South West London Psoriatic Arthritis Drug Pathway

Version 6.0

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Approved by: SWL Integrated Medicines Optimisation Committee

Date: 18th Oct 2023

SWL Drug Pathway - Psoriatic Arthritis: Conventional Synthetic DMARD Pathway Version 6.0 (based on NICE NG65¹ BSR 2022² EULAR 2019³ guidelines - with local adaptation) Involve Assess joints, skin, entheses, axial dermatology if involvement, nails for psoriatic arthritis nails/skin active Use conventional synthetic DMARD (csDMARD) treatment(s) for Psoriatic Arthritis (BSR1 and EULAR2) + Non-Monotherapy: Oral methotrexate (1st line unless contra-indicated), leflunomide, sulfasalazine or hydroxychloroquine monotherapy pharmacological · Escalate dose as tolerated management · Consider short-term bridging treatment with glucocorticoids (oral, intramuscular) and/or NSAIDs for symptomatic relief of musculoskeletal symptoms Step up strategy (if remission or low disease activity not achieved despite dose escalation): • If inadequate response, offer additional csDMARDs (oral methotrexate, leflunomide or sulfasalazine) preferably in combination Escalate dose as tolerated Dose escalation: • Methotrexate: PO usual dose: 7.5mg-15mg/week up to max 25mg/week ➤ If intolerance (ACR 2021⁴): • Split dose over 24 hours or Increase folic acid (e.g. 5mg 6 days/week) or Switch to SC If not at target: • Consider switch to SC (ACR 20214) • Sulphasalazine: PO 2-3g/day in 2-4 divided doses • Leflunomide: PO 20mg OD (10mg OD if used with another DMARD like methotrexate) • Hydroxychloroquine: PO 200mg-400mg/day in 1-2 divided doses Max 5mg/kg/day (use actual bodyweight; start retinopathy monitoring after 5 years if no other risk factors) (doses up to 6.5mg/kg/day using ideal body weight in exceptional cases; start retinopathy monitoring after 1 year) Yes Is the patient responding to csDMARD treatment? No No Does the patient have peripheral arthritis, with 3 or more tender joints and 3 or more swollen joints? Yes Is the psoriatic arthritis responding to adequate trials of at least 2 Yes csDMARDs (administered either individually or in combination)? , No Go to 2

Psoriatic Arthritis: High Cost Drug Pathway

SWL Drug Pathway - Psoriatic Arthritis: High Cost Drug Pathway

Version 6.0 (based on NICE - with local adaptation)

Box A: For 1st treatment only (note 2)

Use with methotrexate (MTX) unless contra-indicated/not

tolerated (exceptions apply)

1st choice: Adalimumab biosimilar (TA199)

(especially if IBD or uveitis)

2nd choice: Etanercept biosimilar (TA199) or

Infliximab SC/IV biosimilar (TA199) or Secukinumab 150mg (TA445) (note 6) or

Tofacitinib + MTX (TA543)

3rd choice: Certolizumab (TA445) or

Ixekizumab (TA537)

4th choice: Golimumab (TA220) (if >100kg) (note 6)

If TNF-alpha inhibitor contra-indicated:

Use with methotrexate (MTX) unless contra-indicated/not

tolerated (exceptions apply)

1st choice: Upadacitinib (TA768)

2nd choice: Secukinumab 150mg (TA445) (note 6) or

Tofacitinib + MTX (TA543) or Guselkumab (TA815)

3rd choice: Bimekizumab (TA916) or Ixekizumab (TA537)

4th choice: Ustekinumab (TA340)

Box B: For subsequent treatment select different mode of action (MOA) in each step (note 1,2,7)

Use with methotrexate (MTX) unless contra-indicated/not tolerated (exceptions apply)

1st choice: Adalimumab biosimilar (TA199)

(especially if IBD or uveitis)

2nd choice: Etanercept biosimilar (TA199) or

Infliximab SC/IV biosimilar (TA199) or

Upadacitinib (TA768)

3rd choice: Tofacitinib + MTX (TA543) or

Guselkumab (TA815)

4th choice: Certolizumab (TA445) or Risankizumab (TA803) or

Bimekizumab (TA916) or Ixekizumab (TA537)

