





North Central London

High Cost Drugs Treatment Pathway

Psoriatic Arthritis Treatment Pathway Following Inadequate Response to DMARDs

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Table of Contents

Introduction	4
Aims	4
NICE Guidance	4
NICE Technology Appraisal Guidance	5
Lines of Therapy	5
Funding	5
Stakeholders	10
Audit	10

Introduction

This clinical pathway outlines the biologic treatment pathway for adult patients with psoriasis. The clinical pathway is to be used in conjunction with NICE Clinical Guidance 65 and the published NICE Technological Appraisals for each of the recommended biologic drugs. The pathway is intended to be adopted by the acute provider trusts within North Central London. Reimbursement for National Tariff excluded Drugs will be in accordance with this pathway.

Aims

The aims of the biologics treatment pathway are;

- 1. To provide a pathway for implementation across NCL allowing consistency of practice in the locality.
- 2. To produce a pathway incorporating the commissioned drugs taking into account the recommendations with the various NICE TAs.
- 3. Providing a guide to support the access to drugs with various mechanisms of actions taking into account patient factors.
- 4. To support the incorporation of biosimilar drugs and use of cost effective drugs first line where clinically appropriate.
- 5. Ensuring equity of access to available treatments in North Central London on the NHS whilst containing spend in an environment with multiple treatment options.
- 6. Enabling the NHS to provide the best quality of care for patients, whilst maximising value for money.

NICE Guidance

Below is a list of the NICE guidance included within this treatment pathway

NICE Guidance 65 – Spondyloarthritis in over 16s: diagnosis and management

NICE Technology Appraisal Guidance

Below is a list of the technology appraisals included within this treatment pathway

- TA433 Apremilast for treating active psoriatic arthritis
- TA445 Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs
- TA340 Ustekinumab for treating active psoriatic arthritis
- TA199 Etanercept, infliximab and adalimumab for the treatment of 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

Lines of Therapy

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.

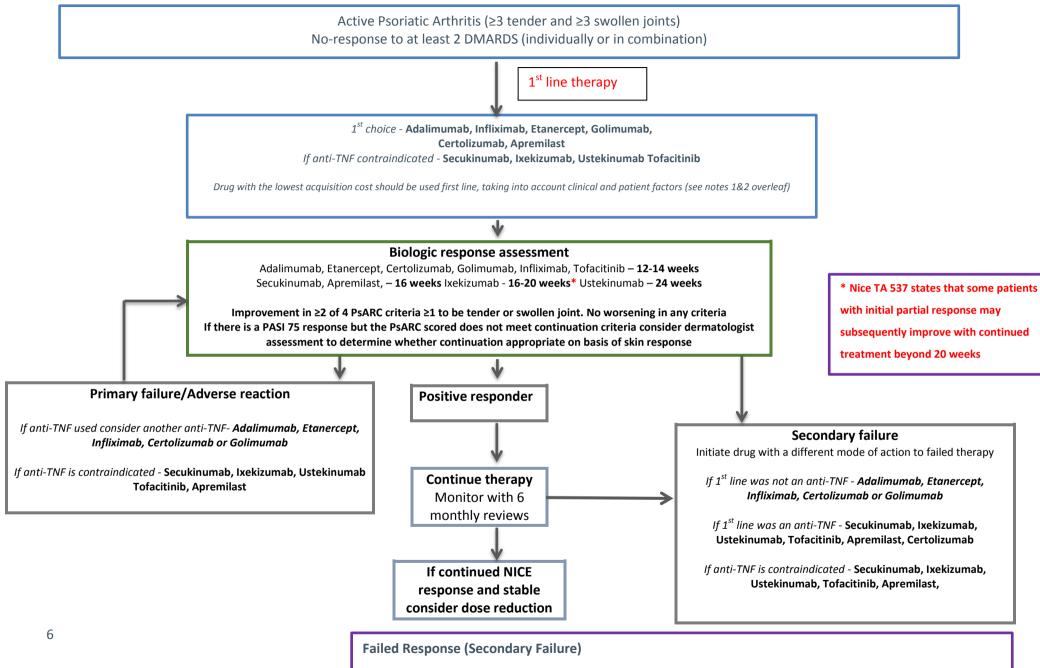
The drugs are categorised into 5 mechanisms of action which are independent of each other and we therefore have limited each patient to a maximum of 5 lines of therapy – each to be of a different mechanism of action. Any patient who has exceeded the maximum number of lines will need to exit the treatment pathway. If the responsible clinician deems the patient could still further benefit from treatment, funding would need to be requested via an Individual Funding Request to the patient's CCG.

Funding

Funding for biologic therapies in line with the treatment pathway will be via the Blueteq online database.

All forms will be created in line with the NICE TA recommendations.

- Treatment initiation funding should be requested in advance of treating patients
- Continuation treatment funding should be requested every 12 months.



