# Spondyloarthritis

**Consultation on draft guideline - Stakeholder comments table**
**13 September–25 October 2016**

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| 1. | SH | Royal College of Nursing | General | General | General | The Royal College of Nursing welcomes the opportunity to review and comment on this draft guideline. The RCN invited members who care for people with this condition to review the document on its behalf. The comments below reflect the views of our reviewers. | Thank you for taking the time to seek out responses from people directly affected by this guideline. |
| 2. | SH | Royal College of Nursing | General | General | General | We would have liked to see references made to specialist nurse services which these patients currently benefit from - particularly access to telephone advice line when they are in a flare and need help quickly to enable them to continue working.<br><br>Unfortunately we currently do not know of any published work / evidence for Axial spondyloarthritis (AxSpA) and telephone advice lines, however, we are aware that there is a body of evidence from nurse led care for inflammatory arthritis (listed below) which could be used to substantiate our comment. Please see examples below:<br><br>• RCN (2010) *Clinical nurse specialists: adding value to care* https://www2.rcn.org.uk/__data/assets/pdf_file/0008/317780/003598.pdf<br>• Ndosi, M; Lewis, M; Hale, C; Quinn, H; Ryan, S; Emery, P; Bird, H; and | Thank you for providing us with information regarding the evidence base in rheumatoid arthritis. The GDG agreed from the outset not to consider extrapolation of evidence from rheumatoid arthritis in this area, as they felt the needs of people may be different in spondyloarthritis due to the differing manifestations of the conditions, and therefore unfortunately these studies were not eligible for consideration.<br><br>However, the GDG did feel it appropriate to add a specific comment about specialist rheumatology nurses in the section on flare management plans, and how these are an appropriate individual to be the point of contact for care during flares. |

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| | | | | | | Hill, J. (2014) *The outcome and cost-effectiveness of nurse-led care in people with rheumatoid arthritis: a multicentre randomised controlled trial* (*Ann Rheum Dis 2014;73:1975–1982. doi:10.1136/annrheumdis-2013-203403*<br><br>• Vinal K.A.; Madill, A; and Firth, J (2014) *Comparison of patient and practitioners perceptions of nurse-led and consultant-led rheumatology outpatient consultations* DOI: 10.1136/annrheumdis-2014-eular.4347<br><br>• Vinall-Collier K; Madill, A; and Firth, J; (2016) *A multi-centre study of interactional style in nurse specialist- and physician-led Rheumatology clinics in the UK* *http://dx.doi.org/10.1016/j.ijnurstu.2016.02.009*<br>• Larsson, I; Fridlund, B; Arvidsson, B; Teleman, A; Svedberg, P; and Bergman S (2015) *A nurse-led rheumatology clinic versus rheumatologist-led clinic in* | |

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| | | | | | | *monitoring of patients with chronic inflammatory arthritis undergoing biological therapy: a cost comparison study in a randomised controlled trial* BMC Musculoskeletal Disorders (2015) 16:354 DOI 10.1186/s12891-015-0817-6 | |
| 3. | SH | Brit-PACT | Full | General | General | We would like to highlight the need to highlight the difference between axial and peripheral SpA with a view to relating peripheral SpA to PsA. We would be grateful if the NICE group could consider inclusion of CASPAR criteria in the diagnosis of PsA, which is a subtype of peripheral SpA. We would also be keen in the consideration of peripheral SpA review made of co-morbidities associated with PsA and additionally the appropriate outcome disease activity measures. | Thank you for your comment. Regarding the CASPAR criteria, we were unable to identify any evidence of the validation of this tool in cohorts or cross-sectional studies of people with suspected (rather than confirmed) PsA. Case-control studies in people with confirmed PsA were excluded as per the pre-specified review protocol. On further consideration the GDG have now decided to include CASPAR in the list of suggested, but not mandatory, tools in the relevant recommendation. The reasons for this have been detailed in the 'Evidence to recommendations' table associated with this chapter. We would nonetheless encourage the research community to evaluate CASPAR in populations of people with suspected spondyloarthritis, and a research recommendation has been made that a validation study be carried out.<br><br>Regarding outcome measures and comorbidities associated with PsA, for each |

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| | | | | | | | review question in the guideline (except for those which were explicitly about other spondyloarthritis subtypes), studies on PsA populations were sought, but eligible evidence was often not found. It has now been clarified in the short guideline that sections on peripheral spondyloarthritis specifically include psoriatic arthritis. |
| 4. | SH | Brit-PACT | Full | General | General | The guidance seems to have missed the point that peripheral spa is, essentially, psoriatic arthritis. Ignoring this means that the committee can call on little evidence on epidemiology, pathophysiology, genetics, clinical features, assessment management and prognosis for a condition which was essentially 'manufactured' by the ASAS criteria. The classification criteria for psoriatic arthritis with the most data are the CASPAR criteria which have been cited over 800 times since their publication in 2003. These are not diagnostic criteria but are often used as such and have been shown to work well in that situation. Recent observational studies have indicated that the sooner the diagnosis is made, and the sooner treatment is started, the better the outcome. We would like to see an emphasis on this in the report - the committee ignored the burgeoning data on early diagnosis and efforts to improve early detection and | Thank you for your comment. Within the guideline, the term 'peripheral spondyloarthritis' is used to describe any type of spondyloarthritis with predominantly peripheral manifestations in the majority of people with the condition, namely psoriatic arthritis, enteropathic arthritis and reactive arthritis (this is defined in the glossary of the full guideline). It has now been clarified in the short guideline that references to peripheral spondyloarthritis do specifically included psoriatic arthritis.<br><br>In most cases any evidence we identified in peripheral arthritis was derived from populations which mostly or exclusively comprised people with psoriatic arthritis. Where evidence from studies in people with PsA met the relevant review protocol it was included in the guideline. Following further discussion with the GDG CASPAR has now |

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| | | | | | | referral from both primary care and secondary care dermatology clinics. Further, since they chose to ignore psoriatic arthritis they were unable to draw on guidance for diagnosis and management, such as that published by the BSR | been included in the relevant recommendations.<br><br>While the guideline scope included questions relating to identifying and mitigating causes of delayed diagnosis, it was not within the remit of this guideline to formally evaluate the long-term outcomes associated with earlier diagnosis. |
| 5. | SH | BRITSpA | Full | General | General | The advice to screen all individuals with suspected Axial Spondyloarthritis with X-rays would not reflect current practice. In young patients with short symptom duration the likelihood of positive findings, particularly at Grade 3 or 4 sacroiliitis would be very low, making the test unhelpful in these circumstances.<br>Reporting/interpretation of grade 1 and 2 changes at sacroiliac joints (SIJ) is unreliable with substantial inter-observer variation so that X-ray examination in the group mentioned above is at substantial risk of both false positive and false negative results. If the guideline advocated use of X-rays as an initial diagnostic step, universally, many patients with early or limited disease would run the risk of having the diagnosis of axSpA excluded | Thank you for your comment. The recommendation has been amended to clarify that X-ray should not be used as an initial investigation in people with an immature skeleton. In all other people with suspected axial SpA, the GDG considered that it was important to perform an X-ray, even if it is uncertain whether sacroiliitis will be detected, as the correct classification of radiographic versus non-radiographic spondyloarthritis may have implications for treatment decisions further down the treatment pathway. Thus, underutilisation of X-ray in women may have the undesired consequence of excluding them from receiving a diagnosis of ankylosing spondylitis and therefore having access to treatments that are currently only approved for radiographic, but not non-radiographic, axial SpA. |

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| | | | | | | erroneously. **This is particularly important in women, in whom sacroiliac joint X-rays are more likely to be normal or show minor changes.** There is a clear need for a universal, simple guideline, and there is some discussion about this issue in the guideline, but as it stands it may result in an increase in the number of sacroiliac joint X-rays requested without any decrease in the number of magnetic imaging (MRI) scans. We would advocate that SIJ X-rays are reserved for the older population, those with long term symptoms and those with reduced range of spinal movements where there is a greater likelihood that sacroiliac joint X-rays will be unequivocally positive. | |
| 6. | SH | Novartis | Full | General | General | We query why the full draft guideline does not cross-reference the related technology appraisals, as per the final scope and the short version of the draft guideline (page 10, lines 14-17 and page 12, line 2 to page 14, line 10). Also see related comments 1-3 above. We request that if information on relevant technology appraisals is included in the full version of the final guideline, this should include reference to both TA407 (secukinumab for active ankylosing spondylitis after treatment with nonsteroidal | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the trea tment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for |

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| | | | | | | anti-inflammatory drugs or TNF-alpha inhibitors) and ID579 (certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs), the latter being due for publication ahead of the final clinical guideline. | ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 7. | SH | AbbVie UK | Full | Title page, 29 and 107 | | Abbvie notes that the guidance title refers to over 16s and section 5.1 refers to TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis), where pharmaceutical technologies are considered within their marketing authorisation. All of the biologics being considered in the technology appraisal have marketing authorisation for adult patients (>18), not over 16s. Abbvie | Thank you for your comment. The guideline as a whole is intended for people with spondyloarthritis, aged 16 or over. NICE would expect clinicians to ensure that they are prescribing medicines appropriately given the marketing authorisations. |

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| | | | | | | suggest that the current guidance is corrected to just adults. | |
| 8. | SH | BRITSpA | Full | | 4.1.5 | Recommendation 4.1.5, Point 3.1 states if "3 criteria are present, perform an HLA-B27 test and refer to a rheumatologist for a spondyloarthritis assessment if this test is positive". This conflicts with recommendation 4.2.5 Point 7.1, "Do not rule out a diagnosis of spondyloarthritis solely on the basis of a negative HLA-B27 result". | Thank you for your comment. Recommendation 4.1.5 (3) relates to referral criteria. People with suspected spondyloarthritis are required to meet at least 4 criteria to be referred for specialist assessment. So as to avoid unnecessary testing, the guideline only advocates testing for HLA-B27 in primary care for people who have already fulfilled 3 of the referral criteria but not yet met the required 4. At this stage, no diagnosis is being made, and the recommendation simply points to a threshold at which someone should be referred to rheumatology. In this circumstance, a person who is HLA-B27 negative and does not receive a referral would be ruled out due to failing to meet 7 of the 10 referral criteria, rather than just the HLA-B27 test. Additionally, there are recommendations for people to seek reassessment if these criteria change, so people are not permanently ruled out from a diagnosis of spondyloarthritis.<br><br>Section 4.2.5 relates to the use of HLA-B27 testing as a diagnostic tool, rather than as a referral criterion. As it states that HLA-B27 should not be used in isolation to make a diagnosis, the GDG do not believe that this |

