# Clinical Protocol

# Psoriasis
# Biologic Drug Treatment Pathway

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

South East London Area Prescribing Committee.
A partnership between NHS organisations in South East London: Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark Clinical Commissioning Groups (CCGs) and GSTFT/KCH /SLAM/ & Oxleas NHS Foundation Trusts/Lewisham & Greenwich NHS Trust

| Document Detail | |
|---|---|
| Document Type | Clinical Guideline |
| Document name | Psoriasis Biologic Drug Treatment Pathway |
| Document location | Intranet of Individual Trusts |
| Version | Draft Version 1.0 |
| Effective from | |
| Review due date | 6 monthly |
| Owner | South East London Psoriasis Steering Group |
| Author | South East London Psoriasis Steering Group:<br>**Guy's & St Thomas' NHS Foundation Trust**<br>Specialist Clinical Pharmacist Dermatology & Allergy<br>Specialist Clinical Pharmacist Dermatology & Allergy<br>Professor of Dermatology and Therapeutics, Consultant Dermatologist<br>Consultant Dermatologist<br>Consultant Nurse Dermatology<br>**King's College London NHS Foundation Trust**<br>Consultant Dermatologist<br>Specialist Pharmacist – Rheumatology & Dermatology<br>Clinical Pharmacy Team Leader – Post-acute and Planned Medicine<br>**Lewisham and Greenwich NHS Trust**<br>Specialist Pharmacist<br>Consultant Dermatologist<br>**Clinical Commissioning Groups**<br>Interface Prescribing Advisor, NHS SEL/ Bromley Clinical Commissioning Group |
| Approved by, date | |
| Superseded documents | Nil |
| Related Documents | Seronegative Spondyloarthropathy Biologic Drug Treatment Pathway<br>Pathway for investigation of hepatic fibrosis in patients with psoriasis |
| Keywords | Dermatology, Psoriasis, biologic, biologics, adalimumab, etanercept, infliximab, ustekinumab, secukinumab, ixekizumab, brodalumab, guselkumab, apremilast, fumaric, acid esters |

| Change History | | |
|---|---|---|
| Date | Change details, since approval | Approved by |
| 24.09.18 | Page 8: statement about contraindications amended to reflect these are relative and absolute<br>Page 15: Clarification added re: IL-17 inhibitors under caution in patients with IBD | |
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| Review History | | |
|---|---|---|
| Date | Review details | Approved by |
| | | |

## Contents

## 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 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 severity

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
Etanercept
Infliximab
Secukinumab
Ustekinumab

### 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 dimethylfumarate 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 Guidance[6].

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.

**Stop biologic therapy for at least 6 months before giving live vaccines, and for 12 months in the case of shingles (herpes zoster) vaccine**. 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 be administered 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 is proposed it must satisfy the following criteria:

- Fund the treatment at zero cost to the NHS up to and for 90 days after the final 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

