

South West London Rheumatoid Arthritis Drug Pathway

Version 7.0

Based on recommendations from the
SWL Rheumatology Medicines Optimisation network meeting held on 22/07/2021

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Approved by: SWL Integrated Medicines Optimisation Committee

Date: 21st August 2024

SWL Drug Pathway - Rheumatoid Arthritis: Conventional DMARD Treatment

Version 7.0 (based on NICE - [with local adaptation](#))

Use conventional synthetic DMARD (csDMARD) treatment(s) for Rheumatoid Arthritis (NG100¹)

Monotherapy (in some patients combination therapy may be indicated from the outset):

- Oral methotrexate (1st line unless contra-indicated), leflunomide or sulfasalazine monotherapy
- Consider hydroxychloroquine if mild or palindromic disease
- Escalate dose as tolerated*

Consider short-term bridging treatment with glucocorticoids (oral, intramuscular or intra-articular) when starting treatment

Step up strategy (if remission or low disease activity not achieved despite dose escalation):

- Offer additional csDMARDs (oral methotrexate, leflunomide, sulfasalazine or hydroxychloroquine) preferably in combination
- Escalate dose as tolerated*

* **Escalate dose as tolerated:**

- **Methotrexate:** PO 15mg/week (doses up to 25mg/week and in exceptional cases 30mg/week (unlicensed) are used)
 - If intolerance (ACR 2021²):
 - Split dose over 24 hours or
 - Increase folic acid (e.g. 5mg 6 days per week)
 - Switch to SC
 - If not at target:
 - Consider switch to SC (ACR 2021²)
- **Sulphasalazine:** 2-3g/day in 2-4 divided doses
- **Hydroxychloroquine:** 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)
- **Leflunomide:** 20mg OD (10mg OD if used with another DMARD like methotrexate)

+ Non-pharmacological management

Yes — Is the patient responding to csDMARD treatment?

No

Has the patient had intensive therapy with a combination of 2 or more conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs), including methotrexate (unless contraindicated)?

