

## South East Regional Medicines Optimisation Group (SERMOG) policy recommendation

<b>Title:</b>	High cost drug pathway for adults with psoriasis
<b>Number:</b>	SERMOG-10
<b>Category:</b>	Treatment pathway
<b>Date determined by SERMOG:</b>	September 2025

### Introduction

This pathway is a guideline for the initiation and maintenance of high cost drugs (biologics and small molecules) for the treatment of plaque psoriasis in adults. These treatments, with the exception of infliximab<sup>1</sup>, are recommended under NICE Technology Appraisal (TA) guidance for patients who have moderate-severe psoriasis, defined as a Psoriasis Area and Severity Index (PASI) score of 10 or more and the Dermatology Life Quality Index (DLQI) score of more than 10, which has not responded to other systemic treatments, including ciclosporin<sup>2</sup>, methotrexate, acitretin and phototherapy, or these options are contraindicated or not tolerated.

The pathway follows NICE TA guidance alongside additional licenced, off-label and unlicenced recommendations for dose escalation considered by the SERMOG. The use of HCDs for the treatment of psoriasis is only approved in line with this pathway and the dosing regimens outlined in Table 3. Any dose regimens outside of these recommendations are not routinely funded, as detailed in SERMOG-02 (Overarching policy on licensed doses or dosing schedules of high-cost drugs not considered in NICE Technology Appraisal (TA) guidance). Where dose escalations are off-label, the guidance for off-label use of HCDs as detailed in Box 1 should be followed. Definitions for terms used in the pathway are set out in Table 2. Where biosimilars are available, these should be used, as detailed in SERMOG-03 (Overarching policy on switching between biosimilars).

Additional considerations when choosing treatment options include speed of action, drug factors such as side effects and safety, patient factors such as administration and monitoring requirements, planning pregnancy (see box 2) or breast feeding and concomitant psoriatic arthritis. HCDs also indicated for treatment of psoriatic arthritis are detailed in Table 3. This may be

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<sup>1</sup> Infliximab is only recommended for the treatment of very severe disease as defined by a total Psoriasis Area Severity Index (PASI) of 20 or more and a Dermatology Life Quality Index (DLQI) of more than 18. Patients are also not required to have trialled all other systemic treatments, they must have trialled (or been intolerant or had contraindications to) ciclosporin, methotrexate or PUVA (psoralen and long-wave ultraviolet radiation).

<sup>2</sup> In line with CG153 use the lowest possible therapeutic dose of ciclosporin to maintain remission for up to 1 year. Do not use ciclosporin continuously for more than 1 year unless disease is severe or unstable and other treatment options, including targeted immunomodulatory treatments, cannot be used. If a patient has trialled all other applicable systemic treatments, they may progress to targeted immunomodulatory treatments without requirement to await relapse from withdrawal of ciclosporin.

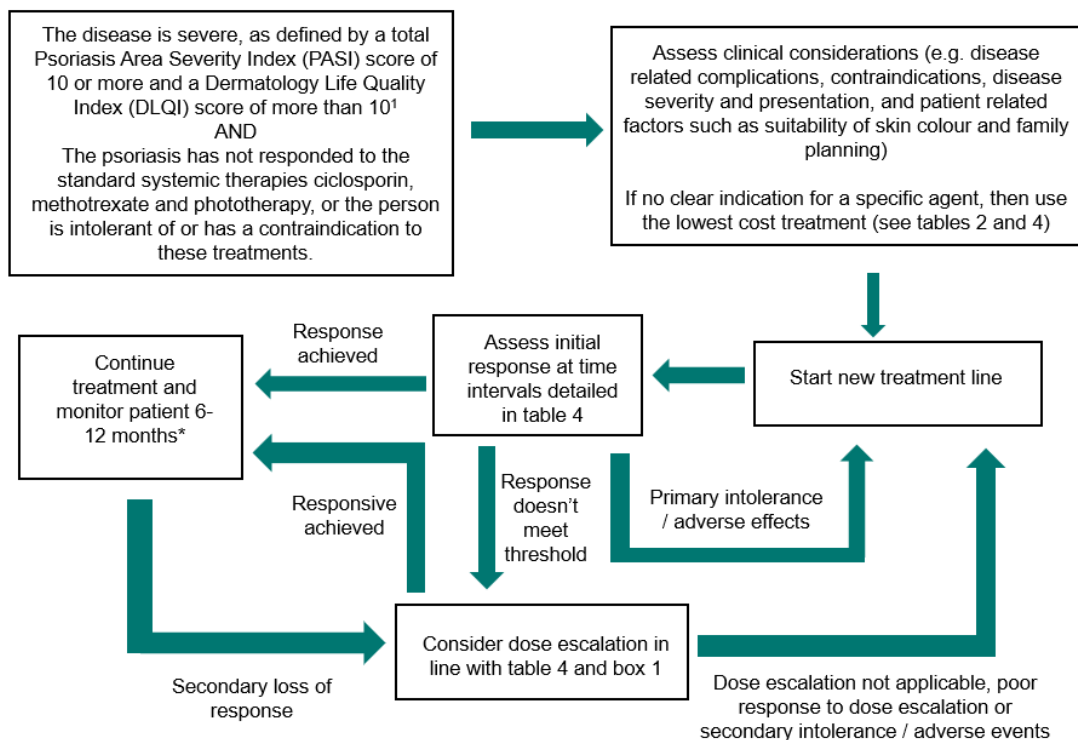
reviewed alongside SERMOG-09 - high-cost immunomodulator drug pathway for adults with psoriatic arthritis.

