National Institute for Health and Care Excellence

4-year surveillance (2017) – Psoriasis (2012) NICE guideline CG153

Appendix B: stakeholder consultation comments table

Consultation dates: 27 March to 7 April 2017

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
Almirall UK	Yes	Almirall recognises that the current landscape of treatment options and pathways is not sufficiently changed to warrant a review of the guideline. However, the advent of novel therapeutic options moving in to 2018 has the potential to alter the treatment paradigm, to an extent that review of the guideline may be important for patients and prescribers. Almirall would recommend a review of the suitability of the guideline in short term time window, such as one year	Thank you for your comment. We agree that an update is not currently warranted. The scheduling of future surveillance reviews is described in the chapter ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual. A formal check of the need to update a guideline is usually undertaken by NICE every 2 years, and is always undertaken at least every 4 years from the date of guideline publication. In exceptional circumstances, the check may be brought forward.
Medac GmbH	No	I would like you to consider updating the dosage regimen for methotrexate, 1.5.2.7. Currently there is no differentiation between oral & subcutaneous methotrexate. I would like to draw your attention to a recent paper published in the Lancet; http://thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)32127-4.pdf ********** **An intensified dosing schedule of subcutaneous methotrexate in patients with moderate to severe plaque-type psoriasis (METOP): a 52 week, multicentre, randomised, double-blind, placebo-controlled, phase 3 trial**	Thank you for your comment. The article you refer to was not identified by the current surveillance process as it was published after the cut-off date for the evidence search. Use of subcutaneous methotrexate was discussed by the guideline development group (GDG) when the guideline was originally developed (see p.576 of the full version of the guideline): 'The GDG noted that in some instances of poor response to oral methotrexate, a switch to subcutaneous administration may improve responses either due to improved adherence or bioavailability. However the GDG could not make a specific national recommendation in the absence of high quality evidence in psoriasis.'

		Between Feb 22, 2013, and May 13, 2015, we randomly assigned 120 patients to receive methotrexate (n=91) or placebo (n=29). At week 16, a PAS I 75 response was achieved in 37 (41%) patients in the methotrexate group compared with three (10%) patients in the placebo group (relative risk 3-93, 95% CI 1-31-11-81; p=0-0026). Serious adverse events were recorded in three (3%) patients who received methotrexate for the full 52 week treatment period. The route of administration and the intensified dosing schedule should be considered when methotrexate is used in this patient group. ********** This study shows the efficacy of methotrexate when an optimal dose and route are used on this cohort of patients. In the guidelines its states to stop the treatment if the response is inadequate – presumably 25mg oral. However it doesn't define a subcutaneous methotrexate step for a patient to try, and assess before going on to the next treatment. I would like to see the guidelines updated to include this point or have this added as a comment in this section.	The evidence you have provided is useful additional information relevant to this issue. However we note that the study examines subcutaneous methotrexate versus placebo, and does not therefore directly address switching to subcutaneous administration following a poor response to oral methotrexate. However we thank you for drawing attention to this issue and the new evidence, which will be considered at the next surveillance review along with any additional new evidence in this area.
Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	Yes	We believe that since the initial publication and given the limited change in evidence, the decision is pragmatic and a sensible approach. In the future with biosimilars increasingly being offered and the potential change that will have on cost-effectiveness, a fuller review might be required to decide how within the pathway these agents could be offered. As more new therapies become available, along with the data from registries, an MTA of all current therapies would also be valuable. With the availability of a wide range of agents there could be the potential to allow earlier cost-effective access, leading to better patients outcomes. In our view, the clearance of psoriasis should be seen as the goal and target, with sub-optimal therapies, potentially being removed from the pathway or moved to a supplementary role or that of a last resort option.	Thank you for your comment. We agree that an update is not currently warranted. The evidence from the current surveillance review, plus any additionally published evidence, will be examined again at the next surveillance review.