5th choice: Secukinumab 150/300mg (TA445) (note 6) or

Golimumab (TA220) (if >100kg) (note 6)

6th choice: Ustekinumab (TA340)

STEP 1 Select from box A (note 1,3,4) STEP 2 Select from box B (note 1,3,4,7) STEP 3 Select from box B (note 1,3,4,7) STEP 4 and subsequent steps Multi-Trust MDT (box B) Discontinue advanced therapy (note 8) Refer to a dermatologist to assess

Refer to a dermatologist to assess whether it is appropriate to continue treatment on the basis of skin response (see relevant NICE TAs for guidance on treatment for psoriasis)

+ Non-pharmacological management

Apremilast +/- csDMARDs (TA433)
May be used at any stage before, in between or after the drugs in this pathway (note 2)

* AFTER EACH STEP

Is there an adequate response to treatment, defined as:

- Improvement in at least 2 of the 4 PsARC criteria (1 of which has to be joint tenderness or swelling score) and
- No worsening in any of the 4 criteria? (note 5,6)

Yes - maintain same treatment & monitor (note 3)

No - move to next step (note 4)

Refer to the relevant technology appraisal for each drug for further information about their eligibility and prescription.

SWL Drug Pathway - Psoriatic Arthritis: High Cost Drug Pathway

Version 6.0 (based on NICE - with local adaptation)

Note 1 - Moving steps: Choose ONE option per step before moving onto the next step due to primary or secondary treatment failure. If there is more than one NICE approved treatment available, NICE recommends a discussion between responsible clinician and patient about advantages and disadvantages of each treatment (consider therapeutic need and likely adherence). If more than one treatment option is suitable, choose the least expensive (take into account administration costs, dosage and price per dose) unless an order of preference is stated in the TAs. The SWL choices in this algorithm are based on cost (including relevant administration costs, using list price or nationally (NICE) / locally (LPP) agreed contract price).

Note 2 - Commercial agreement: Apremilast, bimekizumab, certolizumab pegol, golimumab, guselkumab, secukinumab, tofacitinib, upadacitinib and ustekinumab are recommended as options only if provided according to the commercial agreement (i.e. certolizumab: 1st 12 weeks (10 x 200 mg) free of charge; golimumab: 100mg same cost as the 50mg; guselkumab: 4 weekly maintenance dose cost same as 8 weekly maintenance dose; ustekinumab: 90 mg dose for people who weigh >100 kg at the same cost as the 45 mg dose).

Note 3 – Adverse event or new contra-indication: Consider alternative from same step (in step 1, 2 and 3 only) if treatment had to be stopped due to adverse event or new contra-indication AND:

- patient was responding to the drug OR
- response was not yet assessed i.e. within 12 (TNF-alpha inhibitor, tofacitinib, golimumab, upadacitinib), 16 (bimekizumab, ixekizumab, secukinumab, guselkumab, risankizumab) or 24 (ustekinumab) weeks of initiating treatment.

Note 4 - Primary / secondary treatment failure with TNF-alpha inhibitor: an alternative TNF-alpha inhibitor may be chosen from the same step (in step 1, 2, and 3 only), if considered clinically appropriate. This is restricted to ONE switch within the TNF-alpha inhibitor class only (does not apply to other drug classes).

Note 5 – PsARC assessment: Healthcare professionals should take into account any physical, sensory or learning disabilities or communication difficulties that could affect responses to components of the PsARC and make any adjustments they consider appropriate.

Note 6 - Dose adjustment:

Golimumab: consider increasing to 100mg/month if weight >100kg and inadequate clinical response after 3 or 4 x 50mg doses; consider increased risk of serious adverse drug reactions. Continued therapy should be reconsidered if no therapeutic benefit after 3 to 4 additional doses of 100mg. **Secukinumab:** for TNF-alpha inhibitor non-responders use 300mg/month; for other patients use 150mg/month. Based on clinical response, increase to 300mg/month.

Note 7 - Pregnancy: If, following careful consideration of expected benefits/risks of options, drug therapy is changed due to (planning) pregnancy, consider switch back to previous most cost-effective therapy post-partum (and move back to the previous step).