The most appropriate treatment should be chosen after discussing the advantages and disadvantages of the treatments available with the person having treatment. If patients and clinicians consider more than one treatment to be suitable, choose the least expensive treatment (taking into account drug administration costs, dose needed and frequency, and product price per dose). Treatments are ordered by cost (based on acquisition and administration costs in year one) in table 2, with the lowest cost treatments highlighted. The British Association for Dermatologists have developed a [decision aid](#) which may help patients and clinicians decide on treatments<sup>3</sup>.

According to a Regional Medicines Optimisation Committee (RMOC) Advisory Statement on the sequential use of biologic medicines (May 2020), when a treatment fails, guidance from specialist bodies suggests switching to a biologic with a new mechanism of action is more effective than switching within class. The exception to this is secondary failure of TNF alpha treatment due to formation of anti-drug antibodies (tested where available), in which case switching within class may be a valid treatment option. It is considered there are currently 7 mechanisms of actions in TA recommended high cost drugs for the treatment of psoriasis. In situations where the appropriateness of further treatment options is undecided, a peer multidisciplinary team discussion may be helpful.

Any new high cost drug (HCD) which receives a positive recommendation from NICE between document iterations will be approved through local ICB processes and will be included in future pathway updates.

**Figure 1. High cost drug pathway for psoriasis**



\* Monitoring may be less frequent if the patient is stable on treatment and the clinician deems it suitable

<sup>3</sup> Please note this does not include all current TA recommended drugs.

**Table 1. Pathway definitions and actions**

Description	Definition	Action
Response meets threshold	A timepoint defined in table 4 one of the following is achieved: <ul style="list-style-type: none"> <li>• A 75% reduction in PASI<sup>4</sup> score from when treatment started OR</li> <li>• A 50% reduction in PASI score and a 5 point reduction in the DLQI<sup>5</sup> from when treatment started</li> </ul>	Continue treatment, monitor every 6-12 months*
Response does not meet threshold	Level of improvement does not meet the thresholds above at the timepoint specified in table 4. This includes primary non response and partial response.	Dose escalate or switch mode of action.
Secondary loss of response	Where the improvement meets initial thresholds, but this response is lost over time.	Dose escalate or switch mode of action.
Primary intolerance or adverse events	Where treatment is discontinued within the initial time period specified in table 4 due to inability to tolerate side-effects of treatment	If class specific or a severe adverse event change to a new mode of action. Otherwise consider changing to another option from the same treatment line.
Secondary intolerance or adverse events	Where treatment is discontinued outside of the initial time period specified in table 3 due to inability to tolerate side-effects of treatment	Change to a new mode of action <sup>6</sup> .

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<sup>4</sup> Take into account how skin colour could affect the PASI score and make any adjustments needed.

<sup>5</sup> 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 DLQI and make any adjustments they consider appropriate.

<sup>6</sup> The exception to this is secondary failure of TNF alpha inhibitor treatment due to formation of anti-drug antibodies, in which case switching within class may be a valid treatment option.

