North Central London
Joint Formulary Committee

Psoriasis Prescribing Pathway in Adults

Document control

Date	Version	Amendments
Aug 2019	1.0	New pathway
Nov 2019	1.1	Inclusion of risankizumab as per TA596
Nov 2021	1.2	Inclusion of Bimekizumab as per TA723
Feb 2025	2.0	**Moderate to severe psoriasis:** • Inclusion of deucravacitinib as per NICE TA907 • Removing need for ciclosporin before commencing treatment with a biologic or small molecule • Changing the requirement from PUVA to phototherapy • Allowing patients failing current treatment to move to an alternative treatment irrespective of PASI score. • Addition of dose escalations for adalimumab biosimilar, ustekinumab biosimilar and secukinumab • Addition of bimekizumab as an alternative treatment in those patients with primary or secondary failure to ixekizumab, secukinumab or brodalumab • Inclusion of subcutaneous infliximab • Inclusion of BSR advice on TNF inhibitors during pregnancy & breastfeeding • Preferential use of apremilast vs DMF **High impact site psoriasis** • Change in the definition of high impact psoriasis • Addition of ustekinumab and deucravacitinib as treatment options for high impact site psoriasis • Allowing patients failing current treatment to move to an alternative mechanism of action • Preferential use of apremilast vs DMF

Groups / Individuals who have overseen the development of this guidance:	NCL HCD Team, NCL Specialist Clinicians and Pharmacists, NCL Joint Formulary Principal Pharmacist
Groups which were consulted and have given approval:	NCL wide consultation (NCL Formulary Pharmacists, NCL Specialist Clinicians, NCL ICB), NCL Joint Formulary Committee (Jan and Feb 2025)
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Disclaimer

This guideline is registered at North Central London (NCL) Joint Formulary Committee (JFC) and is intended solely for use by healthcare professionals to aid the treatment of patients within NCL. However, clinical guidelines are for guidance only, their interpretation and application remain the responsibility of the individual clinician. If in doubt, contact a senior colleague or expert. Clinicians are advised to refer to the manufacturer's current prescribing information before treating individual patients.

The authors and NCL JFC accept no liability for use of this information beyond its intended use.

While we have tried to compile accurate information in this guideline, and to keep it updated in a timely manner, we cannot guarantee that it is fully complete and correct at all times. If you identify information within this guideline that is inaccurate, please report this to the admin.ncl-mon@nhs.net. If a patient is harmed as a consequence of following this guideline, please complete a local incident report and inform admin.ncl-mon@nhs.net.

NCL JFC is funded by and provides advice to Acute Trusts and the Integrated Care Board in NCL.

Psoriasis Prescribing Pathway

Green: lowest cost **Amber**: moderate cost **Red**: highest cost.

If more than one treatment is suitable, the least expensive treatment should be used.

Criteria to start treatment for high impact site psoriasis[1]:

- DLQI >10 with moderate to severe psoriasis (PGA 3 or 4) at localised sites and associated with significant functional impairment and/or high levels of distress[2]
- Inadequate response to systemic treatments including methotrexate and phototherapy[3] or these options are contraindicated or not tolerated

1ST LINE TREATMENT OPTIONS

TNF inhibitor: **Adalimumab SC** biosimilar	Ustekinumab SC biosimilar, Apremilast, Deucravacitinib also available but only if TNF inhibitors are contraindicated or not suitable (see clinical considerations) Dimethyl fumarate also available but not preferred[4]

2nd, 3rd and 4th LINE TREATMENT OPTIONS

TNF inhibitor:	IL12 & IL23 inhibitor:	Small molecules:	TKY2 inhibitor:
Adalimumab SC biosimilar	Ustekinumab SC biosimilar	Apremilast (preferred) Dimethyl fumarate also available but not preferred[4]	Deucravacitinib

Criteria to start treatment for moderate to severe psoriasis:

- PASI ≥10 and DLQI >10
- Inadequate response to systemic treatments including methotrexate and phototherapy[3] or these options are contraindicated or not tolerated

1ST LINE TREATMENT OPTIONS

TNF inhibitor: ***Adalimumab SC** [Preferred; TA146] OR Etanercept (TA103) biosimilar Certolizumab (TA574) also available but not preferred	Ustekinumab SC biosimilar (TA180), Apremilast (TA419), Bimekizumab (TA723), Deucravacitinib (TA907), Guselkumab (TA521), Risankizumab (TA596), Tildrakizumab (TA575), Brodalumab (TA511), Ixekizumab (TA442), *Secukinumab (TA350) also available but only if TNF inhibitors are contraindicated or not suitable (see clinical considerations) Dimethyl fumarate (TA475) also available but not preferred[4]

Criteria for very severe psoriasis:

- PASI ≥ 20 and DLQI >18
- Inadequate response to systemic treatments including methotrexate and phototherapy[3] or these options are contraindicated or not tolerated

1ST LINE TREATMENT OPTIONS

TNF inhibitor: **Infliximab IV** biosimilar/ **Infliximab SC** (TA134)

