
Clinical Protocol

Psoriasis Biologic Drug Treatment Pathway

Guideline Summary

This clinical guideline outlines the biologic treatment pathway for adult patients with psoriasis.

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24.09.18	<p>Page 8: statement about contraindications amended to reflect these are relative and absolute</p> <p>Page 15: Clarification added re: IL-17 inhibitors under caution in patients with IBD</p>	
10.09.19	Section 6,12,13,14 , and appendix 3: Addition of certolizumab, tildrakizumab and risankizumab following NICE approval	

10.09.19	Section 7: Updated vaccination section in line with BAD rapid update and green book	
10.09.19	Section 9: Updated free of charge scheme wording in line with RMOc statement	
10.09.19	Section 15: High impact site information clarified and information added to appendix 5. Additional information added to pustular psoriasis section in light of new evidence.	
10.09.19	Supplementary information- section 2,3,4,5,6, 7 in line with BAD rapid update	
10.09.19	Update documents in appendix 1,2,3 based on BAD rapid update and addition of appendix 4 and 5	
09.03.20	Updated related documents- added updated liver assessment and management pathway	
09.03.20	Section 13: Addition of hyperlink to RMOc advisory statement in relation to sequential use of biologic drugs	
09.03.20	Section 14: Removal of B* requirement from dose escalations table	
09.03.20	Section 15: Clarification of high impact site section and addition of assessment timescale	
09.03.20	Section 15.1.2 addition of guselkumab and reference for palmoplantar pustulosis	
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07.09.21	Section 12: Treatment table now contains Bimekizumab (NICE TA723)	
07.09.21	Appendix 4: Update to pricing table, now includes Bimekizumab	
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09.03.20	Updated in line with latest NICE TAGs (see change history)	

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References

Consultation Process

1. Scope

This treatment pathway applies to adult patients with a diagnosis of psoriasis who are approaching treatment with biologic therapy being treated in secondary or tertiary care.

2. Rationale

This treatment pathway provides an evidence-based approach for the treatment of psoriasis whilst maximising cost effectiveness and clinical outcome for use by all healthcare professionals involved in patient care.

3. Principles

This treatment guideline is based on current available national guidance (NICE), the British Association of Dermatology (BAD) guidelines and locally approved guidance for the use of biologics in adults with psoriasis and is subject to frequent change as guidance is updated, new agents emerge and costs change. This guideline will therefore be under active review in light of the above. This pathway is correct at the time of publication. NICE Technology Appraisals (TAs) relating to Psoriasis in adults which are published after the approval date of this guideline will be commissioned 90 days (30 days for fast track NICE TAs) from publication in line with the TA recommendations. This document is not designed to replace the above guidelines; URLs are embedded within the document where relevant. This pathway assumes that prescribers cross-reference a drugs Summary of Product Characteristics (SPC) to inform clinical decision making for individual patients (www.medicines.org.uk/emc). In order to ensure effective service provision in line with the pathway the suggested service quality standards are outlined in appendix 1.

4. Definitions

Severe disease – Psoriasis Area and Severity Index (PASI) score of 10 or more (or a BSA of 10% or greater where PASI is not applicable) and a Dermatology Life Quality Index (DLQI) > 10. In exceptional circumstances (for example, disease affecting high-impact sites with associated significant functional or psychological morbidity such as acral psoriasis), patients with severe disease may fall outside this definition but may be considered for treatment.

Adequate response – Achievement of PASI 75 or alternatively achievement of PASI 50 with at least a 5-point reduction in DLQI score within the outlined timeline for each individual drug as outlined by NICE (see [section 12](#)).

Inadequate response – Failure to achieve the above.

Primary failure – The patient's psoriasis does not respond adequately as described in the NICE technology appraisals.

Secondary failure – The patient's psoriasis initially responds adequately as described above but subsequently loses this response.

5. Recommended disease severity assessments, before and during therapy

5.1. Assessment of disease severity³

- 5.1.1. Physicians global assessment (PGA) classified as clear, nearly clear, mild, moderate, severe or very severe
- 5.1.2. Psoriasis Assessment and Severity Index (PASI)
- 5.1.3. Nail involvement. Use the Nail Psoriasis Severity Index (NAPSI) if major functional or cosmetic impact or pre/ post treatment to assess progress.
- 5.1.4. Body Surface area affected (more than 10% defined as extensive disease)
- 5.1.5. Involvement of high impact and difficult to treat sites e.g. face, scalp, palms, soles, flexures and genitals
- 5.1.6. Screen for psoriatic arthritis, Psoriasis Epidemiological Screening Tool (PEST), if suspected refer to rheumatologist for joined up approach to care and consider referral to the joint psoriasis and rheumatology clinic.
- 5.1.7. Patient's global assessment classified as clear, nearly clear, mild, moderate, severe or very severe
- 5.1.8. Dermatology Life Quality Index (DLQI) or Children and young people version (CDLQI)

6. Pre-Biologic Therapy – Key Considerations

6.1 Strategies for maximising the use of systemic non-biological treatments prior to biologic therapy:

Consider switching to subcutaneous methotrexate where clinically appropriate (e.g. gastrointestinal adverse effects with oral methotrexate, poor compliance or concerns regarding absorption of oral formulation).

6.2. Provide high quality information to patient

The BAD have patient information leaflets on most biologic therapies available:

[Adalimumab](#) [Ixekizumab](#)
[Brodalumab](#) [Risankizumab](#)
[Etanercept](#) [Secukinumab](#)
[Guselkumab](#) [Tildrakizumab](#)
[Infliximab](#) [Ustekinumab](#)
[Bimekizumab](#)

For agents where the BAD patient information leaflet is unavailable, the manufacturers patient information leaflet accessed via [the Electronic Medicines Compendium \(EMC\)](#) will be provided.

6.3. Eligibility criteria for biologic therapy

Methotrexate and ciclosporin have failed, are not tolerated or are contraindicated (see [NICE guidelines CG153](#)).

AND

The psoriasis has a large impact on physical, psychological or social functioning
e.g. DLQI > 10

AND ONE OF THE TWO FOLLOWING CRITERIA ARE MET

NICE Criteria

Extensive psoriasis (BSA > 10% or PASI ≥ 10)

OR

Non-NICE Criteria

Psoriasis is severe at localised sites and associated with significant functional impairment and/or high levels of distress e.g. nail disease or involvement of high-impact and difficult-to-treat sites such as the face, scalp, palms, soles, flexures and genitals, see [section 15, Special Populations](#).

6.4. Complete recommended pre-biologic assessments

Refer to local and national guidance for full list of assessments needed pre-biologic therapy.
See [Appendix 2](#) for BAD guideline suggested schedule for screening and monitoring

6.5 Apremilast/Dimethyl Fumarate

In patients who are contraindicated to or decline biologic therapy, consider the use of apremilast or dimethyl fumarate in individuals meeting the required NICE criteria (psoriasis not responded to standard systemic therapies and PASI ≥ 10 and DLQI >10).