No

Yes

DAS score
≤ 3.2

DAS score
>3.2 and ≤ 5.1

DAS28 score
>5.1

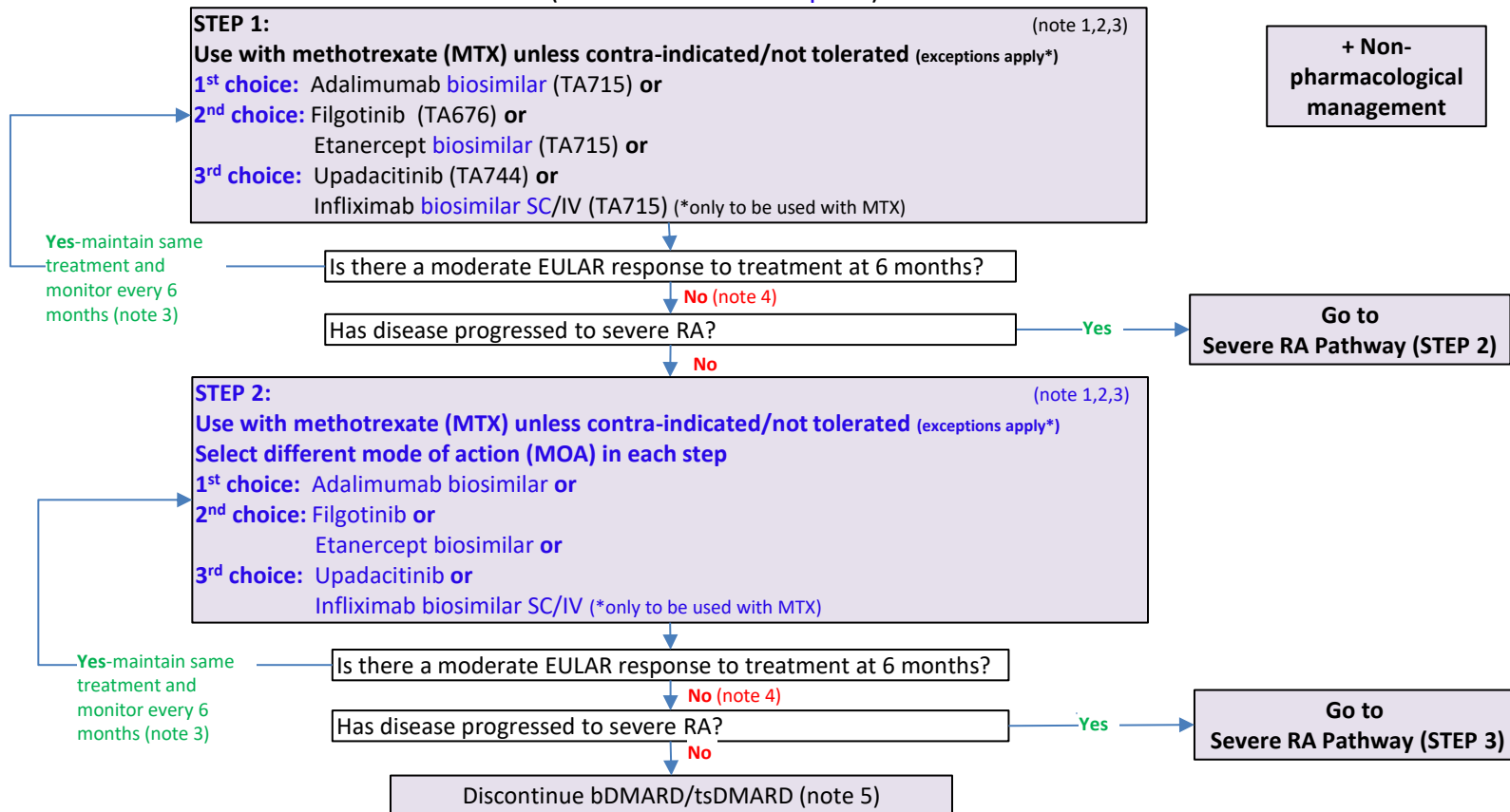
Go to
Moderate RA Pathway

Go to
Severe RA Pathway

Commissioners and clinicians should refer to the relevant technology appraisal for each drug for further information about their eligibility and prescription.

SWL Drug Pathway – MODERATE Rheumatoid Arthritis

Version 7.0 (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 the responsible clinician and the patient about the advantages and disadvantages of each treatment (considering therapeutic need and likely adherence to treatment). If more than one treatment option is suitable, the least expensive will be chosen (taking into account administration costs, dosage and price per dose) unless an order of preference is stated in the TAs. The SWL drug choices in this algorithm are based on cost (including relevant administration costs, using list price or nationally (NICE) / locally (LPP) agreed contract prices).

Note 2- Commercial agreement: Filgotinib is recommended as a treatment option only if the company provides the drug according to the commercial agreement.

Note 3- Adverse event: Consider alternative from same step if treatment had to be stopped due to an adverse event if:

- patient is responding to drug OR
- response was not yet assessed i.e. within 1st 6 months (3 months for certolizumab) of initiation treatment

Note 4- Primary / secondary treatment failure with adalimumab or infliximab: an alternative TNF-alpha inhibitor may be chosen from the same step, if considered clinically appropriate. This is restricted to ONE switch within the TNF-alpha inhibitor class only.

Note 5- IFR: Requests for treatment outside this commissioned pathway can be made via the Individual Funding Request (IFR) process (see <https://swlimo.swlondonccg.nhs.uk/> for IFR policy and application form).