Psoriasis Association	Yes	Issues are with implementation rather than the guideline per se.	Thank you for your comment. Addressing implementation issues is outside the scope of the surveillance review, but any information relevant to these issues is passed to the NICE implementation team.
Novartis Pharmaceuticals UK Ltd.	Yes	We agree that a full update to CG153 is not necessary at this time. However, we consider the planned editorial and factual amendments important, including incorporation of recent technology appraisals, including TA350, “Secukinumab for treating moderate to severe plaque psoriasis”.	Thank you for your comment. We agree that an update is not currently warranted, and agree that there is a need for several editorial and factual amendments including those you have particularly highlighted. These are described in the ‘Editorial and factual amendments’ section of Appendix A evidence summary.
Royal College of Paediatrics and Child Health	Yes	I am happy with decision not to update Psoriasis guideline.	Thank you for your comment. We agree that an update is not currently warranted.
LEO PHARMA	No	Page 29 – impact statement: There is new evidence that over 4 weeks, calcipotriol/betamethasone dipropionate aerosol foam is significantly more effective than calcipotriol/betamethasone dipropionate ointment, calcipotriol foam, betamethasone dipropionate foam, and foam vehicle. The current guideline does not specify the formulation of calcipotriol monohydrate and betamethasone dipropionate to use. At a minimum it would be helpful to add a footnote highlighting that (Enstilar®) the foam formulation is more effective than the gel and ointment.	Thank you for your comment. Commenting on the hierarchy of effectiveness of interventions in a guideline would need to be done via a change to recommendations rather than a footnote. Recommendations would not be changed until a review of the evidence in this area has been conducted, which at this time NICE has deemed is not warranted. The evidence from the current surveillance review, plus any additionally published evidence, will be examined again at the next surveillance review.
Royal College of Nursing	Yes	We have received no comments from our members against this proposal	Thank you for your comment. We agree that an update is not currently warranted.
Eli Lilly and Company	No	On page 54, it is stated that “consideration will be given to covering TA350 in CG153, alongside the other incorporated technology appraisals of biologic treatments for psoriasis”. For consistency, Lilly requests that ID904 (expected to be published in April 2017) also be considered for discussion in the guideline.	Thank you for your comment. ID904 has now published as NICE technology appraisal 442 ‘Ixekizumab for treating moderate to severe plaque psoriasis’. It will be considered for coverage in the guideline alongside the other NICE technology appraisals that have been issued since NICE guideline CG153 was published.
AbbVie Ltd.	Yes		Thank you for your comment.

		The following inaccuracy within the 4 year surveillance document is noted: P53, right side column, 4th bullet, change “An adalimumab biosimilar may be available soon (patents will expire in the US in December 2016 and in Europe in April 2018)” to “An adalimumab biosimilar may be available soon (composition of matter patent will expire in the UK in October 2018).” Note that this is a factual correction as the current statement – also regarding the US patents – is not correct. The following inaccuracy within the 4 year surveillance document is noted: P53, right side column, 6th bullet, change “Ustekinumab can be prescribed at a 90 mg dose if the patient is less than 100kg” to “Ustekinumab can be prescribed at a 90 mg dose if the patient is more than 100kg” The following inaccuracy within the 4 year surveillance document is noted: P53, right side column, 6th bullet, change “Also flat pricing for ustekinumab (45 and 90 mg the same cost – dose escalation effective in partial responders)” to “Also flat pricing for ustekinumab (45 and 90 mg the same cost)”. The following inaccuracy within the 4 year surveillance document is noted: P53, right side column, 8th bullet, change “There have been newer targeted treatments (mainly directed at IL17 [such as secukinumab, ixekizumab, brodalumab] and IL12/23 [such as ustekinumab, tildrakizumab, guselkumab]) approved and available for both psoriasis and psoriatic arthritis” to “There have been newer targeted treatments (mainly directed at IL17 [such as secukinumab, ixekizumab, brodalumab] and IL12/23 [such as ustekinumab]) and at IL23 only [such as guselkumab, tildrakizumab, risankizumab].	Your corrections mainly relate to wording in the ‘Topic expert feedback’ section of the evidence summary document. These are comments provided to us by topic specialists who we liaised with during the surveillance review process. Thank you for drawing our attention to any factual inaccuracies in these comments which we have corrected in the final published version of the Appendix A evidence summary document. Thank you also for drawing our attention to the study presented at the 5th Congress of the Psoriasis International Network. However, surveillance reviews do not consider evidence from conference abstracts. Any full journal articles arising from this study can be considered by future surveillance reviews.