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| | | | | | | | conflicts with the recommendation in section 4.1.5 which states that HLA-B27 testing should be used in combination with other factors in order to make a decision with regard to referral for specialist assessment. |
| 9. | SH | BRITSpA | Full | | 4.1.5 | Referral of people with axial spondyloarthritis to a specialist physiotherapist is advocated to start a structured exercise programme, which should include stretching, deep breathing, spinal extension, range of motion exercises for the lumbar, thoracic and cervical sections of the spine. We agree but emphasis on strengthening and postural exercises is needed here as well | Thank you for your comment. The recommendation has now been edited to mention strengthening and postural exercises. |
| 10. | SH | BRITSpA | Full | | 5.3 | A comment on systemic corticosteroid therapy might still be valuable even though there are high no quality data. | Thank you for your comment. The GDG considered systemic corticosteroid therapy but agreed that in the absence of evidence they were not able to make any recommendations over and above those made in section 5.2 on steroids for the management of peripheral spondyloarthritis. |
| 11. | SH | BRITSpA | Full | General | General | We also recognize the dearth of high quality evidence for hydrotherapy but support the recommendation of hydrotherapy for axial SpA. | Thank you for your comment and for supporting this recommendation. |
| 12. | SH | NASS | Full | General | General | NASS welcomes and supports the general content of the Spondyloarthritis Clinical Guidelines. For such guidelines to be effective in reducing the delay to diagnosis | Thank you for your comment which has been passed on to both the NICE implementation and communication teams, who are |

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| | | | | | | in axial spondyloarthritis (and ankylosing spondylitis) and indeed, in improving levels of care across England and Wales, NASS asks that NICE undertakes to publicise these guidelines through all available channels to all HCPs including primary care on a regular care, helping to raise awareness about the diagnosis and treatment of these conditions. | responsible for these aspects of the NICE process. |
| 13. | SH | AbbVie UK | Full | 19 | 16 | Abbvie wishes to highlight that the latest NMA guidelines (https://www.ispor.org/indirect-treatment-study-use-guideline.pdf) suggest that the random effect models should be preferred irrespective of the DIC. A REM assumes that each study has its own true treatment effect. It is unclear why the network was downgraded if DIC suggested REM to be used. The network should be downgraded if there is evidence of inconsistency; but Abbvie does not believe that DIC implies that there is inconsistency; it's a measure of good model fit. | Thank you for your comment. We agree that the ISPOR guidelines present a reasonable way of undertaking NMAs, but we do not believe the approach taken in developing this guideline is an objectively inferior one. Decisions about fixed/random effects model selection were based on advice from the NICE Technical Support Unit, and the use of the deviance information criterion (DIC) for model selection is a common practice.<br><br>The DIC certainly is a measure of model fit, and therefore if a random effects model provides a significantly better fit to the data than a fixed effects model, this is likely to imply that the assumption of a shared effect size is not justified, and therefore a random effects model should be preferred. Additionally, the DIC is likely to favour random-effects models in situations where there is inconsistency in the network, as in |

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| | | | | | | | these circumstances a random-effects model is likely to provide a better model fit.<br><br>In the particular circumstances of this guideline, it is unlikely that any changes in statistical methodology would lead to different recommendations, as the clear pattern of NSAIDs providing better outcomes than placebo, but there not being consistently measurable difference between NSAIDs would be likely to persist in any model framework used. |
| 14. | SH | AbbVie UK | Full | 20 | 22 | Abbvie suggest expanding this sentence for further clarity to clinicians: *This can be challenging because spondyloarthritis include a number of heterogeneous conditions that effect both peripheral and axial joints, often with additional extra-articular manifestations which are seemingly unconnected to the core disease such as Uveitis, Psoriasis and Inflammatory bowel disease.* | The text has been updated to reflect this suggestion. |
| 15. | SH | AbbVie UK | Full | 20 | 29 | For the purposes of making these guidelines inclusive for non-specialists, Abbvie suggests expanding the 'should also raise awareness amongst clinicians' to '*should also raise awareness amongst clinicians (rheumatologists, general practitioners, and other non-rheum* | The text has been updated to reflect this suggestion. |

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| | | | | | | *specialists, eg gastroenterologists and ophthalmologists)* | |
| 16. | SH | AbbVie UK | Full | 20 | 45 | Abbvie believe that recognition of extra articular manifestations including uveitis, inflammatory bowel disease and psoriasis, can be a decisive indicator of underlying spondyloarthritis and such this critical guidance should assist both the non-rheumatology specialist in making an meaningful referral and specialists in diagnosis and grading severity. | Thank you for your comment and recognition of the value of this guidance. |
| 17. | SH | AbbVie UK | Full | 20 | 50 | Typo, ankylosing spondylitis rather than ankylosing spondyloarthritis. | Thank you for your comment. This correction has been made. |
| 18. | SH | AbbVie UK | Full | 22 | 15 | Abbvie suggest adjusting the wording of the embolden sub-headings in table 4 from 'Axial' to 'Spondyloarthritis with axial predominance' and 'spondyloarthritis with peripheral predominance' to reduce reader confusion. | The text has been updated to reflect this suggestion. |
| 19. | SH | AbbVie UK | Full | 23 | Table 6 | With regard to the 'Intervention box'; Abbvie suggest the inclusion of *chronic back pain*, instead of inflammatory back pain to assist non-specialists in making appropriate referrals as per other universally recognised referral criteria. | Thank you for your comment. The text has been changed to include 'chronic' as well as 'inflammatory' back pain, so as to reflect the approach used in the evidence review. |
| 20. | SH | AbbVie UK | Full | 24 | 0 | Abbvie suggest increased clarity over point 4 in the interventions tab of table 8 by defining 'Co-morbidities', 'extra-articular manifestations' and 'associated inflammatory conditions'. | The text has been updated to reflect this suggestion. |

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| 21. | SH | AbbVie UK | Full | 34 | 21 | Abbvie wishes the authors to clarify why 5% is used as a base case as this is unclear in the text. | Thank you for your comment. The use of 5% as a base case is explained in the 'Economic considerations' section of 4.1.4 Evidence to recommendations, and further detail is provided in Appendix H (section H.2.2). |
| 22. | SH | AbbVie UK | Full | 35 | 16 | Abbvie is unclear in the use of the phrase '**Slight** or **large'** in this paragraph, given the surrounding statements referring to '**moderate'** and '**slight'** risk and believes this comment will be confusing to readers. Abbvie suggests altering to '**large'**, given the other sections reflect slight and moderate already. | Thank you for your comment which we have taken into consideration. However it has been agreed that it would be misleading to omit the fact that data are consistent with a slight increase in risk as well as a moderate or large one. |
| 23. | SH | AbbVie UK | Full | 35 | 23 | Abbvie notes that the statement *'Age 35 or under at onset of back pain (in people aged 45 or under at onset of back pain)'* is confusing to the reader as it states both under 35 and under 45 for onset of back pain and request clarification y using a single age bracket. | Thank you for your comment. The text has been updated to reflect this suggestion. The evidence statement reflects the age stratification in the evaluated evidence. |
| 24. | SH | AbbVie UK | Full | 35 | 25 | Abbvie notes that the statement *'Age 35 or under at onset of back pain (in people aged 45 or under at onset of back pain)'* is confusing to the reader as it states both under 35 and under 45 for onset of back pain and request clarification y using a single age bracket. | Thank you for your comment. The text has been updated to reflect this suggestion. The evidence statement reflects the age stratification in the evaluated evidence. |
| 25. | SH | AbbVie UK | Full | 36 | 29 | Abbvie notes that this statement is contradictory to what has been described on page 35, line 23 and seeks clarification from | Thank you for your comment. The guideline states that, for people with back pain that begins **before** age 45, having it start before |

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| | | | | | | the authors to delineate the evidence statements relating to the onset of back pain in under 35s as both increasing and decreasing the probably that a person presenting with axial symptoms has spondyloarthritis. | age 35 provides an additional increase in risk. By contrast, the guideline states that, for people with back pain that begins before age 45, having it start **after** age 35 provides a decrease in risk. These statements are counterparts and present the same picture. |
| 26. | SH | AbbVie UK | Full | 37 | 31 | Abbvie withes to seek clarification from the authors as to whether a personal history of psoriasis should also be included as the most important risk factors for psoriatic arthritis. Similarly a personal history of inflammatory bowel disease should also be included. | Thank you for your comment. The evidence statements to which this comment refers relate specifically to the clinical features in the studies which were included in the evidence base. Evidence of a personal history of psoriasis or IBD was sought, but many of the included studies were conducted in populations of people with suspected peripheral spondyloarthritis where all participants had psoriasis (or IBD) at baseline, and therefore there were no useful data arising from these studies. |
| 27. | SH | AbbVie UK | Full | 37 | 39 | Abbvie believes the term 'Nail disease' should be altered to 'Psoriatic nail disease' for the utility of non-specialists. | The text has been updated to reflect this suggestion. |
| 28. | SH | AbbVie UK | Full | 38 | 29 | Abbvie notes that the inclusion of inflammatory back pain as both an increasing, decreasing and non-altering risk factor is unclear and confusing for the non-specialist. Abbvie suggests that a summary after each statement be included to assist the reader. | Thank you for your comment. Whilst the GDG noted the possible confusion this has arisen due to the decision not to pool evidence from studies which used different definitions of inflammatory back pain. To mitigate this, we hope that the reader will note the reference to the type of IBP in parentheses. |