SWL Drug Pathway – SEVERE Rheumatoid Arthritis

Version 7.0 (based on NICE - with local adaptation)

Box A: Use with methotrexate (MTX) unless contra-indicated/not tolerated (exceptions apply*)
Select different mode of action (MOA) in each step (note 1,2,7)

1st choice: Adalimumab biosimilar (TA195+375) or Filgotinib (TA676) or Rituximab biosimilar IV:
 •With MTX: in step 1 only if Hx of cancer, ILD, or MS (local agreement) or intolerant to TNF-inhibitor
 •Without MTX: only if Hx of cancer, ILD, or MS (local agreement); rituximab is not licensed for use without methotrexate in RA- this is a local agreement also recommended by BSR and BHPR guidance 2011 or

2nd choice: Etanercept biosimilar (TA195+375) or Upadacitinib (TA665) or

3rd choice: Tofacitinib (TA480) or Baricitinib (TA466) or Infliximab biosimilar SC/IV + MTX (TA195+375) (*only use with MTX) or

4th choice: Tocilizumab biosimilar SC (use without MTX is a local agreement) (TA247+375) (if high BMI) or Sarilumab (TA485) or Certolizumab pegol (TA375+415) (if (planning) pregnancy) or

5th choice: Abatacept SC + MTX (TA195+375) (if high BMI; *only to be used with MTX) or Golimumab + MTX (TA225+375) (if >100kg; *only use with MTX) or

6th choice: Tocilizumab biosimilar IV (TA247+375) (if unable to use SC alternative) or Abatacept IV + MTX (TA195+375) (if unable to use SC alternative; *only use with MTX) or

Box B: Use with methotrexate (MTX) unless contra-indicated/not tolerated (exceptions apply*)
Select different mode of action (MOA) in each step (note 12,7)

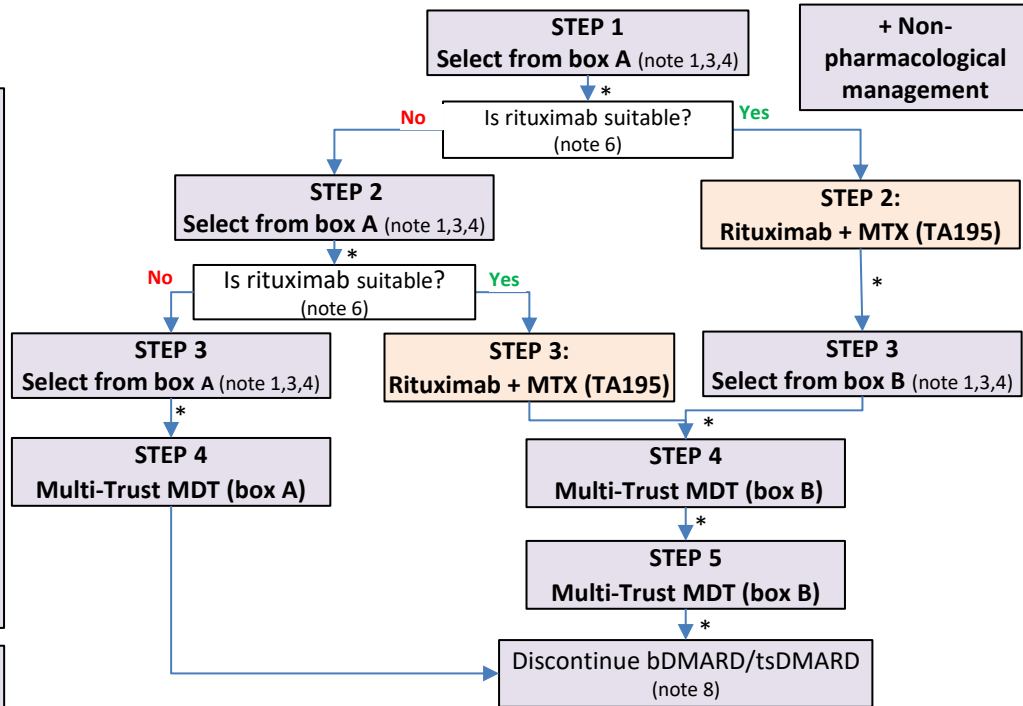
1st choice: Filgotinib (TA676) or

2nd choice: Upadacitinib (TA665) or

3rd choice: Tocilizumab biosimilar SC (TA247+375) or Sarilumab (TA485) or

4th choice: Tocilizumab biosimilar IV (TA247+375) (if unable to use SC alternative)