## 10. Method of medication supply

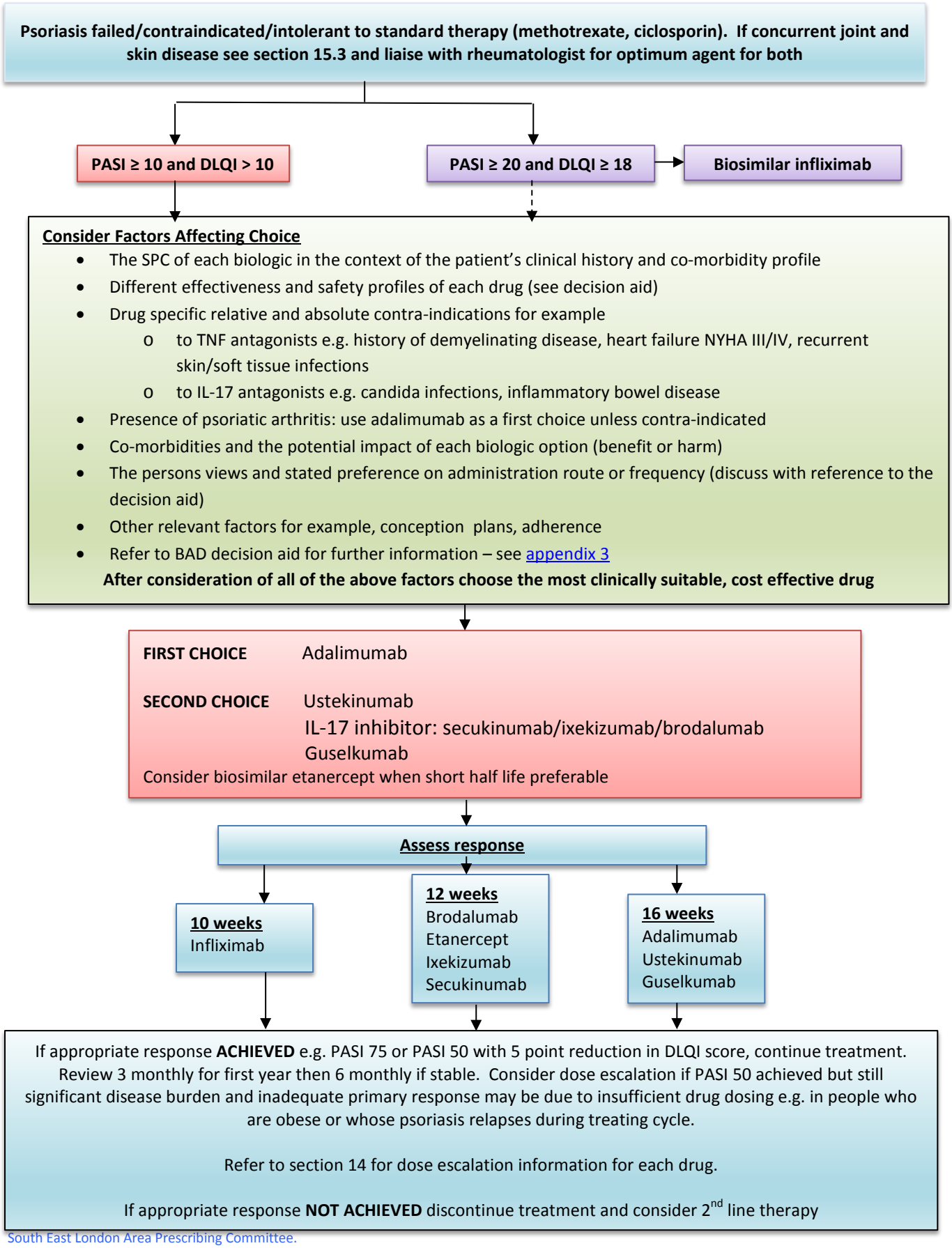
Subject to local arrangements patients may be offered a choice of method of supply. This may include a traditional homecare service or enhanced outpatient pharmacy service via outsourced outpatient pharmacies on main hospital sites. Where there is agreement with pharmaceutical companies, unbundling of 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, 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



## 13. Initiation of Second/Third line options

**Reasons for discontinuation:**

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

- Disease severity
- dose escalations
- mode of action
- the BAD decision aid and
- taken into account all factor affecting choice in box [a] above (in section 12)

If TWO 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

- 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.

| **Biologic agent** | **Dose escalation** | **Licensed Use** | **Category B* Form Required?** |
|---|---|---|---|
| Ustekinumab 45mg every 12 weeks (<100kg) | Ustekinumab 90mg every 12 weeks (<100kg) | No | **No** |
| Ustekinumab 90mg every 12 weeks (>100kg) | Ustekinumab 90mg every 8 weeks (>100kg) for 24 weeks and review | No | Yes |
| Adalimumab 40mg every other week | Adalimumab 40mg weekly for 12 weeks and review | Yes | Yes |
| Etanercept 50mg once weekly | Etanercept 50mg twice weekly for 12 weeks and review | Yes | **No** |
| Infliximab 5mg/kg every 8 weeks | Infliximab 5mg/kg every 6 weeks for 24 weeks and review | No | Yes |

## 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, scalp[1], palms, soles[2], flexures and genitals
- Associated with significant functional impairment and/or high levels of distress
- It cannot be controlled with topical therapy or optimised standard systemic therapy[3]
- It has significant impact on physical, psychological or social wellbeing[4]

1. Measures or severe scalp disease comprise Psoriasis Scalp Severity Index (PSSI) score of ≥20 (0-72 scale), with ≥30% of scalp surface area affected and an IGA of =/>3 (0-4 scale)
2. Measure of severe palm/sole disease ppPASI >20
3. Optimised standard systemic therapy includes acitretin, ciclosporin and methotrexate subcutaneous to recommended doses as tolerated for at least 3 months. 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

**Category B* forms are required when initiating biologics in patients with high impact site psoriasis.**

### 15.1.2 Pustular Psoriasis

TNF antagonists may be considered for patients with severe, disabling acral forms of pustular psoriasis, for example, acropustulosis (acrodermatitis continua) of Hallopeau, which has failed to respond to standard systemic agents.

