

NHS Kent and Medway ICB

Clinical guideline for biologic therapy for psoriasis in adults

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Change history

Version	Date	Comments
1.0 & 2.0	October 2019	Developed by Dimil Patel
3.0	May 2021	Updated by Geoffrey Howell – new template and inclusion of updated BAD guidance
3.1	September 2021	Inclusion of Bimekizumab NICE TA
4.1	April 2022	Update by Geoffrey Howell following first meeting of the K&M Dermatology MDT
5	July 2023	Inclusion of Deucravacitinib NICE TA907, removal of weight based dosing information (PR2014-12 terminated 18/05/23) and updated equality impact assessment, Change to reflect new organization (ICB) by Thelma Okunuga
5.1	April 2024	Inclusion of PRGC 2024-07 Weight-based dosing of secukinumab for plaque psoriasis with or without psoriatic arthritis

NHS Kent and Medway ICB include four integrated care partnerships: Medway and Swale HCP, West Kent HCP, East Kent HCP and Dartford Gravesham and Swanley HCP. They are referred to collectively in this document forthwith as “Kent and Medway ICB” or the “Authority”.

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1. Introduction

Psoriasis is an inflammatory skin disease that typically follows a relapsing and remitting course. The prevalence of psoriasis is estimated to be around 1.3–2.2% in the UK. Psoriasis can occur at any age, although is uncommon in children (0.71%) and the majority of cases occur before 35 years. Plaque psoriasis is characterised by well-delineated red, scaly plaques that vary in extent from a few patches to generalised involvement.

Psoriasis for many people results in profound functional, psychological, and social morbidity, with consequent reduced levels of employment and income

1st line therapy includes traditional topical therapies such as corticosteroids, vitamin D and vitamin D analogues, dithranol and tar preparations.

2nd line therapy includes the phototherapies (broad or narrow band ultraviolet B-light and psoralen plus UVA light [PUVA]) and systemic non-biological agents such as ciclosporin, methotrexate and acitretin.

3rd line therapy includes the use systemic biological therapies in line with their respective NICE technology appraisal guidance.

2. Aims

The aims of the biologic clinical guidance for psoriasis are:

1. To present the evidence behind the use of each biologic in order to enable consistent evidence based clinical practice.
2. To reduce the number of Individual Funding Requests (IFRs) across the region.
3. To illustrate particular instances where the use of a particular biologic drug may be preferred over another, based on mode of action and current safety data.
4. To promote cost containment by using the most appropriate biologic therapy, by supporting the use of biosimilar drugs and by promoting dose reduction, where appropriate.
5. To improve patient care by ensuring appropriate use of biologics for psoriasis and reducing the number of dermatology hospital admissions.

3. National guidance

NICE have produced individual Technology Appraisals for each of the 12 biological drugs currently available for the treatment of plaque psoriasis. The NICE pathway lists the following options for the treatment of 'severe psoriasis', defined as exhibiting a Psoriasis Area and Severity Index (PASI) of ≥ 10 and Dermatology Life quality Index (DLQI) of > 10 (patients will have failed, not tolerated or have a contraindication to standard systemic therapies including ciclosporin, methotrexate and PUVA):

AntiTNF

Adalimumab - <https://www.nice.org.uk/guidance/ta146>

Etanercept - <https://www.nice.org.uk/guidance/ta103>

Certolizumab pegol - <https://www.nice.org.uk/guidance/ta574>

Infliximab – 'very severe' - PASI ≥ 20 and DLQI > 18 - <https://www.nice.org.uk/guidance/ta134>

Interleukin (IL)-12/23p40

Ustekinumab - <https://www.nice.org.uk/guidance/ta180>

IL-17A

Ixekizumab - <https://www.nice.org.uk/guidance/ta442>

Secukinumab - <https://www.nice.org.uk/guidance/ta350>

IL-17RA

Brodalumab - <https://www.nice.org.uk/guidance/ta511>

IL-17A & 17F

Bimekizumab - <https://www.nice.org.uk/guidance/ta723>

IL-23p19

Guselkumab - <https://www.nice.org.uk/guidance/ta521>

Risankizumab - <https://www.nice.org.uk/guidance/ta596>

Tildrakizumab - <https://www.nice.org.uk/guidance/ta575>

TYK2 inhibitor

Deucravatinicib - <https://www.nice.org.uk/guidance/ta907>

The drugs each target a different cytokine, or has varying affinity or avidity where the target is the same cytokine. It is likely that the key driver of any individual's disease is one of these cytokines. Therefore if one agent fails, a subsequent line of therapy is likely to work.

