

Clinical Protocol

Treatment Pathway for Adults with Moderate to Severe Psoriasis

Guideline Summary

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

Approval date: August 2024 **Review date:** August 2025 (or sooner if evidence or practice changes)



	Document Detail
Document Type	Clinical Guideline
Document name	Psoriasis Drug Treatment Pathway
Document location	Intranet of Individual Trusts
Version	Version 4.0
Effective from	December 2021
Review due date	12 monthly
Owner	South East London Dermatology Treatment Pathway Group
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Approved by, date	SEL Dermatology Pathway Group: September 2021; SEL IMOC: November 2021,
	SEL Medicines Optimisation sub-Committee: July 2020 (ratification)
Superseded	Psoriasis Biologic Drug Treatment Pathway V3.0
documents	
Related Documents	Seronegative Spondyloarthropathy Biologic Drug Treatment Pathway
	Liver Assessment and Management Pathway in Immune-Mediated Inflammatory Diseases
Keywords	Dermatology, Psoriasis, biologic, biologics, adalimumab, bimekizumab, etanercept, infliximab, ustekinumab, secukinumab, ixekizumab, brodalumab, guselkumab, certolizumab, tildrakizumab, risankizumab, bimekizumab, apremilast, fumaric acid esters, deucravacitinib, targeted immunomodulatory medications



	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	
	Page 15: Clarification added re: IL-17 inhibitors under caution in patients	
	with IBD	
10.09.19	Section 6,12,13,14, and appendix 3: Addition of certolizumab,	
	tildrakizumab and risankizumab following NICE approval	
10.09.19	Section 7: Updated vaccination section in line with BAD rapid update and	
	green book	
10.09.19	Section 9: Updated free of charge scheme wording in line with RMOC	
	statement	
10.09.19	Section 15: High impact site information clarified and information added	
	to appendix 5. Additional information added to pustular psoriasis section	
	in light of new evidence.	
10.09.19	Supplementary information- section 2,3,4,5,6, 7 in line with BAD rapid	
	update	
10.09.19	Update documents in appendix 1,2,3 based on BAD rapid update and	
	addition of appendix 4 and 5	
09.03.20	Updated related documents- added updated liver assessment and	
	management pathway	
09.03.20	Section 13: Addition of hyperlink to RMOC advisory statement in relation	
	to sequential use of biologic drugs	
09.03.20	Section 14: Removal of B* requirement from dose escalations table	
09.03.20	Section 15: Clarification of high impact site section and addition of	
	assessment timescale	
09.03.20	Section 15.1.2 addition of guselkumab and reference for palmoplantar	
	pustulosis	
13.05.20	Section 3: Addition of NICE Technology Appraisal statement	
07.09.21	Section 12: Treatment table now contains Bimekizumab (NICE TA723)	
07.09.21	Appendix 4: Update to pricing table, now includes Bimekizumab	
07.09.21	Section 15.1 – Category B form changed to Blueteq/clinical audit	
07.09.21	Section 15.1.2 – Category B form changed to Blueteq/clinical audit	
12.05.24	Section 12 Treatment table now contains deucravacitinib (NICE TA907)	
12.05.24	Section 14 dose escalations table updated to reflect new licensed dose	
	escalations for bimekizumab, guselkumab and secukinumab	
12.05.24	Appendix 2 schedule for monitoring updated	
12.05.24	Appendix 3 Added footnotes to BAD decision Aid	
12.05.24	Appendix 4 Updated costing tool	
12.05.24	Updated hyperlinks throughout document and references	
12.05.24	Amended wording throughout document to remove biologic terminology	
	and include targeted immunomodulatory medications where applicable	
12.05.24	Hyperlink to the most up to date (2023) British Association of	
	Dermatologists Treatment Decision Aid included and old copy removed.	

	Review History			
Date	Review details	Approved by		
09.03.20	Updated in line with latest NICE TAGs (see change history)			
12.05.24	Updated in line with latest NICE TAGs (see change history)			

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References

Consultation Process

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1. Scope

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

4. Definitions

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

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

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.

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5. Recommended disease severity assessments, before and during therapy

5.1. Assessment of disease severity³

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

Pre-Immunomodulator Therapy – Key Considerations 6.