**Table 2. Drug treatment options (In cost order<sup>7</sup> by mode of action with the lowest acquisition cost option highlighted)**

Mode of action		Drug	Method of administration
TNF alpha inhibitor		Adalimumab	Subcutaneous (SC) injection
		Infliximab <sup>1</sup>	<ul style="list-style-type: none"> <li>Intravenous injection (IV)</li> <li>SC</li> </ul>
		Etanercept	SC
		Certolizumab	
Interleukin (IL) inhibitor	IL 12/23	Ustekinumab	SC
	IL 17	Brodalumab	
		Bimekizumab	
		Ixekizumab	
		Secukinumab	
	IL 23	Guselkumab	
		Tildrakizumab	
Risankizumab			
Fumaric acid ester		Dimethyl fumarate	Oral
Phosphodiesterase (PDE4) inhibitor		Apremilast	
TYK2 inhibitor		Deucravacitinib	

### Box 1. Using off-label dose escalations

The use of licenced dosing of high-cost drugs (HCD) including biologics and small molecules for the treatment of psoriasis is the preferred treatment option. However, it is acknowledged that there are instances where off-label dose escalation may be most clinically appropriate for the individual.

The use of off-label dose escalations as detailed within the SER psoriasis HCD pathway is supported if all the following criteria are met, response is monitored and treatment discontinued if adequate response is not achieved. The prescribing doctor must take responsibility for prescribing the medicine and for overseeing the patient’s care, monitoring, and any follow up treatment.

**Criteria for use**

- Treatment response is not sufficient despite escalated dosing in line with the licenced, locally approved or TA recommended escalations.
- There is consensus at MDT (or local equivalent) that off-label dose escalation is the most clinically appropriate treatment option for the individual.
- If escalating anti-TNF medications, where antibody testing is available, the results are indicative that treatment escalation has a good chance of therapeutic effect
- There is clear reasoning for continuing the current treatment over switching to another treatment option (e.g. response has been previously achieved, and it is considered likely that escalation will recapture response)

<sup>7</sup> Considering drug acquisition and administration cost in first year

- The individual has optimised concomitant treatment where appropriate
- There is recorded informed consent from the individual being treated

### Assessment of response

- Response should be assessed in line with the TA recommended initial treatment interval (e.g. if NICE recommends response is assessed 12 weeks after initiation, response should be assessed 12 weeks after dose escalation is initiated).
- If a significant improvement has not been achieved (a 75% reduction in the PASI score from when treatment first started [PASI 75] or a 50% reduction in the PASI score [PASI 50] and a 5-point reduction in DLQI from when treatment started) treatment should be stopped and the individual switched to an alternative treatment option (if available)
- If the individual responds at the initial assessment interval, response should be re-assessed at six months.
- If there has been a secondary loss of response, then treatment should be stopped and the individual switched to an alternative treatment option

### De-escalation

- If the individual is in remission (PASI100) at six months, de-escalation to licenced doses should be considered. If it is not deemed clinically appropriate to de-escalate, this should be recorded and re-assessed at regular intervals.

### Monitoring

- The use of off-label dose escalations should be recorded. This record should include details on approval, response, outcomes and adverse events.

## Box 2. Information on treatment during 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.

Certolizumab is considered to be compatible with all three stages of pregnancy. Other Anti-TNF medications, such as infliximab, adalimumab and etanercept, may be used during early pregnancy. However, it is recommended they should be stopped during the 2<sup>nd</sup> or 3<sup>rd</sup> trimester if there is a low risk of disease flare.

Consideration should be given to stopping IL17 and IL12/23 drugs at conception. They should only be used during pregnancy if disease is severe and no alternatives are available. JAK inhibitors should be stopped 2 weeks or more before pregnancy.

Patients who stop therapy during pregnancy should be re-loaded with biological therapy soon after delivery.

Further information on the use of drugs in pregnancy can be found from the [UK teratology information service](#), the [British Society for Rheumatology](#) and individual drug [SPCs](#).

**Table 3. TA recommendations and other approved dosing regimens (licenced, unless otherwise indicated)**

Treatment	TA	Biosimilar available	Also licenced for psoriatic arthritis	Continuation assessment (weeks)	Initiation and Maintenance dose	Approved dose escalations
Adalimumab	<a href="#">TA146 (2008)</a>	✓	✓	16	<ul style="list-style-type: none"> <li>80 mg dose at week 0, then 40mg at 1 week</li> <li>Every other week thereafter</li> </ul>	<ul style="list-style-type: none"> <li>40mg weekly</li> <li>80mg every other week</li> </ul>
Infliximab <sup>1</sup>	<a href="#">TA134 (2008)</a>	✓	✓	10	<ul style="list-style-type: none"> <li>5mg/kg at weeks 0, 2 and 6</li> <li>Every 8 weeks thereafter</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Etanercept	<a href="#">TA103<sup>8</sup> (2006)</a>	✓	✓	12	<ul style="list-style-type: none"> <li>25mg twice weekly</li> <li>50mg weekly</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Certolizumab	<a href="#">TA574 (2019)</a>	x	✓	16	<ul style="list-style-type: none"> <li>400 mg at weeks 0, 2 and 4</li> <li>200mg every 2 weeks thereafter</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Ustekinumab	<a href="#">TA180 (2017)</a>	✓	Only when TNF alpha inhibitors have failed	16	<ul style="list-style-type: none"> <li>Dosing at weeks 0 and 4, then every 12 weeks thereafter</li> <li>45 mg for people who weigh 100 kg or less, and 90 mg for people who weigh over 100 kg.</li> </ul>	<ul style="list-style-type: none"> <li>8 weekly (off-label)</li> <li>10 weekly (unlicenced)</li> <li>90mg every 12 weeks (people &lt;100kg, off label)</li> </ul>
Brodalumab	<a href="#">TA511 (2018)</a>	x	x	12	<ul style="list-style-type: none"> <li>210 mg at weeks 0, 1 and 2.</li> <li>Then every 2 weeks thereafter</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>

