NICE guidance is in line with BAD guidance may be misleading. BAD & SIGN allow for moderate patient populations and thus the last statement of this section '…exceptional circumstances where biological therapy should be used earlier in the disease course" may be	Thank you. The wording of the scope has been amended with this comment in mind.

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				misinterpreted.	
SH	NHS Direct	1	General	NHS Direct welcome the guideline and has no comment on its content.	Thank you for your comment.
NICE	NICE – Technical Adviser	1	4.1.1	b) Section 4.3.2 states that people with psoriatic arthritis will be excluded which seems to contradict this statement that they will be given special consideration. Please clarify	Thank you for your comment. Section 4.3.2 does not say that people with psoriatic arthritis will be excluded. It says that the management of psoriatic arthritis will be excluded, which is not the same thing. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise the needs of patients with psoriasis who also have psoriatic arthritis and it will be specifically considered throughout the guideline. We recognise, and will take into consideration the fact that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa. However, in the time available, we are unable to produce a comprehensive guideline on ALL aspects of care for patients with psoriatic arthritis and we will not be dealing with aspects specific to the arthritis. Indeed another SH has acknowledged this 'Treatments for psoriasis and psoriatic arthritis frequently overlap. Particularly in the sphere of systemic therapy. The guideline must acknowledge this and look at ways to combine therapies'.
NICE	NICE – Technical Adviser	2	4.3.1	a) This needs clarifying - impact of what? And on whom/what will the impact be effected?	Thank you for your comment. Impact includes co-morbidities. We have now specified: impact on people with psoriasis.
NICE	NICE – Technical Adviser	3	4.3.1	c) Topical therapy specifies a specialist setting. Does the setting need to be defined for the other interventions?	Thank you but the developers feel that specifying a setting for all other defined interventions will make the scope overly prescriptive.
NICE	NICE – Technical Adviser	4	4.3.1	c) Fumaric acid esters cannot be assessed in the guideline when they do not have a UK licence.	Thank you, the guideline manual does not state this. We discussed this at the scoping meetings and we were under the impression these could be included.
NICE	NICE – Technical Adviser	5	4.3.1	c) ABT-874 cannot be assessed in the guideline when it does not have a UK licence; this will also need checking with appraisals as to whether it	This is currently listed on the NICE website http://guidance.nice.org.uk/TA/Wave20/76

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				can be assessed within a guideline even if it has been granted a licence before the guideline is complete.	The developers normally cross-refer to the appropriate TAs and this was discussed at the scoping meetings.
NICE	NICE – Technical Adviser	6	4.3.2	b) Section 4.1.1 states that special consideration will be given to people with psoriatic arthritis which seems to contradict this statement that they will be excluded. Please clarify.	Section 4.3.2 does not say that people with psoriatic arthritis will be excluded. It says that the management of psoriatic arthritis will be excluded, which is not the same thing. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa; but we will not be dealing with aspects specific to the arthritis. Indeed another SH has acknowledged this 'Treatments for psoriasis and psoriatic arthritis frequently overlap. Particularly in the sphere of systemic therapy. The guideline must acknowledge this and look at ways to combine therapies'.
NICE	NICE – Technical Adviser	7	4.4	a) Please define DLQI and Eq-5D b) Please define PASI	Thank you, the definitions have been added to the scope. DLQI: Dermatology Life Quality Index Eq-5D: European Quality of Life-5 Dimensions PASI: Psoriasis Area Severity Index
SH	Pfizer Limited	1	General	Pfizer welcomes the development of the guideline for the management of Psoriasis in young people and adults. We think that it offers a good framework for improving the care of people with Psoriasis.	Thank you for your comment.
SH	Pfizer Limited	2	2	We note the removal of the diagnosis of Psoriasis from the Scope. This is explained in section 4 and we feel the rationale is appropriate.	Thank you for your comment.
SH	Pfizer Limited	3	4.1.1	We note that "young people" has now been defined as "15 years or under". This differs from the draft scope which was discussed at the July 27th Scoping workshop, in which children would be a group that consideration would be given to	Thank you for your comment. In light of the stakeholders' comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups.