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| 29. | SH | AbbVie UK | Full | 42 | 27 | Abbvie suggest to use the formal term 'Quality Adjusted Life Expectancy' for the utility of non-specialists | The text has been updated to reflect this suggestion. |
| 30. | SH | BRITSpA | Full | 43, 50 | | P43: bottom of page: "The GDG consider that only inflammatory polyarthritis was likely to be indicative of spondyloarthritis…….". This may reflect the references but is the reverse of clinical practice. See also bottom of P50. We think that inflammatory polyarthritis should raise suspicion of RA but that inflammatory oligo- or mono-arthritis should raise the possibility of SpA. | Thank you for your comment. After further consideration, the GDG agreed that the recommendation should be amended to read 'inflammatory arthritis' without reference to the number of affected joints. As the recommendation in question relates to referral rather than diagnosis, any overlap between this and the recognition of RA was not considered to be problematic, as further investigations in secondary care would distinguish between the two conditions. |
| 31. | SH | AbbVie UK | Full | 45 | 0 | The recommendations provided in section 4.1.4 (economic considerations) utilise *buttock pain*, *psoriasis* and *improvement of back pain with movement* to construct the model's base case. However, given the strength of evidence described in section 4 for uveitis, as a key clinical feature, then this should be included as part of the referral strategy – it is a prevalent extra-articular manifestation. | Thank you for your comment. The currently available evidence for this review question, did not suggest that any referral strategies that included uveitis as a criterion (van Hoeven [SSB27] and van Hoeven [ASAS]) resulted in a superior balance of sensitivity and specificity than the recommended strategy. This suggests that anyone presenting with uveitis and fewer than 4 of the 10 recommended criteria is unlikely to have axial SpA. However, in recognition of the evidence showing that extra-articular symptoms (including uveitis) should raise suspicion of SpA, the GDG have now added recommendation 3.2, which encourages careful re-evaluation of any cases where |

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| | | | | | | | these features are present, but the primary referral criteria are not met. |
| 32. | SH | AbbVie UK | Full | 46 | 4.1.4 | Economic considerations box. Abbvie wishes to highlight that the ASAS classification criteria described in the evidence to recommendations are designed for the inclusion of a homogenous population in clinical trials not designed for diagnosis and therefore should not be positioned as such. | Thank you for your comment. We acknowledge the original purpose of the ASAS criteria, but note that several studies provide evidence relating to their evaluation in the context of diagnosis of spondyloarthritis. The GDG therefore agreed that it was appropriate to use this evidence to evaluate the utility of the criteria for diagnosis. |
| 33. | SH | AbbVie UK | Full | 50 | 1-14 | Abbvie believes that the inclusion of *inflammatory bowel disease* as an extra-articular manifestation in this line would satisfy the comments on page 47 (Quality of evidence), and in particular the initial recognition section; *'no major harm would result provided it did not lead to inappropriate referrals*. The symptomology of inflammatory bowel disease can be vague although by not asking about these clinical features in primary care, prermits a significant risk of missing 'red flag' signs of inflammatory bowel disease. Furthermore Abbvie believes primary care physicians, non-specialists and specialists should join their specialist colleagues in inquiring specifically about extra-articular manifestations in their clinical history taking. Abbvie believes point 2.3 refers to an | Thank you for your comment. Recommendation 2.1 highlights signs and symptoms which, on their own, had statistically significant evidence of association of a positive diagnosis of spondyloarthritis. Unfortunately, the evidence base for the role of inflammatory bowel disease as a presenting feature of spondyloarthritis was limited. The rationale for the listed features is outlined at the beginning of the 'Quality of evidence' section of the LETR table.<br><br>Inflammatory bowel disease is however mentioned in recommendation 2.2, which should alert non-specialists to its occurrence as a potential comorbidity. It is also highlighted in recommendation 3.2, which encourages careful re-evaluation of any |

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| | | | | | | 'awareness of extra-articular manifestations, which is non-specific and does not call the clinician to any particular action such as clarification from the clinical history. | cases where these features are present, but the primary referral criteria are not met. |
| 34. | SH | MSD | Full | 50 | 17 | MSD supports the criteria for referral, for a suspected case of axial spondyloarthritis, and feel it comprehensively recognises the minimum requirements for referral to a specialist rheumatologist. | Thank you for your comment and endorsement for the referral criteria for axial spondyloarthritis |
| 35. | SH | AbbVie UK | Full | 50 | 19 | Abbvie wishes to highlight that the strategy described may miss (false negative) a substantial number of patients in whom the presence of uveitis or positive imaging has not been accounted. | Thank you for your comment. The strategy outlined at this point in the recommendations was an externally developed and validated referral tool, which has been evaluated by NICE in cost-utility analysis (see appendix H). As such, it would not be appropriate for additional criteria to be added to this list.<br><br>Regarding uveitis, we are confident that people presenting with current uveitis will be appropriately evaluated and referred if appropriate by recommendations 6.1 and 7.1. Regarding positive imaging findings, the recommendation in question relates to referral from non-specialist settings, where the guideline does not advocate that imaging should be requested. After consideration of the evidence the GDG agreed that the referral criteria outlined were optimal for detecting cases without causing an excessive increase in imaging requests. |

# Spondyloarthritis

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| 36. | SH | AbbVie UK | Full | 50 | 30 | Abbvie believes '*current or passed uveitis'* should be included into this list as indicated in the remainder of this section. | Thank you for your comment. The strategy outlined at this point in the recommendations was an externally developed and validated referral tool, which has been evaluated by NICE in cost-utility analysis (see appendix H). As such, it would not be appropriate for additional criteria to be added to this list. |
| 37. | SH | BRITSpA | Full | 50 | 4.1.3.1 | We are concerned that putting the emphasis on diagnosing individuals <35 years with Inflammatory Back Pain (IBP) will lead to underdiagnosis. Including patients <45 years with back pain (not necessarily inflammatory back pain) will identify fewer patients with axSpA but will also miss fewer. | Thank you for your comment. The recommendation states that onset of lower back pain before the age of 45 is a necessary criterion for referral to specialist services. People aged under 35 at age of onset of back pain are considered at even higher likelihood of having spondyloarthritis and therefore need to meet fewer additional criteria for referral.<br><br>While the content of this recommendation has not changed, we have modified the format/structure for clarity. |
| 38. | SH | AbbVie UK | Full | 51 | 34 | Abbvie notes that this sub-section includes guidance for 'case finding in people with extra-articular manifestations' such as uveitis, psoriasis and enthesitis but does not include a similar section for inflammatory bowel disease and that this section should be adjusted to reflect all relevant extra-articular manifestations. | Thank you for your comment. The section referred to was included following identification of a specific study with a validated tool for detecting spondyloarthritis in people with uveitis which was found to be effective. No such prospectively validated tools were identified for inflammatory bowel disease, but we agree that such tools would be of value, and a research recommendation has been made on this topic. |

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| 39. | SH | AbbVie UK | Full | 62 | 34 | Abbvie seeks clarification form the author with regard to specificity of either spinal and/or pelvic X-rays when detecting sacroiliitis using radiography. | Thank you for your comment. The GDG discussed differing types of X-rays and agreed that wherever possible it would be appropriate to obtain sacroiliac joint (SIJ) radiographs. However, in cases where a spinal radiograph has been obtained, the SIJ can be reviewed from this. The evidence considered by the GDG which demonstrated the diagnostic value of sacroiliitis on X-ray was all from X-rays of the sacroiliac joint, and therefore this was the form of imaging recommended. |
| 40. | SH | Leeds Teaching Hospitals Trust | Full | 67 | 16 | Same as above applies to point 8.6 of the Clinical guidelines document. | Thank you for your comment. The recommendation in question is part of a sequence of recommendations which feed into the diagnostic process, and does not advocate diagnosis on the basis of MRI criteria alone. In order to receive a positive diagnosis of axial spondyloarthritis, a person will have already presented with a number of relevant signs, symptoms and risk factors in order to be referred for investigation including MRI.<br><br>Nonetheless, we acknowledge that the way the recommendations are laid out may not have made this clear and we have edited them to improve usability. |
| 41. | SH | UCB | Full | 83 | 25 | We would like to note that the statement about NSAIDs and radiographic progression | The text has been edited in light of this suggestion. |

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| | | | | | | is not accurate, as currently the evidence is conflicting and recent publication (Sieper et al. 2016) did not show any effect of NSAIDs on spinal radiographic progression. It is thus not clear if NSAIDs reduce radiographic progression in axSpA patients. Furthermore, although an earlier study in AS patients with raised inflammatory markers have shown a reduced rate of spinal damage progression with continuous NSAID use, these findings were contradicted by those of a more recent randomized study (Sieper et al. 2016).<br><br>Reference:<br>- Sieper J., Listing J., Poddubnyy D., Song I-H, Hermann K-G, Callhoff J, Syrbe U, Braun J, Rudwaleit *M. Effect of continuous versus on-demand treatment of ankylosing spondylitis with diclofenac over 2 years on radiographic progression of the spine: results from a randomised multicentre trial (ENRADAS).* Ann Rheum Dis 2016 Aug 4;75(8):1438-43. | |
| 42. | SH | AbbVie UK | Full | 83 | 30 | Abbvie wishes to correct the notion that biological efficacy is similar between agents given that there are significant and meaningful differences in efficacy for the treatment of extra-articular manifestations. | The text has been updated to reflect this suggestion. |

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| 43. | SH | Brit-PACT | Full | 83 | 34 | One factual inaccuracy 'B27 related comorbidities such as psoriasis, inflammatory bowel disease and uveitis', neither the first 3 are remotely B27 related. Also the section on PsA therapy refers the reader to the psoriasis guidelines | Thank you for your comment. The text was intended to note that HLA-B27 is genetically associated with a variety of extra-articular conditions in addition to spondyloarthritis. However, in order to clarify that HLA-B27-positivity is not a necessary requirement for diagnosis with these comorbidities we have removed 'HLA-B27 from this sentence. |
| 44. | SH | AbbVie UK | Full | 83 | 37 | Abbvie suggest that 'comorbid conditions' is clarified for the non-specialist user to extra-articular manifestations. | Thank you for your comment. The text has now been edited to amend 'comorbid conditions' to 'extra-articular manifestations' |
| 45. | SH | AbbVie UK | Full | 84 | 20 | Abbvie suggest to rephrasing from "non-randomised interventions" to "non-randomised studies" for reader ease. | Thank you for your comment. The text has been updated to reflect this suggestion. |
| 46. | SH | AbbVie UK | Full | 87 | 25 | Abbvie wishes to highlight that the application of the AE cost only to the first year seems an implausible assumption given the long term exposure to NSAIDs experienced in the patient journey and would therefore not be a true reflection of clinical practice. | Thank you for your comment. We agree and it was partially in reflection of oversimplifying assumptions like this that this evidence was judged to be subject to potentially serious limitations. |
| 47. | SH | AbbVie UK | Full | 87 | 25 | Typo: BASDAI instead of BASDI | Thank you for your comment. The correction has now been made. |
| 48. | SH | AbbVie UK | Full | 90 | 3 | Abbvie acknowledges that NSAIDS may be appropriate for pain relief in patients with axial spondyloarthritis but also wishes to add the use of biologics such as TNF and IL-17 inhibitors should be placed under the pharmacological recommendations for | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline: |