7. [Vaccinations](#) (click for Department of Health Green Book)

Vaccination requirements should be reviewed and brought up to date prior to initiation of biologic therapy with reference to Department of Health Guidance⁶.

Do not give live vaccines to people on biologic therapy or to infants (up to 6 months of age) whose mothers have received biologic therapy beyond 16 weeks' gestation. Patients should be counselled on the need to avoid live vaccines and the implication that may have for travelling.

In general stop biologic therapy for at least 12 months before giving live vaccines, including the shingles (herpes zoster) vaccine. However, expert opinion suggested that 12 months may not be necessary for all biologics, and where live vaccinations need to be considered then expert advice should be sought and/or the individual specifications checked in the SPC where timelines are stated explicitly for some of the biologic drugs.

In general, biologic therapy can be started 4 weeks after administration of a live vaccine. Refer to the drug-specific SPC and Green Book for further information.

Where possible, complete all required vaccinations prior to initiation of biologic therapy and review vaccination requirements during therapy with reference to the Green Book and the clinical risk category 'immunosuppression'.

Inactivated vaccines are safe to administer concurrently with biologic therapy.

Where possible, inactivated vaccines should ideally be administered at least 2 weeks before starting therapy to ensure optimal immune responses.

Patients should receive annual influenza vaccine (intramuscular only) and pandemic influenza vaccine when recommended and pneumococcal vaccination prior to biologic therapy. Clinicians should be aware that TNF antagonist mono-therapy may lead to reduced antibody responses to influenza vaccine and that TNF antagonists in combination with methotrexate (only) may lead to reduced antibody responses to pneumococcal vaccine

Refer to [BAD immunisation document](#) for further information.

8. Recruitment into clinical trials

Where possible, patients should be invited to participate in clinical trials being undertaken within the dermatology departments.

Patients with psoriasis who are starting biologic therapy should be offered the opportunity to participate in long-term safety registries such as the British Association of Dermatologists Biologic Interventions Register (BADBIR)

9. Free of charge schemes

New biologic and non-biologic DMARDs are often licensed and made commercially available many months before NICE are due to issue their NICE Technology Appraisal Guidance. Where this situation exists, individual dermatology departments may enter discussions with the pharmaceutical company to determine if a 'free of charge' (FOC) early access scheme is feasible.

When a FOC scheme is proposed it must satisfy the following criteria:

- The scheme must not replace or override the agreed pathway and the FOC drug should only be considered if pathway options are exhausted or not clinically appropriate.
- Treatment must be funded at negligible cost to the Trust and zero cost to NHS commissioners until the end of the agreed implementation period in the positive NICE Technology Appraisal guidance.
- Continue to fund treatment in the event of a negative NICE Technology Appraisal Guidance until:
 - 90 days after a future positive NICE Technology Appraisal Guidance
 - The dermatologists consider it no longer clinically appropriate to continue the drug.
- All schemes require sign off in each NHS Trust and this usually requires the Chief Pharmacist, the Pharmacy Procurement Lead and Director of Finance to authorise the scheme.

[For more detail refer to the principles outlined by the Regional Medicines Optimisation Committee \(RMOC\).](#)⁷

A locally adapted version of the RMOC guidance is currently under development. This will replace the RMOC link once available.

10. Method of medication supply

Subject to local arrangements patients may be offered a choice of method of supply. This may include a traditional homecare service or enhanced outpatient pharmacy service via outsourced outpatient pharmacies on main hospital sites. Where there is agreement with pharmaceutical companies, unbundling of homecare and direct procurement via outsourced pharmacies may result in a reduction in the drug acquisition cost. This may further influence the biologic choice at local Trust level.

Subject to local arrangements and eligibility guidelines, in order to reduce the time to biologic initiation, the first biologic doses (2 – 4 weeks supply) may be given in the infusion suite or dermatology day centre as part of an outpatient biologic initiation service. As the first dose(s) are administered in the outpatient clinic, the cost will incur VAT and this will be passed onto commissioners.

11. Biosimilars

The introduction of biosimilars can deliver significant savings to the NHS whilst achieving similar clinical outcomes. Where appropriate, biosimilars should be used, providing they are licensed for psoriasis and are registered with BADBIR. Prescribing should be brand specific and patients maintained on the Trust's brand of choice unless a clinical decision has been made to switch. This approach is supported by the BAD, as per their [position statement](#). Patients who have responded well to an originator product and who are then switched to biosimilar should be closely monitored to ensure efficacy and safety.

12. Treatment Choice: First Biologic

Psoriasis failed/contraindicated/intolerant to standard therapy (methotrexate, ciclosporin). If concurrent joint and skin disease see section 15.3 and liaise with rheumatologist for optimum agent for both

PASI ≥ 10 and DLQI > 10

PASI ≥ 20 and DLQI ≥ 18

Biosimilar infliximab

Consider Factors Affecting Choice

- The SPC of each biologic in the context of the patient's clinical history and co-morbidity profile
- Different effectiveness and safety profiles of each drug (see decision aid)
- Drug specific relative and absolute contra-indications for example
 - to TNF antagonists e.g. history of demyelinating disease, heart failure NYHA III/IV, recurrent skin/soft tissue infections
 - to IL-17 antagonists e.g. candida infections, inflammatory bowel disease
- Presence of psoriatic arthritis: use adalimumab as a first choice unless contra-indicated
- Co-morbidities and the potential impact of each biologic option (benefit or harm)
- The persons views and stated preference on administration route or frequency (discuss with reference to the decision aid)
- Other relevant factors for example, conception plans, adherence
- Refer to BAD decision aid for further information – see [appendix 3](#)

After consideration of all of the above factors choose the most clinically suitable, cost effective drug

FIRST CHOICE

Adalimumab

Consider certolizumab for women planning conception

SECOND CHOICE

IL12/23 p40 : Ustekinumab

IL17A or IL17RA: Ixekizumab/secukinumab /brodalumab

IL17A/IL17-F: Bimekizumab

IL23p19 : Guselkumab/ risankizumab/ tildrakizumab

Consider biosimilar etanercept when short half-life preferable

Assess response

10 weeks

Infliximab

12 weeks

Brodalumab

Etanercept

Ixekizumab

Secukinumab

16 weeks

Adalimumab

Bimekizumab

Certolizumab

Guselkumab

Risankizumab

Ustekinumab

28 weeks

Tildrakizumab

If appropriate response **ACHIEVED** e.g. PASI 75 or PASI 50 with 5 point reduction in DLQI score, continue treatment. Review 3 monthly for first year then 6 monthly if stable. Consider dose escalation if PASI 50 achieved but still significant disease burden and inadequate primary response may be due to insufficient drug dosing e.g. in people who are obese or whose psoriasis relapses during treating cycle.

Refer to section 14 for dose escalation information for each drug.

If appropriate response **NOT ACHIEVED** discontinue treatment and consider 2nd line therapy

South East London: South East London Clinical Commissioning Group (covering the boroughs of Bexley/Bromley/Greenwich/Lambeth/Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts and Lewisham & Greenwich NHS

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13. Initiation of Second line and Subsequent options

[Refer to the Regional Medicines Optimisation Committee \(RMOC\) advisory statement issued in January 2020 regarding the sequential use of biologic medicines.](#)

Where adalimumab has been initiated as the first line option, consider requesting adalimumab drug level and antibody titre where available to assess whether dose escalation should be considered in the first instance before switching therapy.

