

## South East Regional Medicines Optimisation Group (SERMOG) policy recommendation

<b>Title:</b>	Rheumatoid arthritis high-cost drug pathway for adults
<b>Number:</b>	SERMOG-11
<b>Category:</b>	Treatment pathway
<b>Date determined by SERMOG:</b>	November 2025

### Introduction

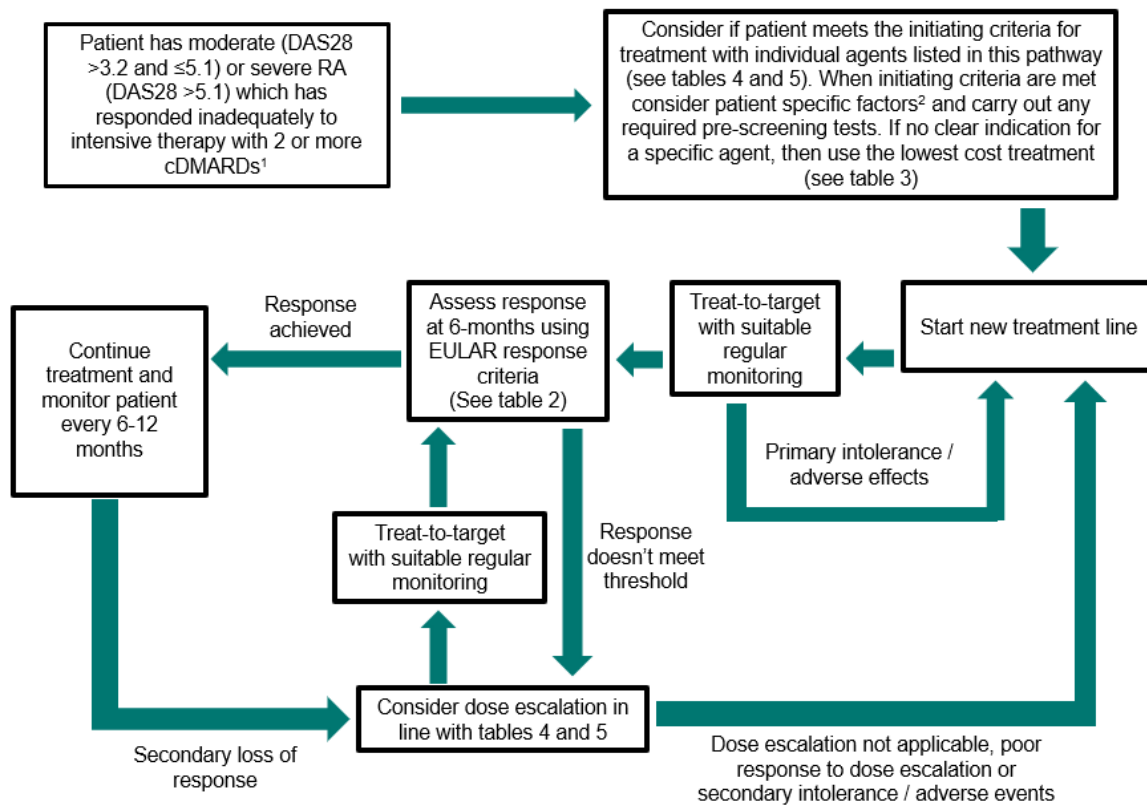
This pathway is a guideline for the initiation and maintenance of high-cost drugs (biologics and small molecules) for the treatment of rheumatoid arthritis (RA) in adults. The pathway follows NICE Technology Appraisal (TA) guidance alongside additional recommendations for dosing regimens considered by the SERMOG. The use of high-cost drugs (HCDs) for the treatment of RA is only approved in line with this pathway and dosing regimens outlined in tables 4 and 5. Any dose regimens outside of these recommendations are not routinely funded, as detailed in SERMOG-02 (Overarching policy on licensed doses or dosing schedules of high-cost drugs not considered in NICE Technology Appraisal (TA) guidance). Where dosing regimens are off label, the guidance in box 1 should be followed. See tables 4 and 5 for considerations when choosing treatment and table 2 on assessing response. Definitions for terms used in the pathway are set out in table 1. Where biosimilars are available, these should be used, as detailed in SERMOG-03 (Overarching policy on switching between biosimilars).