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| | | | | | | completeness and ease of utility for the non-specialist. | TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA 372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 49. | SH | MSD | Full | 96 | 11 | The list of factors to take into account when deciding which DMARD to offer is missing two key factors. | Thank you for your comment. This recommendation was intended to refer to standard DMARDs, not biological DMARDs, and has been edited to clarify this point. As such, issues such as injection site reactions |

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| | | | | | | Firstly, frequency of drug administration. A low frequency of administration minimises the impact on patients' lives, this is particularly helpful to economically active patients.<br><br>Secondly, consideration of the DMARD's adverse event profile. A treatment with a positive adverse event profile e.g. low frequency of injection site reaction is less likely to be discontinued. | do not apply. Following further discussion the GDG agreed that no further edits to this recommendation were required. |
| 50. | SH | AbbVie UK | Full | 96 | 2 | Abbvie acknowledges that DMARDS may be appropriate in patients with peripheral spondyloarthritis but also wishes to add the use of biologics under the pharmacological recommendations for completeness and ease of utility for the non-specialist. | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 |

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| | | | | | | | (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 51. | SH | AbbVie UK | Full | 96 | 5.2.4 | Quality of Evidence box. Abbvie suggest that *intramuscular* injection be replaced with *intra-articular* injection of steroid to reflect clinical practice. | Thank you for your comment which has been considered by the GDG, who agreed that the original wording of 'intramuscular injection' is more appropriate in this specific context. |
| 52. | SH | AbbVie UK | Full | 100 | 5.3.4 | Trade off box. Abbvie wishes to highlight that classical DMARDs are not routinely prescribed in axial spondyloarthritis and contrary to guidance offered in NICE TA343. | Thank you for your comment. This section was intended to refer only to the use of standard DMARDs in peripheral spondyloarthritis. The text has been edited to make this clear. |
| 53. | SH | AbbVie UK | Full | 102 | 5.3.4 | Quality of Evidence box. Abbvie suggest that the notion of switching between DMARDs is inappropriate, and likely to could unnecessary delay and irreversible joint damage before biologic agents are utilised. | Thank you for your comment. The GDG considered that switching from one standard DMARD to another is both part of routine practice and allowable under the TA guidelines for biological DMARDs. Furthermore the latter guidance requires failure on two standard DMARDs before initiation of biological therapies and for many people this will involve a switch between |

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| | | | | | | | standard DMARDs, rather than two treatments being initiated simultaneously. |
| 54. | SH | AbbVie UK | Full | 102 | Table 5.3.4 | Abbvie suggests amending the 'quality of evidence' section to comply with NICE TA383 in that the requirement for patients to have failed two NSAIDs before moving to an anti-TNF agent in longer stipulated. | Thank you for your comment. This suggested amendment has been made. |
| 55. | SH | AbbVie UK | Full | 103 | 5 | Abbvie is very surprised to note that DMARDS are being considered for joint efficacy in axial disease as there is very little data supporting this strategy and this contradicts the guidance offered in TA343 in axial spondyloarthropathy. | Thank you for your comment. These recommendations are only intended for application to peripheral spondyloarthritis, as indicated in the subheading. The text has been edited to read 'peripheral spondyloarthritis' to further clarify. The same change has been made in the Short Guideline. |
| 56. | SH | AbbVie UK | Full | 103 | 7 | Abbvie wishes to contest the sequential use of DMARDS if the first DMARD does not demonstrate efficacy as this contradicts NICE TA199 and produces significant delay to biologic agents. | Thank you for your comment. NICE Technology Appraisal (TA) 199 states:<br><br>"Etanercept, infliximab and adalimumab are recommended for the treatment of adults with active and progressive psoriatic arthritis when the following criteria are met.<br><br>The person has peripheral arthritis with three or more tender joints and three or more swollen joints, and<br><br>The psoriatic arthritis has not responded to adequate trials of at least two standard disease-modifying antirheumatic drugs |

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| | | | | | | | (DMARDs), administered either individually or in combination."<br><br>Recommendation 16.2 does not contradict the above TA, and additionally allows for the management of existing extra-articular comorbidities to be considered alongside the new management of peripheral arthritis. |
| 57. | SH | Novartis | Full | 107 | General (within Quality of Evidence) | "The GDG discussed whether it would be possible to make any recommendations in this area. It considered the very limited evidence identified and whether it would be appropriate to consider biological DMARDs for enteropathic, reactive and undifferentiated spondyloarthritis as an extrapolation from the NICE Technology Appraisals (TAs) which considered the use of biological DMARDs in those with ankylosing spondylitis and/or non-radiographic axial spondyloarthritis (TA383) and psoriatic arthritis (TA199, TA220 and TA340)."<br>TA407 on "Secukinumab for active ankylosing spondylitis after treatment with nonsteroidal anti-inflammatory drugs or TNF-alpha inhibitors" was published on September 28th 2016. Secukinumab represents an alternative biological disease-modifying anti-rheumatic drug, which the Technology Appraisal Committee accepted | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which |

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| | | | | | | as being "a promising new advance" and "an innovative new treatment for the treatment of active AS". We therefore request that the "Spondyloarthritis in over 16s: diagnosis and management" final guideline should make reference to both TA407 and TA383 as providing relevant guidance on the use of biological DMARDs in those with ankylosing spondylitis. | will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 58. | SH | AbbVie UK | Full | 165 | 35 | Abbvie wishes to raise the relevance of emerging research relating to subclinical/microscopic gut lesions which are more increasingly being recognised as a precursor to inflammatory bowel disease – an extra-articular manifestation of spondyloarthritis, which should be incorporated into the guidance to assist clinicians more precisely and prevent unnecessary examinations or investigations. | Thank you for your comment. Consideration of methods of diagnosis of inflammatory bowel disease was outside of the scope of this question, and the guideline as a whole. |
| 59. | SH | BRITSpA | Full | 170 | 8.6.6.17 | Evidence relating to Cardiovacular Disease (CVD) risk is conflicting so that there are significant uncertainties. The research agenda should include clarifying this risk and identifying risk factors for reduced life expectancy | Thank you for your comment. Following further discussion the GDG agreed with this suggestion, and a research recommendation on CVD has been added to the guideline. |
| 60. | SH | BRITSpA | Full | 126 | 9 | We recognise the dearth of high quality evidence in the area of aerobic exercise. However, some comment should be made regarding (1) the level of intensity e.g moderate-using a rate of perceived exertion | Thank you for your comment. The evidence review was limited to intervention studies and as such we did not have the scope to incorporate 'grey literature' (including guidelines from other organisations) into the |

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| | | | | | | scale (RPE 12-16) in line with WHO exercise recommendations for 16-64yr olds and (2) the importance of non-contact / low impact aerobic exercise in those in advanced ankylosis. | recommendations. The GDG opted not to elaborate further on the specific details of aerobic activity, but has edited the recommendation to emphasise that the exercise programme should be individualised to the needs of the person. |
| 61. | SH | BAPO | Full | 142 | 1–8 | BAPO have identified that the orthotist is not listed as a specialist therapist in this section.<br><br>This section discusses 'braces, physical supports and splints'. These devices are all classed as orthoses – externally applied devices which target pathology through influence of biomechanics.<br><br>The orthotist is considered as the principal professional responsible for assessing, measuring, fitting, supplying and reviewing orthoses (this is supported by the BAPO Standards for Best Practice.). Orthotists are autonomous registered practitioners who provide gait analysis and engineering solutions to patients with problems of the neuro, muscular and skeletal systems. They are extensively trained at undergraduate level in mechanics, bio-mechanics, and material science along with anatomy, physiology and pathophysiology. Their qualifications make them competent to design and provide orthoses that modify the | Thank you for your comment. Orthotist has been added to the list of specialist therapists in both the full and short guideline. |

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| | | | | | | structural or functional characteristics of the patients' neuro-muscular and skeletal systems enabling patients to mobilise, eliminate gait deviations, reduce falls, reduce pain, prevent and facilitate healing of ulcers. They are also qualified to modify CE marked Orthoses or componentry taking responsibility for the impact of any changes. As such it is of importance that the orthotist is stated within the list of specialist therapist to whom a patient may be referred. | |
| 62. | SH | Psoriasis Association | Short | 3 | 11 | We welcome the statement that spondyloarthritis should not be ruled out based upon any one sign, symptom or test result. Somewhere in this document, however, we would recommend that is explicitly stated that a negative Rheumatoid Factor test does not rule out psoriatic arthritis (or other non-rheumatoid types of arthritis). We frequently hear from individuals who have been told by clinicians in both primary and secondary care that a negative Rheumatoid Factor test means that they cannot have 'arthritis'. | Thank you for your comment. The GDG discussed the issue raised and acknowledged that sometimes rheumatoid factor testing will be undertaken in people with peripheral joint presentation to rule rheumatoid arthritis in or out. As the use of rheumatoid factor in the assessment of suspected spondyloarthritis was outside the scope of this guideline, the GDG agreed that it was not appropriate to draft a 'Do not do' type recommendation for this test. The recommendations nonetheless state that spondyloarthritis should not be ruled out on the basis of the "presence or absence of any individual sign, symptom or test result", which would include rheumatoid factor testing<br><br>They additionally noted that the incorrect notion that people with a negative rheumatoid |