6.1 Strategies for maximising the use of systemic treatments prior to targeted

immunomodulatory medications 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 therapies available:

Adalimumab Ixekizumab Brodalumab Risankizumab Certolizumab Secukinumab Tildrakizumab Etanercept Guselkumab Ustekinumab

Infliximab

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

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6.3. Eligibility criteria for targeted immunomodulatory therapy

Methotrexate and ciclosporin have failed, are not tolerated or are contraindicated (see <u>NICE guidelines CG153</u>).

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-treatment assessments

Refer to local and national guidance for full list of assessments needed pre- targeted immunomodulator therapy. See <u>Appendix 2</u> for BAD guideline suggested schedule for screening and monitoring

6.5 Apremilast/Dimethyl Fumarate

In patients who are contraindicated to or decline biologic therapy or deucravacitinib, consider the use of apremilast or dimethyl fumarate in individuals meeting the required NICE criteria (psoriasis not responded to standard systemic therapies and PASI \geq 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 therapy with reference to Department of Health Guidance.

Generally, immunosuppressants can be started **4 weeks** after administration of a <u>live</u> or <u>live</u> attenuated vaccine. Stop immunosuppressants for at least **3 months** (**12 months** advised for some biologic treatments) before giving **live** vaccines, unless otherwise directed by a specialist. Patients should be counselled on the need to avoid live vaccines and the implication that may have for travelling.

Refer to the drug-specific <u>SPC</u> and Green Book (immunisation against infectious disease; <u>Chapter</u> 6) for further information.

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

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Inactivated vaccines are safe to administer concurrently with immunosuppressants; however, where possible, inactivated vaccines should be administered at least 2 weeks before starting therapy to ensure optimal immune responses.

Consider checking varicella serology prior to biologic therapy. Patients with absent or low immunity to varicella can consider varicella vaccination (e.g. Shingrix® inactive recombinant vaccine if already on systemic immunosuppressant agent) although this may not be available via local NHS pathways (as per the Green Book Chapter 28a).

While on immunosuppressant therapy, patients should be advised to receive the pneumococcal polysaccharide vaccine (PPV), 'inactivated' influenza vaccine (annual) and Covid-19 vaccine (in line with current guidance; Green Book, Chapter 14). The GP should be asked to ensure that the patient is flagged as being on immunosuppression and requiring vaccination according to Department of Health Guidance. 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.

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

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

- The scheme must not replace or override the agreed pathway and the FOC drug should only be considered if pathway options are exhausted or not clinically appropriate.
- Treatment must be funded at negligible cost to the Trust and zero cost to NHS commissioners until the end of the agreed implementation period in the positive NICE Technology Appraisal guidance.
- Continue to fund treatment in the event of a negative NICE Technology Appraisal Guidance until:
 - 90 days after a future positive NICE Technology Appraisal Guidance
 - The dermatologists consider it no longer clinically appropriate to continue the drug.

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 All schemes require sign off in each NHS Trust and this usually requires the Chief Pharmacist, the Pharmacy Procurement Lead and Director of Finance to authorise the scheme.

For more detail refer to the principles outlined within the <u>Free of Charge Schemes - National</u> Recommendations for Local Systems⁷ by NHS England.

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

10. Method of medication supply

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

Subject to local arrangements and eligibility guidelines, in order to reduce the time to initiation, the first doses (2-4 weeks supply) may be given in the infusion suite or dermatology day centre as part of an outpatient 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.

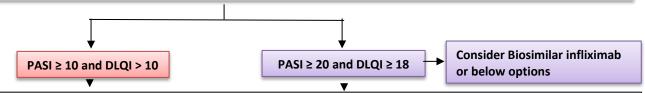
11. Biosimilars

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 <u>position statement</u>. 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 Immunomodulator

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



Consider Factors Affecting Choice

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

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

FIRST CHOICE Adalimumab Consider certolizumab for women planning conception Consider deucravacitinib (needle phobia, need for short half-life) SECOND CHOICE IL12/23 p40: Ustekinumab IL17A or IL17RA: Ixekizumab/secukinumab /brodalumab IL17A/IL17-F: Bimekizumab IL23p19: Guselkumab/ risankizumab/ tildrakizumab TYK2: Deucravacitinib (oral) Consider biosimilar etanercept when biologic agent with short half-life preferable Assess response (usually around 16 weeks see NICE time points below) and then as clinically indicated in the first year (for example 6 monthly). Annual review thereafter may be appropriate for patients on monotherapy 12 weeks 16 weeks 16- 24 weeks 28 weeks 10 weeks Brodalumab Adalimumab Deucravacitinib Tildrakizumab Infliximah Etanercept Bimekizumab Ixekizumab Certolizumab Secukinumab Guselkumab Risankizumah Ustekinumah