If there is more than one NICE approved treatment available, NICE recommends a discussion between the clinician and the patient about the advantages and disadvantages of each treatment (considering therapeutic need and likely adherence to treatment). If more than one treatment option is suitable, then the least expensive will be choice (taking into account administration costs, dosage and price per dose) unless an order of preference is stated in the TAs.

Bimekizumab:

Evidence from clinical trials shows **that bimekizumab is more effective than adalimumab, secukinumab and ustekinumab**. Indirect comparisons suggest that bimekizumab is similarly or more effective than other biological treatments. NICE compared bimekizumab with brodalumab, secukinumab and ixekizumab because they work in a similar way and would likely be used as an alternative to those treatments. **The total costs associated with bimekizumab are similar to or lower than those associated with brodalumab, secukinumab and ixekizumab.**















Deucravacitinib:

NICE states that deucravacitinib is recommended as an option for treating moderate to severe plaque psoriasis which has not responded to other systemic treatments if people with the condition and their clinicians do not consider **adalimumab, bimekizumab or tildrakizumab to be suitable treatment options.**






















The British Association of Dermatologists have produced the following decision aid to support clinicians and patients on selecting the most appropriate biological drug treatment for their psoriasis. *this does not include bimekizumab and deucravaticinib. (British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020 – a rapid update) link <https://onlinelibrary.wiley.com/action/downloadSupplement?doi=10.1111%2Fbjd.19039&file=bjd19039-sup-0001-FileS1.pdf>

TABLE S2: DECISION AID – BIOLOGICAL 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 (see File S2, Appendix D).

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? ^a	For how long has this treatment been around? ^b	Roughly what proportion of people becomes clear or nearly clear (PASI90) after 3-4 months? ^c	What is the likelihood of staying on this treatment past 1 year? ^d	Roughly what proportion of people stops their treatment in the first 3-4 months due to unwanted effects? ^e	Roughly what proportion of people gets a serious infection in the first 3-4 months? ^f	What are <i>some</i> of the conditions that would make your doctor hesitant about giving you the treatment? ^g	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	
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, ^h 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

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? ^a	For how long has this treatment been around? ^a	Roughly what proportion of people becomes clear or nearly clear (PASI90) after 3-4 months? ^c	What is the likelihood of staying on this treatment past 1 year? ^d	Roughly what proportion of people stops their treatment in the first 3-4 months due to unwanted effects? ^e	Roughly what proportion of people gets a serious infection in the first 3-4 months? ^f	What are <i>some</i> of the conditions that would make your doctor hesitant about giving you the treatment? ^g	What if I have psoriatic arthritis?	
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 colitis), recurrent candida infection (i.e. thrush)	This treatment is not licensed ⁵⁵ for psoriatic arthritis	
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 ⁵⁵ 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 ⁵⁵ for 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 ⁵⁵ 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	

NICE eligibility criteria, infliximab: PASI ≥20, DLQI >18; other biologic therapies: PASI ≥10, DLQI >10

⁵⁵ 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.

Choice of agent – tailored to the individual person and considering the following factors:

Psoriasis factors:

- The goal of therapy [for example, Physician's Global Assessment of clear or nearly clear]
- Disease phenotype and pattern of activity

- Disease severity and impact
- The presence of psoriatic arthritis (in consultation with an adult rheumatologist)
- The outcomes of previous treatments for psoriasis

Other individual factors:

- Person's age
- Past or current comorbid conditions (e.g. inflammatory bowel disease, heart failure)
- Conception plans
- Body weight
- The person's views and any stated preference on administration route or frequency
- Likelihood of adherence to treatment

Drug costs:

- Including administration costs, dosage, price per dose and commercial arrangements.

4. Drug Choice (Refer to treatment flow chart – Section 5)

First line:

The biological agents listed above can only be initiated if the patient's psoriasis has not responded to standard systemic therapies including ciclosporin, methotrexate and PUVA; or the person is intolerant of, or has a contraindication to, these treatments.

- In those people with psoriasis, with or without signs of, or risks of psoriatic arthritis, **ADALIMUMAB BIOSIMILAR** is the preferred first line treatment option, in accordance with NICE, on the basis of a well-established safety record.
- In those people who are thinking of conceiving or are pregnant, CERTOLIZUMAB PEGOL is the preferred treatment option backed by its well-recognized better safety profile.