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| | | | | | | | factor test result do not have some form of arthritis is unlikely to be corrected by this guideline as on occasions where this assumption is made it is unlikely that this guideline would be consulted. |
| 63. | SH | UCB | Short | 3 | 13 | Inflammatory bowel disease is also an important extra-articular manifestation that should be mentioned in section 1.1.2. | Thank you for your comment. Recommendation 1.1.2 highlights signs and symptoms which, on their own, had statistically significant evidence of association of a positive diagnosis of spondyloarthritis. Unfortunately, the evidence base for the role of inflammatory bowel disease as a presenting feature of spondyloarthritis was limited. The rationale for the listed features is outlined at the beginning of the 'Quality of evidence' section of the LETR table in the Full guideline. |
| 64. | SH | Psoriasis Association | Short | 3 | 17-19 | The wording around risk factors needs to be clarified. Recent genitourinary infection is a risk factor for Reactive Arthritis, but not for psoriatic arthritis. | Thank you for your comment. This section discusses features associated with spondyloarthritis in general, before any recommendations relating to axial or peripheral disease, or specific types of spondyloarthritis. |
| 65. | SH | UCB | Short | 3 | 20 | The clinical guideline indicates several established comorbidities to be considered when recognising peripheral spondyloarthritis (page 4, section 1.1.4), however no such mention is being made when recognising axial spondyloarthritis, thus indirectly implying that these are not | Thank you for your comment. The recommendation has been edited to reflect the relevance of these comorbidities to both axial and peripheral spondyloarthritis. |

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| | | | | | | relevant for axial spondyloarthritis. Given that similar comorbidities are equally important to be considered when recognising axial spondyloarthritis, we would suggest addition of similar statements in section 1.1.3. | |
| 66. | SH | Psoriasis Association | Short | 3 | 4-6 | Psoriatic arthritis can be predominantly peripheral, axial, or a mixture of both. We are concerned that the initial comment that psoriatic arthritis is predominantly peripheral will be misleading to the reader. | Thank you for your comment. We have edited the introductory text to highlight the possibility of spondyloarthritis with mixed presentations. |
| 67. | SH | UCB | Short | 3-4 | general | While the referral criteria are reasonable, we suggest that it would be better to use the recent ASAS recommended referral criteria as this has been better validated.<br><br>Reference:<br>- Poddubnyy,D., van Tubergen, A., Landewé, R., Sieper, J., van der Heijde, D. Development of an ASAS-endorsed recommendation for the early referral of patients with a suspicion of axial spondyloarthritis. Ann Rheum Dis 2015;0:1–5. doi:10.1136/annrheumdis-2014-207151. | Thank you for your comment. The ASAS referral criteria, as described in the reference cited, are not, in themselves, evidence-based, but represent expert opinion. However, the performance of the criteria has been evaluated in a relevant dataset, the CaFaSpA cohort (see van Hoeven et al. 2015).<br><br>Our original cost–utility analysis used these data to simulate the costs, benefits and harms of using the proposed ASAS referral criteria (at a variety of cut-offs, including the ASAS-recommended referral if 1 or more criteria is met). It showed that, while the sensitivity of that strategy is perfect, it comes at a cost of very poor specificity of 29%. In consequence, if these criteria were |

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| | | | | | | | assiduously adopted by all healthcare professionals at first contact, then there would be 14.5 false-positive referrals for every true-positive case correctly referred (assuming the true prevalence of AxSpA in people presenting with chronic back pain with onset ≤45 years is 5% – the estimate favoured by the GDG). This represents an unacceptable burden on specialist services; therefore, it is necessary to prefer a strategy that benefits from much better specificity, without making too substantial a compromise on sensitivity. Our analysis showed that the optimal choice, in this regard, is the recommended strategy. |
| 68. | SH | Psoriasis Association | Short | 4 | 1-2 | All types of spondyloarthropathy can occur in people who are HLAB27 negative, this is not unique to axial spondyloarthropathy. | Thank you for your comment. We agree that this is the case, which is reflected in recommendation 1.2.2 on page 7. However, the GDG reported that negative HLA-B27 testing leading to inappropriate ruling out of spondyloarthritis particularly affects people presenting with axial symptoms, and agreed that this was a misconception that needed to be addressed. |
| 69. | SH | Primary Care Rheumatology Society | Short | 4 | 23, 24, 25 | The referral criteria suggest a blood test for HLAB27 if only 3 clinical criteria are present. We wonder about the validity of the HLAB27 test and its Positive/negative predictive value. We also feel that this recommendation feels counter intuitive to | Thank you for your comment. Cost-utility analysis identified this set of referral criteria as the optimal approach for enabling correct referral of people with likely spondyloarthritis versus avoiding excessive numbers of referrals for specialist assessment in people |

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| | | | | | | primary care in the context if rheumatic disease, as we have always been taught to refer early for possible rheumatological conditions and not wait for the outcome of blood tests. We feel awaiting and interpreting the HLA B27 test could be confusing and perhaps lead to delays in referral for these patients. We also feel the recommendation to ask patients to seek repeat assessments if all the criteria are not met is not helpful for Primary care, as patients do not always return if things change and the liability if diagnosis does get delayed rests solely with the GP.<br>We however recognise that increased referrals to rheumatologists for assessments does incur a cost | with a low likelihood of spondyloarthritis. While we acknowledge that awaiting the results of a blood test may lead to a delay in referral, this will only affect a subset of people: those with 4 or more features present will be directly referred, and those with fewer than 3 features will not qualify for referral at that stage irrespective of the test result, and hence should not be tested unless further features emerge at a later date.<br><br>People presenting with exactly 3 features on the list will, as suggested, experience a slight delay and represent an increased demand on primary care resources. However, given that people with axial spondyloarthritis typically experience years of delay in their diagnosis, with associated repeat primary care presentations, on balance we consider this to be a beneficial strategy for both patients and healthcare providers.<br><br>In addition we also want to support commissioners in allowing HLA-B27 testing where appropriate in primary care, as we understand that practice varies across the country. This recommendation gives a clear set of circumstances in which such testing is appropriate and likely to be of benefit. |

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| 70. | SH | Psoriasis Association | Short | 4 | 4-5 | All types of spondyloarthropathy may be missed, even if onset is associated with comorbidities, this is not unique to peripheral spondyloarthritis. For example, psoriatic arthritis that presents as axial spondyloarthritis can be missed just as easily as psoriatic arthritis where the peripheral joints are involved. In fact, axial psoriatic arthritis may be more likely to be missed, due to greater awareness of the peripheral 'small joint' symptoms. | Thank you for your comment. The recommendation has been edited to reflect the relevance of these comorbidities to both axial and peripheral spondyloarthritis. |
| 71. | SH | Primary Care Rheumatology Society | Short | 5 | 14, 15, 16, 17 | We are concerned that the recommendation to refer for persistent enthesitis or enthesitis in multiple sites is quite vague for a primary care clinician. How long is persistent? How many sites constitutes multiple? Many primary care clinicians will be dealing with very few of these cases and so may need more clarity about the degree of symptomatology to be concerned about. | Thank you for your comment. The GDG discussed this comment and considered the addition of specific thresholds, but concluded that it would be beneficial to allow clinicians to use their own judgement when assessing enthesitis in the context of other presenting signs and symptoms. The intention of the recommendation is to be inclusive of a wide range of enthesitis presentations, excluding those which have a mechanical origin or only affect one enthesis (e.g. tennis elbow). |
| 72. | SH | Primary Care Rheumatology Society | Short | 5 | 4,5 | We felt it may have been more helpful to include the relevant section from the psoriasis guideline in this section rather than redirecting people to view a different guideline. Primary care clinicians are reviewing these patients within 10 mins and taking time to check a particular guideline, | Thank you for your comment. We are unable to incorporate the exact wording from another guideline, as the cross-referred guideline may be updated subsequently, leaving this guideline inappropriately out of date.<br><br>However, we do recognise the time pressures during primary care consultations. |

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| | | | | | | only to be redirected to yet another guideline can be time consuming.<br>Question 1: Is there a need to include annual screening of Psoriasis patients with the Psoriasis Epidemiology Screening Tool (PEST) as recommended in NICE psoriasis Guidelines 2012? We are unsure about the effectiveness of this tool in identifying cases of psoriatic arthritis and its use in either the primary care or Secondary care settings. We wondered if such a tool could be used innovatively, such as an app on a smartphone or tablet? | Accordingly we have edited the hyperlink to take readers directly to the relevant part of the Psoriasis guideline.<br><br>We agree that tools may have increased usability when turned into apps or online tools. However, it is not part of NICE's remit to develop tools in this way. |
| 73. | SH | UCB | Short | 5 | 5 | The clinical guideline refers to the NICE CG153 for guidance on identifying spondyloarthritis in people with an existing diagnosis of psoriasis. The clinical guideline should make clear reference to diagnosis of peripheral SpA in patients with psoriasis and it would be preferable to have some clear statements regarding the identification of the condition in patients with psoriasis, perhaps similar to those listed in 1.2.2 'Assessment and referral for psoriatic arthritis' in the NICE CG153, in particular the annual assessment for psoriatic arthritis for patients with psoriasis. | Thank you for your comment. We are unable to directly incorporate wording from another clinical guideline into this guideline, as if the former is subsequently updated then the latter may be inappropriately out of date. However, to aid primary care practitioners we have amended the hyperlink to cross refer directly to the recommendations concerning diagnosis of spondyloarthritis in people with psoriasis. |
| 74. | SH | UCB | Short | 6 | 19 | Classification criteria are used to define a homogeneous group of patients for clinical research once a diagnosis has been made | Thank you for your comment. We acknowledge that some of the listed criteria were developed for classification rather than |