Reasons for discontinuation:

- Psoriasis not responded to first biologic drug as defined in NICE technology appraisals (10 weeks after starting infliximab, 12 weeks for brodalumab, etanercept, ixekizumab or secukinumab, 16 weeks for adalimumab, bimekizumab, certolizumab, guselkumab, risankizumab or ustekinumab, and 28 weeks for tildrakizumab); **primary failure**
- Psoriasis initially responded but subsequently lost the response; **secondary failure**
- First drug cannot be tolerated or becomes contraindicated

Offer any of the currently licensed and NICE approved biologic therapies when psoriasis has not responded to a first biologic therapy (e.g. adalimumab, bimekizumab, brodalumab, certolizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, ustekinumab).

Consider:

- disease severity
- dose escalations
- mode of action
- drug cost – see appendix 4
- the [BAD decision aid](#) and
- take into account all factor affecting choice in box ^a above (in section 12)

If TWO or MORE biologic therapies failed

- reiterate advice about modifiable factors contributing to poor response (e.g. obesity and poor adherence)
- optimise adjunctive therapy (e.g. switch from oral to subcutaneous methotrexate)
- switch to an alternative biologic agent
- consider non-biologic therapy approaches (e.g. apremilast, dimethyl fumarate, inpatient topical therapy, phototherapy or standard systemic therapy)

When choosing therapy

- A specialist multi-disciplinary review meeting including a consultant with extensive experience/ expertise of prescribing biologics should discuss individual next steps.
- Consider different mechanism of actions when considering treatment options (TNFi/p40i/IL-17i, p19i)

- Reserve infliximab for patients with very severe disease or where supervised administration or dosing / kg body weight is critical or where other available biologic agents have failed or cannot be used.

Where there has been rapid secondary failure, consider the co-prescribing of methotrexate. Methotrexate may also be recommend as co-medication in certain clinical circumstances e.g. where required for associated arthropathy.

14. Dose escalation

Dose escalation should be considered when an inadequate primary response may be due to insufficient dosing e.g. in patients who are obese or whose psoriasis relapses during the treatment cycle. Take into account that this may be associated with an increased risk of infection, and, depending on the drug (e.g. ustekinumab and infliximab), off license. Patients should be informed if treatment is off-license and counselled on the risks and benefits of this.

For the current pathway update, the requirement for submission of notification forms (B* forms) for biologic dose escalation in psoriasis has been removed. Monitoring of dose escalation will instead be through the KPIs, which have been updated to include:

- Monitoring and reporting of patient numbers for each dose escalation Monitoring and reporting to demonstrate that initiation criteria have been met and adequate response has been achieved by 24 weeks or earlier in accordance with product license.
- Monitoring and reporting to demonstrate that the patient has been counselled on the relevant risks versus benefit of using an off license escalated dose, and verbally consented. This should be documented in clinical notes/letter.

Biologic agent	Dose escalation	Licensed Use
Adalimumab 40mg every other week	Adalimumab 40mg weekly for 12 weeks and review	Yes
Certolizumab 200mg every 2 weeks	Certolizumab 400mg every 2 weeks for 12 weeks and review	Yes
Etanercept 50mg once weekly	Etanercept 50mg twice weekly for 12 weeks and review	Yes
Infliximab 5mg/kg every 8 weeks	Infliximab 5mg/kg every 6 weeks for 24 weeks and review	No
Ixekizumab 80 mg every 4 weeks	Ixekizumab 80 mg every 2 weeks	No
Tildrakizumab 100 mg every 12 weeks	Tildrakizumab 200 mg every 12 weeks (high disease burden or ≥ 90 kg) for 28 weeks and review	Yes
Ustekinumab 45mg every 12 weeks (<100kg)	Ustekinumab 90mg every 8 or 12 weeks (<100kg)	No
Ustekinumab 90mg every 12 weeks (>100kg)	Ustekinumab 90mg every 8 weeks (>100kg) for 24 weeks and review	No

15. Special Populations

15.1 High Impact Sites not meeting NICE criteria

Biologic therapy may be considered in people with psoriasis where the PASI <10 if **all** the following criteria are fully met:

- The psoriasis is severe at localised, high impact and difficult to treat sites such as the face, scalp¹, palms, soles², flexures and genitals
 - It cannot be controlled with topical therapy or optimised standard systemic therapy³
 - It has significant impact on physical, psychological or social wellbeing⁴
 - Associated with significant functional impairment and/or high levels of distress
1. Measures of severe scalp disease must be confirmed by documenting ≥30% of scalp surface area affected and a PGA of severe. A Psoriasis Scalp Severity Index (PSSI) score of ≥20 (0-72 scale) may also be used although it is recognised that this is not currently widely used in clinical practice.
 2. Measure of severe palm/sole disease or other high impact sites may utilise an adjusted PASI score to assist with assessing response from baseline. A NAPSI score may be used for severe nail disease or a ppPASI >20 for palmoplantar pustulosis.
 3. Optimised standard systemic therapy includes ciclosporin and subcutaneous methotrexate to recommended doses as tolerated for at least 3 months. Consider acitretin in the context of palmoplantar disease. Long term ciclosporin cannot usually be used to control disease beyond one year
 4. Significant impact as measured by a DLQI >10 and or/depression attributable to psoriasis

See Appendix 5 for more information on disease scores

Successful response assessed by a 50% improvement in an appropriate disease score outlined by clinician **and/or** 5 point reduction in DLQI score at 16 weeks. Description of functional improvement, improvement in social wellbeing and reduction in measures of distress such as anxiety and depression will also be considered.

Clinical audit or Blueteq forms will be used to monitor outcomes and usage.

15.1.2 Pustular Psoriasis

TNF antagonists or IL-23 agents (guselkumab)⁸ may be considered (unlicensed) for patients with severe, disabling acral forms of pustular psoriasis, for example palmoplantar pustulosis or acropustulosis (acrodermatitis continua) of Hallopeau, which has failed to respond to standard systemic agents. As with the chronic plaque psoriasis algorithm, adalimumab (best value biologic) should be considered first line.

TNF antagonists (infliximab or adalimumab) may be considered for patients with generalised pustular psoriasis. As above, adalimumab (best value biologic) should be considered first line.

Clinical audit or Blueteq forms will be used to monitor outcomes and usage.

15.2 Patients with concurrent skin & Joint disease

Refer to SEL Guideline "[Treatment of Seronegative spondyloarthropathy biologic drug treatment pathway](#)"⁹ and discuss with rheumatology to consider best agent to target both aspects of disease.

Facilitate a shared care approach with rheumatologists.