TNF antagonists (infliximab or adalimumab) may be considered for patients with generalised pustular psoriasis.

**Category B* forms are required when initiating biologics in patients with pustular psoriasis**

### 15.2 Patients with concurrent skin & Joint disease

Refer to SEL Guideline "Treatment of Seronegative spondyloarthropathy biologic drug treatment pathway" 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 Area Prescribing Committee. See http://www.lambethccg.nhs.uk 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 patient information leaflet – immunisation recommendations for children and adult patients treated with immune-suppressing medicines

Pathway for investigation of hepatic fibrosis in patients with psoriasis – Guy's and St Thomas' NHS Foundation Trust, February 2017

**Supplementary Information: Recommendations on safe prescribing of biologics**

(Taken from BAD Biologics guidelines for psoriasis 2017)

## 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

Provide information about the possible effects of biologic therapy during conception and pregnancy including:

- the importance of controlling severe or unstable psoriasis to maintain maternal health
- that most pregnancies reported in women taking biologic therapy at conception and during pregnancy have successful outcomes
- that evidence about the effect of biologic therapy on conception and pregnancy mostly relates to tumour necrosis factor (TNF) antagonists in women with rheumatological and inflammatory bowel disease; this evidence indicates a potential risk associated with exposure to TNF antagonists but is of low quality, and may relate to other factors (e.g. other co-therapies or the underlying disease). (Major congenital malformations reported in 3.6–5.0% of women exposed to anti-TNF compared with 1.5–4.7% in control groups, odds ratios 1.32–1.64.)
- that the risk of fetal abnormalities in women with psoriasis who conceive on biologic therapy has not been adequately studied and therefore cannot be quantified
- that maternal IgG, and therefore biologic drugs currently licensed for psoriasis, is actively transferred to the developing fetus during the second and third trimester and that the

impact of this on fetal and neonatal development and risk of infection have not been adequately studied

- that live vaccines must be avoided in infants born to mothers taking biologic therapy beyond 16 weeks' gestation
- relevant patient information resources.

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

Discuss the risks and benefits of continuing vs. stopping biologic therapy with women who are of childbearing potential or who become pregnant. Offer advice on a case-by-case basis by taking into account the woman's views and:

- the course of psoriasis disease and the fetal outcome during any prior pregnancies
- 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, non-biologic treatment strategies.

Assess whether biologic therapy for psoriasis can be stopped in women who become pregnant. 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.

Advise mothers who have received biologic therapy for psoriasis beyond 16 weeks' gestation that their infants should not receive any live vaccinations until they have reached 6 months of age (for example, rotavirus and BCG).

## 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 (e.g. previously treated non-melanoma skin cancer).

## 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 of HIV seroconversion.
- 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 using VZ immunoglobulin in VZ-susceptible individuals.

## 6. Use of biologic therapy and tuberculosis

- Screen for latent tuberculosis (TB) with an interferon-γ release assay. Arrange a plain chest radiograph 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 IL-17 inhibitors in people with inflammatory bowel disease.
- In people undergoing elective surgery balance the potential benefit of preventing postoperative infection by stopping biologic therapy against the risk of developing severe or unstable disease. 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 2017 BAD biologics guidelines<br><br>Quality Statement 3<br>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. | R2 2017 BAD biologics guidelines<br><br>R8 2017 BAD biologics guidelines<br><br>Quality Statement 6<br>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.<br>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