<sup>8</sup> Efalizumab was also recommended under this TA, but it is no longer available in the UK

Treatment	TA	Biosimilar available	Also licenced for psoriatic arthritis	Continuation assessment (weeks)	Initiation and Maintenance dose	Approved dose escalations
Bimekizumab	<a href="#">TA723</a> (2021)	x	✓	16	<ul style="list-style-type: none"> <li>• 320 mg at week 0, 4, 8, 12 and 16</li> <li>• Every 8 weeks thereafter</li> </ul>	<ul style="list-style-type: none"> <li>• 320mg every 4 weeks for patients weighing ≥120kg without complete skin clearance at week 16</li> </ul>
Ixekizumab	<a href="#">TA442</a> (2017)	x	✓	12	<ul style="list-style-type: none"> <li>• 160mg at week 0, then 80 mg every 2 weeks until week 12</li> <li>• 80 mg every 4 weeks thereafter</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Secukinumab	<a href="#">TA350</a> (2015)	x	✓	12	<ul style="list-style-type: none"> <li>• 300mg at weeks 0,1, 2 and 3 and 4</li> <li>• Monthly dosing thereafter</li> </ul>	<ul style="list-style-type: none"> <li>• 300mg every 2 weeks for patients weighing ≥90kg</li> </ul>
Guselkumab	<a href="#">TA521</a> (2018)	x	✓	16	<ul style="list-style-type: none"> <li>• 100mg at weeks 0 and 4</li> <li>• 100 mg every 8 weeks thereafter</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Tildrakizumab	<a href="#">TA575</a> (2019)	x	x	12-28	<ul style="list-style-type: none"> <li>• 100 mg at weeks 0 and 4</li> <li>• Every 12 weeks thereafter.</li> </ul>	<ul style="list-style-type: none"> <li>• 200mg every 12 weeks for patients with certain characteristics e.g. high disease burden, body weight of 90 kg or more</li> </ul>

Treatment	TA	Biosimilar available	Also licenced for psoriatic arthritis	Continuation assessment (weeks)	Initiation and Maintenance dose	Approved dose escalations
Risankizumab	<a href="#">TA596 (2019)</a>	x	✓	16	<ul style="list-style-type: none"> <li>• 150mg at weeks 0 and 4</li> <li>• Then every 12 weeks thereafter</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Dimethyl fumarate	<a href="#">TA475 (2017)</a>	x	x	16	<ul style="list-style-type: none"> <li>• 30mg daily in week one</li> <li>• 30mg twice daily in week 2</li> <li>• 30mg three times daily in week 3</li> <li>• 120mg daily in week 4 increased weekly to a maximum of 240mg three times daily<sup>9</sup></li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Apremilast	<a href="#">TA419 (2016)</a>	x	✓	16	<ul style="list-style-type: none"> <li>• 10mg titrated to 30mg twice daily over 5 days</li> <li>• 30mg twice daily thereafter</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Deucravacitinib	<a href="#">TA907 (2023)</a>	x	x	16-24	<ul style="list-style-type: none"> <li>• 6mg once daily</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

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<sup>9</sup> Company submission used a dose of 360mg daily. The external assessment group conducted an analysis using 480mg daily, but found this to not be cost-effective.

<b>Version control:</b>
Version 1.0 – Circulated to ICBs for ratification on 26 <sup>th</sup> September 2025
<b>Notes:</b>
<p>This policy recommendation will be reviewed when new information becomes available that is likely to have a material effect on the current recommendation.</p> <p>South East region ICBs will always consider appropriate individual funding requests (IFRs) through their IFR processes.</p>