16 Monitoring adherence with the guideline

Adherence to this pathway will be reviewed using the SEL Dermatology Pathways, Outcomes and Monitoring Framework which includes Key Performance Indicators agreed by South East London Integrated Medicines Optimisation Committee. See <http://www.selondonics.org/selimoc> for further details. The Dermatology and Pharmacy Departments may undertake separate clinical audits as part of their annual clinical audit plan.

17 Supporting documents (see relevant local guidelines)

[British Association of Dermatologists guidelines](#) for biologic therapy for psoriasis 2017

[British Association of Dermatologists guideline](#) for biologic therapy for psoriasis 202: a rapid update

[British Association of Dermatologists patient information leaflet](#) – immunisation recommendations for children and adult patients treated with immune-suppressing medicines

[Liver Assessment and Management Pathway in Immune-Mediated Inflammatory Diseases](#) – Guy's and St Thomas' NHS Foundation Trust, August 2019

Supplementary Information: Recommendations on safe prescribing of biologics

(Taken from BAD Biologics guidelines for psoriasis 2019)

1. Transitioning to or between biologic therapies

When choosing the transitioning strategy from one drug therapy to another and whether a therapy washout (or no washout) should be used, take into consideration:

- the pharmacology of the drugs that are being started and stopped
- the person's clinical circumstances
- the person's views on the risks and benefits of transitioning option(s).

Consider the following strategies when transitioning from standard systemic to biologic therapy:

- in stable disease, aim to allow 1 month to elapse between the last dose of any current standard systemic immunosuppressant psoriasis therapy (except methotrexate) and the planned date of biologic initiation
- start a biologic therapy with no drug washout period in people taking methotrexate, or in people on other therapies where this would lead to unstable disease
- when standard, systemic immunosuppressant therapy cannot be stopped (e.g. in people for whom a disease flare would be severe or hazardous), rationalize use of therapy and stop as soon as possible (e.g. when a minimum response has been achieved).

When transitioning to a new biologic therapy (from a previous biologic therapy) consider using a 1-month washout period, or the length of the treatment cycle (whichever is longer), between the last dose of the current biologic therapy and the planned date of biologic initiation.

2. Conception and Pregnancy

Advise women of childbearing potential, who are starting biologic therapy for psoriasis, to use effective contraception and to discuss conception plans with the consultant supervising their care. There are no known interactions between biologic therapies and contraceptive methods (see drug-specific SPCs).

Provide information about what is known about the effects of biologic therapy, including:

- the importance of controlling severe or unstable psoriasis to maintain maternal health
- that most of the available evidence relates to TNF antagonists in women with rheumatological or inflammatory bowel disease
- that most pregnancies reported in women exposed to TNF antagonists at conception and/or during pregnancy have successful outcomes, with no increase in stillbirths, congenital malformations, preterm births or neonatal infections
- that exposure to TNF antagonists during pregnancy may increase the risk of maternal infection
- that maternal IgG, and therefore biologic drugs currently licensed for psoriasis (with the exception of certolizumab pegol), is actively transferred to the developing fetus during the second and third trimester and that the impact of this on neonatal development and risk of infection has not been adequately studied

- that certolizumab pegol transfer across the placenta is low or negligible
- that live vaccines must be avoided for the first 6 months of life of infants born to mothers taking biologic therapy beyond 16 weeks' gestation
- relevant patient information resources.

Discuss the risks and benefits of using biologic therapy in women who are planning conception or who are pregnant. Offer advice on a case-by-case basis by taking into account the woman's views and:

- the available evidence
- her current disease status
- the course of psoriasis disease and the fetal outcome during any prior pregnancies
- the risk of severe or unstable psoriasis without biologic therapy
- her physical, psychological and social functioning without biologic therapy
- the options for alternative treatment strategies in the event of disease flare

If the decision to use biologic therapy when planning conception or during pregnancy has been made:

- consider using certolizumab pegol as a first-line choice when starting biologic therapy in women planning conception
- consider stopping biologic therapy in the second/third trimester to minimize fetal exposure and limit potential risk to neonate, taking into account individual biologics' pharmacokinetics and transfer across the placenta
- consider using ciclosporin or certolizumab pegol as first-line options when it is necessary to start a systemic therapy during the second or third trimester
- Consider continuing or restarting biologic therapy in women wishing to breastfeed. Explain the benefits of breastfeeding and that the small amounts of biologic therapy present in breast milk are unlikely to be absorbed systemically by the infant.

Ensure consultation and information sharing across specialities, including with an obstetrician who has expertise in caring for pregnant women with medical problems. Collect pregnancy outcome data for safety registries, for example BADBIR in the U.K. and Republic of Ireland.

Be aware that limited evidence reports that use of TNF antagonist therapy by men around the time of conception resulted in successful outcomes in most pregnancies, with no increased risk of congenital malformations, preterm births or small for gestational age infants.

3. Biologic therapy and cancer risk

Assess people with psoriasis prior to, and during treatment with, biologic therapy with respect to:

- their past or current history of cancer and/or
- any future risk of cancer.

Provide information to people with psoriasis about the importance of participating in national cancer screening programmes.

Exercise caution and discuss with the relevant cancer specialist when prescribing biologics in people with psoriasis and:

- a history of cancer, particularly if this has been diagnosed and treated < 5 years previously and/or
- where the baseline risk of skin cancer is increased

Discuss the risks and benefits of continuing vs. stopping biologic therapy in patients who develop or have completed recent treatment for cancer. Offer advice on a case-by-case basis by taking into account the advice from the treating oncologist, MDT discussion and patient choice considering:

- the risk of severe or unstable psoriasis if the biologic therapy were stopped
- the physical, psychological and social functioning if the biologic therapy were stopped
- the options for alternative treatment strategies
- the impact of cancer progression/recurrence

4. Biologic therapy and infections

Assess people with psoriasis prior to, and during treatment with, biologic therapy with respect to

- risk factors for infection (e.g. comorbidities, co-therapy, lifestyle and travel)
- known infections (past or current)
- signs or symptoms suggestive of infection.

5. Biologic therapy and chronic viral infections – hepatitis B, hepatitis C and HIV

- Test for hepatitis B (surface antigen and core antibody), hepatitis C (IgG) and HIV (HIV-1 and HIV-2 antibodies and HIV-1 antigen) infection in people starting biologic therapy
- Consider ongoing screening (e.g. annually) for hepatitis B, hepatitis C and HIV, particularly in people who belong to a group at increased risk of infection
- Retest for viral hepatitis in any person who develops unexplained transaminitis (raised alanine aminotransferase and/or aspartate aminotransferase); retest for HIV infection in any person who has symptoms or other conditions that might represent HIV seroconversion/infection.
- Consult a hepatitis specialist when treating all people with biologic therapy who have hepatitis B or C infection, whether newly diagnosed or previously known.
- Provide treatment options to people with psoriasis who are HIV seropositive on a case-by-case basis; be aware that severe psoriasis can occur in people with uncontrolled HIV infection. Involve relevant specialists and ensure HIV viral load is suppressed on ART before considering biologic therapy.