| | | Baseline | Monitoring |
|---|---|---|---|
| **History/symptom enquiry** | | | |
| Psoriasis | Disease phenotype (stable/unstable); response & adverse effects to prior therapies | Yes | Ongoing |
| Psoriatic arthritis | Screen for psoriatic arthritis (e.g. using the PEST questionnaire); 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 | Yes | Every 3-6 months |
| Infection | Any past or current chronic infection including turberculosis, candidiasis | Yes | Every 3-6 months |
| | Identify risk factors for tuberculosis, hepatitis B, C and HIV | | |
| | Ascertain history for chicken pox | | N/A |
| Alert card | Ensure people carry an alert card with them at all times in line with MHRA guidance | Yes | At each review appointment |
| Cardiovascular assessment | 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 every 3-6 months |
| Neurological assessment | Past or current history or symptoms of demyelinating disease | Yes | Every 3-6 months |
| Gastrointestinal assessment | Past or current history or symptoms of inflammatory bowel disease | Yes | Every 3-6 months |
| Malignancy | Any past or current malignancy (including skin cancer) | Yes | Every 3-6 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 or clear or nearly clear | Yes | To establish disease response; every 6 months therafter |
| | 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; every 3-6 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; 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 |
| | 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 |
| | 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 chicken pox | | 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 |
| 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 | | |

## Appendix 3

BAD Decision Aid (excluding brodalumab and guselkumab)

This table support the decision making process during the consultation for patients and clinicians before the initiation of biologic therapy.

| Frequently Asked Questions | Adalimumab | Etanercept | Infliximab | Ixekizumab | Secukinumab | Ustekinumab | No active treatment (placebo) |
|---|---|---|---|---|---|---|---|
| **How often do I need to inject the treatment?** | 1 injection under the skin every other week | 1 injection under the skin once or twice a week | 1 injection in the vein every 8 weeks | 1 injection under the skin every 2 weeks for the first 3 months, every 4 weeks thereafter | 2 injections under the skin every 4 weeks | 1 injection under the skin every 12 weeks | Not applicable |
| **Who gives the treatment** | You or your carer will earn to give the injection after training | You or your carer will earn to give the injection after training | You will need to go to hospital where the injection will be given by a healthcare professional | You or your carer will earn to give the injection after training | You or your carer will earn to give the injection after training | Given by a nurse in your home | Not applicable |
| **How long has this treatment been around for?** | Since 2008 | Since 2004 | Since 2006 | Since 2017 | Since 2015 | Since 2009 | Does not apply |
| **In UK clinical practice what are the chances of staying on this treatment past 1 year?** | 77-81% chance | 67-73% chance | 54-74% chance | Not known at present | Not known at present | 86-92% chance | Does not apply |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **How many people experience unwanted effects that are serious enough to stop treatment?** | Up to 2 per 1000 people after 3-4 months of treatment | Up to 10 per 1000 people after 3-4 months of treatment | Up to 82 per 1000 people after 3-4 months of treatment | Up to 39 per 1000 people after 3-4 months of treatment | Up to 5 per 1000 people after 3-4 months of treatment | Up to 1 per 1000 people after 3-4 months of treatment | Roughly 19 per 1000 people taking a placebo withdraw after 3-4 months of monitoring |
| **What conditions make your doctor hesitant about giving you the treatment?** | Moderate or severe heart failure, demylinating disorders (e.g. multiple sclerosis) | Moderate or severe heart failure, demylinating disorders (e.g. multiple sclerosis) | Moderate or severe heart failure, demylinating disorders (e.g. multiple sclerosis | Inflammatory bowel disease (i.e. Crohn's disease or ulcerative colitis), recurrent candidia infection (i.e. thrush) | Inflammatory bowel disease (i.e. Crohn's disease or ulcerative colitis), recurrent candidia infection (i.e. thrush) | No particular condition | Does not apply |
| **What if I want to have children?** | Women and men have had children on this treatment. The risk to the baby is unknown. Your dermatologist will discuss this with you | Women and men have had children on this treatment. The risk to the baby is unknown. Your dermatologist will discuss this with you | Women and men have had children on this treatment. The risk to the baby is unknown. Your dermatologist will discuss this with you | The risk to the baby is unknown. Your dermatologist will discuss this with you. | The risk to the baby is unknown. Your dermatologist will discuss this with you. | The risk to the baby is unknown. Your dermatologist will discuss this with you. | During pregnancy, psoriasis may get better, stay the same or become worse. |

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## Consultation Process

South East London Psoriasis Steering Group (See Authors) December 2015