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| | | | | | | and hence should not be used for diagnostic purposes as there is the risk of misclassification (specificity of criteria ~85%) and inappropriate treatment. Consequently we suggest revising the text in section 1.2.1, lines 19-20, to read (revisions underlined):<br><br>"*In specialist settings classification criteria may be helpful as reminder of the important disease features to aid diagnosis by a rheumatologist, but should not be in the absence of clinical judgement to make a diagnosis*"<br><br>Source: Rudwaleit, M., Landewé R, Sieper J. 2016; Correspondence to Taurog et al publication *Ankylosing Spondylitis and Axial Spondyloarthritis*. N Engl J Med 2016; 375:1302-1303; September 29, 2016DOI: 10.1056/NEJMc1609622<br><br>The same comment applies to the Full Draft Guideline, page 78, section 4.5.5, line 2. | diagnosis. However, the identified evidence base allowed the evaluation of the utility of these criteria sets for diagnosis. None of these criteria were of sufficiently high diagnostic utility to recommend at the exclusion of other criteria, and the recommendation of their use is intended to support clinician diagnosis. We have amended the wording of the recommendation to reflect this. |
| 75. | SH | Primary Care Rheumatology Society | Short | 6 | 21-27 | In the specialist care section, the guideline mentions several different validated criteria to diagnose Spondyloarthritis. We feel the range of options to be used should be narrower. Furthermore, page 7 mentions the New York criteria as the preferred tool for | Thank you for your comment. Each of the listed criteria were evaluated and found to be of use in supporting clinicians in making a diagnosis. There was insufficient evidence to recommend the use of one tool to the exclusion of others, so it would be difficult to |

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| | | | | | | diagnosing the condition using Xrays and the ASA/OMERACT MRI criteria as the preferred mode of diagnosing cases when an MRI scan has been done. It appears confusing. | justify shortening this list. The tools listed in the imaging section are for the interpretation of imaging findings rather than for the overall diagnosis of spondyloarthritis. |
| 76. | SH | Psoriasis Association | Short | 6 | 8 | Why stop at whether the individual has consulted their GP about joint pains? Could also ask if the individual has noticed any swollen joints, morning stiffness, dactylitis, and other risk factors or telltale signs of spondyloarthritis, including recent genitourinary infection. | Thank you for your comment. The wording of this recommendation reflects a specific tool which was designed for case-finding in uveitis, and evaluated in the evidence review. As such, it would be inappropriate for us to modifying the criteria without being able to validate the tool on participant data. |
| 77. | SH | Psoriasis Association | Short | 7 | 1-2 | Include do not rule out diagnosis of spondyloarthritis solely on the basis of a negative test for Rheumatoid Factor. We frequently hear from individuals who have been told by clinicians in both primary and secondary care that a negative Rheumatoid Factor test means that they cannot have 'arthritis'. | Thank you for your comment. The GDG discussed the issue raised and acknowledged that sometimes rheumatoid factor testing will be undertaken in people with peripheral joint presentation to rule rheumatoid arthritis in or out. As the use of Rheumatoid Factor in the assessment of suspected spondyloarthritis was outside the scope of this guideline, the GDG did not feel it appropriate to draft a 'Do not do' type recommendation for this test. Recommendation 1.1.1 nonetheless states that spondyloarthritis should not be ruled out on the basis of the "presence or absence of any individual sign, symptom or test result"<br><br>The GDG additionally noted that the incorrect notion that people with a negative rheumatoid |

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| | | | | | | | factor test result do not have some form of arthritis is unlikely to be corrected by this guideline as on occasions where this assumption is made it is unlikely that this guideline would be consulted. |
| 78. | SH | UCB | Short | 7 | 18 | We would like to note that as per the standard practice and further indicated in key references on the use of MRI for SIJ (Siebert S et al, 2016), the SIJ MRI should not be coronal, but semi- coronal (oblique) slices as the coronal slices are not correct and are unclear. Consequently, we suggest replacing 'coronal' with 'semi-coronal' in Section 8.4, so that the text reads (revisions underlined).<br><br>"*Radiologists receiving a request for an inflammatory back pain MRI should perform short T1 inversion recovery (STIR), T1 (both views), cervical, thoracic and lumbar (whole spine, sagittal view), and sacroiliac joints (semi-coronal view).*"<br><br>Reference: Siebert S, Sengupta R, Tsoukas A. *Axial Spondyloarthritis.* Oxford University Press, Sep 2016.<br><br>The same comment applies to the Full Draft Guideline, page 67, line 14. | Thank you for your comment. The GDG, including the co-opted radiologists, discussed this issue and concluded that 'coronal' was a suitable description of the appropriate imaging, and that the terminology used would be well understood by radiologists. |

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| 79. | SH | UCB | Short | 7 | 20 | To ensure consistency with the taxonomy used in the ASAS classification criteria and given the difference in the licensed indications for biologics, the clinical guideline should clearly indicate whether the diagnosis is for radiographic or non-radiographic axial spondyloarthritis. We would thus suggest the following revision to the text in section 1.2.5 (revision underlined):<br><br>"*Diagnose axial spondyloarthritis (radiographic axial spondyloarthritis or ankylosing spondylitis) if the plain film X-ray shows sacroiliitis 9 meeting the modified New York criteria (bilateral grade 2–4 or unilateral grade 3–4 sacroiliitis)*." | Thank you for your comment. The recommendation has been edited as suggested. |
| 80. | SH | UCB | Short | 7 | 9 | To ensure consistency with the taxonomy used in the ASAS classification criteria and given the difference in the licensed indications for biologics, the clinical guideline should clearly indicate whether the diagnosis is for radiographic or non-radiographic axial spondyloarthritis. We would thus suggest the following revision to the text in section 1.2.5 (revision underlined): | Thank you for your comment. The recommendation has been edited as suggested |

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| | | | | | | "*Diagnose axial spondyloarthritis (non-radiographic axial spondyloarthritis) if the MRI meets the ASAS/OMERACT MRI criteria*." | |
| 81. | SH | UCB | Short | 10 | 10 | While it is reasonable to recommend NSAIDs for pain control or reducing inflammation in axial spondyloarthritis, the clinical guidance should also reflect the recognised risks of long term regular NSAID use (e.g. gastrointestinal, cardiovascular risks) and that, as part of the treatment decision making, the potential benefits and harms of long term therapy with NSAID should be carefully considered. | Thank you for your comment. The recommendations on NSAID use have been edited to draw attention to the need for ongoing monitoring of risks and the use of gastroprotection. |
| 82. | SH | UCB | Short | 10 | 14 | Section 1.4.3 refers to the NICE TA383 recommendation for TNF-alpha inhibitors in ankylosing spondylitis and non-radiographic axial spondyloarthritis. It is important to note, that given the difference in licenses of the TNF-alpha inhibitors, the NICE TA383 makes a clear distinction in the recommendations made for ankylosing spondylitis and non-radiographic axial spondyloarthritis. To provide an accurate information of the recommendations made in TA383 and ensure consistency with the information provided for the NICE technology appraisals in psoriatic arthritis, | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 |

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| | | | | | | we would suggest that section 1.4.3 of the clinical guideline summarizes the NICE TA383 recommendations (NICE TA383, sections 1.1 to 1.6, pages 4-5). | (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 83. | SH | Novartis | Short | 10 | 14-17 | TA407 on "Secukinumab for active ankylosing spondylitis after treatment with nonsteroidal anti-inflammatory drugs or TNF-alpha inhibitors" was published on September 28th 2016. Secukinumab represents an alternative biological disease-modifying anti-rheumatic drug, which the Technology Appraisal Committee accepted as being "a promising new advance" and "an innovative new treatment for the treatment of active AS". We therefore request that the "Spondyloarthritis in over 16s: diagnosis and management" final | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic |

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| | | | | | | guideline should make reference to both TA407 and TA383 as providing relevant guidance on treating axial spondyloarthritis. | axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 84. | SH | Psoriasis Association | Short | 10 | 14-17 | Psoriatic arthritis is not always peripheral, it can also be axial. NICE guidance on the use of biologics for psoriatic arthritis should be used when treating axial psoriatic arthritis. | Thank you for your comment. The NICE Technology Appraisals (TAs) for the use of biological DMARDs are existing pieces of guidance, which we are unable to modify or rename in the development of this clinical guideline. We are therefore not able to advocate use of these TAs for populations other than those for which they were intended. We would nonetheless expect that rheumatologists would thoroughly evaluate the signs and symptoms of people with predominantly peripheral spondyloarthritis, |

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| | | | | | | | and treat any axial manifestations appropriately. |
| 85. | SH | UCB | Short | 10 | 7 | Section 1.4.6 on page 11 discusses the importance of certain considerations related to non-biological DMARDs but these are equally relevant and important to prescribing decisions for biological DMARDs. To ensure consistency and accuracy in the description of the specific considerations or circumstances for the pharmacological management of spondyloarthritis, Section 1.4 should also include a section on general considerations to reflect the various factors which should be taken into account in the treatment decision making, including special disease-related considerations (e.g. presence of extra-articular or extra-spinal manifestations), patient-factors such as women of child bearing age or co-morbid conditions, route and frequency of treatment administration. We would thus suggest the addition of a general sub-section at the beginning of Section 1.4, summarizing these general considerations that should be accounted for in the decision making of treatment with biological and non-biological DMARDs. | Thank you for your comment. A bullet point has been added to draw attention to the need for consideration of side effects in the selection of a standard DMARD. With regard to biological DMARDs, specific considerations relating to these drugs will be outlined in the relevant Technology Appraisals, and it is therefore not necessary to repeat them here in a section of recommendations on non-biological therapies. |

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| 86. | SH | Novartis | Short | 10,12-14 | Pg 10: 14-17 Page 12: 2 – Page 14:10 | We query why greater detail has been provided on TA199 ("Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis") and TA220 ("Golimumab for the treatment of psoriatic arthritis") in comparison with TA383 ("TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis"), TA340 ("Ustekinumab for treating active psoriatic arthritis") and TA372 ("Apremilast for treating active psoriatic arthritis).<br>Page 104, lines 14-16 of the full draft guideline state: "Evaluation of biological DMARDs for axial spondyloarthritis and psoriatic arthritis was outside of the scope of this guideline". Therefore we query whether the level of detail provided on TA199 and TA220 is appropriate. | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will |

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| | | | | | | | not publish sufficiently early to be included as part of this guideline. |
| 87. | SH | Royal College of Nursing | Short | 11 | 12 | There is no mention of Certolizumab pegol which is licensed and used in psoriatic arthritis though currently undergoing NICE technology appraisal for PsA.<br><br>As Certolizumab pegol is also licensed and used for spondyloarthritis, we consider that this spondyloarthropathy guideline should be in line with the Clinical Guideline for Rheumatoid Arthritis (CG79) for the Multi-disciplinary team (MDT). | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the |