Subsequent lines of treatment:

Consider changing to **an alternative biological drug with a different mechanism of action (box B)** if:

1. The psoriasis does not respond adequately to a first biological drug as defined in NICE technology appraisals at: (i.e., primary failure)
OR
2. The psoriasis initially responds adequately but subsequently loses this response, (secondary failure)
OR
3. The first biological drug cannot be tolerated or becomes contraindicated.

An **adequate response** is defined as either:

- A 75% reduction in the PASI score (PASI 75) from when treatment started **OR**
- A 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from start of treatment.

When using DLQI healthcare professionals should take into account any physical, sensory or learning disabilities or communication difficulties that could affect the responses to DLQI and make any adjustments they consider appropriate. When using the PASI, healthcare professionals should take

into account skin colour and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.

Transitioning biologic therapies – consider using a ONE month washout period, or the length of the treatment cycle, between the last dose of the current biologic therapy and the planned date of biologic initiation

Sixth line +

- Patients who have failed to respond to **SIX** lines of treatment are subject to a K&M Dermatology MDT decision on alternative treatment options.
- Ongoing clinical response to treatment will be monitored and reviewed by the MDT.
- For complex patients, advice on their management and alternative treatment options can be sought from the supra-specialist centre, Guys and St. Thomas Hospital (GSTT).

Other treatment options

- **Etanercept** – to consider where an antiTNF (secondary loss of response to adalimumab) is indicated and other available biologics agents have failed or cannot be used, or where a short half-life is important.
- **Infliximab** – reserved for people with very severe disease, or where other biological agents have failed, or cannot be used, or where weight-based dosing is a priority.
- **Apremilast** <https://www.nice.org.uk/guidance/ta146> - recommended as treatment options pre-biologic therapy, in between or after the use of systemic biologics. It could be considered pre-biologic therapy as some people with psoriasis do not adhere to treatment, so it is important to consider patient choice to encourage adherence because they are oral treatments. Apremilast has an advantage over other biological agents because it is not contraindicated in people with tuberculosis. On the other hand, the patient expert stated that because apremilast is less effective than biological therapies, offering apremilast as a first-line treatment could delay more effective treatments, so patients may prefer biological therapies. Therefore the committee recognised that the treatment decision would be driven by patient choice.
- **Dimethyl Fumarate** <https://www.nice.org.uk/guidance/ta475> - recommended as an alternative to biological therapies and apremilast or after biologicals or apremilast have failed or contraindicated, as an alternative to best supportive care.

Psoriasis and psoriatic arthritis (PsA)

If the person has both psoriasis and psoriatic arthritis, in consultation with a consultant rheumatologist, take into account both conditions before initiating or making changes to the biologic drug.

1st line: AntiTNF or an IL-17* antagonist (*brodalumab is not licensed in PsA)

5. Biosimilars

Initiating treatment with a biologic

- The choice of biologic used should be guided by clinical judgement, national or local guidance and the overall value proposition offered by the individual medicines. The