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

Refer to section 14 for dose escalation information for each drug. If appropriate response **NOT ACHIEVED** discontinue treatment and consider 2nd line therapy

South Ea



13. Initiation of Second line and Subsequent options

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

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

Reasons for discontinuation:

- Psoriasis not responded to first targeted immunomodulator as defined in NICE technology appraisals primary failure
- Psoriasis initially responded but subsequently lost the response; secondary failure
- First drug cannot be tolerated or becomes contraindicated

Offer any of the currently licensed and NICE approved targeted immunomodulatory medications when psoriasis has not responded to a first line targeted therapy

disease severity

Consider:

- dose escalations
- mode of action
- drug cost see appendix 4
- the BAD decision aid and
- consider all factor affecting choice in box ^a above (in section 12)

If TWO or MORE Immunomodulator 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. deucravacitinib, apremilast, dimethyl fumarate, inpatient topical therapy, phototherapy or standard systemic therapy)

When choosing therapy

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

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

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

14. Dose escalation

Dose escalation should be considered when

- there has been an inadequate primary response due to insufficient dosing e.g. in patients who are obese or whose psoriasis relapses during the treatment cycle.
- for patients with very severe disease who have achieved NICE response criteria during induction dosing, but will require escalated dosing to maintain response during maintenance therapy
- where therapeutic drug monitoring indicates inadequate drug exposure
- Take into account escalated dosing may be associated with an increased risk of infection, and, depending on the drug (e.g. ustekinumab and infliximab), off license. Patients should be informed if treatment is off-license and counselled on the risks and benefits of this.

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

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

Biologic agent	Dose escalation	Licensed Use
Adalimumab 40mg every other week	Adalimumab 40mg weekly for 12 weeks and review	Yes
Bimekizumab 320mg every 8 weeks	Bimekizumab 320mg every 4 weeks (>120kg)	Yes
Certolizumab 200mg every 2 weeks	Certolizumab 400mg every 2 weeks for 12 weeks and review	Yes
Etanercept 50mg once weekly	Etanercept 50mg twice weekly for 12 weeks and review	Yes
Guselkumab 100mg every 8 weeks	Guselkumab every 4 weeks in those who meet the <u>PSA criteria</u> on discussion with rheumatology where the indication is listed as PSA	Yes

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Infliximab 5mg/kg every 8 weeks	Infliximab 5mg/kg every 6 weeks for 24 weeks and review	No
Secukinumab 300mg ever month	Secukinumab 300mg every 2 weeks (>90kg)	Yes
Ixekizumab 80 mg every 4 weeks	Ixekizumab 80 mg every 2 weeks	No
Tildrakizumab 100 mg every 12 weeks	Tildrakizumab 200 mg every 12 weeks (high disease burden or ≥ 90 kg) for 28 weeks and review	Yes
Ustekinumab 45mg every 12 weeks (<100kg)	Ustekinumab 90mg every 8 or 12 weeks (<100kg)	No No
Ustekinumab 90mg every 12 weeks (>100kg)	Ustekinumab 90mg every 8 weeks (>100kg) for 24 weeks and review	No

15. Special Populations

15.1 High Impact Sites not meeting NICE criteria

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

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

See Appendix 5 for more information on disease scores

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

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

15.1.2 Pustular Psoriasis

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

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

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

15.2 Patients with concurrent skin & Joint disease

Refer to SEL Guideline "<u>Treatment of Seronegative spondyloarthropathy biologic drug treatment pathway</u>" 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 <u>Key Performance Indicators</u> agreed by South East London Integrated Medicines Optimisation Committee. The Dermatology and Pharmacy Departments may undertake separate clinical audits as part of their annual clinical audit plan.