2nd LINE ONWARDS TREATMENT OPTIONS

TNF inhibitor:	IL12 and IL-23 inhibitor:	Small molecules:	TKY2 inhibitor:	IL-23 inhibitor:	IL-17 inhibitor:
*Adalimumab SC (TA146) OR Etanercept (TA103) biosimilar Certolizumab (TA574) also available but not preferred	*Ustekinumab SC (TA180) biosimilar	Apremilast (TA419) (preferred) Dimethyl fumarate (TA475) also available but not preferred[4]	Deucravacitinib (TA907)	Guselkumab (TA521) OR Risankizumab (TA596) OR Tildrakizumab (TA575)	Bimekizumab[5] (TA723) OR Brodalumab (TA511) OR Ixekizumab (TA442) OR *Secukinumab (TA350)

Sequential treatments routinely commissioned: Up to one drug per mechanism of action, plus a second biosimilar TNF inhibitor. If more than one treatment is suitable, the least expensive treatment should be used (see RAG rating below).

* Dose escalation available. See dosing table for further information.

Drug	Price	Usual maintenance	Dose escalation	Additional Information
Adalimumab	£	40mg SC every 2 weeks	Dose escalation: 40mg SC every week. Dose escalation guided by drug levels, anti-drug antibodies, and response.	Preferred agent for those with signs or risk factors for psoriatic arthritis. IL17 inhibitors are preferred for those with axial disease
Ustekinumab	£	Weight <100kg: 45mg SC every 12 weeks Weight >100kg: 90mg SC every 12 weeks	Consider dose escalation to 90mg every 8 or 12 weeks (≤100kg) and 90mg every 8 weeks (>100kg).	In patients weighing less than 100kg, 90mg 12 weekly dose escalation should be trialled first before escalating to 8 weekly dose.
Etanercept	£	50mg SC every 2 weeks	Not available	Lower risk of TB compared to other TNF alpha inhibitors and shorter half- life.
Infliximab	£	120mg SC every 2 weeks 5mg/kg IV every 8 weeks	Not available	
Dimethyl fumarate	£	Up to a maximum of 240mg three times a day	Not available	
Apremilast	££	30mg twice daily	Not available	
Deucravacitinib	££	6mg daily	Not available	
Guselkumab	££	100mg SC every 8 weeks	Not available	
Tildrakizumab	££	100mg SC every 12 weeks	Not available	
Risankizumab	££	150mg SC every 12 weeks	Not available	
Bimekizumab	££	320mg SC every 8 weeks	Not available	IL17 inhibitors should be avoided in those with inflammatory bowel disease.
Ixekizumab	£££	80mg SC every 4 weeks	Not available	IL17 inhibitors should be avoided in those with inflammatory bowel disease.
Brodalumab	£££	210mg SC every 2 weeks	Not available	IL17 inhibitors should be avoided in those with inflammatory bowel disease.
Secukinumab	£££	300mg SC every 4 weeks	300mg SC every 2 weeks for those with a body weight >90kg and are partial responders	IL17 inhibitors should be avoided in those with inflammatory bowel disease.
Certolizumab	£££	200mg SC every 2 weeks	Not available	

Assessment of response: Assess initial induction and/or dose escalation response between 10-28 weeks (as per NICE guidance for each individual drug):

- For severe (PASI ≥10 and DLQI ≥10) or very severe (PASI≥20 and DLQI ≥ 18) psoriasis - adequate response is defined as a 75% reduction in PASI score from baseline OR
  50% reduction in PASI score and a 5 point reduction in DLQI from the start of treatment.
- For high impact site psoriasis – adequate response is defined as a 50% reduction in DLQI from baseline and a PGA of clear, nearly clear or mild disease.

Consider escalating the dose of/reducing the interval for biologic therapy in adults achieving PASI 50 but still having significant disease burden (defined as a DLQI reduction from baseline of <5) and inadequate primary response which may be a result of insufficient drug exposure e.g. in people who are obese, where psoriasis relapse during the treatment cycle and/ or if the drug level is known to be subtherapeutic. If no response, stop biologic and consider initiating alternative drug [BAD 2020]. Patients are not required to deteriorate back to an absolute PASI score of 10 to be eligible to for the next line of therapy if they are failing to demonstrate an adequate response to current therapy (as defined above) [JFC January 2025].

Continuation of biologic treatment - Treat for 12 months or until treatment failure. Reassess at 3 monthly intervals for the first year and then 6 monthly if stable to determine whether ongoing treatment is still clinically appropriate.

Adverse drug reactions (ADRs) – For patients who experience an immediate ADR [within 1 month] or have responded to treatment but experience an ADR within 6 months of treatment initiation, another treatment option within the same mechanism of action (if available and appropriate) can be accessed. Where the ADR is likely to be a drug class effect, an alternative mechanism of action is preferable.