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				their specific needs, if any. Young people under the age of 15 suffer from psoriasis and are routinely treated with both topical and systemic therapies for the disease. We feel that this patient group should be included within the scope of this guideline.	
SH	Pfizer Limited	4	4.1.1	Etanercept has a licensed indication for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or photo therapies. We therefore recommend that children aged 14 years and younger should be covered by this guideline.	Thank you for your comment. In light of the stakeholders' comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups.
SH	Pfizer Limited	5	4.1.2 a	We note that the group: Children aged 14 and younger; has been added to the groups that will not be covered by this guideline. This group suffer from psoriasis and are routinely treated with both topical and systemic therapies for the disease. We feel that this patient group should be included within the scope of this guideline.	Thank you for your comment. In light of the stakeholders' comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups.
SH	Pfizer Limited	6	4.1.2 a	Etanercept has a licensed indication for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or photo therapies. We therefore recommend that children aged 14 years and younger should be covered by this guideline.	Thank you for your comment. In light of the stakeholders' comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups.
SH	Pfizer Limited	7	4.3.1	Pfizer welcomes the inclusion of the identification	Thank you for your comment.

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			b	of psoriatic arthritis as a key clinical issue that will be covered within the scope of this guideline.	
SH	Primary Care Dermatology Society	1	General	We are happy with the scope as it stands and have no additional comments or suggested exclusions other than to expect the treatment evaluations to consider patient access to all forms of treatment to be nationwide and with maximum convenience for the patient.	Thank you for your comment.
SH	Psoriasis Association	1	4.4	Our comments are as follows – please add "suitability of treatments" –as points f) treatment adherence and g) withdrawal rates may not promote equality of opportunity for example, age (common age-related illnesses can render some treatments for psoriasis unsuitable), disability (unable to reach the area required to treat, or stand unaided in UV cabinet) and socio-economic status (people in low-paid employment who find it difficult to raise the funds for regular prescriptions with a number of items may withdraw from treatment for cost reasons)	Thank you the GDG will take ethnicity and diversity issues into consideration throughout the development of the guideline. Based upon other guideline work undertaken within the NCGC we are aware that 'suitability of treatment' is not an outcome that tends to be reported by the trials or evidence. Suitability of treatments will be taken into account by the GDG when reviewing the clinical and cost effectiveness evidence and based upon the study populations.
SH	Royal College of Nursing	1	general	The Royal College of Nursing welcomes proposals to develop this guideline.	Thank you for your comment.
SH	Royal College of Nursing	2	2	It would be helpful to define the age of young people and adults. Is there any adjustment for pregnancy?	Thank you for your comment. In light of the stakeholders' comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups. There is an adjustment in treatment for pregnant women, but the developers feel it is not necessary to explicitly add this subgroup to the scope (it has not been explicitly excluded).
SH	Royal College of Nursing	3	3.2 a	Involvement of qualified nurse with dermatology experience may aid concordance with topical regimes leading to improved outcomes for patients	Thank you for your comment.

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SH	Royal College of Nursing	4	General	Involvement with nurse with dermatological knowledge and skills at all stages of the patient's journey leads to improved patient experience and outcomes.	Thank you for your comment.
SH	Royal College of Nursing	5	4.3.1	Does this include co-morbidity screening?	Thank you. We are unable to cover the management of associated co-morbidities within the time available but we will take these into consideration in terms of evaluation of disease severity and impact (see 4.3.1 a).
SH	Royal College of Nursing	6	4.3.1 c	What about Dithranol (Anathralin) short contact - this is missing as a therapeutic treatment that has good evidence of effectiveness. It can be used in the home under supervision of a nurse specialist to only restrict it to day centres deny some patients access to this treatment. Phototherapy – hours of opening for access/concerns re skin cancer.	Thank you, we have noted your comment and edited the scope accordingly about Dithranol. We cannot pre-judge the evidence on phototherapy.
SH	Royal College of Nursing	7	4.3.1 d	Self management – expert patient programme	Thank you for your comment.
SH	Royal College of Nursing	8	4.3.2 a	Commissioners/PBC for joint clinics with dermatologist/rheumatologist/psychologists/social worker – how would this be integrated	Thank you. The GDG will be careful to consider the concept of multidisciplinary team working throughout the guideline.
SH	Royal College of Nursing	9	4.4 a	CDLQI depending on age of young people	Thank you. We have amended the scope accordingly.
SH	Royal College of Nursing	10	4.4 b	Commissioning issue for specialist nursing if admitted in to district general hospital	Thank you, your comment will be passed onto the Commissioning team within NICE.
SH	Royal College of Nursing	11	General	Patient pathway access – SOS when skin flares to re-access services without having to be re-referred	Thank you for your comment. In general the Guideline will focus on what should be done rather than where and by whom.
SH	Royal College	1	General	We note that that there is no position allocated to	Thank you for your comment. In light of the stakeholders'

