# North Central London

## High Cost Drugs Treatment Pathway

## Psoriatic Arthritis Treatment Pathway Following Inadequate Response to DMARDs

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| Related Documents | |

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# 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.

# Psoriatic Arthritis Treatment Pathway Following Inadequate Response to DMARDs

Active Psoriatic Arthritis (≥3 tender and ≥3 swollen joints)
No-response to at least 2 DMARDS (individually or in combination)

1st line therapy

*1st choice* - **Adalimumab, Infliximab, Etanercept, Golimumab, Certolizumab, Apremilast**
*If anti-TNF contraindicated* - **Secukinumab, Ixekizumab, Ustekinumab Tofacitinib**

*Drug with the lowest acquisition cost should be used first line, taking into account clinical and patient factors (see notes 1&2 overleaf)*

**Biologic response assessment**
Adalimumab, Etanercept, Certolizumab, Golimumab, Infliximab, Tofacitinib – **12-14 weeks**
Secukinumab, Apremilast, – **16 weeks** Ixekizumab - **16-20 weeks*** Ustekinumab – **24 weeks**

**Improvement in ≥2 of 4 PsARC criteria ≥1 to be tender or swollen joint. No worsening in any criteria**
**If there is a PASI 75 response but the PsARC scored does not meet continuation criteria consider dermatologist assessment to determine whether continuation appropriate on basis of skin response**

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

**Primary failure/Adverse reaction**

*If anti-TNF used consider another anti-TNF-* ***Adalimumab, Etanercept, Infliximab, Certolizumab or Golimumab***

*If anti-TNF is contraindicated* - **Secukinumab, Ixekizumab, Ustekinumab Tofacitinib, Apremilast**

**Positive responder**

**Continue therapy**
Monitor with 6 monthly reviews

**If continued NICE response and stable consider dose reduction**

**Secondary failure**
Initiate drug with a different mode of action to failed therapy

*If 1st line was not an anti-TNF* - ***Adalimumab, Etanercept, Infliximab, Certolizumab or Golimumab***

*If 1st line was an anti-TNF* - **Secukinumab, Ixekizumab, Ustekinumab, Tofacitinib, Apremilast, Certolizumab**

*If anti-TNF is contraindicated* - **Secukinumab, Ixekizumab, Ustekinumab, Tofacitinib, Apremilast,**

**Failed Response (Secondary Failure)**

**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 | 1st and 2nd 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 | 1st and 2nd 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 |
| | | | Nail psoriasis |

**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<br>Or<br>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<br>Or<br>Following primary or secondary failure with anti-TNFα<br>Or<br>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<br>Or<br>Following primary or secondary failure with anti-TNFα<br>Or<br>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<br>Or<br>Following primary or secondary failure with anti-TNFα<br>Or<br>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<br>Or<br>Following primary or secondary failure with 1 or more anti-TNFα<br>Or<br>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.