5th choice: Other treatment options listed in Box A



*After each step:
 Is there a moderate EULAR response to treatment at 6 months (3 months for certolizumab, note 5)? If :

- **No-** move to next step (note 4)
- **Yes-** maintain same treatment & monitor every 6 months (note 3)

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 the responsible clinician and the patient about the advantages and disadvantages of each treatment (considering therapeutic need and likely adherence to treatment). If more than one treatment option is suitable, the least expensive will be chosen (taking into account administration costs, dosage and price per dose) unless an order of preference is stated in the TAs. The SWL drug choices in this algorithm are based on cost (including relevant administration costs, using list price or nationally (NICE) / locally (LPP) agreed contract prices).

Note 2- Commercial agreement: Abatacept, baricitinib, certolizumab pegol, filgotinib, golimumab, sarilumab, tocilizumab, tofacitinib and upadacitinib are recommended as options only if provided it according to the commercial agreement (Certolizumab: 1st 12 weeks (10 x 200 mg) free of charge; Golimumab: 100mg same cost as the 50mg)

Note 3- Adverse event: Consider alternative from same step (in step 1,2 and 3 only) if treatment had to be stopped due to an adverse event if:

- patient is responding to drug OR
- response was not yet assessed i.e. within 1st 6 months (3 months for certolizumab) of initiation treatment

Note 4- Primary / secondary treatment failure with adalimumab or infliximab: 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.

Note 5- Certolizumab: available data suggest that clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment.

Note 6- Rituximab: is not suitable if it is contra-indicated or when following discussion between the clinician and patient, rituximab is not considered suitable.

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 <https://swlimo.swlondonccg.nhs.uk/> for IFR policy and application form).

SWL Drug Pathway - Rheumatoid Arthritis: Non-Pharmacological Management

Version 7.0 (based on NICE - [with local adaptation](#))

NG 100:

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 nuerve stimulatros (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 –Rheumatoid Arthritis- Drug information for advanced therapies

(see summary of product characteristics (SPC) for full information)

Version 7.0 (based on NICE - with local adaptation)