The most appropriate treatment should be chosen after discussing the advantages and disadvantages of the treatments available with the person having treatment. If patients and clinicians consider more than one treatment to be suitable, choose the least expensive treatment (taking into account drug administration costs, dose needed and frequency, and product price per dose). The lowest cost treatments within each mode of action are highlighted in table 3.

According to a Regional Medicines Optimisation Committee (RMOC) Advisory Statement on the sequential use of biologic medicines (May 2020), when a treatment fails, guidance from specialist bodies suggests switching to a biologic with a new mechanism of action is more effective than switching within class. The exception to this is secondary failure of anti-TNF treatment due to formation of anti-drug antibodies, in which case switching within class may be a valid treatment option. It is considered there are currently 5 mechanisms of action in TA recommended HCDs for the treatment of severe RA, and 2 mechanisms of action available for moderate RA. In situations where the appropriateness of further treatment options is undecided, a peer multidisciplinary team discussion may be helpful.

Any new HCDs which receive a positive recommendation from NICE between document iterations will be approved through local ICB processes and will be included in future pathway updates.

**Figure 1. High-cost drug pathway for rheumatoid arthritis**



**Table 1. Pathway definitions and actions**

Description	Definition	Action
Response achieved	A moderate EULAR response (See table 2) is achieved.	Continue treatment and monitor patient as required. Review response every 6-12 months.
Response does not meet threshold	A moderate EULAR response is not achieved. Includes primary nonresponse and partial response.	If available for that agent consider dose escalation <sup>3</sup> or switch mode of action.
Secondary loss of response	Where the improvement at 6-months meets required EULAR response, but this response is lost at a later review	If available for that agent consider dose escalation or switch mode of action <sup>4</sup> .
Primary intolerance or adverse events	Where treatment is discontinued within the initial 6-months due to an inability to tolerate the side-effects of treatment	If class specific or a severe adverse event switch to a new mode of action.

<sup>1</sup> Intensified treatment with at least 2 conventional DMARDs will usually follow a [step-up strategy](#). In most cases cDMARDs will be used in combination.

<sup>2</sup> Such as considerations listed in the [BSR biologic DMARD safety guidelines](#), or the [EULAR recommendations for the management of RA with synthetic and biological DMARDs](#)

<sup>3</sup> Approved dose escalations are detailed in tables 4 and 5.

<sup>4</sup> The exception to this is secondary failure of anti-TNF treatment due to formation of anti-drug antibodies, in which case switching within class may be a valid treatment option (RMOC, 2020).

Secondary intolerance or adverse events	Where treatment is discontinued after 6-months due to inability to tolerate side-effects of treatment	Change to a new mode of action. Switch within class acceptable if loss of response considered to be treatment specific.
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**Table 2. EULAR response criteria**

Current DAS28	Reduction in DAS28		
	>1.2	>0.6 and ≤1.2	≤0.6
≤3.2 Low disease / remission	Good response	Moderate response	No response
>3.2 and ≤5.1 Moderate disease	Moderate response	Moderate response	No response
>5.1 Severe disease	Moderate response	No response	No response

Healthcare professionals should take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DAS28 and make any adjustments they consider appropriate.