Note 8 – IFR: Requests for treatment outside this commissioned pathway can be made via the Individual Funding Request (IFR) process (see swlimo.southwestlondon.icb.nhs.uk for IFR policy and application form).

SWL Drug Pathway - Psoriatic Arthritis: Non-Pharmacological Management

Version 6.0 (based on NG1005)

Physiotherapy

Patients should have access to specialist physiotherapy with periodic review to:

- Improve general fitness and encourage regular exercise
- Learn exercises for enhancing joint flexibility, muscle strength and managing other functional impairments
- Learn about the short-term pain relieve provided by methods such as transcutaneous electrical nerve stimulators (TENS) and wax baths

Occupational therapy

Patients should have access to specialist occupational therapy with periodic review if they have:

- Difficulties with any of their everyday activities
- Problems with hand function

Hand exercise programmes

Consider tailored strengthening and stretching hand exercise programme for patients with pain and dysfunction in the hands or wrists if:

- Not on a drug regimen
- Been on a stable drug regimen for at least 3 months

Podiatry

All patients with foot problems should have access to a podiatrist for:

- Assessment and periodic review of their foot health needs
- Functional and therapeutic footwear should be available if indicated

Psychological interventions

Offer psychological interventions e.g. relaxation, stress management and cognitive coping skills to help patients living with their condition

SWL Drug Pathway – Psoriatic Arthritis- Drug Information for Advanced Therapies

Version 6.0 (this list is not exhaustive; see summary of product characteristics (SPC) for full information)

version o.o (this list is not exhaustive, see summary or product characteristics (SFC) for full information)								
Drug Class	Drug Name	Administration	Contra-indications	Special warnings and precautions				
Tumour necrosis factor (TNF) alpha inhibitors	Adalimumab biosimilar Certolizumab pegol Etanercept Golimumab Infliximab biosimilar	SC – alternate weeks SC – alternate weeks or 4 weekly SC – weekly SC – monthly SC – 2 weekly IV – 8 weekly	 Hypersensitivity to active substance or excipients Active, severe infections (e.g. TB, sepsis, abscesses) and opportunistic infections Moderate to severe heart failure (NYHA class III/IV) 	 >65 years of age Autoimmune processes (Lupus) More susceptible to serious infections (e.g. TB) Viral reactivation (e.g. hepatitis B) Malignancy and lymphoproliferative disorder Congestive heart failure 	•Neurological events •Immunosuppression •Haematologic reactions •Infusion-related reactions (infliximab) •COPD (Certolizumab) •Latex sensitivity (adalimumab, certolizumab, golimumab) •Diabetes (etanercept)			
Interleukin (IL) 17 inhibitor	Bimekizumab	SC – 4 weekly	•Hypersensitivity to the active substance or excipients •Active, severe infections (e.g. TB)	 More susceptible to serious infections (e.g. TB) Hypersensitivity Inflammatory bowel disease Latex sensitivity (for ustekinumab and secukinumab 150mg PFS and PFP only) Contraception 	 Hepatic transaminase elevations (guselkumab) Skin condition (ustekinumab) Lupus-related conditions (ustekinumab) >65 years (ustekinumab) 			
	Ixekizumab	SC – 4 weekly						
	Secukinumab	SC – week 0, 1, 2, 3 and 4, then monthly						
Interleukin (IL) 12/23 inhibitor	Ustekinumab	SC – week 0 and 4, then 12 weekly						
Interleukin (IL) 23 inhibitor	Guselkumab	SC – week 0 and 4, then 4 or 8 weekly						
	Risankizumab	SC – week 0 and 4, then 12 weekly						
JAK inhibitors	Tofacitinib	PO – once or twice daily	•Hypersensitivity to the active substance or excipients •Age 65 years or older •Current or past long-time smoking •Known risk factors for cardiovascular disease or malignancy •Active, severe infections (e.g. TB, sepsis, abscesses) and opportunistic infections •Severe hepatic impairment •Pregnancy •Lactation (tofacitinib)	•More susceptible to serious infections (e.g. TB); viral reactivation (e.g.	 MHRA update (26/4/23): Do not use in patients with these risk factors unless there is no suitable alternative: age 65 years or older current or past long-time smokers other risk factors for cardiovascular disease or malignancy Use with caution in patients with risk factors for VTE other than those listed above Where no suitable alternative, use lower doses Carry out periodic skin examinations to check for signs of skin malignancy 			
	Upadacitinib	PO – once daily		hepatitis B) •Malignancy and lymphoproliferative disorder •Interstitial lung disease •GI perforation •Liver enzyme elevation •Derangement of neutrophils, haemoglobin, lipids, glycaemic control •Tofacitinib: Retinal venous thrombosis (RVT); fractures; liver enzyme elevation				
Phosphodies- terase 4 (PDE4)	Apremilast	PO – twice daily	•Hypersensitivity to the active substance or excipients •Pregnancy	Diarrhoea, headache, nausea and vomiting Psychiatric disorders	•Severe renal impairment •Underweight patients •Lactose content			