Drug	Name	Administration	Contra-indications	Cautions	
Tumour necrosis factor (TNF) alpha inhibitors	Adalimumab	SC – every other week	<ul style="list-style-type: none"> • Hypersensitivity to active substance or excipients • Active TB and other severe infections (sepsis, abscesses) and opportunistic infections • Moderate to severe heart failure (NYHA class III/IV) 	<ul style="list-style-type: none"> • Infections (impaired lung function) • Hepatitis B reactivation • Demyelinating diseases • Malignancies –lymphomas • Non-melanoma skin cancer (history of prolonged immuno-modulator therapy, PUVA) 	<ul style="list-style-type: none"> • Mild heart failure (NYHA class I/II) • Autoimmune processes (Lupus) • Infusion-related reactions (IRR) and hypersensitivity (infliximab only)
	Certolizumab pegol	SC – every other week or 4 weekly			
	Etanercept	SC - weekly			
	Golimumab	SC - monthly			
	Infliximab	SC– 2 weekly IV – 8 weekly			
Interleukin (IL) inhibitors	Sarilumab	SC – 2 weekly	<ul style="list-style-type: none"> • Hypersensitivity to active substance or excipients • Active, severe infections 	<ul style="list-style-type: none"> • Infections (e.g. TB, HIV) • Malignancies • Intestinal ulceration or diverticulitis • Active hepatic disease or impairment • Laboratory parameters (neutrophils, platelets, transaminases, lipids)-see SPC for details 	<ul style="list-style-type: none"> • Acute liver failure, hepatitis, and jaundice (tocilizumab only) • Reactivation of herpes zoster (sarilumab only) • Reactivation of hepatitis B virus (tocilizumab only) • Demyelinating diseases (tocilizumab only) • History of diabetes, interstitial lung disease (tocilizumab only)
	Tocilizumab	SC – weekly IV – 4 weekly			
T-cell inhibitor	Abatacept	SC – weekly IV – 4 weekly	<ul style="list-style-type: none"> • Hypersensitivity to active substance or excipients • Severe and uncontrolled infections (sepsis and opportunistic infections) 	<ul style="list-style-type: none"> • Infections (sepsis and pneumonia) • Hepatitis B reactivation 	<ul style="list-style-type: none"> • Malignancies –lymphomas, non-melanoma skin cancer • Elderly (>65 years)
CD20 inhibitor	Rituximab	IV – 1 course (2 doses) 6 monthly	<ul style="list-style-type: none"> • Hypersensitivity to active substance or murine proteins or excipients • Active, severe infections (e.g. TB, sepsis or opportunistic infections) • Severely immunocompromised • Severe heart failure (NYHA class IV) or severe, uncontrolled cardiac disease 	<ul style="list-style-type: none"> • Infusion-related reactions (IRR) and hypersensitivity • Cardiac disorders (angina pectoris, cardiac arrhythmias e.g. atrial flutter and fibrillation, heart failure and/or MI) • History of recurring or chronic Infections 	<ul style="list-style-type: none"> • Fatal progressive multifocal leukoencephalopathy (PML) • Hepatitis B reactivation • Late neutropenia • Skin reactions (Lyell's and Stevens-Johnson syndrome)
JAK inhibitors	Baricitinib	PO – once daily	<ul style="list-style-type: none"> • Hypersensitivity to active substance or excipients (and murine proteins – baricitinib only) • Active TB and severe infections (sepsis - tofacitinib) and opportunistic infections • Severe hepatic impairment (tofacitinib, upadacitinib) • Pregnancy (tofacitinib, upadacitinib, filgotinib) • Lactation (tofacitinib) • Severely immunocompromised (baricitinib) • Severe heart failure (NYHA class IV) or severe, uncontrolled cardiac disease (baricitinib) 	<ul style="list-style-type: none"> • Infections and TB (all JAK inhibitors) - upper respiratory tract infections and lymphoproliferative disorders (baricitinib only); pneumonia (filgotinib only) • Viral reactivation (all JAK inhibitors) - herpes zoster (baricitinib/filgotinib only); herpes simplex and hepatitis B/C (baricitinib only) • Deep venous thrombosis (DVT) and pulmonary embolism (PE) • Laboratory parameters (all JAK inhibitors) - lymphocytes, neutrophils, haemoglobin, lipids, transaminases (baricitinib/ upadacitinib only) -see SPC for details • Malignancies (tofacitinib/upadacitinib/ filgotinib only) - lymphomas (upadacitinib/ tofacitinib only), lymphoproliferative disorder lung cancers (tofacitinib only) 	<ul style="list-style-type: none"> • Non-melanoma skin cancer (tofacitinib/ upadacitinib/ filgotinib only) • Diverticulitis (baricitinib only) <p>Tofacitinib only: Interstitial lung disease, GI perforations, Liver enzymes, Hypersensitivity.</p> <p>Do not use in the following, unless there are no suitable alternatives (MHRA drug update 6 Oct 2021)</p> <ul style="list-style-type: none"> • Age > 65 years • Current or past smokers • Other cardiovascular risk factors (e.g. diabetes or coronary artery disease incl. past MI, CHD, stable angina pectoris or coronary artery procedures) • Malignancy risk factors (current or previous history of malignancy excl successfully treated non-melanoma skin cancer (NMSC)
	Tofacitinib	PO – once or twice daily			
	Upadacitinib	PO – once daily			
	Filgotinib	PO – once daily			

SWL Drug Pathway –Rheumatoid Arthritis- References

Version 7.0 (based on NICE - [with local adaptation](#))