**Table 3. Drug treatment options (In drug acquisition cost<sup>5</sup> order with lowest cost option by mode of action highlighted)**

Mode of action	Drug	Method of administration	Moderate RA	Severe RA
TNF alpha inhibitor	Adalimumab	SC Injection	✓	✓
	Infliximab	IV infusion	✓	✓
		SC injection	x	✓
	Etanercept <sup>6</sup>	SC injection	✓	✓
	Golimumab	SC injection	x	✓
	Certolizumab	SC injection	x	✓
B-cell inhibitor	Rituximab	IV infusion	x	✓
T-cell co-stimulation inhibitor	Abatacept	SC injection	x	✓
		IV infusion	x	✓
Interleukin (IL) 6 inhibitor	Tocilizumab	SC injection	x	✓
		IV infusion	x	✓
	Sarilumab	SC injection	x	✓
Janus Kinase (JAK) inhibitor <sup>7</sup>	Filgotinib	IR tablet	✓	✓
	Upadacitinib	PR tablet	✓	✓
	Tofacitinib	IR and PR tablet	x	✓
	Baricitinib	IR tablet	x	✓

<sup>5</sup> Based on year 1 costs. Correct at time of recommendation.

<sup>6</sup> 50 mg once weekly has a lower acquisition cost than 25mg twice a week

<sup>7</sup> Clinicians should consider [measures to reduce risks of major cardiovascular events \(MACE\), malignancy, venous thromboembolism \(VTE\), serious infections and increased mortality](#) when prescribing JAK inhibitors in certain patient groups with RA

## Box 1. Off-label use of drugs in this pathway

The use of HCDs for the treatment of rheumatoid arthritis in line with their license (for example, any requirements for concomitant methotrexate, or stipulated place in therapy) is the preferred treatment option. However, it is acknowledged that there are instances where off-label use may be most clinically appropriate for an individual patient.

Off-label use of agents as a monotherapy (without methotrexate), or as an earlier line of therapy than stipulated in the products licence as detailed within this pathway is supported if the following criteria are met, response is monitored and treatment discontinued if adequate response is not achieved. The prescriber must take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment.

### Criteria for use

- There is consensus at a local level MDT that off-label use is the most clinically appropriate treatment option for the individual.
- There is clear reasoning for off-label use of the treatment over use of another licensed treatment option
- There is recorded informed consent from the individual being treated

### Assessment of response

- Suitable patient monitoring arrangements should be put in place which consider the unique needs of the individual patient.
- High-risk patients<sup>8</sup>, should be regularly reviewed. When required, drug safety monitoring should take place every 3-months.
- If a moderate EULAR response has not been achieved by 6-months, treatment should be stopped and the individual switched to an alternative treatment option (if available).
- If the individual responds at 6 months, response should be re-assessed at 6-12 monthly intervals.
- If there has been a secondary loss of response, then treatment should be stopped and the individual switched to an alternative treatment option.

### Monitoring

The off-label use of agents as detailed in this pathway should be recorded. This record should include details on MDT discussions, response, outcomes and adverse events.

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<sup>8</sup> Such as patient groups defined in the [BSR biologic DMARD safety guidelines](#)

**Table 4. TA recommendations and other agreed drug preparations / dose escalations for moderate (DAS28 >3.2-≤5.1) rheumatoid arthritis**

Treatment	TA	Biosimilar available	Can be used first line	Can be used without methotrexate	Option following prior inadequate treatment with	Dose	Dose escalations	
Adalimumab	TA715 (2021)	✓	✓	✓	2 or more cDMARDs	<ul style="list-style-type: none"> <li>40mg every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>40mg weekly or 80mg every 2 weeks<sup>9</sup></li> </ul>	
Infliximab		✓	✓	x		<ul style="list-style-type: none"> <li>IV - 3mg/kg at weeks 0,2, and 6, followed by every 8 weeks</li> <li>SC – 120mg at week 0, 1, 2, 3, and 4, then every 2 weeks<sup>10</sup></li> </ul>	<ul style="list-style-type: none"> <li>IV – Stepwise increase of 1.5mg from 3mg/kg to 7mg/kg every 8 weeks</li> <li>IV – 3mg/kg every 4 weeks</li> <li>SC – N/A</li> </ul>	
Etanercept		✓	✓	✓		<ul style="list-style-type: none"> <li>50-mg once weekly or 25-mg twice weekly</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>	
Filgotinib		TA676 (2021)	x	✓		✓	<ul style="list-style-type: none"> <li>200 mg once daily<sup>11</sup></li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Upadacitinib		TA744 (2021)	x	✓		✓	<ul style="list-style-type: none"> <li>15mg once daily</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>

<sup>9</sup> Only when used as a monotherapy and the patient demonstrates a diminished response.