17 Supporting documents (see relevant local guidelines)

British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017

British Association of Dermatologists guideline for biologic therapy for psoriasis 2020: a rapid update

<u>Liver Assessment and Management Pathway in Immune-Mediated Inflammatory Diseases</u> – Guy's and St Thomas' NHS Foundation Trust, August 2019

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Supplementary Information: Recommendations on safe prescribing of BIOLOGICS (Taken

from BAD Biologics guidelines for psoriasis 2020)

Not applicable for deucravacitinib, please refer to the <u>product information</u> and relevant JAKi sections of the <u>Treatment Pathway for Adults with Moderate to Severe Atopic Dermatitis</u> may provide additional information which will help to guide use of TYK2 Inhibitors.

1. Transitioning to or between biologic therapies

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

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

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

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

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

2. Conception and Pregnancy

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

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

- the importance of controlling severe or unstable psoriasis to maintain maternal health
- that most of the available evidence relates to TNF antagonists in women with rheumatological or inflammatory bowel disease
- that most pregnancies reported in women exposed to TNF antagonists at conception and/or during pregnancy have successful outcomes, with no increase in stillbirths, congenital malformations, preterm births or neonatal infections

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- that exposure to TNF antagonists during pregnancy may increase the risk of maternal infection
- that maternal IgG, and therefore biologic drugs currently licensed for psoriasis (with the exception
 of certolizumab pegol), is actively transferred to the developing fetus during the second and third
 trimester and that the impact of this on neonatal development and risk of infection has not been
 adequately studied
- that certolizumab pegol transfer across the placenta is low or negligible
- that live vaccines must be avoided for the first 6 months of life of infants born to mothers taking biologic therapy beyond 16 weeks' gestation
- relevant patient information resources.

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

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

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

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

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

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

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3. Biologic therapy and cancer risk

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

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

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

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

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

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

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

4. Biologic therapy and infections

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

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

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

- Test for hepatitis B (surface antigen and core antibody), hepatitis C (IgG) and HIV (HIV-1 and HIV-2 antibodies and HIV-1 antigen) infection in people starting biologic therapy
- Consider ongoing screening (e.g. annually) for hepatitis B, hepatitis C and HIV, particularly
 in people who belong to a group at increased risk of infection
- Retest for viral hepatitis in any person who develops unexplained transaminitis (raised alanine aminotransferase and/or aspartate aminotransferase); retest for HIV infection in any person who has symptoms or other conditions that might represent HIV seroconversion/infection.

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- 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-bycase basis; be aware that severe psoriasis can occur in people with uncontrolled HIV infection. Involve relevant specialists and ensure HIV viral load is suppressed on ART before considering biologic therapy.
- Test for varicella zoster (VZ) virus antibody in people with a negative or uncertain history for chickenpox; consider varicella vaccination in those who are not varicella immune and seek expert advice. Be aware of the indications for post-exposure prophylaxis in VZsusceptible individuals with VZ immunoglobulin or oral acyclovir/valaciclovir.

6. Use of biologic therapy and tuberculosis

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

7. Important contraindications to biologic therapies

- Do not use TNF antagonists in people with demyelinating diseases and review alternative interventions in people who have an affected first-degree relative with demyelinating disease.
- Stop treatment and seek specialist advice if neurological symptoms suggestive of demyelinating disease develop during TNF antagonist therapy. Symptoms include loss or reduction of vision in one eye with painful eye movements; double vision; ascending sensory disturbance and/or weakness; problems with balance, unsteadiness or clumsiness; altered sensation travelling down the back and sometimes into the limbs when bending the neck forwards (Lhermitte symptom); please see NICE guidelines NG220
- 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.

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- Stop TNF antagonist therapy in the event of new or worsening pre-existing heart failure and seek specialist advice.
- Exercise caution and consult a gastroenterology specialist before using brodalumab, ixekizumab or secukinumab in people with inflammatory bowel disease.
- In people undergoing elective surgery balance the risk of postoperative infection against the risk of developing severe or unstable disease by stopping biologic therapy Advise stopping biologic therapy 3–5 times the half-life of the drug in question or the length of the treatment cycle (whichever is longer) between the last dose of therapy and the planned surgery. Inform the surgical team that the patient may be at a higher risk of infection postoperatively. Restart biologic therapy postoperatively if there is no evidence of infection and wound healing is satisfactory.



Practical Points for Primary Care

1. Identification of patient on a targeted immunomodulatory medication

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 targeted immunomodulatory medication.

2. Vaccinations

Do not give live vaccines to people on a targeted immunomodulatory medication 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 targeted immunomodulatory medicines.

