NHS
North East London

North East London

High-Cost Drugs Pathway

Psoriatic Arthritis Treatment Pathway following the failure of DMARDs

Document detail	
Document type	Clinical pathway
Document name	North East London High-Cost Drugs Treatment pathway for Psoriatic Arthritis
Document location	TBC
Version	1.1
Effective from	May 2022
Review date	May 2024
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Document Version History		
Date	**Version**	**Comment/Changes**
This pathway was designed by the NEL Psoriatic Arthritis working group. The pathway was pre-dated by the East London Health & Care Partnership Psoriatic Arthritis: treatment pathway for patients with inadequate response to DMARDs.		

Contents

Scope

This document outlines the treatment pathway for adult patients in North East London diagnosed with active Psoriatic Arthritis (PsA) and:

- peripheral arthritis with three or more tender joints and three or more swollen joints, **and**
- have not responded to adequate trials of at least two standard disease-modifying antirheumatic drugs (DMARDs), administered either individually or in combination.

It is to be used in conjunction with the National Institute for Health and Care Excellence (NICE) guidance and the published NICE Technology Appraisal (TA) guidance for each individual biologic therapy. The pathway is intended to be adopted by all acute provider Trusts within North East London.

NICE Guidance and Technology Appraisals

At the time of publication, this treatment pathway considers the following NICE guidance: NICE NG65 Spondyloarthritis in over 16s: diagnosis and management.

Table 1: NICE Technology Appraisals for Psoriatic Arthritis

NICE Technology Appraisal Number	Title
TA433	Apremilast for treating active psoriatic arthritis
TA199	Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis
TA445	Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs
TA340	Ustekinumab for treating active psoriatic arthritis
TA220	Golimumab for the treatment of psoriatic arthritis
TA543	Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs
TA537	Ixekizumab for treating active psoriatic arthritis after inadequate response to DMARDs
TA768	Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDs
TA803	Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs
TA815	Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs

At the time of publication, this treatment pathway considers the above NICE TAs

Principles

This document is based on current NICE TAs available for the management of psoriatic arthritis, as well as local agreements which are based on clinical evidence collated by the NEL PsA working group. This prescribing pathway has taken into consideration the Regional Medicines Optimisation Committee (RMOC) Advisory statement on the sequential use of biologic medicines (updated 07 May 2020) to formulate a position which meets the need of patients in the region.

The pathway is subject to change as new evidence, NICE TAs or local agreements are released or updated that will impact on the information outlined in this document. This includes

changes in drug costs that may impact on cost-effectiveness and drug choice in the treatment pathway.

It is expected that where possible, drugs approved for use through a NICE TA are selected in preference to non-NICE approved options. It is also expected that drugs presenting best value are selected where clinically appropriate. For further prescribing information including contraindications and cautions, please refer to the relevant drug monograph in the latest version of the British National Formulary or the respective drug's Summary of Product Characteristics.

Definitions and Lines of therapy

The Psoriatic Arthritis Response Criteria (PsARC) scoring system is used in the assessment and monitoring of PsA. An adequate response is defined as an improvement in at least two of the four PsARC criteria, (one of which has to be joint tenderness or swelling score) with no worsening in any of the four criteria. People whose disease has a Psoriasis Area and Severity Index (PASI) 75 response at 12 weeks but whose PsARC response does not justify continuation of treatment should be assessed by a dermatologist to determine whether continuing treatment is appropriate on the basis of skin response

Taking into consideration the presence of multiple drugs recommended by NICE, the number of lines of therapy has been based on the number of varying mechanisms of actions of the drugs. The drugs are categorised into 5 mechanisms of action which are independent of each other, and we therefore have limited each patient to a maximum of 5 lines of therapy – each to be of a different mechanism of action. *This is except for Certolizumab which, as per NICE TA445, can be used following anti-TNF secondary failure.* Any patient who has exceeded the maximum number of lines will need to exit the treatment pathway. If the responsible clinician deems the patient could still further benefit from treatment, funding will need to be requested via an Individual Funding Request to the patient's ICB.

Primary Failure
The patient's PsA does not demonstrate a response to therapy as outlined in the NICE TA.

Secondary Failure
The patient's PsA initially achieves a response to therapy which is subsequently not sustained, resulting in failure to maintain a response as outlined in the NICE TA.

Adverse Reaction
An adverse drug reaction to a medicine will not count as a line of therapy. However, the patient must have shown a response to therapy for that biologic after the response assessment time for it not to count as a line of therapy. If the patient has the adverse event before the biologic assessment period it will not count as a line of therapy.

Funding

Trusts are required to obtain funding for the use of bDMARDs and tsDMARDs in the management of Psoriatic arthritis via Blueteq prior to starting therapy and for continuation of therapy as described on the Blueteq forms.

With a view to support data-driven care, commissioners will be extracting outcome data from Blueteq. Blueteq must therefore be used for the management of **all funding requests**. This includes recording treatment switches and cessation because of clinical review and/or remission and drug switching for patients who are confirmed or planning for pregnancy.
Where Blueteq is not currently in use by the Trust, an alternative mechanism for requesting funding and monitoring (e.g clinical audit) will be agreed with commissioners.

Patients transferred from out of area or from overseas

For patients who have already commenced on their treatment for PsA:

- If the current treatment is covered by a NICE TA, then the patient can continue their treatment as per the TA.
- If the treatment is not covered by a NICE TA, or this pathway, then an application to IFR must be submitted to continue the funding for therapy.