SWL Drug Pathway – Psoriatic Arthritis- References

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SWL Drug Pathway – Psoriatic Arthritis- Version Control Version 6.0

Version number	Previous version label	Main amendments	Date of approval		
0		NICE Psoriatic Arthritis commissioning algorithm	28 th Aug 2011		
1.0	final v1- 21/07/16	Include approved recommendations from South West London Rheumatology network meeting (9 th March 2016): • Include preferred drug choices and clinical criteria that may influence choice • Local agreement: etanercept biosimilar extra 2 nd line option (if considered appropriate)	21st Jul 2016		
2.0	final v2- 01/04/17	Interim update: • Add apremilast (NICE TA433) as treatment option before biologic drugs	01 st Apr 2017		
3.0	final v3- 10/05/17	Include approved recommendations from South West London Rheumatology network meeting (10 th May 2017): • Update notes • Update preferred drug choices in step 1 • New local agreement: infliximab biosimilar step 2 (if considered appropriate) • Add certolizumab and secukinumab (150mg/300mg) (NICE TA445) in step 1 (3 rd choice option - local agreement) • Add certolizumab (NICE TA445) to step 3 (1 st choice option - local agreement) if secondary treatment failure with TNF-alpha inhibitors • Add secukinumab (NICE TA445) to step 1 (1 st choice - local agreement) if TNF-alpha inhibitors are contra-indicated (ustekinumab is 2 nd choice) and step 3 (1 st choice – local agreement) if failure to TNF-alpha inhibitors or TNF-alpha inhibitors are contra-indicated	01 st Aug 2017		
4.0	final v1- 04/10/17	Include approved recommendations from South West London Rheumatology network meeting (4 th October 2017): • Update title and note 1 • Apremilast (NICE TA433) as treatment option at any point in the pathway	07 th Feb 2018		
4.0	(addendum 1) final v1- 04/10/17	• Addendum 1: Add ixekizumab (NICE TA537) to step 1 (3 rd choice; 1 st choice if TNF-alpha inhibitors are contra-indicated - local agreements) and step 3 (1 st choice - local agreement)	27 th Sep 2018		
5.0		 Include recommendation from virtual South West London Rheumatology network (7th January 2019): Update preferred drug choices in step 1 and 3 Add tofacitinib + methotrexate (TA543) to step 1, 2 and 3 (1st choice option - local agreement) and to step 1 if TNF-alpha inhibitors contra-indicated (1st choice - local agreement) Add ixekizumab (NICE TA537) to step 1 (2nd choice option - local agreement; 2nd choice option if TNF-alpha inhibitor contra-indicated - local agreement) and step 3 (2nd choice option- local agreement) Add adalimumab to step 2 (local agreement) Change note 1 and step 2 (clarify that step 2 is optional and not mandatory) Add reference to IFR (note 6) Change "biological DMARD" to "biological DMARD/targeted synthetic DMARD" 	11 th Mar 2019		
6.0		 Add conventional synthetic DMARD pathway Add guselkumab (TA815), upadacitinib (TA768), risankizumab (TA803), bimekizumab (TA916) Update preferred drug choices Introduce multi-trust MDT step for 4th line treatment Add non-pharmacological management Add drug information for advanced therapies and MHRA update for JAK inhibitors (26/4/23) 	18 th Oct 2023		
Date of next review: Oct 2026 (or earlier if indicated)					