Patient can be initiated on another drug with a different mode of action to previous therapies to a maximum of 5 lines of

therapy

Note 1: Patient factors

Adapted from GMMG Biologics Pathway for Psoriatic Arthritis (PsA)

Treatment	TA (other indications)	Pregnancy	Other indications/factors
Adalimumab	TA146 – Psoriasis	1 st and 2 nd trimesters	Uveitis**
	TA187 – Crohn's		Dactylitis ***
	TA329 – Ulcerative colitis		Enthesitis ***
	TA392 – Hidradenitis suppurativa		Nail psoriasis***
Apremilast	TA 419 - Psoriasis		Consider for patients with needle phobia
Certolizumab	TA574 – Plaque psoriasis	1st, 2nd and 3rd trimesters	Dactylitis ***
			Enthesitis ***
			Nail psoriasis***
Etanercept	TA103 - Psoriasis	1 st and 2 nd trimesters	Potential risk of TB # ***
			Dactylitis ***
			Enthesitis ***
			Nail psoriasis***
Golimumab	TA329 – Ulcerative colitis	No data	Consider if patient >100kg (TA233)
			Dactylitis ***
			Enthesitis ***
			Nail psoriasis*
			Not licensed for psoriasis
Infliximab	TA187 – Crohn's	Until 16 weeks of pregnancy	Uveitis**
	TA 329, TA140 -Ulcerative colitis		Dactylitis ***
	TA134 - Psoriasis		Enthesitis ***
			Nail psoriasis*
Secukinumab	TA350 - Psoriasis	No data	
Ustekinumab	TA180 - Psoriasis	No data	Dactylitis
	TA 340 – when anti-TNF contraindicated		Enthesitis

With all anti-TNFs there is a generalised increased risk of infection

*Level I evidence, grade of recommendation A **Level II evidence, grade of recommendation B ***Level III, grade of recommendation C # extrapolated from RA data

Note 2: Psoriatic Arthritis Treatments – Modes of Action

Mode of Action	Drug Name	Nice TA	Indicated for	Method of administration	Frequency of administration	Review at
Anti-TNFα	Adalimumab	TA199	Inadequate response to at least 2 previous DMARDs	Sub-cutaneous injection	Every 2 weeks	12 weeks
	Certolizumab	TA445	Inadequate response to at least 2 previous DMARDs Or Following secondary failure with anti-TNFα	Sub-cutaneous injection	3 doses (weeks 0, 2 and 4) then every 2 or 4 weeks	12 weeks
	Etanercept	TA199	Inadequate response to at least 2 previous DMARDs	Sub-cutaneous injection	25mg twice weekly/50mg weekly	12 weeks
	Golimumab	TA220	Inadequate response to at least 2 previous DMARDs	Sub-cutaneous injection	Monthly	12-14 weeks (after 3-4 doses)
	Infliximab	TA199	Inadequate response to at least 2 previous DMARDs	Intravenous infusion	3 infusions (weeks 0, 2 and 6) then every 8 weeks	14 weeks (after 4 doses)
Small-molecule inhibitor of phosphodiesterase 4 (PDE4)	Apremilast	TA433	Inadequate response to at least 2 previous DMARDs	Oral	Twice daily (following titration)	16 weeks

Mode of Action	Drug Name	Nice TA	Indicated for	Method of administration	Frequency of administration	Review at
IL17 inhibitor	Ixekizumab	TA537	Inadequate response to at least 2 previous DMARDs Or Following primary or secondary failure with anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	Sub-cutaneous injection	1 injection (week 0) then every 4 weeks	16 to 20 weeks*
	Secukinumab	TA445	Inadequate response to at least 2 previous DMARDs Or Following primary or secondary failure with anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	Sub-cutaneous injection	5 doses weekly (weeks 0-4) then monthly	16 weeks
Janus kinase inhibitor	Tofacitinib	TA543	Inadequate response to at least 2 previous DMARDs Or Following primary or secondary failure with anti-TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	Oral	Twice daily	12 weeks
IL-12 and IL-23 inhibitor	Ustekinumab	TA340	Inadequate response to at least 2 previous DMARDs Or Following primary or secondary failure with 1 or more anti- TNFα Or Anti-TNFα are contra-indicated but would otherwise be considered	Sub-cutaneous injection	2 doses (week 0 and 4) then every 12 weeks	24 weeks

^{*} Nice TA 537 states that some patients with initial partial response may subsequently improve with continued treatment beyond 20 weeks

Stakeholders

This treatment pathway has been composed in collaboration between NEL Medicines Management team and Consultants and Pharmacist at the following acute trust

- Royal National Orthopaedic Hospital NHS Trust
- North Middlesex University Hospital NHS Trust
- Royal Free London NHS Foundation Trust
- University College London Hospitals NHS Foundation Trust

Audit

The commissioners may choose to audit pathway adherence by use of data from Blueteq or by direct request of audit within the trust at patient record level.