What is the place of the technology in current practice?

We would like to know how the condition is currently treated in the NHS.

Is there significant geographical variation in current practice?
YES DUE TO LOCAL VARIATIONS IN FUNDING ARRANGEMENTS

Are there differences in opinion between professionals as to what current practice should be?
REASONABLY STANDARDISED NOW ALTHOUGH SOME PHYSICIANS HAVE A HIGHER THRESHOLD THAN OTHERS FOR PRESCRIBING BIOLOGICS

What are the current alternatives to the technology and what are their respective advantages and disadvantages?
CYTOTOXIC AGENTS: ADVANTAGES – LONG TERM SAFETY PROFILE WELL DOCUMENTED WITH METHOTREXATE; DISADVANTAGES – NOT EFFECTIVE IN ALL, HENCE BIOLOGICS MAY BECOME ESSENTIAL AFTER A CERTAIN STAGE, CUMULATIVE DAMAGE TO ORGANS LIKE LIVER (WITH MTX)

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient?
THERE ARE SEVERAL DIFFERENT TYPES OF PSORIATIC ARTHRITIS AND PROGNOSIS VARIES ACCORDINGLY. THE ARTHRITIS MUTILANS VARIANT GENERALLY HAS THE WORST PROGNOSIS IN TERMS OF DISABILITY

Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology? **NOT GENERALLY**

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics?
SECONDARY CARE AND SPECIALIST CLINICS

Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?
YES, NEEDS EXTENSIVE SPECIALIST NURSING INPUT AND COMMUNITY CARE

If the technology is already available, is there variation in how it is being used in the NHS?
PROBABLY YES, DUE TO PHYSICIANS' CHOICE AND INDIVIVIDUAL PATIENT NEEDS

Is it always used within its licensed indications?
MOSTLY YES

If not, under what circumstances does this occur?
WITHIN DERMATOLOGY, RARELY BIOLOGIC AGENTS MAY BE USED OUTSIDE LICENSED INDICATIONS FOR PATIENTS WITH SEVERE/RARE/RECALCITRANT CONDITIONS WHERE THERE IS SOME EVIDENCE THAT THEY MAY BE EFFECTIVE, ALSO IN CERTAIN CIRCUMSTANCES A PATIENT MAY REQUIRE A BIOLOGIC EARLIER THAN CURRENT RECOMMENDATIONS

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.
BAD PROVIDES EXCELLENT GUIDELINES ON USE OF BIOLOGIC AGENTS IN PSORIASIS. THE LATEST UPDATE WHICH INVOLVED RIGOROUS METHODOLOGY IS DUE TO BE PUBLISHED IN BRITISH JOURNAL OF DERMATOLOGY IN OCTOBER 2009

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, if available, compares with current alternatives used in the UK. Is the technology easier or more difficult to use and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its use?
ONCE A BIOLOGICS SERVICE IS SET UP, THEY ARE MUCH EASIER TO USE WITH INCREASED COMPLIANCE FROM PATIENTS AND HIGHER RESPONSE RATES TO THE CONDITION. THE NEED FOR MONITORING BLOOD TESTS IS GENERALLY LESS THAN WITH CURRENT ALTERNATIVES AND HOSPITAL ADMISSIONS CAN BE SIGNIFICANTLY REDUCED. SOME PATIENTS MAY PREFER THE COMPARATORS BECAUSE THEY CAN BE ADMINISTERED ORALLY

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include the requirement for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.
THIS IS COVERED WELL IN THE NEW BAD GUIDELINES

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology in clinical practice reflects that observed under clinical trial conditions. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting?
YES CLNICAL PRACTICE DOES GENERALLY REFLECT THE DATA FROM PREVIOUS TRIALS

What, in your view, are the most important outcomes and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

IMPORTANT OUTCOMES WERE ADEQUATELY ASSESSED IN THE TRIALS

What is the relative significance of any side effects or adverse reactions? In what ways do these have an impact on the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in the clinical trials but have come to light subsequently during routine clinical practice?
SIDE EFFECTS GENERALLY LESS THAN COMPARATORS. RISKS RELATED TO IMMUNOSUPPRESSION APPLY TO BOTH AND ARE PARTICULARLY RELEVANT CURRENTLY RE SWINE FLU. THERE IS STILL UNCERTAINTY ESPECIALLY WITH THE NEWER AGENTS RE LONGTERM RISK OF MALIGNANCIES

Any additional sources of evidence?

Are you aware of any relevant evidence which may not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence or information from registries and other nationally coordinated clinical audits.
NOT AT PRESENT BUT ADDITIONAL INFORMATION MAY COME FROM THE BSR AND BAD BIOLOGICS REGISTRIES

Any such additional information must be accompanied by sufficient detail to enable a judgement to be made as to the quality of the evidence and to enable potential sources of bias to be determined.

Implementation issues

How would possible guidance have an impact on the delivery of care for patients with this condition? Would there be any need for NHS staff to be educated and trained?
INCREASED NUMBERS OF SPECIALIST NURSING STAFF REQUIRED TO WORK UP PATIENTS FOR BIOLOGIC AGENTS AND ALSO FOR MONITORING PROGRESS

Would any additional resources be required (for example, facilities or equipment)?
GENERALLY, NO SPECILAISED FACILITIES OR EQUIPMENT REQUIRED EXCEPT DAY UNITS MAY BE NEEDED FOR INFUSIONS

Under the Department of Health and Welsh Assembly Government, the NHS is required to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisals. This provision has to be made within 3 months from the date of publication of the guidance. If the technology is unlikely to be available in sufficient quantity or the staff and facilities to fulfil the general nature of the guidance can not be put in place within 3 months,
NICE may advise the Department of Health and Welsh Assembly Government to vary this direction.

Please note that NICE can not suggest variation in the direction on the basis of budgetary constraints alone.