- Test for varicella zoster (VZ) virus antibody in people with a negative or uncertain history for chickenpox; consider varicella vaccination in those who are not varicella immune and seek expert advice. Be aware of the indications for post-exposure prophylaxis in VZ-susceptible individuals with VZ immunoglobulin or oral acyclovir/valaciclovir.

6. Use of biologic therapy and tuberculosis

- Screen for latent tuberculosis (TB) with an interferon- γ release assay; be aware of the individual's risk factors for TB when interpreting results.
- Consider a plain chest radiograph, with reference to local policy for screening for TB, to rule out abnormalities at baseline including granulomas indicative of prior infection and other confounding lung diseases. If positive, assess for active TB and/or management of latent TB in consultation with a TB specialist (see NICE tuberculosis guideline) ¹².
- In people who require treatment for latent TB [3 months of isoniazid (with pyridoxine) and rifampicin, or 6 months of isoniazid (with pyridoxine)] aim to complete 2 months of treatment before commencing biologic therapy.
- Any symptoms or signs suggestive of TB, or new exposure to TB or prolonged residence in a high-incidence setting should prompt further clinical assessment and investigation, including a repeat interferon-gamma release assay. Be aware that active TB on TNF antagonist therapy is often disseminated and extra-pulmonary; symptoms may include unexplained weight loss, night sweats, non-resolving cough, haemoptysis and lymphadenopathy.
- Inform people that they should seek medical advice if symptoms of tuberculosis develop during or after treatment with a biologic therapy and issue a patient alert card in line with MHRA guidance

7. Important contraindications to biologic therapies

- Do not use TNF antagonists in people with demyelinating diseases and review alternative interventions in people who have an affected first-degree relative with demyelinating disease.
- Stop treatment and seek specialist advice if neurological symptoms suggestive of demyelinating disease develop during TNF antagonist therapy. Symptoms include loss or reduction of vision in one eye with painful eye movements; double vision; ascending sensory disturbance and/or weakness; problems with balance, unsteadiness or clumsiness; altered sensation travelling down the back and sometimes into the limbs when bending the neck forwards (Lhermitte symptom); please see [NICE guidelines CG186](#).
- Avoid TNF antagonist therapy in people with severe cardiac failure (NYHA class III and IV).
- Assess people with well-compensated (NYHA class I and II) cardiac failure see the NICE pathway) and consult with a cardiology specialist before using TNF antagonist therapy.
- Stop TNF antagonist therapy in the event of new or worsening pre-existing heart failure and seek specialist advice.
- Exercise caution and consult a gastroenterology specialist before using brodalumab, ixekizumab or secukinumab in people with inflammatory bowel disease.
- In people undergoing elective surgery balance the risk of postoperative infection against the risk of developing severe or unstable disease by stopping biologic therapy Advise stopping biologic

therapy 3–5 times the half-life of the drug in question or the length of the treatment cycle (whichever is longer) between the last dose of therapy and the planned surgery. Inform the surgical team that the patient may be at a higher risk of infection postoperatively. Restart biologic therapy postoperatively if there is no evidence of infection and wound healing is satisfactory.

Practical Points for Primary Care

1. Identification of patient on biologic treatment

Following communication from the specialist dermatology team it is the GP's responsibility to update a person's medical record to state that they are receiving treatment with a biologic therapy.

2. Vaccinations

Do not give live vaccines to people on biologic therapy or to infants (up to 6 months of age) whose mothers have received biologic therapy beyond 16 weeks' gestation.

Inactivated vaccines are safe to administer concurrently with biologic therapy.

Patients should receive annual influenza vaccine (intramuscular only) and pandemic influenza vaccine when recommended and pneumococcal vaccination prior to biologic therapy.

3. Increased risk of infection (TB, skin and soft tissue)

GPs must be aware that patients on biologic therapy are at an increased risk of infection, including TB, skin and soft tissue. They should therefore have a high index of suspicion if a patient on biologic therapy presents with signs or symptoms of the above infections. Any symptoms or signs suggestive of TB, or new exposure or prolonged residence in a high-incidence setting should prompt further clinical assessment and investigation. Active TB on TNF-antagonist therapy is often disseminated and extrapulmonary; symptoms may include unexplained weight loss, night sweats, non-resolving cough, haemoptysis and lymphadenopathy.

4. Pregnancy

If a patient who is receiving biologic therapy or who has recently stopped therapy (within 16 weeks of gestation) reports a pregnancy to the GP, the GP must inform the dermatologist as soon as possible to arrange urgent follow-up and monitoring.

5. Surgery (elective)

If a patient is due to have elective surgery, advise them to contact their dermatologist/clinical nurse specialist for advice on when/if to stop therapy prior to surgery.

Biologic therapy can be restarted postoperatively if there is no evidence of infection and wound healing is satisfactory.

Appendix 1

Service Quality Standards

Service Quality Standard	Statement	Supporting Evidence
1	Initiation and supervision of biologic therapy for people with psoriasis should be undertaken by specialist Physicians experienced in the diagnosis and treatment of psoriasis.	R1 2019 BAD biologics guidelines Quality Statement 3 NICE quality standards for psoriasis
2	Arrangements for drug administration, monitoring and follow-up should be agreed between health carers and the person receiving treatment, utilising the support and expertise of a multidisciplinary team e.g. clinical nurse specialists and specialist pharmacists following locally agreed protocols.	R1 2019 BAD biologics guidelines R2 2019 BAD biologics guidelines R8 2019 BAD biologics guidelines Quality Statement 6 NICE quality standards for psoriasis
3	Provision of biologic therapy via Homecare services is overseen by an appropriate group within each trust, accountable to the Chief Pharmacist. All medicines ordered via homecare services are clinically screened and processed via pharmacy.	DH Report- Homecare Medicines "Towards a vision for the future" November 2011.

Appendix 2 BAD Suggested schedule for screening and monitoring

Table S3: SUGGESTED SCHEDULE FOR SCREENING AND MONITORING

		Baseline ^I	Monitoring ^I
History/symptom enquiry			
Psoriasis	Disease phenotype including involvement of nails and high-impact sites; course (stable/unstable); response & adverse effects to prior therapies	Yes	Ongoing
Psoriatic arthritis	Screen for psoriatic arthritis (e.g. using the PEST questionnaire ^{II}); for people with psoriatic arthritis symptom enquiry to assess control	Yes	Every 12 months
Identification of contraindications to therapy and/or development of therapy-induced toxicity	Thorough history, symptom enquiry, conception plans and family history (and lifestyle regarding infection risks?)	Yes	At least every 6 months
Infection	Any past or current chronic infection including tuberculosis, candidiasis	Yes	At least every 6 months
	Identify risk factors for tuberculosis, hepatitis B, C and HIV ^{III}		
	Ascertain history for chickenpox		N/A
Alert card ^{IV}	Ensure people carry an alert card with them at all times in line with MHRA guidance	Yes	At each review appointment
Cardiovascular assessment ^V	Include symptom enquiry about heart failure [NYHA III. Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation or dyspnea. NYHA IV. Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.]	Yes	Clinical assessment at least every 6 months
Neurological assessment ^V	Past or current history or symptoms of demyelinating disease ^V	Yes	At least every 6 months
Gastrointestinal assessment ^{VI}	Past or current history or symptoms of inflammatory bowel disease	Yes	At least every 6 months
Malignancy	Any past or current malignancy (including skin cancer)	Yes	At least every 6 months
	Ensure concordant with national cancer screening programmes		
	Gynaecological review of patients with history of cervical dysplasia		