Patients should receive annual influenza vaccine (intramuscular only) COVID-19 booster 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 targeted immunomodulatory medications 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 one of these medicines 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 a targeted immunomodulatory medication 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.

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

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Appendix 1

Service Quality Standards

Service	Statement	Supporting Evidence
Quality		
Standard		
1	Initiation and supervision of targeted	R1 2017 BAD biologics guidelines
	immunomodulatory therapy for people with psoriasis	
	should be undertaken by specialist Physicians	Quality Statement 3
	experienced in the diagnosis and treatment of	NICE quality standards for psoriasis
	psoriasis.	
2	Arrangements for drug administration, monitoring	R1 2017 BAD biologics guidelines
	and follow-up should be agreed between health	
	carers and the person receiving treatment, utilising	R2 2017 BAD biologics guidelines
	the support and expertise of a multidisciplinary team	
	e.g. clinical nurse specialists and specialist	R8 2017 BAD biologics guidelines
	pharmacists following locally agreed protocols.	
		Quality Statement 6
		NICE quality standards for psoriasis
3	Provision of therapy via Homecare services is	DH Report- Homecare Medicines
	overseen by an appropriate group within each trust,	"Towards a vision for the future"
	accountable to the Chief Pharmacist.	November 2011.
	All medicines ordered via homecare services are	
	clinically screened and processed via pharmacy.	



Appendix 2 BAD Suggested schedule for screening and monitoring

Table S3: SUGGESTED MONITORING for Biolo	SCHEDULE FOR SCREENING AND ogic Therapies.	Baseline ¹	Monitoring ^l
*For Deucravacitinib (1	TYK2 inhibitor) follow Screening and		
Monitoring outlined fo	r JAKi therapy in the Atopic Dermatitis		
Treatment Pathway- no	ot subject to MHRA drug safety update.		
History/symptom enqui	ry		
Psoriasis	Disease phenotype including involvement of nails and high-impact sites; course (stable/unstable); response & adverse effects to prior therapies	Yes	Ongoing
Psoriatic arthritis	Screen for psoriatic arthritis (e.g. using the PEST questionnaire); for people with psoriatic arthritis symptom enquiry to assess control	Yes	Every 12 months
Identification of contraindications to therapy and/or development of therapy-induced toxicity	Thorough history, symptom enquiry, conception plans and family history (and lifestyle regarding infection risks?)	Yes	Every 6-12 months
Infection	Any past or current chronic infection including tuberculosis, candidiasis Identify risk factors for tuberculosis, hepatitis B, C and HIV	Yes	At least every 6-12 months
	Ascertain history for chickenpox		N/A
Alert card ^{IV}	Ensure people on an Anti- TNF carry an alert card with them at all times in line with MHRA guidance- available from via the product SPC	Yes	At each review appointment
Cardiovascular assessment ^v	Include symptom enquiry about heart failure [NYHA III. Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation or dyspnoea. NYHA IV. Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.]	Yes	Clinical assessment at least every 6- 12 months
Neurological assessment ^v	Past or current history or symptoms of demyelinating disease ^V	Yes	At least every 6-12 months
Gastrointestinal assessment ^{VI}	Past of current history or symptoms of inflammatory bowel disease	Yes	At least every 6-12 months
Malignancy	Any past or current malignancy (including skin cancer)	Yes	At least every 6-12 months

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	Ensure concordant with national cancer		
	screening programmes		
	Gynaecological review of patients with history of cervical dysplasia		
BADBIR	Offer the opportunity to participate	Yes	Every 6-12 months (to complete follow-up data)
Clinical assessments			
Psoriasis disease severity	Goal of therapy, e.g. a PGA of clear or nearly		
assessment	clear	V	To establish disease response;
	PASI (or BSA if PASI not applicable)	Yes	every 6-12 months thereafter
	DLQI		
Skin cancer	Full skin examination	Yes	As indicated by risk at baseline and in the context of immunosuppression
Psoriatic arthritis	Consult with a rheumatologist	Yes	To establish disease response; at least every 6-12 months thereafter and/or as clinically indicated
General physical	To identify contra-indications to therapy	Yes	As indicated by history/symptom
examination	and/or development of therapy-induced toxicity		enquiry
Investigations			
Blood tests	Full blood count; creatinine and electrolytes; liver function tests		At 3-4 months; at least every 6-12 months thereafter and/or as clinically indicated
	Hepatitis B (surface antigen and core antibody) hepatitis C (IgG)		If clinically indicated, e.g. transaminitis (raised ALT and/or AST), or ongoing (annually) in people who belong to a group at increased risk of infection ^{III}
	Human immunodeficiency virus (HIV-1 and HIV-2 antibody, and HIV-1 antigen)	Yes	If clinically indicated, e.g. symptoms of seroconversion, or ongoing (annually) in people who belong to a group at increased risk of infection ^{III}
	Autoantibodies (anti-nuclear antibodies, anti- nuclear double-stranded DNA antibodies)		If symptoms or signs suggest development of autoimmune phenomena, e.g. transaminitis (raised ALT and/or AST)
	Test for varicella zoster virus antibody in people with a negative or uncertain history for chickenpox		Consider varicella vaccination in those who are not varicella-immune and seek expert advice; although this may not be available via local NHS pathways