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| | | | | | | | time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 88. | SH | Psoriasis Association | Short | 11 | 14 | Oral steroid therapy can cause psoriasis to become dangerously unstable. If psoriasis exists on the skin or nails, even if mild in severity, oral steroid therapy should not be given without consulting with Dermatology. | Thank you for your comment. The GDG agreed that there were potential issues with the use of steroids in people with psoriasis, but following discussion agreed that these issues were sufficiently well understood that there was not a need for a specific comment in the guideline. |
| 89. | SH | Psoriasis Association | Short | 11 | 6-7 | We suggest expanding the 'comorbidities' and/or 'disease characteristics' bullet point to specifically state both psoriasis and inflammatory bowel disease. It is common for spondyloarthritis to exist alongside these conditions, which also use treatments that fall under the 'DMARD' banner. It is essential to consider that patients with co-existing psoriasis or inflammatory bowel conditions may already be on a DMARD therapy regime; may have tried certain DMARD therapies in the past and stopped due to adverse events; or may have skin or gut symptoms that they would welcome an improvement in, and so it may be possible to choose a DMARD that may improve both the arthritis symptoms and the skin/gut, leading to improved patient outcomes. Whilst other less-related comorbidities are of course still important, psoriasis and | Thank you for your comment. This recommendation has now been edited to read: "comorbidities such as uveitis, psoriasis and inflammatory bowel disease" in both the short and full guidelines. |

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| | | | | | | inflammatory bowel disease are common enough to warrant being explicitly stated. | |
| 90. | SH | UCB | Short | 12 | 1 | We would like to note that both certolizumab pegol and secukinumab are currently being appraised by NICE for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs (NICE ID579), with the final guidance expected to be published in February 2017. Given the relevance to the clinical guideline under consultation, we would thus consider that it would be beneficial to include the final NICE recommendations for certolizumab pegol and secukinumab in PsA and that the timing of the issue of the clinical guideline is aligned with the later appraisal recommendation. | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the |

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| | | | | | | | time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 91. | SH | Psoriasis Association | Short | 12 | General | NICE will have published technology appraisals for certolizumab pegol and secukinumab for psoriatic arthritis by the time this guideline is published – consider including. | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for |

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| | | | | | | | psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 92. | SH | Leeds Teaching Hospitals Trust | Short | 12 of 24 | 2 | We note that certolizumab pegol (ESNM42) is not included on the summary of biological DMARDS for treatment of PsA. This drug is now fully incorporated into the clinical armamentarium of this group of patients and we feel that a mention should be made even in the absence of a full NICE TA. | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather than incorporated. Finally, ID579 |

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| | | | | | | | (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 93. | SH | Novartis | Short | 14 | 10 | Page 104, lines 14-16 of the full draft guideline state: "Evaluation of biological DMARDs for axial spondyloarthritis and psoriatic arthritis was outside of the scope of this guideline, as NICE guidance can be found in existing ***or forthcoming*** NICE Technology Appraisals, which are either cross-refered to or incorporated within this guideline".<br>We therefore request that a section be added to the short version of the guideline entitled "Biological DMARDs - certolizumab pegol and secukinumab", making reference to the Multiple Technology Appraisal on certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs (ID579). Publication of final Technology Appraisal Guidance for this appraisal is expected in February 2017, ahead of publication of the final guideline on "Spondyloarthritis in over 16s: diagnosis and management" in March 2017. | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology appraisal has been cross-refered to rather |

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| | | | | | | | than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 94. | SH | UCB | Short | 14 | 4 | Given the difference in the NICE recommendations for licensed biologics in psoriatic arthritis, the clinical guideline should briefly indicate the NICE recommendation for ustekinumab, to ensure accurate reflection of differences in the recommendations made. | Thank you for your comment. To ensure consistency in how Technology Appraisals (TAs) are included in the guideline the following changes have been made to the guideline:<br><br>TA199 (etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis), TA220 (golimumab for the treatment of psoriatic arthritis), TA340 (ustekinumab for treating active psoriatic arthritis), TA383 (TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis) and TA407 (secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors) have now all been fully incorporated into this guideline. TA372 (apremilast for treating active psoriatic arthritis) was going through a rapid review at the time of publication of this guideline which will not be completed in time for it to be fully incorporated, and hence this technology |

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| | | | | | | | appraisal has been cross-refered to rather than incorporated. Finally, ID579 (certolizumab pegol and secukinumab for psoriatic arthritis) was in development at the time of publication of this guideline, but will not publish sufficiently early to be included as part of this guideline. |
| 95. | SH | UCB | Short | 14 | 7 | We would like to note that apremilast is a targeted synthetic DMARD, and not a biologic DMARD, as inaccurately stated in the clinical guideline. We would thus suggest revisions in the clinical guideline to ensure accurate reflection of the mechanisms of actions of different therapies considered.<br><br>The same comment applies to the Full Draft Guideline, pages 104-105. | Thank you for your comment. The heading has been now been amended to read 'Synthetic DMARDs – apremilast' in both the short and full guidelines. |
| 96. | SH | Royal College of General Practitioners | Short | 16 | 19 | 1.9.1 In primary care we have noticed increased use of biological DMARDs without adequate monitoring. Secondary care appears unable to provide this for many patients and is sending patients to their GPs for monitoring. Whilst recognising the convenience of local places to have their bloods taken many in primary care are unfamiliar and inexperienced with safe monitoring of DMARD. Commissioners do not appear to be able to resolve these issues. | Thank you for your comment. The GDG noted and, based on its own experience, agreed with the comment. The increasing lack of adequate monitoring supported the rationale for robust arrangements being put in place to co-ordinate primary and secondary care. This was reflected in the GDG's recommendation that 'Commissioners should ensure that local arrangements are in place to coordinate care for people across primary and secondary (specialist) care… |

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| | | | | | | (MH) | [covering] monitoring NSAIDs, standard DMARDs and biological DMARDs'.<br>The GDG further noted that the British Society for Rheumatology has produced guidelines on monitoring DMARDs, which could be used as the basis for local arrangements. The relevant 'evidence to recommendations' discussion has been updated to make explicit reference to this resource (9.5.4). |
| 97. | SH | UCB | Short | 16 | 4 | Section 1.8.3 of the short version of the clinical guideline indicates that there is a greater risk of skin cancer in people treated with TNF-alpha inhibitors. Section 8.7.4 of the full guideline (pages 172-174) summarizes the evidence and considerations made by the GDG, stating that "*It was discussed that people with psoriatic arthritis who undergo PUVA (Psoralen with UVA) treatment for comorbid psoriasis may have an elevated risk of skin cancer and this should be taken into consideration when advising people about the benefits and risks associated with biological DMARDs.".* The guidance further states that "*The GDG noted that in their experience, people were particularly concerned about cancer risks, and that this may sometimes dissuade people from initiating anti-TNF therapies or standard* | Thank you for your comment which was discussed by the GDG, who agreed that there was sufficient support for the use of biological DMARDs elsewhere in the guideline, and that this recommendation should draw attention only to the risks which should be appropriately communicated to people who may be receiving or initiating these therapies. The recommendation has been revised explicitly to recommend that people should be advised of this risk. |

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| | | | | | | *DMARD therapies who may otherwise have benefitted. However, it was noted that some people with spondyloarthritis are keen to access these therapies as soon as possible. In the GDG's experience an individual's perception of risk may therefore be an important determinant of treatment choice. The GDG noted that there has historically been concern about possible increased malignancy risk in people taking anti-TNFs for other indications, and that this may also apply to this population, though not necessarily at sufficiently high rates to outweigh the potential treatment benefits*." and that "*The GDG noted that skin cancer is a well-established complication of biological DMARD use in other populations, and it was therefore felt to be a particularly important to make people with spondyloarthritis aware of this, though the risks are not sufficiently great to negate the benefits of these therapies for managing this group of conditions*."<br><br>In order to accurately reflect the GDG discussions and the existing evidence, we would thus suggest that the text in section 1.8.3 states (revisions underlined): "*Be aware there may be a greater risk of skin cancer in people treated with TNF-alpha* | |

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| | | | | | | *inhibitors, though the risks are not sufficiently great to negate the benefits of these therapies for managing this group of conditions*."<br><br>Source: van Lümig PP, Menting SP, van den Reek JM, Spuls PI, van Riel PL, van de Kerkhof PC, Fransen J, Kievit W, de Jong EM. *An increased risk of non-melanoma skin cancer during TNF-inhibitor treatment in psoriasis patients compared to rheumatoid arthritis patients probably relates to disease-related factors*. J Eur Acad Dermatol Venereol. 2015 Apr;29(4):752-60. doi: 10.1111/jdv.12675. Epub 2014 Sep 17 | |
| 98. | SH | Psoriasis Association | Short | 20 | 20-22 | It is not only spinal symptoms that are commonly unrecognised – ethesitis for example is often misdiagnosed as tendonitis, which itself can also contribute to delays in diagnosis and treatment. We frequently hear from individuals whose psoriatic arthritis was initially misdiagnosed as tennis elbow (enthesitis), Achilles tendonitis (enthesitis), gout (peripheral joint involvement and/or enthesitis), fungal nail infection (dactylitis and/or psoriatic nails), as well as mis diagnosis of lower back symptoms. | Thank you for your comment. The GDG has sought to address under-recognition of enthesitis as a feature of SpA in recommendation 1.1.10 which aims to achieve referral for anyone with enthesitis which is multisite, persistent, or presents in combination with other features of spondyloarthritis. In addition, recommendation 1.1.1 emphasises the need to avoid ruling out a diagnosis of spondyloarthritis on the basis of any individual sign, symptom or test result, to encourage investigation of a range of presenting clinical features. |