BADBIR	Offer the opportunity to participate	Yes	Every 6 months (to complete follow-up data)
Clinical assessments			
Psoriasis disease severity assessment	Goal of therapy, e.g. a PGA of clear or nearly clear	Yes	To establish disease response; every 6 months thereafter
	PASI (or BSA if PASI not applicable)		
	DLQI		
Skin cancer	Full skin examination	Yes	As indicated by risk at baseline and in the context of immunosuppression
Psoriatic arthritis	Consult with a rheumatologist	Yes	To establish disease response; at least every 6 months thereafter and/or as clinically indicated
General physical examination	To identify contra-indications to therapy and/or development of therapy-induced toxicity	Yes	As indicated by history/symptom enquiry
Investigations			
Blood tests	Full blood count; creatinine and electrolytes; liver function tests	Yes	At 3-4 months; at least every 6 months thereafter and/or as clinically indicated
	Hepatitis B (surface antigen and core antibody) hepatitis C (IgG)		If clinically indicated, e.g. transaminitis (raised ALT and/or AST), or ongoing (annually) in people who belong to a group at increased risk of infection ^{III}
	Human immunodeficiency virus (HIV-1 and HIV-2 antibody, and HIV-1 antigen)		If clinically indicated, e.g. symptoms of seroconversion, or ongoing (annually) in people who belong to a group at increased risk of infection ^{III}
	Autoantibodies (anti-nuclear antibodies, anti-nuclear double-stranded DNA antibodies)		If symptoms or signs suggest development of autoimmune phenomena, e.g. transaminitis (raised ALT and/or AST)
	Test for varicella zoster virus antibody in people with a negative or uncertain history for chickenpox		Consider varicella vaccination in those who are not varicella-immune and seek expert advice; be aware of the indications for using VZ immunoglobulin in VZ-susceptible individuals ^{VII}
Tuberculosis	Interferon-gamma release assay and chest X-ray	Yes	If clinically indicated, e.g. symptoms or signs of tuberculosis, new exposure to tuberculosis or residence in high-incidence setting

Urine	Urine analysis	Yes	If clinically indicated
	Urine pregnancy test		

^I Additional assessment and monitoring may be required in patients on concomitant therapy or in certain clinical circumstances; when switching therapy use the recommended monitoring advice

^{II} www.bad.org.uk/healthcare-professionals/forms-downloads

^{III} See S4: Groups at increased risk of tuberculosis, hepatitis B, hepatitis C and HIV

^{IV} <https://www.gov.uk/drug-safety-update/tumour-necrosis-factor-alpha-inhibitors>

^V Evidence of demyelination/heart failure may preclude use of TNF antagonists

^{VI} Exercise caution using brodalumab, ixekizumab or secukinumab in people with inflammatory bowel disease

^{VII} [Chapter 34 \(publishing.service.gov.uk\)](http://publishing.service.gov.uk)

Consultation Process for the latest review:

South East London Dermatology Pathway Group (See Authors) - September 2021

South East London Medicines and Pathways Review Group:







South East London Integrated Medicines Optimisation Committee

Appendix 3

BAD Decision Aid

TABLE S2: DECISION AID – BIOLOGIC THERAPY FOR PSORIASIS

This is a decision aid to help clinicians and patients decide their treatment choice and not a comprehensive data source or replacement for the individual drug Summary of Product Characteristics. Please use in conjunction with the published guidelines, pathway algorithm and discussions in the online supporting information document.

Questions you might want to ask	How do I take it?		How effective is it?		How common are the side effects?		Is there anything else to consider?	
	How often do I need to inject the treatment? ¹	For how long has this treatment been around? ²	Roughly what proportion of people becomes clear or nearly clear (PASI90) after 3-4 months? ³	What is the likelihood of staying on this treatment past 1 year? ⁴	Roughly what proportion of people stops their treatment in the first 3-4 months due to unwanted effects? ¹⁰	Roughly what proportion of people gets a serious infection in the first 3-4 months? ⁵	What are <i>some</i> of the conditions that would make your doctor hesitant about giving you the treatment? ⁶	What if I have psoriatic arthritis?
TNF								
Adalimumab	1 injection under the skin, every other week	Since 2008	 41%	77-81% chance ¹	 2%	 < 1%	Moderate or severe heart failure, multiple sclerosis (or other conditions affecting the nerves)	Recommended treatment for psoriatic arthritis
Certolizumab pegol	1 or 2 injections under the skin, every 2 weeks	Since 2019	 41-48%	Not known at present	 2%	 < 1%	Moderate or severe heart failure, multiple sclerosis (or other conditions affecting the nerves)	Recommended treatment for psoriatic arthritis

¹ Only licensed maintenance doses are featured; see File S1: Table S1 for information on initiation dosing schedules

² First approval of the drug for moderate to severe plaque psoriasis

³ The evidence is drawn from clinical trials including a mixed biologic-naïve and experienced population; figures quoted are based on results from network meta-analyses of licensed biologic doses

⁴ The evidence is drawn from a real-world UK biologic-naïve population; it may not apply to biologic choice for subsequent lines of treatment

⁵ The evidence is drawn from clinical trials including a mixed biologic-naïve and experienced population; figures quoted are based on Peto odds ratio analyses of all biologic doses

⁶ Please refer to individual drugs' summary of product characteristics for a more comprehensive list (www.medicines.org.uk)

TABLE S2: DECISION AID – BIOLOGIC THERAPY FOR PSORIASIS

This is a decision aid to help clinicians and patients decide their treatment choice and not a comprehensive data source or replacement for the individual drug Summary of Product Characteristics. Please use in conjunction with the published guidelines, pathway algorithm and discussions in the online supporting information document.

Questions you might want to ask	How do I take it?		How effective is it?		How common are the side effects?		Is there anything else to consider?	
	How often do I need to inject the treatment? ¹	For how long has this treatment been around? ²	Roughly what proportion of people becomes clear or nearly clear (PASI90) after 3-4 months? ³	What is the likelihood of staying on this treatment past 1 year? ⁴	Roughly what proportion of people stops their treatment in the first 3-4 months due to unwanted effects? ¹⁰	Roughly what proportion of people gets a serious infection in the first 3-4 months? ⁵	What are <i>some</i> of the conditions that would make your doctor hesitant about giving you the treatment? ⁶	What if I have psoriatic arthritis?
Etanercept	1 injection under the skin, once or twice a week	Since 2004	23%	67-73% chance ¹	2%	< 1%	Moderate or severe heart failure, multiple sclerosis (or other conditions affecting the nerves)	Recommended treatment for psoriatic arthritis
Infliximab	1 injection in the vein, ⁷ every 8 weeks	Since 2006	53%	54-74% chance ¹	5%	Not known at present	Moderate or severe heart failure, multiple sclerosis (or other conditions affecting the nerves)	Recommended treatment for psoriatic arthritis
IL12/23								
Ustekinumab	1 injection under the skin, every 12 weeks	Since 2009	46%	86-92% chance ¹	1%	< 1%	No particular condition	Recommended treatment for psoriatic arthritis only when TNF inhibitors have failed
IL17								
Brodalumab	1 injection under the skin, every 2 weeks	Since 2018	73%	Not known at present	2%	< 1%	Inflammatory bowel disease (e.g. Crohn's disease or ulcerative	This treatment is not licensed ⁸ for psoriatic arthritis

⁷ Requires attendance to hospital

⁸ A treatment that is not licensed for a particular condition means it has not been awarded a Market Authorisation from the U.K. Medicines Healthcare Products Regulatory Agency (MHRA) for that condition. Once awarded, the licensed treatment can be marketed and sold in the U.K.