1. NICE Guideline 100 (NG100), Rheumatoid arthritis in adults: management. 11 July 2018 (last updated 12 Oct 2020)
2. Fraenkel L *et al.* 2021 American College of Rheumatology Guideline for the treatment of Rheumatoid Arthritis. *Arthritis Care & Research.* 0 (0): 1–16
3. MHRA. Tofacitinib (Xeljanz ▼): new measures to minimise risk of major adverse cardiovascular events and malignancies. 6 Oct 2021. <https://www.gov.uk/drug-safety-update/tofacitinib-xeljanzv-new-measures-to-minimise-risk-of-major-adverse-cardiovascular-events-and-malignancies>
4. NICE Rheumatoid Arthritis pathway (see: <https://pathways.nice.org.uk/pathways/rheumatoid-arthritis>)
3. NICE TA247: Tocilizumab for the treatment of rheumatoid arthritis. 22 Feb 2012
4. NICE TA375: Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed. 29 Jan 2016
5. NICE TA415: Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor. 26 Oct 2016
6. NICE TA466: Baricitinib for moderate to severe rheumatoid arthritis. 9 Aug 2017
7. NICE TA480: Tofacitinib for moderate to severe rheumatoid arthritis. 11 Oct 2017
8. NICE TA485: Sarilumab for moderate to severe rheumatoid arthritis. 1 Nov 2017
9. NICE TA665: Upadacitinib for treating severe rheumatoid arthritis. 9 Dec 2020
10. NICE TA 676: Filgotinib for treating moderate to severe rheumatoid arthritis. 24 Feb 2021
11. NICE TA715: Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed, 14 Jul 2021
12. NICE guideline 167. Covid-19 rapid guideline: rheumatological auto-immune, inflammatory and metabolic bone disorders. 3 Apr 2020, updated 31 Mar 2021
13. Specialist Pharmacy Service. RMOc Advisory statement: Sequential Use of Biologic Medicines - v2. May 2020. Available from: <https://www.sps.nhs.uk/articles/rmoc-advisory-statement-sequential-use-of-biologic-medicines/>
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16. Flint J *et al.* BSR and BHRP guideline on prescribing drugs in pregnancy and breastfeeding—Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids. *Rheumatology* 2016; 55 (9): 1693–1697
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19. Midlands Therapeutic Review and Advisory Committee (MTRAC). Considerations for Commissioners- Biologic and targeted-synthetic disease modifying anti-rheumatic drugs (bDMARDs and tsDMARDs). March 2019
20. Holroyd C *et al.* The British Society for Rheumatology biologic DMARD safety guidelines in inflammatory arthritis. *Rheumatology* 2019;58:e3-e42
21. Cimizia® (certolizumab) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/product/4450/smpc> Accessed 15/10/21; last updated 15/10/21
22. Idacio® (adalimumab) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/product/11308/smpc> Accessed 15/10/2021; last updated 14/01/2021
23. Remsima® (infliximab) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/product/3709/smpc> Accessed 15/10/2021; last updated 10/11/2020
24. Xeljanz® (tofacitinib) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/product/9410/smpc> Accessed 15/10/2021; last updated 13/10/2021
25. Benepali® (etanercept) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/product/8032/smpc> Accessed 15/10/2021; last updated 19/08/2021
26. Simponi® (golimumab) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/product/5133/smpc> Accessed 15/10/2021; last updated 01/07/2021
27. Kevzara® (sarilumab) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/product/8143/smpc> Accessed 15/10/2021; last updated 28/04/2021
28. RoActemra® (tocilizumab) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/search?q=tocilizumab> Accessed 15/10/2021; last updated 10/09/2021
29. Orencia® (abatacept) Summary of Product Characteristics (SPC) <https://www.medicines.org.uk/emc/product/2877/smpc> Accessed 15/10/2021; last updated 19/07/2021
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SWL Drug Pathway –Rheumatoid Arthritis- Version control

Version 7.0 (based on NICE - [with local adaptation](#))