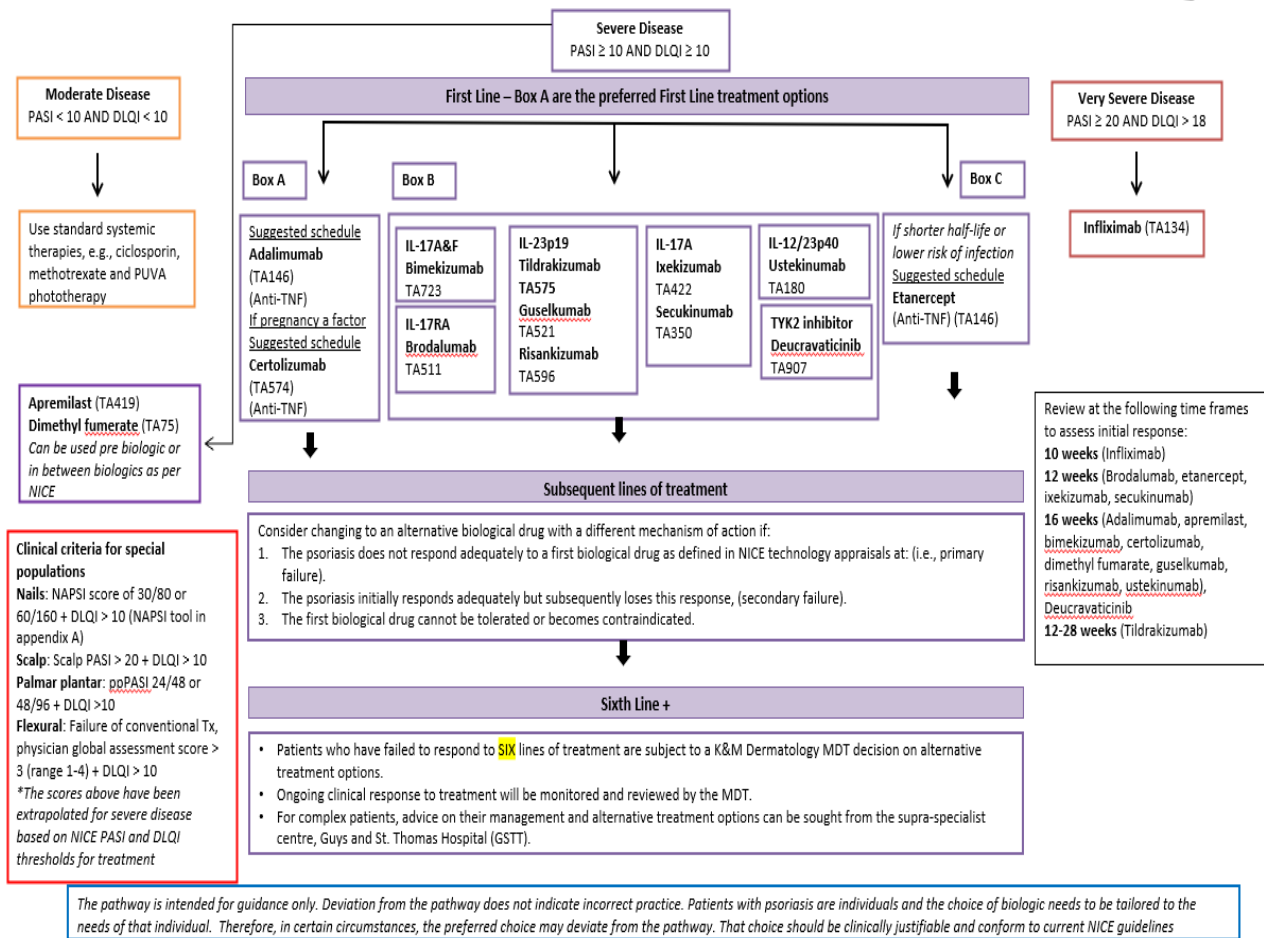
rationale for choice should be documented.

- **If more than one treatment is suitable, the least expensive should be chosen** (taking into account administration costs, dosage and price per dose). You may be expected to retrospectively audit your practice, for which we recommend keeping an accurate record of the most cost effective biologic for your trust (and update this on a 6-12 monthly basis).
- When the biologic treatment has been selected, the least expensive product, either biosimilar or originator should be prescribed.
- Where NICE has already recommended the originator biological medicine, the same guidance will apply to the biosimilar medicine.
- In line with MHRA guidelines: [Gov.uk/drug-safety-update/biosimilar-products](https://www.gov.uk/drug-safety-update/biosimilar-products) biologics, including biosimilars must be prescribed by brand name to support on-going pharmacovigilance of the individual products.
- Pharmacovigilance is essential for any new biological medicine including biosimilars and additional monitoring is indicated through the black triangle. Patients prescribed a biologic should be enrolled on to relevant registries which gather data on the safety and effectiveness of the medicine in clinical practice.

Changing from originator to a biosimilar

- There is evidence that patients who are in a stable clinical response or remission may be changed over to the biosimilar at the same dose and dose interval. This should be done after discussion and agreement with individual patients.
- Changing a patient on a biologic originator medicine to a biosimilar should be done at the point of prescribing and in discussion with the hospital pharmacy department.
- There should be no automatic substitution of a biologic with a biosimilar at the point of dispensing.