		Secukinumab and ustekinumab are licensed for psoriasis and psoriatic arthritis. Ixekizumab is licensed for psoriasis. Guselkumab, tildrakizumab, risankizumab and brodalumab are not presently licensed for psoriasis or psoriatic arthritis" The following inaccuracy within the 4 year surveillance document is noted P53, right side column, 3rd bullet, change "Biosimilars are available and licensed for infliximab and etanercept now they are off-patent (which are cheaper than the original drug, and will also push down costs of parent compounds). It would be useful to add information and details of these biosimilar drugs and where they fit into the pathway. Patients are being offered biosimilars in place of current branded versions of infliximab and etanercept, therefore efficacy and safety data might need to be considered, so that patients can make an informed choice" to "Biosimilars are available and licensed for infliximab and etanercept, following patent expiry. This has led to savings in some areas, owing to commercial offers made by both Biosimilar and originator manufacturers. It may be useful to add information and details of these biosimilar drugs and where they may fit into the pathway. In some areas, patients are being offered biosimilars in place of current branded versions of infliximab and Etanercept. NHS guidance on the use of Biosimilar medicines can be found at https://www.england.nhs.uk/wp-content/uploads/2015/09/biosimilar-guide.pdf and includes, amongst other things, guidance on informed patient consent, accurate PV reporting requirements and the need for good standards of governance." The following inaccuracy within the 4 year surveillance document is noted: P11 and 12, "PASI: body regions and components" section, change "An RCT (n=not stated in the abstract) analysed body regions and components of PASI scores during adalimumab or methotrexate treatment in people with moderate-to-severe psoriasis … However the evidence is from a single trial of an unknown number of patients, and any impact on CG153 is unlikely until further studies validate these findings". To "An RCT (n= 271 stated in the article) analysed body regions and components of PASI scores during adalimumab or	

		methotrexate treatment in people with moderate-to-severe psoriasis". The following omission from the 4 year surveillance document is noted: P55, left column, 2nd paragraph, the search strategy should have identified Adalimumab for Nail Psoriasis: Efficacy and Safety from the First 26 Weeks of a Phase-3, Randomized, Placebo-Controlled Trial. Presented at the 5th Congress of the Psoriasis International Network (Psoriasis 2016) at Paris, France. July 7 – 9, 2016.	
British Association of Dermatologists	Partially agree	On behalf of the British Association of Dermatologists, thank you for the opportunity to comment on this consultation. We have some concern about existing recommendations around the eligibility criteria for biologic therapy, specifically on continuing with PUVA due to increased risk of cancer.	Thank you for your comment. Eligibility criteria for biological therapy are within the remit of the NICE technology appraisals for the individual biologic drugs. All relevant information has been passed to the NICE technology appraisals team.
Royal College of Physicians	-	We would like to endorse the response submitted by the British Association of Dermatologists	Thank you for your comment. Please see the above response to the comment from the British Association of Dermatologists.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Almirall UK	No	No comment	Thank you for your answer.
Medac GmbH	No	No comment	Thank you for your answer.
Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	Yes	We've always considered that psoriatic arthritis should have been given greater prominence within this guideline. We accept that the recent spondyloarthritis guideline attempted to cover this area, but feel that in clinical use there may be a lost opportunity to provide useful advice in one guideline for the group of individuals who are affected by both psoriasis and psoriatic arthritis. We do not believe that much cross reference takes place, but would be interested in seeing evidence that this happens.	Thank you for your comment. As you have noted, diagnosis and management of psoriatic arthritis is within the scope of the recently published NICE guideline on spondyloarthritis in over 16s. The scope of the spondyloarthritis guideline also identified people with comorbidities related to HLA B27 (such as psoriasis) as needing specific consideration. Along with recommendations on psoriatic arthritis, the spondyloarthritis guideline