Version number	Main amendments	Date of approval
0	NICE Rheumatoid Arthritis commissioning algorithm	12 th Aug 2013
1.0 (originally labelled as final v1- 21/07/16)	<p>Include approved recommendations from South West London Rheumatology network meeting (9th March 2016):</p> <ul style="list-style-type: none"> • Preferred drug choices and clinical criteria that may influence choice • Local agreement: etanercept biosimilar +/- methotrexate – extra 2nd line step • Local agreement: rituximab +/- methotrexate as 1st line treatment option for patients with RA and MS, ILD or history of cancer. • Local agreement: if methotrexate is contra-indicated tocilizumab SC 2nd line option after use of TNF-alpha inhibitor 	21 st Jul 2016
2.0 (originally labelled as final v2- 24/11/16)	<p>Interim update:</p> <ul style="list-style-type: none"> • Add certolizumab +/- methotrexate (NICE TA415) to step 3 (3rd choice when used with methotrexate - local agreement) 	24 th Nov 2016
3.0 (originally labelled as final v3- 10/05/17)	<p>Include approved recommendations from South West London Rheumatology network meeting (10th May 2017):</p> <ul style="list-style-type: none"> • Update pathway presentation, title and notes • Update preferred drug choices (with methotrexate step 1 and 3; without methotrexate step 1) • New local agreement: infliximab biosimilar + methotrexate step 2 • Add note 5 (recommend alternative synthetic DMARD with biologic if methotrexate is contra-indicated) 	01 st Aug 2017
4.0 (originally labelled as final v1- 04/10/17)	<p>Include approved recommendations from South West London Rheumatology network meeting (4th October 2017):</p> <ul style="list-style-type: none"> • Update title and change “biologic DMARD” to “bDMARD/tsDMARD” • Add baricitinib +methotrexate (NICE TA466) to step 1, 2 and 3 (1st choice option - local agreement) • Add baricitinib monotherapy (NICE TA466) to step 1, 2 and 3 (1st choice option - local agreement) • Add tofacitinib + methotrexate (NICE TA480) to step 1 and 3 (3rd choice option - local agreement) • Add tofacitinib monotherapy (NICE TA480) to step 1 (3rd choice- local agreement) and step 3 (2nd choice - local agreement) • Add sarilumab +methotrexate (NICE TA485) to step 1 and 3 (3rd choice option - local agreement) and step 4 (1st choice option ahead of tocilizumab - local agreement) • Add sarilumab monotherapy (NICE TA485) to step 1 (3rd choice option - local agreement) and step 3 (2nd choice option - local agreement) • Include order of preference in step 3 of pathway B 	07 th Feb 2018
5.0	<p>Include recommendation from virtual South West London Rheumatology network (7th January 2019):</p> <ul style="list-style-type: none"> • Update preferred drug choices (pathway A: step 1 and 3; pathway B step 1 and 3) • Local agreement: add adalimumab and tofacitinib to step 2 (pathways A and B) • Change note 1 and step 2 (clarify that step 2 is optional) • Change note 1 and step 2 (clarify that step 2 is optional and not mandatory) • Add reference to IFR (note 5 - pathway A; note 6 - pathway B) 	11 th Mar 2019
6.0	<p>Include approved recommendations from South West London Rheumatology medicines optimisation network meeting (22 July 2021):</p> <ul style="list-style-type: none"> • Add moderate RA treatment pathway • Add filgotinib (TA676), adalimumab, etanercept and infliximab (TA715) and upadacitinib (TA744) for moderate RA • Add upadacitinib (TA665) and filgotinib (TA676) for severe RA • Update preferred drug choices • New local agreements: <ul style="list-style-type: none"> • Increase flexibility for selecting rituximab • Allow alternative drugs to be used after rituximab, if those approved by NICE have been tried/not suitable • Allow switch to alternative anti-TNF if primary/secondary treatment failure with adalimumab and infliximab • Allow temporary switch due to (planning) pregnancy • Introduce multi-Trust MDT step for 4th and 5th line treatment requests (in line with RMOC recommendations) 	15 th June 2022
6.1	<ul style="list-style-type: none"> • Change hydroxychloroquine dose so it is based on actual (instead of ideal) bodyweight to reflect latest Royal College of Ophthalmologists guidance 	16 th January 2023
7.0	<ul style="list-style-type: none"> • Update preferred drug choices for severe RA treatment pathway to reflect tocilizumab biosimilar SC and IV availability 	21 st August 2024

Date of next review: June 2025 (or earlier if indicated)