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	of Paediatrics and Child Health			a paediatric professional on the guideline development group. As the draft scope covers young people aged 15 and over, the College feels it is essential that a paediatric professional, with experience in psoriasis in young people, be recruited to the GDG, preferably as a full, voting member. This will ensure that the needs of this population group are adequately addressed.	comments, we have now removed the age limit from the scope, to include all people with psoriasis and will ensure that the GDG expertise will cover all age groups.
SH	Royal College of Paediatrics and Child Health	2	General	The scope addresses the issue of skin disease in psoriasis, but excludes the issue of arthritis. This can affect patients prior to developing skin disease, and can cause physical disability if it is not adequately controlled. Not addressing the issue of arthritis in patients with psoriasis is a major disservice to this group of patients. The issue of arthritis occurring prior to skin disease particularly affects children and teenagers, who have also been excluded from the scope.	Thank you for your comment. Consideration will be given to the specific needs, if any, of people with psoriatic arthritis. The wording in 4.1.1 taken with that in 4.2.3 means that we will recognise the needs of patients with psoriasis who also have psoriatic arthritis and it will be specifically considered throughout the guideline. We recognise, and will take into consideration the fact that drugs used for psoriasis per se may have inter-relationship and potential benefits for psoriatic arthritis, and vice-versa. However, in the time available, we are unable to produce a comprehensive guideline on ALL aspects of care for patients with psoriatic arthritis and we will not be dealing with aspects specific to the arthritis. We encourage you to suggest psoriatic arthritis to the topic selection panel at NICE details of which can be found at http://www.nice.org.uk/getinvolved/topicselection/topicselection.jsp
SH	Royal College of Paediatrics and Child Health	3	General	With the advent of biologic therapies, the need for registries to monitor patients is paramount. If these patients are not included within the scope, there will be no incentive for groups to fund this activity.	Thank you for your comment. Initiation of disease registries are outside the remit of this scope. The comment has been forwarded to the NICE implementation team.
SH	Royal College of Paediatrics and Child Health	4	4.3.1	The College thinks the guideline could cover an assessment of co-morbidity (e.g. metabolic syndrome).	Thank you. We are unable to cover the management of associated co-morbidities within the time available but we will take these into consideration in terms of evaluation of disease severity and impact (see 4.3.1 a).

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SH	Royal College of Paediatrics and Child Health	5	4.3.1	We think the guideline could cover the treatment of severe psoriasis, i.e. erythrodermic psoriasis and generalised pustular psoriasis.	Thank you, we have noted your comment. All the different types of psoriasis come under the general term psoriasis.
SH	Royal College of Paediatrics and Child Health	6	4.3.1 c	We think this should include information on how to 'step up' to more effective treatments.	Thank you, the GDG will bear this in mind when reviewing the evidence base.
SH	Royal College of Paediatrics and Child Health	7	4.3.1 c	We think the guideline could topical retinoids.	Thanks you for your comment. Topical retinoids are not explicitly excluded from the scope; the list of topical therapies is not exhaustive. The GDG will consider which specific drugs to cover in the guideline, including topical retinoids, although given the timelines and resources, not all interventions can be considered.
SH	Royal College of Paediatrics and Child Health	8	4.3.2	We note that the treatment of psoriatic arthritis is not included.	Thank you, consideration will be given to the specific needs, if any, of people with psoriatic arthritis.
SH	Royal College of Paediatrics and Child Health	9	4.4	We think this could include a dermatology life quality index for young people.	Thank you. We have amended the scope accordingly.
SH	RPSGB	1	General	The RPSGB welcomes the development of these guidelines	Thank you for your comment.
SH	RPSGB	2	4.4	Could an additional outcome include the use of complementary and alternative treatments as a result of the failure of conventional treatments	Thank you but stakeholders and expert opinion indicated that this was not a priority area to be addressed by the developers. We are not able to cover all aspects in the time available and have focused upon those that the weight of opinion indicated were important.
SH	The British Dietetic Association	1	General	We do not have any comments at this stage	Thank you for your comment.
SH	Welsh	1	General	Thank you for giving the Welsh Assembly	Thank you for your comment.

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	Assembly Government			Government the opportunity to comment. Please note that we have no comment to submit at this stage	