5. Psoriasis HCD treatment flow chart



7. PR 2024-07: Weight-based dosing of secukinumab for plaque psoriasis with or without psoriatic arthritis

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered NICE guidance, the evidence base, baseline position, other Integrated Care Board (ICB) policies, the views of clinical specialists, equality and equity issues, and the potential impact of implementing a new policy. All decisions were made with reference to the Kent and Medway ICB principles for clinical decision-making. Taking these into account, the PRGC recommends:

- Weight-based dosing of secukinumab (i.e., 300mg every 2 weeks in the maintenance phase) is routinely funded by Kent and Medway ICB for patients with plaque psoriasis with/without concomitant psoriatic arthritis and a bodyweight of 90kg or over as a treatment option if there is a sub-optimal response* at week 16 to secukinumab 300mg every 4 weeks.
- Treatment with weight-based dosing of secukinumab (300mg every 2 weeks) should be discontinued if PASI 90 is not achieved at 12-16 weeks (following up-titration).
- Prior to initiating an individual with plaque psoriasis with/without concomitant psoriatic arthritis and a weight of 90kg or over on 300mg secukinumab every 2 weeks, a new Blueteq form specifying this dosing schedule needs to be completed. Collection of this information can be utilised for audit purposes.

- Secukinumab is commissioned by NHS Kent and Medway according to criteria set out in the Kent and Medway Psoriasis High-Cost Drug pathway in line with NICE TA350 criteria.

8. Contraindications, special warnings and precautions

a) Contraindications to:

- [Bimekizumab](#)
 - [Brodalumab](#)
 - [Guselkumab](#)
 - [Ixekizumab](#)
 - [Risankizumab](#)
 - [Secukinumab](#)
 - [Tildrakizumab](#)
 - [Ustekinumab](#)
 - Hypersensitivity to the active substance or to any of the excipients
 - Clinically important, active infection (e.g. active tuberculosis)
- Special warnings and precautions for use with:

b) Contraindications to anti-TNF's:

- [Adalimumab](#)
 - [Certolizumab](#)
 - [Infliximab](#)
 - Moderate to severe heart failure (NYHA class III/IV heart)
 - Active tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections.
 - History of hypersensitivity to the active substance, to other murine proteins, or to any of the excipients.
- Special warnings and precautions for use with:

c) Contraindications to [etanercept](#)

- Hypersensitivity to the active substance or to any of the excipients
- Sepsis or risk of sepsis
- Treatment with etanercept should not be initiated in patients with active infections including chronic or localised infections

d) Contraindications to [apremilast](#)

- Hypersensitivity to the active substance(s) or to any of the excipients
- Pregnancy

e) Contraindications to [dimethyl fumarate](#)

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Severe gastrointestinal disorders
- Severe hepatic or renal impairment
- Pregnancy and breast-feeding

f) Contraindications to [Deucravacitinib](#)

- Active tuberculosis (TB) infection
- Other clinically important active infections (as assessed by Clinician)
- Hypersensitivity to the active substance or to any of the excipients
- **It is not known whether tyrosine kinase 2 (TYK2) inhibition may be associated with the**

adverse reactions of Janus Kinase (JAK)inhibition. *(An increased risk of major adverse cardiovascular events (MACE), deep venous thrombosis (DVT) and pulmonary embolism (PE) was not observed in clinical trials with deucravacitinib. Long-term safety evaluations are ongoing. The risks and benefits of deucravacitinib treatment should be considered prior to initiating patients.)*

- The risks and benefits of deucravacitinib treatment should be considered prior to initiating patients with higher risk of malignancy. *(Malignancies, including lymphomas and non-melanoma skin cancer (NMSC), were observed in clinical studies with deucravacitinib.)*

9. Special situations

- Prevention of potential post-operative infection risk by temporarily stopping a patient's biologic treatment should be carefully balanced against the possibility of a peri-operative flare of psoriasis.
- Should treatment be stopped prior to surgery, consider stopping the drug 3-5 times the half-life for the relevant drug (see table below).
- Treatment should be recommenced post operatively once the infection is excluded and the wound is healed.

Biologic	Half-life*	Time to stop treatment prior to surgery
Etanercept	3 days (approx. 70 hours)	9 - 15 days
Adalimumab	12 - 14 days	6 – 10 weeks
Infliximab	9 days	4 – 7 weeks
Ustekinumab	Median half-life 3 weeks (15-32)	9 – 15 weeks
Secukinumab	Median half-life 27 days (18-46 days)	12 – 19 weeks
Ixekizumab	13 days	6 – 10 weeks
Guselkumab	17 days	7 – 12 weeks
Brodalumab	11 days	9 weeks
Apremilast	9 hours	n/a
Bimekizumab	23 days	10 – 17 weeks
Dimethyl fumarate	2 hours	n/a
Certolizumab	14 days	6 -10 weeks
Tildrakizumab	24 days	10 - 17 weeks
Risankizumab	28 - 29 days	13 - 21 weeks
Deucravacitinib	10 hours	No data

* Summary of product characteristics (SmPC) / drug manufacturer

a) Pregnancy and breast feeding

Pregnancy

There are limited data for safety of biologic drugs in pregnancy and lactation. The decision to continue biologic agents in pregnancy needs to be individualised. This needs to take into account alternative therapies, the severity of the mother's condition prior to therapy, the risk of a disease flare by cessation of therapy, and the impact of a flare on the mother and the unborn child. This should be discussed by a multi-disciplinary team.