TABLE S2: DECISION AID – BIOLOGIC THERAPY FOR PSORIASIS

This is a decision aid to help clinicians and patients decide their treatment choice and not a comprehensive data source or replacement for the individual drug Summary of Product Characteristics. Please use in conjunction with the published guidelines, pathway algorithm and discussions in the online supporting information document.



















Questions you might want to ask	How do I take it?		How effective is it?		How common are the side effects?		Is there anything else to consider?	
	How often do I need to inject the treatment? ¹	For how long has this treatment been around? ²	Roughly what proportion of people becomes clear or nearly clear (PASI90) after 3-4 months? ³	What is the likelihood of staying on this treatment past 1 year? ⁴	Roughly what proportion of people stops their treatment in the first 3-4 months due to unwanted effects? ¹⁰	Roughly what proportion of people gets a serious infection in the first 3-4 months? ⁵	What are <i>some</i> of the conditions that would make your doctor hesitant about giving you the treatment? ⁶	What if I have psoriatic arthritis?
							colitis), recurrent candida infection (i.e. thrush)	
Ixekizumab	1 injection under the skin, every 4 weeks	Since 2016	 72%	Not known at present	 3%	 < 1%	Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis), recurrent candida infection (i.e. thrush)	Recommended treatment for psoriatic arthritis
Secukinumab	2 injections under the skin, every month	Since 2015	 60%	Not known at present	 2%	 < 1%	Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis), recurrent candida infection (i.e. thrush)	Recommended treatment for psoriatic arthritis
IL23								
Guselkumab	1 injection under the skin, every 8 weeks	Since 2018	 68%	Not known at present	 2%	 < 1%	No particular condition	This treatment is not licensed§§ for psoriatic arthritis
Risankizumab	2 injections under the skin, every 12 weeks	Since 2019	 74%	Not known at present	 1%	 < 1%	No particular condition	This treatment is not licensed§§ for psoriatic arthritis

TABLE S2: DECISION AID – BIOLOGIC THERAPY FOR PSORIASIS

This is a decision aid to help clinicians and patients decide their treatment choice and not a comprehensive data source or replacement for the individual drug Summary of Product Characteristics. Please use in conjunction with the published guidelines, pathway algorithm and discussions in the online supporting information document.

Questions you might want to ask	How do I take it?		How effective is it?		How common are the side effects?		Is there anything else to consider?	
	How often do I need to inject the treatment? ¹	For how long has this treatment been around? ²	Roughly what proportion of people becomes clear or nearly clear (PASI90) after 3-4 months? ³	What is the likelihood of staying on this treatment past 1 year? ⁴	Roughly what proportion of people stops their treatment in the first 3-4 months due to unwanted effects? ¹⁰	Roughly what proportion of people gets a serious infection in the first 3-4 months? ⁵	What are <i>some</i> of the conditions that would make your doctor hesitant about giving you the treatment? ⁶	What if I have psoriatic arthritis?
Tildrakizumab	1 or 2 injections under the skin, every 12 weeks	Since 2019	 39%	Not known at present	 2%	 < 1%	No particular condition	This treatment is not licensed for psoriatic arthritis
Placebo								
No active treatment	Does not apply	Does not apply	 2%	Does not apply	 2%	 < 1%	Does not apply	Does not apply

Appendix 4

Drug costs

Drug costs, including administration costs, dosage, price per dose and commercial arrangements, should be one of the factors considered when initiating, switching or escalating biologic therapy. Adalimumab is currently the best value biologic (BVB) available for the treatment of psoriasis in the South East London region. The table below provides approximate costs for each biologic drug per year of maintenance treatment, including dose escalations, compared to adalimumab. The cost of the first year of treatment will vary depending on loading dose schedules and commercial arrangements for short-term free of charge supplies. Biosimilar brands are included where available and the best value product for each drug.

Prices for all subcutaneous drugs include homecare services and exclude VAT. See section 10 (method of medication supply) for further information regarding alternative supply arrangements and associated costs. Infliximab prices include VAT for intravenous administration in a hospital setting, but do not include the infusion suite tariff which will be charged to commissioners separately according to local arrangements.

Prices are correct as of September 2021 and may be subject to change.

Drug	Maintenance Dose	Mode of action	Route of administration	Cost Tier
Adalimumab (Biosimilar)**	40mg 2 weekly	Anti-TNF	Subcutaneous	£
Infliximab (Biosimilar)*	5mg/kg 8 weekly	Anti-TNF	Intravenous	£ plus IFT
Infliximab (biosimilar)* Dose Escalation	5mg/kg 6 weekly	Anti-TNF	Intravenous	£ plus IFT
Etanercept (Biosimilar)	50mg weekly/25mg twice weekly	Anti-TNF	Subcutaneous	£
Tildrakizumab (Illumetri)	100mg every 12 weeks (200mg dose escalation at no extra cost)	IL23 Inhibitor	Subcutaneous	££
Etanercept (Biosimilar) Dose Escalation	50mg twice weekly	Anti-TNF	Subcutaneous	££
Risankizumab (Skyrizi)	150mg every 12 weeks	IL23	Subcutaneous	££
Bimekizumab (Bimzelx)	320mg every 8 weeks	IL17-A/IL17-F	Subcutaneous	££
Ixekizumab (Taltz)	80mg every month	IL17	Subcutaneous	££
Guselkumab (Tremfya)	100mg every 8 weeks	IL23 Inhibitor	Subcutaneous	££
Brodalumab (Kyntheum)	210mg every 2 weeks	IL17 Inhibitor	Subcutaneous	££
Secukinumab (Cosentyx)	300mg every month	IL17 Inhibitor	Subcutaneous	££
Certolizumab pegol (Cimzia)	200mg every 2 weeks (400mg escalation at no extra cost)	Anti-TNF	Subcutaneous	££
Ustekinumab (Stelara)	45mg or 90mg every 12 weeks	IL12/23	Subcutaneous	££
Ustekinumab (Stelara) Dose escalation	45mg or 90mg every 8 weeks	IL12/23	Subcutaneous	£££