<sup>10</sup> SC injections of infliximab may also be used following IV loading doses of 3mg/kg at week 0, and 2. The first dose of SC infliximab should be given 4-weeks after the last IV dose.

<sup>11</sup> In adults at increased risk of VTE, MACE and malignancy the recommended dose is 100 mg once daily and may be escalated to 200 mg once daily in case of insufficient disease control. For long term treatment, the lowest effective dose should be used.

**Table 5. TA recommendations and other agreed drug preparations / dose escalations for severe (DAS28 >5.1) rheumatoid arthritis**

Treatment	TA	Biosimilar available	Can be used first line	Can be used without methotrexate	Option following prior inadequate treatment with	Dose	Dose escalations
Adalimumab	<a href="#">TA375</a> (2016)  <a href="#">TA195</a> (2010)	✓	✓	✓	A combination of cDMARDs <b>OR</b> Other DMARDs including at least 1 anti-TNF and can't have rituximab	<ul style="list-style-type: none"> <li>40mg every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>40mg weekly or 80mg every 2 weeks<sup>9</sup></li> </ul>
Infliximab		✓	✓	✓ <sup>12</sup>		<ul style="list-style-type: none"> <li>IV - 3mg/kg at weeks 0,2, and 6, followed by every 8 weeks</li> <li>SC – 120mg at week 0, 1, 2, 3, and 4, then every 2 weeks<sup>10</sup></li> </ul>	<ul style="list-style-type: none"> <li>IV – Stepwise increase of 1.5mg from 3mg/kg to 7mg/kg every 8 weeks</li> <li>IV – 3mg/kg every 4 weeks</li> <li>S/C – N/A</li> </ul>
Etanercept		✓	✓	✓		<ul style="list-style-type: none"> <li>50-mg once weekly or 25-mg twice weekly</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>

<sup>12</sup> Only in patients with severe disease (DAS28 >5.1) who are unable to take methotrexate. Consider guidance in box 1.

Treatment	TA	Biosimilar available	Can be used first line	Can be used without methotrexate	Option following prior inadequate treatment with	Dose	Dose escalations
Golimumab	<a href="#">TA375</a> (2016) <a href="#">TA225</a> (2011)	✓	✓	x	A combination of cDMARDs <b>OR</b> Other DMARDs including at least 1 anti-TNF and can't have rituximab	<ul style="list-style-type: none"> <li>50mg every month</li> </ul>	<ul style="list-style-type: none"> <li>100mg every month<sup>13</sup></li> </ul>
Certolizumab	<a href="#">TA415</a> (2016) <a href="#">TA375</a> (2016)	x	✓	✓		<ul style="list-style-type: none"> <li>400mg at week 0,2,4 then 200mg every 2 weeks<sup>14</sup></li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Rituximab	<a href="#">TA195</a> (2010)	✓	✓ <sup>15</sup>	✓ <sup>12</sup>	Other DMARDs, including at least 1 anti-TNF	<ul style="list-style-type: none"> <li>2 1000mg infusions<sup>16</sup> given 2 weeks apart<sup>17</sup>.</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>

<sup>13</sup> For use in patients weighing 100kg or more who have had an inadequate response following 3 or 4 doses at 50mg per month. Consideration should be given to the increased risk of certain serious adverse reactions noted in the product SmPC when used at this dose. Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit after receiving 3 to 4 doses at 100 mg per month.