Patients who stop therapy during pregnancy should be re-loaded with biological therapy soon after delivery. Consideration should be given to stopping biologic therapy in a woman who becomes pregnant as listed below:

Biologic	Compatible with 1st trimester	Compatible with 2nd / 3rd trimester
Etanercept	Yes	Second but not third
Adalimumab	Yes	Second but not third
Infliximab	Yes	Stop at 16 weeks
Ustekinumab	No data	No data
Secukinumab	No data	No data
Ixekizumab	Limited data	Limited data
Brodalumab	Limited data	Limited data
Bimekizumab	Avoid	Avoid
Apremilast	Limited data	Limited data
Dimethyl	Limited data	Limited data
Guselkumab	Limited data	Limited data
Certolizumab	Yes	Limited data but considered safe
Tildrakizumab	No data	No data
Risankizumab	No data	No data
deucravacitinib	Avoid	Avoid

To ensure low/no levels of drug in cord blood at delivery, etanercept and adalimumab should be avoided in the third trimester and infliximab stopped at 16 weeks. If these drugs are continued later in pregnancy to treat active disease, then live vaccines should be avoided in the infant until 7 months of age.

Breast feeding

There is insufficient information on the excretion of biologics in breast milk. Since immunoglobulins are excreted into human breast milk, a risk to the breastfeeding child cannot be excluded. A decision on whether to breastfeed or to continue/discontinue therapy should be made taking into account the benefit of breastfeeding to the child and the benefit of therapy to the woman.

Manufacturers recommend that it is not advisable to breast feed during drug treatment or for the duration specified below after treatment has stopped.

No data available for Apremilast, Brodalumab, Dimethyl fumarate, Etanercept, Ixekizumab, Tildrakizumab and Risankizumab.

Bimekizumab: A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Bimzelx therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Biologic	Time to elapse between stopping treatment and starting breastfeeding	Breastmilk peak drug excretion
Adalimumab	5 months	1 - 4 days post infusion 1 – 6 day post injection
Infliximab	6 months	1 - 4 days post infusion

		1 – 4 days post infusion
Ustekinumab	15 weeks	Peak excretion 1 post injection
Secukinumab	20 weeks	Unable to locate data
Certolizumab	Compatible	0.5 – 2 days post injection

B) *Vaccination of Infants*

Any infant who has been exposed to immunosuppressive treatment from the mother either in utero during pregnancy or via breastfeeding should have any live attenuated vaccination deferred for as long as a postnatal influence on the immune status of the infant remains possible.

In the case of in utero exposure to anti-TNF and other biological medicines, this period should be until the infant is six months old, after which, vaccination should be considered.

The MHRA has received four Yellow Card reports regarding neonates who have died from disseminated BCG or tuberculosis infection after exposure to an anti-TNF in utero; they were probably not known to be immunosuppressed at the time of vaccination.

Current vaccination strategies with non-live vaccines for infants who have been exposed to anti-TNF in utero do not differ from those for unexposed infants.

As a precaution, any infant who has been exposed to immunosuppressive treatment from the mother either in utero during pregnancy or via breastfeeding should have any live attenuated vaccination deferred for as long as a postnatal influence on the immune status of the infant remains possible.

The risk of a natural rotavirus infection is high. Although the vaccine is a live attenuated virus, with the exception of severe combined immune-deficiency (SCID), the benefit from vaccination may exceed any risk in other forms of immunosuppression. Therefore, there are very few infants who cannot receive rotavirus vaccine. Vaccination should be discussed on an individual basis.