		Our experience and feedback from patients appears to indicate that the psoriasis guideline is not being used that much within primary care and the recommendation to monitor signs of psoriatic arthritis are not being acted upon, which is potentially leading to delays in treatment and referral, which subsequently may be having a detrimental effect on the long-term patient outcomes.	also makes reference to psoriasis and cross-refers to the NICE guideline on psoriasis. Additionally NICE Pathways bring together everything NICE has said on this topic in an interactive flowchart. The NICE Pathways on spondyloarthritis and psoriasis link to one-another at relevant points. The psoriasis guideline was published prior to the spondyloarthritis guideline, therefore as detailed in the 'Editorial and factual amendments' section of the Appendix A evidence summary, we plan to add a cross-referral to the spondyloarthritis guideline from the psoriasis guideline. Regarding your comment that the psoriasis guideline is not being used much within primary care, addressing implementation issues is outside the scope of the surveillance review, but this information will be passed to the NICE implementation team.
Psoriasis Association	No	No comment	Thank you for your answer.
Novartis Pharmaceuticals UK Ltd.	No comment	No comment	No answer provided by stakeholder.
Royal College of Paediatrics and Child Health	No comment	No comment	No answer provided by stakeholder.
LEO PHARMA	No	No comment	Thank you for your answer.
Royal College of Nursing	No	No comment	Thank you for your answer.
Eli Lilly and Company	Yes	Since CG153 was published, the recent innovation of IL-17 agents have demonstrated a greater proportion of patients achieving high response levels (PASI90-100) compared to TNF-alpha inhibitors and ustekinumab. Inclusion in the guideline of the evidence for the potential shift in the expectations of response to psoriasis treatment, i.e. PASI90 instead of PASI75 and the benefits that would deliver to patients are an important area for consideration.	Thank you for your comment. The interleukin-17 agents you refer to are biological drugs covered by published or in-development NICE technology appraisals. Appraising evidence for biological therapy is within the remit of the NICE technology appraisals for the individual biologic drugs. All relevant information has been passed to the NICE technology appraisals team.
AbbVie Ltd.	No	No comment	Thank you for your answer.

British Association of Dermatologists	Yes	Some psoriasis patients with severe disease might benefit from early intervention by going straight on to biologic therapy, and this has not been addressed in the guideline.	Thank you for your comment. First line use of biological agents are within the remit of the NICE technology appraisals for the individual biologic drugs. All relevant information has been passed to the NICE technology appraisals team.
Royal College of Physicians	-	We would like to endorse the response submitted by the British Association of Dermatologists	Thank you for your comment. Please see the above response to the comment from the British Association of Dermatologists.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Almirall UK	No	No comment	Thank you for your answer.
Medac GmbH	No	No comment	Thank you for your answer.
Psoriasis and Psoriatic Arthritis Alliance (PAPAA)	No	No comment	Thank you for your answer.
Psoriasis Association	No	No comment	Thank you for your answer.
Novartis Pharmaceuticals UK Ltd.	No comment	No comment	No answer provided by stakeholder.
Royal College of Paediatrics and Child Health	No comment	No comment	No answer provided by stakeholder.
LEO PHARMA	No	No comment	Thank you for your answer.
Royal College of Nursing	No	No comment	Thank you for your answer.
Eli Lilly and Company	No	No comment	Thank you for your answer.
AbbVie Ltd.	No	No comment	Thank you for your answer.

British Association of Dermatologists	No	No comment	Thank you for your answer.