Dual biologic therapy for the same disease is not routinely commissioned; for individual cases, please consider RMOC advisory statement, discuss at MDT and contact Trust formulary teams for advice re IFR submission. **Concurrent biologic treatment for different co-morbidities,** is permissible provided NICE eligibility criteria for both treatments are met and there is MDT agreement across both specialities that dual therapy is appropriate and a single drug which is active against both co-morbidities is not available.

Treatment breaks & dose reductions – patients who reduce dose or hold biologic treatment can resume the standard biologic regimen (i.e. licensed dose), with an assessment of response made at 12-28 weeks.

Pregnancy – updated guidance from BSR

- Women with no/low disease activity established on a TNF inhibitor with known placental transfer (infliximab, adalimumab, golimumab) do not need to be switched to an alternative TNF inhibitor with established minimal placental transfer (certolizumab) either before or during pregnancy (GRADE 1B, Strength of agreement 100%).
- Certolizumab is compatible with all three trimesters of pregnancy, has no to minimal placental transfer compared with other TNF inhibitor, and does not require any alteration to the infant vaccination schedule (GRADE 1B, Strength of agreement 100%).
- Women considered to have low risk of disease flare on withdrawal of TNF inhibitor in pregnancy could stop infliximab at 20 weeks, adalimumab at 28 weeks, and etanercept at 32 weeks so that a full-term infant can have a normal vaccination schedule, with rotavirus vaccination at 8 weeks as per the UK schedule (GRADE 1B, Strength of agreement 99.5%).
- Infliximab, adalimumab or etanercept may be continued throughout pregnancy to maintain maternal disease control; in these circumstances, live vaccines should be avoided in infants until they are 6 months of age (GRADE 1B, Strength of agreement 100%).
- If a TNF inhibitor is stopped in pregnancy, it can be restarted as soon as practical post-partum in the absence of infections or surgical complications, regardless of breastfeeding status, to ensure control of maternal disease (GRADE 1C, Strength of agreement 100%).

Clinical considerations

- Factors to consider when choosing appropriate drug:
  - Different efficacy and safety profile of each drug
  - Co-morbidities and potential impact of each drug option (benefit or harm), including drug specific contraindications
  - The person's view and stated preference on administration route or frequency – discuss with decision aid
  - Other relevant factors e.g conception plans, adherence, travels
- TB – lower risk associated with etanercept. Safe to use IL-17 inhibitors and apremilast
- People with axial disease may benefit from first line treatment with IL-17 inhibitors [BAD 2020]
- Avoid TNF inhibitors in people with demyelinating diseases and consider alternative interventions in people who have a first-degree relative with demyelinating disease [BAD 2020]
- Avoid TNF antagonist therapy in people with severe cardiac failure (NYHA class III and IV) [BAD 2020]
- Avoid use of IL-17 inhibitors in people with inflammatory bowel disease [BAD 2020]
- Consider risk of infection
- If a higher level of clearance is required consider brodalumab, guselkumab, ixekizumab and risankizumab achieve a higher PASI 90

Footnotes

[1] There is no NICE technology appraisal supporting use of biologics in high impact site psoriasis, however within NCL treatment with either adalimumab, apremilast or dimethyl fumarate was approved by JFC [JFC June 2017, JFC June 2019]. Further review to allow alternative options for those failing to respond has been approved locally [JFC February 2025]

[2]BAD guidance define high impact site psoriasis as psoriasis that is severe at localized sites and associated with significant functional impairment and/or high levels of distress (for example nail disease or involvement of high impact and difficult-to-treat sites such as the face, scalp, palms, soles, flexures and genitals). NICE define moderate to severe psoriasis as a PASI of ≥10 and a DLQI ≥10. As PASI cannot be used to assess high impact psoriasis a PGA of moderate (3) to severe (4) and a DLQI of ≥10 is used as measure [JFC February 2025]

[3] Whilst NICE guidance recommends that biologics are recommended in patients in whom ciclosporin is contraindicated or clinically inappropriate, clinical practice has changed and resulted in ciclosporin not routinely being offered because of adverse effect profile (including renal dysfunction and risk of serious infection), and the significant reduction in cost of TNF inhibitors (adalimumab, etanercept and infliximab) given availability of biosimilars and the high cost associated with prescribing and monitoring ciclosporin. In line with more recent NICE TA publications (from April 2019) the requirement to have trialled PUVA has been changed to phototherapy [JFC January 2025]

[4]Dimethyl fumarate is not preferred due to it's adverse effect profile and risk of lymphopenia and Fanconi Syndrome [JFC January 2025]

[5]Bimekizumab selectively binds with both IL-17A and IL-17F receptors blocking their interaction with the IL-17RA/IL-17RC receptor complex. This differs from other IL-17 inhibitors, which inhibit only the IL-17A receptor. It has been agreed locally that bimekizumab may be offered to patients with primary or secondary loss of efficacy with secukinumab, ixekizumab or brodalumab due to the superiority of bimekizumab [JFC January 2025]

[6]Clinically, patients with axial disease may require treatment with an IL-17 as a first line agent [BAD guidelines for biologic therapy for psoriasis 2020]

References

British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update, October 2020.