10. Vaccinations

- Any necessary vaccinations provided by the NHS required prior to starting biologics or whilst on biologic therapy will be requested from the GP as advised by the specialist.
- Any vaccinations not provided by the NHS and required by the patient due to travel reasons should be obtained privately by the patient.

a) Live vaccines

- The administration of live vaccines is contraindicated in patients on biologic agents.
- It is safe to administer a live vaccine 4 weeks prior to commencing biologic therapy, when necessary.
- There is no contra-indication for the administration of live vaccines to relatives or friends of patients on biologic or immunosuppressant drugs.
- The table below shows all live vaccines available in the UK.

Live Vaccine

BCG

Influenza
Measles, Mumps and Rubella combined vaccine (MMR)
Poliomyelitis (Live oral vaccine)
Rotavirus (Live oral vaccine)
Typhoid (Live oral vaccine)
Varicella-Zoster Vaccine
Herpes Zoster Vaccine*
Yellow Fever

* Herpes zoster vaccination is contraindicated in patients treated with any biologic therapy. The herpes zoster vaccine should not be given to those who are receiving or have received in the past 12 month's biological therapy (e.g. anti-TNF therapy such as adalimumab, infliximab and rituximab) unless otherwise directed by a specialist - NB see statement above regarding live vaccine. Patients who have already received the herpes zoster vaccine should wait a period of 2 – 4 weeks prior to starting biologic therapy.

When a live vaccine is required by a patient on a biologic, the cessation of treatment may permit a necessary vaccination to be administered. The table below shows the time period required to elapse off each biologic therapy, prior to the administration of a live vaccination (except herpes zoster live vaccine).

Biologic	Time to elapse before administering a live vaccine
Adalimumab	3 months
Apremilast	n/a
Brodalumab	6 months
Bimekizumab	No data
Certolizumab	3 months
Dimethyl	n/a
Etanercept	1-2 months
Guselkumab	3 months
Infliximab	3 months
Ixekizumab	6 months
Secukinumab	6 months
Risankizumab	21 weeks
Tildrakizumab	17 weeks
Ustekinumab	6 months
Deucravatinib	No data

General Advice from British association of dermatologists: Live vaccines should not be given within 3 months of stopping prednisolone and other immunosuppressant medicines and for at least 12 months after stopping biological treatment. Link: <https://www.skinhealthinfo.org.uk/condition/immunisation-recommendations-for-children-and-adult-patients-treated-with-immune-suppressing-medicines/>

b) Non-live vaccines

- Non-live vaccines are deemed safe to administer to people on immunosuppressant and on biologic therapies.

- Pneumococcal vaccine should be given 2-4 weeks before starting a biologic as response after starting treatment can be poor.
- The table below gives a list of non-live vaccines available in the UK.

Vaccine
Cholera Vaccine (Oral preparation only)
COVID- 19
Diphtheria
Hepatitis A
Hepatitis B
Hepatitis A and B Combined
Influenza
Pneumococcal
Poliomyelitis (Injection)
Meningococcal Group C
Meningococcal polysaccharide A,C, W135 and Y vaccine
Rabies
Tetanus
Tick-borne encephalitis
Typhoid (Polysaccharide injection for vaccination)

11. Checklist for patient screening on pre-admission for biologic agents

Name:..... Number:..... Consultant:.....

Screening Investigations Requested in Clinic			
	Y/N	Initial	Results/Details
FBC/U&E/LFT/ESR/CRP/Renal Function			
Rheumatoid Factor (if negative check anti-CCP) Don't repeat if previously positive result			
ANA (If positive also order ENA/dsDNA/C3/C4)			
HIV, HBV (surface antigen, core antibody)*, HCV (antibody test) If positive result please refer to Hepatology/GUM <small>* Reactivation has been reported in HBsAg-ve as well as HbsAg +ve patients stressing the</small>			
Varicella Zoster IgG (If negative inform GP and patient)			
TB screening (g-IFN testing) If positive refer to respiratory			

Chest X-Ray (within the last 6 months) (\pm pulmonary function tests/HRCT thorax) CXR checked by/date			
Screening questions asked in clinic			
	Y/N	Initial	Details
Previous TB/TB contact (details)			
Recent travel abroad (i.e. TB high risk countries) Which Country/Dates			
History of heart failure (NYHA class III or IV) (details)			
History of recurrent infection (details)			
History of Multiple Sclerosis, IBD, interstitial lung disease? Relevant (details such as extent of ILD²¹)			
History of cancer (Type/Date when occurred/Date of all clear)			
Date of last mammogram (50yr +) (Encourage patient to visit GP if >3 years)			
Date of last smear (25yr +) (Encourage patient to visit GP if >3 years)			
History of infusion reaction to any agent (To what/type of reaction)			
Allergy (details)			
Education and funding			
	Initial	Details	
Request for funding			
Pregnancy/breastfeeding advice given			
Annual influenza vaccination advice given			
Pneumococcal vaccination advice given			
Patient counselled and educated			
Patient education pack given			
Patient consent to be approached for research			

Completing Clinician Signature.....