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			(as per the Green Book Chapter 28a). Be aware of the indications for using VZ immunoglobulin in VZ-susceptible individuals ^{vII}
Tuberculosis	Interferon-gamma release assay and chest X-ray		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		,

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

Consultation Process for the latest review:

South East London Dermatology Pathway Group (See Authors) – July 2024 South East London Integrated Medicines Optimisation Committee – August 2024

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[&]quot; https://cdn.bad.org.uk/uploads/2021/12/29200150/The-PEST-screening-questionnaire-updated-aug-2013-v5.pdf

BAD 2020 rapid update implementation tool kit. Table S5: <u>Groups at increased risk of tuberculosis</u>, hepatitis B, hepatitis C and HIV

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

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

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

VII Chapter 34 (publishing.service.gov.uk)



Appendix 3

Please find the most up to date decision aid on the link below.

<u>DECISION AID</u> – BIOLOGIC THERAPY FOR PSORIASIS This is a decision aid to help clinicians and patients decide their treatment choice and not a comprehensive data source or replacement for the individual drug Summary of Product Characteristics. © 2023 BRITISH ASSOCIATION OF DERMATOLOGISTS

Appendix 4

Drug costs

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

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

Prices are correct as of April 2024 and may be subject to change.

Drug	Mode of action	Route of administration	Maintenance dose	Cost tier
Adalimumab best value biologic	Anti-TNF	Subcutaneous	40mg every 2 weeks	£
Adalimumab best value biologic dose escalation	Anti-TNF	Subcutaneous	40mg every week	£
Infliximab biosimilar*	Anti-TNF	Intravenous	5mg/kg every 8 weeks	£ plus IFT
Infliximab biosimilar* dose escalation	Anti-TNF	Intravenous	5mg/kg every 6 weeks	£ plus IFT
Etanercept biosimilar	Anti-TNF	Subcutaneous	50mg weekly/25mg twice weekly	£
Deucravacitinib	TYK2 inhibitor	Oral	6mg daily	££
			100mg every 8 weeks (100mg every 4 weeks dose escalation at no extra	
Guselkumab	IL-23 inhibitor	Subcutaneous	cost^)	££

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Tildrakizumab	IL-23 inhibitor	Subcutaneous	100mg every 12 weeks (200mg dose escalation at no extra cost)	££
Etanercept biosimilar dose escalation	Anti-TNF	Subcutaneous	50mg twice weekly	££
Ixekizumab	IL-17 inhibitor	Subcutaneous	80mg every 4 weeks	££
Risankizumab	IL-23 inhibitor	Subcutaneous	150mg every 12 weeks	££
Brodalumab	IL-17 inhibitor	Subcutaneous	210mg every 2 weeks	£££
Secukinumab	IL-17 inhibitor	Subcutaneous	300mg every month (300mg alternate weeks for 90kg or over at no extra cost)	£££
Bimekizumab	IL-17A/IL-17F inhibitor	Subcutaneous	320mg every 8 weeks	£££
Certolizumab	Anti-TNF	Subcutaneous	200mg every 2 weeks (400mg escalation at no extra cost)	£££
Ustekinumab	IL-12/23 inhibitor	Subcutaneous	45mg or 90mg every 12 weeks	£££
Ustekinumab dose escalation	IL-12/23 inhibitor	Subcutaneous	45mg or 90mg every 8 weeks	££££
Bimekizumab dose escalation	IL-17 inhibitor	Subcutaneous	320mg every 4 weeks (for 120kg or over)	££££
Ixekizumab dose escalation	IL-17 inhibitor	Subcutaneous	80mg every 2 weeks	££££