It is the responsibility of the specialist Rheumatologist to ensure the patient's GP is informed that the patient is receiving treatment with a biologic. It will then be the responsibility of the GP to update a person's medical record with this biologic.

Pathway

Active Psoriatic Arthritis

≥3 tender and ≥3 swollen joints and unresponsive to at least 2 DMARDs (individually or in combination)

Green	Preferred, best value medicine.	**Amber**	To be used when green not suitable.	**Red**	Least cost-effective. To be used when green and amber not suitable.

1st line

Adalimumab, Infliximab, Etanercept,

Certolizumab, Golimumab

If anti-TNF contraindicated:

Apremilast, Tofacitinib

Upadacitinib

Guselkumab, Ixekizumab, Secukinumab, Ustekinumab

Primary failure.
Has the patient demonstrated a response to treatment after [1] 12-14 weeks, [2]16 weeks, [3]16-20 weeks or [4]24 weeks of treatment?

No → (return to 1st line)

Yes

Continue, monitor and review

Secondary failure
Initiate drug with a different mode of action to failed therapy. Patients can be initiated on another drug with a different mode of action to previous therapies to a maximum of 5 lines of therapy.

2nd to 5th line

[1]Adalimumab, [1]Infliximab, [1]Etanercept, [1]Apremilast, [2]Tofacitinib

[1]Certolizumab, [1]Golimumab, [2]Upadacitinib

[1]Guselkumab, [3]Ixekizumab, [2]Risankizumab, [1]Secukinumab, [4]Ustekinumab

Primary failure.
Has the patient demonstrated a response to treatment after [1] 12-14 weeks, [2]16 weeks, [3]16-20 weeks or [4]24 weeks of treatment?

No → (return to 2nd to 5th line)

Yes

Continue, monitor and review

Secondary failure
Initiate drug with a different mode of action to failed therapy. Patients can be initiated on another drug with a different mode of action to previous therapies to a maximum of 5 lines of therapy.

Has the patient received treatment with less than 5 lines of therapy?

Yes → (return to 2nd to 5th line)

No

Exit pathway

Adverse reaction:

A patient can switch biologics due to an adverse reaction **at any point**. However, if the reaction occurs after the biologic response assessment time the patient must have shown an initial response to therapy for it not to count as a line of therapy.

Appendix 1. Drug factors to consider (including modes of action)

The table below provides an approximate drug cost for each biologic based upon first year of therapy, with the loading dose schedule taken into consideration. The cost will vary depending upon commercial arrangements and access to short-term free of charge supplies, which has not been taken into consideration for this guidance.

Mode of Action	Drug Name	Indicated for	TA (other indications)	Reviewed within	Drug cost
Anti-TNF	Adalimumab	Inadequate response to at least 2 previous DMARDs	TA146 – Psoriasis TA187 – Crohn's TA375 – Rheumatoid arthritis TA329 – Ulcerative colitis TA392 – Hidradenitis suppurativa	12 weeks	£
	Certolizumab	Inadequate response to at least 2 previous DMARDs Or Following secondary failure with anti-TNFα	TA574 – Psoriasis TA375 – Rheumatoid arthritis	12 weeks	££
	Etanercept (biosimilar)	Inadequate response to at least 2 previous DMARDs	TA103 - Psoriasis TA375 – Rheumatoid arthritis	12 weeks	£
	Golimumab	Inadequate response to at least 2 previous DMARDs	TA329 – Ulcerative colitis TA225 - Rheumatoid arthritis	12-14 weeks (after 3-4 doses)	££
	Infliximab (biosimilar)	Inadequate response to at least 2 previous DMARDs	TA187 – Crohn's TA 329 - Ulcerative colitis TA134 - Psoriasis TA375 – Rheumatoid arthritis	14 weeks (after 4 doses)	£
Small-molecule inhibitor of phosphodiesterase 4 (PDE4)	Apremilast	Inadequate response to at least 2 previous DMARDs	TA 419 - Psoriasis	16 weeks	£

Mode of Action	Drug Name	Indicated for	TA (other indications)	Reviewed within	Drug cost
IL17 inhibitor	Ixekizumab	Inadequate response to at least 2 previous DMARDs AND Following primary or secondary failure with anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	TA146 – Psoriasis TA718 – Axial spondylarthritis	16 to 20 weeks*	£££
	Secukinumab	Inadequate response to at least 2 previous DMARDs AND Following primary or secondary failure with anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	TA350 - Psoriasis	16 weeks	£££
Janus kinase inhibitor	Tofacitinib	Inadequate response to at least 2 previous DMARDs AND Following primary or secondary failure with anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	TA547 – Ulcerative colitis TA480 - Rheumatoid arthritis	12 weeks	£
	Upadacitinib	Inadequate response to at least 2 previous DMARDs AND Following primary or secondary failure with anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	TA665 - Rheumatoid arthritis	12 weeks	££
IL-12 and IL-23 inhibitor	Ustekinumab	Inadequate response to at least 2 previous DMARDs AND Following primary or secondary failure with 1 or more anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	TA180 – Psoriasis TA633 - Ulcerative colitis	24 weeks	£££
IL-23 inhibitor	Guselkumab	Inadequate response to at least 2 previous DMARDs AND Following primary or secondary failure with anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	TA521 – Psoriasis	16 weeks	£££
IL-23 inhibitor	Risankizumab	Inadequate response to at least 2 previous conventional DMARDs AND	TA596 - Psoriasis	16 weeks	£££

		Following primary or secondary failure with 1 or more biological DMARDs			

**Prices are correct as of January 2022 and may be subject to change*