Date.....

Nurse Practitioner Signature.....

Date.....

12. References

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13. Appendices

A. NAPI scoring tool proforma

Nail Bed			Nail Matrix		
Change	Quadrants	Scoring	Change	Quadrants	Scoring
Onycholysis	0 of 4	0 points	Grooves	0 of 4	0 points
Hyperkeratosis	1 of 4	1 point	Leukonychia	1 of 4	1 point
Oil Spots	2 of 4	2 points	Lunula erythema	2 of 4	2 points
Haemorrhage	3 of 4	3 points	Crumbly nails	3 of 4	3 points
	4 of 4	4 points		4 of 4	4 points
Affected Fingers (nail bed)		Affected fingers (nail matrix)			
Right Hand	Quadrants affected	Quadrants affected			
Digit 1					
Digit 2					
Digit 3					
Digit 4					
Digit 5					
Sum					
Left Hand	Quadrants affected	Quadrants affected			
Digit 1					
Digit 2					
Digit 3					
Digit 4					
Digit 5					
Sum					
Affected Toes (nail bed)		Affected Toes (nail matrix)			
Right Foot	Quadrants affected	Quadrants affected			
Digit 1					
Digit 2					
Digit 3					
Digit 4					
Digit 5					
Sum					
Left Foot	Quadrants affected	Quadrants affected			
Digit 1					
Digit 2					
Digit 3					
Digit 4					
Digit 5					
Sum					
		Sum, Hand Right	0-40		
Patient Name		Sum, Hand Left	0-40		
Hospital Number		Sum, Foot Right	0-40		
Date of assessment		Sum, Foot Left	0-40		
		Total	0-160		

B. Equality analysis data collection tool

Date of assessment	21 ST Of July 2023
Assessor name	Thelma Okunuga, Lead Medicines Optimisation Pharmacist – High Cost Drugs, K&M ICB
Name of topic under review	Clinical guideline for biologic therapy for psoriasis in adults
Purpose of this policy	To provide guidance on the biological treatment options available for treating psoriasis across Kent and Medway based on clinical evidence appraised by NICE, BAD and local clinical practice

Please outline below any issues that have been identified relating to the topic under policy review that may have an adverse equality impact / health inequality impact on any of the protected groups as defined by the Equality Act 2010.

Protected Group	Issue	Source	Mitigating Actions
Age	This pathway only covers adult patients. The DLQI was noted to have limited validity in some people, for example older people.	NICE TA907	NHSE are the responsible commissioners for paediatrics. NICE concluded that, when using the DLQI, healthcare professionals should take into account any physical sensory or learning disabilities, or communication difficulties, that could affect the responses to the questionnaire and make any adjustments needed.
Disability	The DLQI was noted to have limited validity in some people, for example those with a learning disability. It may also miss anxiety and depression.	NICE TA907	NICE concluded that, when using the DLQI, healthcare professionals should take into account any physical sensory or learning disabilities, or communication difficulties, that could affect the responses to the questionnaire and make any adjustments needed.
Gender	None	-	-
Gender reassignment	None	-	-
Pregnancy / Maternity	None	-	-

Race	The PASI which is used to assess response to treatments for plaque psoriasis was noted to have the potential to underestimate psoriasis severity in people with black or brown skin.	NICE TA907	NICE concluded that healthcare professionals should take into account how skin colour could affect the PASI score and make any adjustments needed.
Marriage/Civil partnership	None	-	-
Religion/Belief	None	-	-
Sexual orientation	The DLQI was noted to have limited validity in some people, for example those who are not sexually active. It may also miss anxiety and depression.	NICE TA907	NICE concluded that, when using the DLQI, healthcare professionals should take into account any physical sensory or learning disabilities, or communication difficulties, that could affect the responses to the questionnaire and make any adjustments needed.

C. PR 2024-07: Weight-based dosing of secukinumab for plaque psoriasis with or without psoriatic arthritis



PR2024-07

Secukinumab for PsO



WB dosing

Secukinumab for PsO