Notes:

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

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^{*}based on 80kg patient, ^Guselkumab escalated dose is as per NICE TA815 for patients with concomitant psoriatic arthritis



Appendix 5

High impact sites disease severity measurement tools:

PSSI or Adjusted PASI Score for High Impact Sites

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



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

Affix Hospital Label			<u>Date:</u>							
	Score	0	1	1 2		3	4	5	6	
	Erythema Induration Scaling	none	slight	moderat	е	severe	very severe			
	Area %	0	1-9	10-29		30-49	50-69	70-89	90-100	
					Oth	Scalp/ er:				
			Erythema (E)							
			Induration (I)							
			Scaling (S)							
			Sum = E+I+S							
			Area Sum x Area = Total =							
Globa	l Evaluation Sco	re (circle)								
Very S	evere	*Severe*	*Mo	derate*	+	'Mild*	*Almost Clear	r* *Cl	lear*	

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ppPASI

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

Affix Hospi	ital Label					<u>Date:</u>			
Score	0	1	2 3		4		5	6	
Erythema Pustules	none	slight	moderate	severe	`	very			
Desquamation	Horic	Silgrit	moderate	Jevere	•	severe			
Area %	0	1-9	10-29 30-49			50-69	70-89	90-100	
7 4 5 4 7 5									
	L	eft Palm	Right Pa	alm		Left Sole	R	ight Sole	
				1					
Erythema (E)									
Pustules (P)									
Desquamation(D)									
Sum = E+I+S									
Guill - E111G							L		
Area									
Sum x Area =									
		X 0.2	X 0.2			X 0.3		X 0.3	
Total =									
ppPASI Score Total = Total Left Palm									
+ Total Right Palm									
+ Total Left Sole									
+ Total Right Sole =									
Global Evaluation Score (circle)									

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Very Severe

Severe

Moderate

Mild

Almost Clear



NAPSI

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

How to perform the target nail NAPSI:

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

Nail quadrant									
Nail Matrix:	Tick box if criteria is present for each quadrant assessed								
Pitting		P. 555111 151 55111 1							
Leukonychia									
Red Spots in the lunula									
Nail plate crumbling									
Nail Bed	Tick box if criteria i	s present for each q	uadrant assessed						
Onycholysis									
Splinter haemorrhage									
Oil drop (salmon patch)									
Nail bed hyperkeratosis									
Total score / nail quadrant* (0 - 8)									

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Sum of total nail quadrant scores (0 - 32) =

* Each tick equates to a score of 1.

DLQI



⊗A Y Finlay, G K Khan April 1992 www.dermatology.org.uk

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

Dermatology Life Quality Index (DLQI)

Date:

DI OI Score:

HO	spital No.	Date.		DEGLE	core.	
Na	me:					
	The aim of the questionnaire is to n OVER THE LAST WE					fe
	Over the last week, how itchy, sore tinging has your skin been?	e, painful	Very much A lot A little Not at all			
	Over the last week, how embarrass f-conscious have you been because 1?		Very much A lot A little Not at all			
inte	Over the last week, how much has y rfered with you going shopping or lo er your home or garden?		Very much A lot A little Not at all		Not relevant	
	Over the last week, how much has y lenced the clothes you wear?	your skin	Very much A lot A little Not at all		Not relevant	
	Over the last week, how much has yeted any social or leisure activities?		Very much A lot A little Not at all		Not relevant	
	Over the last week, how much has y de it difficult for you to do any sport?		Very much A lot A little Not at all		Not relevant	
	Over the last week, has your skin poor from working or studying?	revented	Yes No		Not relevant	
	lo', over the last week how much has been a problem at work or studyin		A lot A little Not at all			
	Over the last week, how much has yated problems with your partner or a se friends or relatives?		Very much A lot A little Not at all		Not relevant	
	Over the last week, how much has y sed any sexual difficulties?	your skin	Very much A lot A little Not at all		Not relevant	
has	Over the last week, how much of a the treatment for your skin been, for making your home messy, or by takin	r example	Very much A lot A little Not at all		Not relevant	

Approval date: July 2024 Review date: July 2025 (or sooner if evidence or practice changes)



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