South East London Integrated Medicines Optimisation Committee (SEL IMOC). A partnership between NHS organisations in South East London: South East London Clinical Commissioning Group (covering the boroughs of Bexley/Bromley/Greenwich/ Lambeth/Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts and Lewisham & Greenwich NHS. Originally

developed: June 2018. Date last reviewed and approved: January 2022 Next review date: January 2023

Not to be used for commercial or marketing purposes. Strictly for use within the NHS. Page 29 of 36

* based on 80kg patient

** due to the COVID-19 pandemic, switching to the best value product will be undertaken in due course

Notes:

1. Choice of best value biologic will be dependent upon a number of factors (for example disease severity, contraindications to therapy, co-morbidities and other patient factors). Where more than one agent is suitable for the patient, the agent with the lowest acquisition cost (taking into account method of administration) should be chosen.
2. IFT = infusion suite tariff, the additional cost per dose of infliximab should be taken into consideration when comparing drug costs.
3. Cost tier rating is a banded price range of £ (low) to £££ (high) and drugs are listed on order of cost, low to high.
4. Price banding is based on maintenance drug cost per patient per year.

Appendix 5

High impact sites disease severity measurement tools:

PSSI or Adjusted PASI Score for High Impact Sites

The psoriasis scalp severity index (PSSI) is a modified version of the PASI scale. The scale for PSSI ranges from 0 (absent) to 4 (very severe) for each of the three categories of erythema, desquamation and thickness, which are rated separately. The individual scores are then added and **multiplied by a number based on the area of the scalp or body that is covered by psoriasis**. The final PSSI score can range from 0 to 72. **Note this can also be used for high impact sites.**

The Psoriasis Scalp Severity Index (PSSI) Score/ Adjusted PASI Score for High Impact Site

Affix Hospital Label

Date: _____

Score	0	1	2	3	4	5	6
Erythema	none	slight	moderate	severe	very severe		
Induration							
Scaling							
Area %	0	1-9	10-29	30-49	50-69	70-89	90-100

	Scalp/ Other:.....
Erythema (E)	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Induration (I)	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Scaling (S)	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Sum = E+I+S	<div style="display: inline-block; border: 1px solid black; width: 20px; height: 20px;"></div> <div style="display: inline-block; border: 1px solid black; width: 20px; height: 20px;"></div>
Area	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Sum x Area =	<div style="display: inline-block; border: 1px solid black; width: 20px; height: 20px;"></div> <div style="display: inline-block; border: 1px solid black; width: 20px; height: 20px;"></div>
Total =	<div style="display: inline-block; border: 1px solid black; width: 20px; height: 20px;"></div> <div style="display: inline-block; border: 1px solid black; width: 20px; height: 20px;"></div> <div style="display: inline-block; border: 1px solid black; width: 20px; height: 20px;"></div>

Global Evaluation Score (circle)

Very Severe

Severe

Moderate

Mild

Almost Clear

Clear

Palmo-Plantar Pustulosis Area and Severity Index (PPPASI) Score

Affix Hospital Label

Date: _____

Score	0	1	2	3	4	5	6
Erythema	none	slight	moderate	severe	very severe		
Pustules							
Desquamation							
Area %	0	1-9	10-29	30-49	50-69	70-89	90-100

	Left Palm	Right Palm	Left Sole	Right Sole
Erythema (E)	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Pustules (P)	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Desquamation(D)	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Sum = E+I+S	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Area	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
Sum x Area =	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
	X 0.2	X 0.2	X 0.3	X 0.3
Total =	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>

ppPASI Score Total =

Total Left Palm
 +
 Total Right Palm
 +
 Total Left Sole
 +
 Total Right Sole =

Global Evaluation Score (circle)

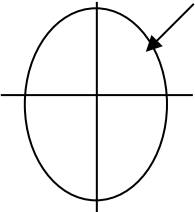
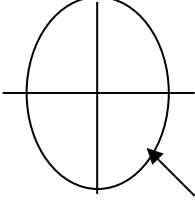
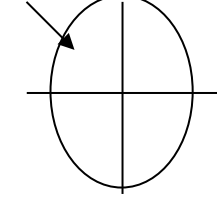
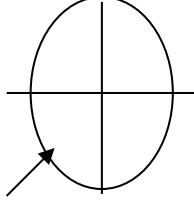
Very Severe *Severe* *Moderate* *Mild* *Almost Clear* *Clear*

NAPSI

Nail Psoriasis Severity Index (NAPSI) Score sheet for target nail assessment Developed as per Rich and Scher tool¹ 2003

How to perform the target nail NAPSI:

1. Select a target nail that represents the worst affected nail (always use this nail for subsequent NAPSI scores).
2. The target nail is divided into 4 quadrants and each quadrant is evaluated for the presence of the nail disease criteria which are: pitting, leukonychia, red spots, nail plate crumbling, onycholysis, splinter haemorrhage, oil drop, nail bed hyperkeratosis. For each criterion present a score of 1 is applied. Each quadrant can therefore have a maximum score of 8.
3. The total scores for each quadrant are added together to provide the target nail NAPSI score (max 32).

Nail quadrant				
Nail Matrix:	Tick box if criteria is present for each quadrant assessed			
Pitting				
Leukonychia				
Red Spots in the lunula				
Nail plate crumbling				
Nail Bed	Tick box if criteria is present for each quadrant assessed			
Onycholysis				
Splinter haemorrhage				
Oil drop (salmon patch)				
Nail bed hyperkeratosis				
Total score / nail quadrant* (0 - 8)				
Sum of total nail quadrant scores (0 – 32) =				

* Each tick equates to a score of 1.

DLQI

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Once completed, please hand this form to the nurse or doctor that you see.

Dermatology Life Quality Index (DLQI)

Hospital No:

Date:

DLQI Score:

Name:

The aim of the questionnaire is to measure how much your skin problem has affected your life
OVER THE LAST WEEK. Please tick ☐ one box for each question.

1. Over the last week, how **itchy, sore, painful** or **stinging** has your skin been?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
2. Over the last week, how **embarrassed** or **self-conscious** have you been because of your skin?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
3. Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
Not relevant	<input type="checkbox"/>
4. Over the last week, how much has your skin influenced the **clothes** you wear?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
Not relevant	<input type="checkbox"/>
5. Over the last week, how much has your skin affected any **social** or **leisure** activities?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
Not relevant	<input type="checkbox"/>
6. Over the last week, how much has your skin made it difficult for you to do any sport?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
Not relevant	<input type="checkbox"/>
7. Over the last week, has your skin prevented You from **working** or **studying**?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Not relevant	<input type="checkbox"/>
- If 'No', over the last week how much has your skin been a problem at **work** or **studying**?

A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
8. Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
Not relevant	<input type="checkbox"/>
9. Over the last week, how much has your skin caused any **sexual difficulties**?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
Not relevant	<input type="checkbox"/>
10. Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?

Very much	<input type="checkbox"/>
A lot	<input type="checkbox"/>
A little	<input type="checkbox"/>
Not at all	<input type="checkbox"/>
Not relevant	<input type="checkbox"/>

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