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| 99. | SH | Psoriasis Association | Short | 20 | 7 | Skin and/or nail involvement may also be present but very mild – to the extent that the individual themselves may not have noticed it (for example, small amounts of psoriasis on the scalp or in skin folds can easily go unnoticed). As this may aid diagnosis, a full examination of the skin is essential if spondyloarthritis is suspected. | Thank you for your comment. A new recommendation has now been added to the guideline noting that for people presenting with suspected spondyloarthritis, if there are also signs and symptoms of undiagnosed psoriasis, then this person should be assessed and managed according to the NICE guideline on psoriasis. It is, however, beyond the scope of this guideline to recommend what steps should be taken in the suspicion and recognition of psoriasis. |
| 100. | SH | Royal College of General Practitioners | Short | 21 | 8 | Repeat the CaFaSpA study (van Hoeven et al. 2014, 2015) in a UK population<br>Whilst there are clearly potential differences from the study to the UK population there should be some practical guidance we can implement now rather than waiting for several years before we achieve any change.<br>(MH) | Thank you for your comment. In forming the recommendations, the GDG have made use of the best currently available evidence, including the existing CaFaSpA study and other similar research. The research recommendation therefore aims to further extend the evidence base in the future with data that has greater relevance to the UK population. The research recommendation does not delay implementation of recommendations based on the current best available evidence. |
| 101. | SH | Leeds Teaching Hospitals Trust | Short | 7 of 24 | 20-21 | We are concerned about the statement "diagnose axial SpA if the MRI meets the ASAS/OMERACT MRI criteria". We believe that it is important to clarify that the diagnosis of axSpA is not made solely based on MRI findings. Rather, MRI is one of the criterion given on the ASAS | Thank you for your comment. The recommendation in question is part of a sequence of recommendations which feed into the diagnostic process, and does not advocate diagnosis on the basis of MRI criteria alone. In order to receive a positive diagnosis of axial spondyloarthritis, a person |

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| | | | | | | classification criteria to aid the diagnosis which should always be made by the physicians based on symptoms, signs of disease as well as expected prevalence in a given population. It is important to remember that the ASAS criteria was developed for classification rather than diagnosis, as such does not have adequately high sensitivity and specificity to be used for diagnosis in all settings.<br>We suggest that this statement is removed as it is confusing and does not add beyond statement 1.2.8 "Use the ASAS/OMERACT MRI criteria to interpret MRI" and statement 1.2.10 which correctly states "If the MRI does not meet …. ".<br><br>We suggest that the above would be helped by adding the correct references to each statement so to avoid confusion, as the ASAS/OMERACT definition of a positive MRI (Rudwaleit M, et al. Ann Rheum Dis. 2009 Oct;68(10):1520-7) was developed to aid the implementation of the MRI criterion in order to apply the ASAS classification criteria for axSpA (Rudwaleit M, et al. Ann Rheum Dis. 2009 Jun;68(6):777-83). We find that this is already an important problem in daily clinical practice even among experts on the field and we strongly | will have already presented with a number of relevant signs, symptoms and risk factors in order to be referred for investigation including MRI.<br><br>Nonetheless, we acknowledge that the way the recommendations are laid out may not have made this clear and we have edited them to improve usability. |

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| | | | | | | advise that these statements are clarified on the guideline so to avoid further confusion in the clinical setting. | |
| 102. | SH | Psoriasis Association | Short | 8 | 7 | Peripheral arthritis refers to arthritis of the arms and legs, not only the hands and feet. Although involvement of hand and foot joints is common in people with peripheral psoriatic arthritis, they may also have involvement in larger arm and leg joints including shoulders, elbows, wrists, knees, heels and ankles. Psoriatic arthritis can take on a number of different patterns. The concern with this recommendation is that peripheral spondyloarthritis is suspected without symptomatic hands and feet, there will be no opportunity to X-Ray problematic larger peripheral joints. | Thank you for your comment. The GDG discussed these recommendations and agreed that the recommendation to consider X-rays of other peripheral symptomatic sites should allow for the appropriate investigations of people with suspected peripheral spondyloarthritis without symptomatic hands and feet. |
| 103. | SH | UCB | Short | 9 | 23 | Considering the age demographics of this cohort of patients, we feel that it would be important to include information regarding 'Work & their employment rights'. Sources such as those provided by NASS http://nass.co.uk/about-as/living-well-with-as/work/ could be signposted. | Thank you for your comment. Your suggestion has now been added into the recommendation in both the short and full guidelines. |
| 104. | SH | UCB | Short | 22 | 3 | There are established questionnaires for patients with IBD to screen for SpA that could be used and should be indicated in the clinical guideline. | Thank you for your comment. However we are not aware of any relevant instruments that have been prospectively validated. |

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| 105. | SH | PAPAA | Short | General | General | As much as we are pleased, as an organisation, to see a guideline on spondyloarthritis, we are disappointed that psoriatic arthritis has been bundled under such a broad heading and scope, we therefore feel that psoriatic arthritis deserves a guideline on its own merit.<br><br>The guideline does appear to be more aimed at an axial disease based group of patients, than those with the peripheral psoriatic arthritis. We accept that there is an overlap of symptoms but feel that the psoriatic population is being under served by this guideline; it also appears that psoriatic arthritis is perceived to be a less important aspect and given a secondary role within the diagnosis process.<br>For those with psoriatic arthritis the problem is often a late diagnosis with a lack of recognition of the condition. We accept that there was a brief reference within the psoriasis clinical guideline (CG153) to the possibility of psoriatic arthritis and the need to monitor for joint pain; it did not give any guidance on the management. CG153 appears to have had little impact on raising the awareness of psoriatic arthritis and we believe that this guideline by placing | Thank you for your comment. We understand the perception that, relative to axial spondyloarthritis, peripheral spondyloarthritis including psoriatic arthritis appears to have fewer specific recommendations. However, this reflects the evidence base that was identified rather than a decision by the GDG; that being the case a standalone guideline on psoriatic arthritis would not contain any more PsA-specific recommendations unless other questions were included in the scope. Furthermore, there is value in having a single guideline covering both axial and peripheral spondyloarthritides, for the benefit of people presenting with features of both. There are many aspects of the recommendations (e.g. flare management) where the advice applies equally to axial and peripheral spondyloarthritis.<br><br>However, we acknowledge that the term 'peripheral spondyloarthritis' is not yet well recognised in non-specialist settings, so at several points in the recommendations we have now sought to highlight that psoriatic arthritis is contained within this group.<br><br>The GDG discussed the role of CG153 in drawing attention to psoriatic arthritis and acknowledged that the increased awareness |

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| | | | | | | psoriatic arthritis within a group of conditions, will not improve that situation.<br><br>We are not convinced that this guideline will raise the level of awareness at primary care where in our view the problems lie. The provision of primary care education is briefly addressed and we feel that for patients to gain any real benefit from the development of any guideline this lack of knowledge, awareness and recognition of early diseases should be seen as priority, otherwise patients will continue to go undiagnosed. | of PsA triggered by the publication of CG153 may not have been sustained. Nonetheless, the existence of CG153 placed any questions relating to initial recognition (but not final diagnosis) of PsA outside of the scope of the spondyloarthritis guideline. |
| 106. | SH | Psoriasis Association | Short | General | General | We suggest considering that at some point in this document there is a recommendation regarding referral to Dermatology/encouragement to visit GP if required, for individuals whose psoriatic arthritis has been diagnosed before their psoriasis but who are experiencing skin and/or nail symptoms. Skin and/or nail symptoms may cause the individual significant discomfort as well as cosmetic or functional impairment and, if present, may need to be treated separately. | Thank you for your comment. A new recommendation has now been added to the guideline noting that for people presenting with suspected spondyloarthritis, if there are also signs and symptoms of undiagnosed psoriasis, then this person should be assessed and managed according to the NICE guideline on psoriasis. |
| 107. | SH | Royal College of General Practitioners | Short | General | General | This could be a potentially useful guideline for a group of conditions that remain difficult to diagnose particularly in primary care before occurrence of irreversible damage. | Thank you for your comments. We would like to draw attention to the structure of the recommendations for both referral and diagnosis. The GDG felt confident that its |

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| | | | | | | However it does not really suggest any thing new that will improve early diagnosis. The nomenclature could be simplified. With an average time span for diagnosis is 8-11 years from onset of symptoms and definite diagnosis spondyloarthritis is difficult to diagnose in primary care, mainly due to:<br>1. Symptoms confused with mechanical back pain<br>2. Past medical training has not recognised the incidence in women<br>3. Multiple complex testing and follow up is required in primary care<br><br>With the advent of effective treatments earlier diagnosis must remain a priority. This guideline should at least include a diagram of a diagnostic algorithm particularly to distinguish inflammatory back pain from mechanical back pain.<br>It could be available as a pop up in GP systems when certain Read codes are used. This method has been effective in recruiting patients to studies such as Timeli for memory loss and could be used for other uncommon conditions.<br><br>Consideration needs to be given to screening in Physiotherapy and musculoskeletal services as these young | clear, straightforward referral rule for people with chronic low back pain will, if implemented by GPs, have a very substantial impact on the underdiagnosis of spondyloarthritis in primary care.<br><br>At no stage is a formal diagnosis of Inflammatory Back Pain required. There are elements of IBP criteria in the axial referral criteria list, but it is possible for a person to be referred without meeting any standard IBP criteria if they have sufficient other signs, symptoms and risk factors. Hence, removing the term 'inflammatory back pain' from the pathway was felt to be an important step in the simplification of nomenclature.<br><br>Consideration was given to providing an algorithm to depict the referral decision; however, it was concluded that it would not be helpful, as there is only 1 substantive step in the process (does the patient meet the criteria? If yes then refer).<br><br>We agree that tools may have increased usability when turned into apps or online tools. However, it is not part of NICE's remit to develop tools in this way. |

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| | | | | | | patients with low back pain are often referred or self refer to private services so this presents a significant opportunity for detection of inflammatory back pain.<br>(MH)<br><br>There doesn't seem to be a section on diet. There has been published research on diet for ankylosing spondylitis- the London AS diet for instance.<br>http://www.kickas.org/londondiet.shtml<br>Most patients often ask about diet. Alcohol can have a great influence too.<br>The RCGP feels that diet merits a section going through the evidence and coming to a balanced conclusion.<br>(JM) | The GDG was aware that routes of presentation are not always straightforward and that referral pathways vary in different localities; it was for this reason that all referral recommendations relate to 'non-specialist settings' in general, not primary care in particular.<br><br>Regarding diet, this was not an area that was agreed for inclusion at the scoping stage, and therefore we did not have the remit to undertake a review of dietary interventions in this version of the guideline. |
| 108. | SH | AbbVie UK | Appendix J | 7 | | Table 3 has been referred to as Table 2 | Thank you for your comment. We have now corrected this error. |

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*