<sup>14</sup> Once a suitable treatment response has been displayed maintenance dosing may be extended to 400mg every 4 weeks.

<sup>15</sup> Rituximab may be used as a first line option only in patients who have severe disease (DAS28 >5.1) and are unable to take TNF alpha inhibitors, or patients with a prior history of malignancy, or those who have RA ILD. Consider guidance in box 1.

<sup>16</sup> Premedication with 100 mg intravenous methylprednisolone should be completed 30 minutes prior to each infusion.

<sup>17</sup> As per [TA195](#), retreatment should not occur within 6 months.

Treatment	TA	Biosimilar available	Can be used first line	Can be used without methotrexate	Option following prior inadequate treatment with	Dose	Dose escalations
Abatacept	<a href="#">TA195</a> (2010) <a href="#">TA375</a> (2016)	x	✓	✓ <sup>12</sup>	A combination of cDMARDS <b>OR</b> Other DMARDS including at least 1 anti-TNF and can't have rituximab	<ul style="list-style-type: none"> <li>• SC injection – 125mg each week</li> <li>• IV infusion - 500 mg for a person weighing &lt;60 kg, 750 mg for a person weighing 60kg-100 kg, and 1,000 mg for a person weighing &gt;100kg given at week 0, 2, and 4, then every 4 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Tocilizumab	<a href="#">TA375</a> (2016) <a href="#">TA247</a> (2012)	✓	✓	✓		<ul style="list-style-type: none"> <li>• SC injection – 162mg once every week</li> <li>• IV infusion – 8mg/kg every 4 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Sarilumab	<a href="#">TA485</a> (2017)	x	✓	✓	A combination of cDMARDS <b>OR</b> Other DMARDS including at least 1 bDMARD and can't have rituximab	<ul style="list-style-type: none"> <li>• 200mg every 2 weeks<sup>18</sup></li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

<sup>18</sup> A reduced dose of 150 mg once every 2 weeks is recommended for management of neutropenia, thrombocytopenia, and liver enzyme elevations.

Treatment	TA	Biosimilar available	Can be used first line	Can be used without methotrexate	Option following prior inadequate treatment with	Dose	Dose escalations
Filgotinib <sup>7</sup>	<a href="#">TA676</a> (2021)	x	✓	✓	2 or more cDMARDs <b>OR</b> they can't have other DMARDS including at least 1 bDMARD <b>OR</b> Rituximab and at least 1 bDMARD	<ul style="list-style-type: none"> <li>200mg once daily<sup>11</sup></li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Upadacitinib <sup>7</sup>	<a href="#">TA665</a> (2020)	x	✓	✓	A combination of cDMARDS	<ul style="list-style-type: none"> <li>15mg once daily</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Tofacitinib <sup>7</sup>	<a href="#">TA480</a> (2017)	x	✓	✓	<b>OR</b> Other DMARDS including at least 1 bDMARD and can't have rituximab	<ul style="list-style-type: none"> <li>IR tablet – 5mg twice daily</li> <li>PR tablet – 11mg once daily</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Baricitinib <sup>7</sup>	<a href="#">TA466</a> (2017)	x	✓	✓		<ul style="list-style-type: none"> <li>4mg once daily<sup>19</sup></li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>

<sup>19</sup> A 2 mg once-daily dose is recommended for patients at increased risk of VTE, MACE, or malignancy, for those aged ≥65 years, and for patients with chronic or recurrent infections. A 4 mg once-daily dose may be used where disease control is inadequate on 2 mg. Patients with sustained disease control on 4 mg who are suitable for dose tapering should be considered for reduction to 2 mg once daily.

**Version control:**

Version 1.0 – Circulated to ICBs for ratification on 27th November 2025

**Notes:**

This policy recommendation will be reviewed when new information becomes available that is likely to have a material effect on the current recommendation.

South East region ICBs will always consider appropriate individual funding requests (IFRs) through their IFR processes.