

## Integrated Impact Assessment Report for Clinical Commissioning Policies

|                                |   |                        |                     |
|--------------------------------|---|------------------------|---------------------|
| <b>Policy Reference Number</b> | 1713  |                        |                     |
| <b>Policy Title</b>            | Anakinra for periodic fevers and autoinflammatory disease<br>Proposal <b><u>for routine commission</u></b> (ref A3.1) |                        |                     |
| <b>Lead Commissioner</b>       | Joan Ward   | <b>Clinical Lead</b>   | Prof Philip Hawkins |
| <b>Finance Lead</b>            | Keith Moulds  | <b>Analytical Lead</b> | Craig Charlton      |

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### About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.

## Section A - Activity Impact

### A1 Current Patient Population & Demography / Growth

A1.1 Prevalence of the disease/condition.

This policy addresses the need to provide anakinra for patients with periodic fevers and autoinflammatory disease. These are very rarer diseases. There are four main diseases, 1.**Familial Mediterranean Fever** Incidence <40 new cases a year. Prevalence <400 patients in England Proportion of patients who may require anakinra: estimated at 20-40 patients, assuming 5-10% of patients will have colchicine-resistant disease, or be unable to tolerate colchicine 2.**Hyperimmunoglobulin D syndrome (HIDS) / Mevalonate Kinase Deficiency (MKD)** Incidence: <5 new cases a year

Prevalence <50 patients in England (<300 globally)

Proportion of patients who may require anakinra: approximately 70%

#### 3.Schnitzler's syndrome

Incidence: < 5 new cases a year.

Prevalence <50 patients in England.

Proportion of patients who may require anakinra: 100% (as anakinra is recommended as the first line treatment for this disease)

#### 4.Tumour necrosis factor receptor-associated periodic syndrome (TRAPS)

Incidence: <10 new cases a year

Prevalence <100 patients in England

Proportion of patients who may require anakinra: 75%

The best aggregated estimates for these conditions taken together are:

- Incidence: approx. 40-60 new cases a year
- Prevalence <600, of whom approx. 200 may require anakinra.

|  |   |       |         |                 |         |        |         |       |         |
|--|---|-------|---------|-----------------|---------|--------|---------|-------|---------|
|  | <p><i>Source: Policy Proposition section 6</i></p>  |       |         |                 |         |        |         |       |         |
| <p>A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.</p> | <p>Between 35 and 47 patients<br/> <i>Source: Click here to enter text.</i><br/> Please specify Clinical estimate<br/> Click here to enter text.</p>  |       |         |                 |         |        |         |       |         |
| <p>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</p>                    | <p><b><u>All ages</u></b><br/> Please specify<br/> Click here to enter text.</p>  |       |         |                 |         |        |         |       |         |
| <p>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</p>      | <p>enter number. if relevant not relevant<br/> <i>Source: required</i><br/> Please specify<br/> Click here to enter text.</p>   |       |         |                 |         |        |         |       |         |
| <p>A1.5 How is the population currently distributed geographically?</p>  | <p><b><u>unknown</u></b><br/> Geographic distribution is believed to be random and in proportion to denominator population</p> <table border="1" data-bbox="1088 1000 1599 1219"> <tr> <td>North</td> <td>enter %</td> </tr> <tr> <td>Midlands &amp; East</td> <td>enter %</td> </tr> <tr> <td>London</td> <td>enter %</td> </tr> <tr> <td>South</td> <td>enter %</td> </tr> </table> <p><i>Source: Policy Proposition section 6</i><br/> Please specify<br/> Click here to enter text.</p> | North | enter % | Midlands & East | enter % | London | enter % | South | enter % |
| North  | enter %   |       |         |                 |         |        |         |       |         |
| Midlands & East  | enter %   |       |         |                 |         |        |         |       |         |
| London   | enter %   |       |         |                 |         |        |         |       |         |
| South  | enter %   |       |         |                 |         |        |         |       |         |

## A2 Future Patient Population & Demography

A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?

### **Increasing**

We expect the incidence to increase in line with population growth, and that prevalence may increase in the longer term due to improved patient survival as a result of the use of anakinra, but that it is not possible to model this with any accuracy.

If other, [Click here to enter text.](#)

*Source: Policy Proposition section 6*

A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?

### **Not known**

Please specify

[Click here to enter text.](#)

*Source: Policy Proposition section 6/other*

A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?

|          |   |
|----------|---|
| YR2 +/-  | 0 |
| YR3 +/-  | 1 |
| YR4 +/-  | 1 |
| YR5 +/-  | 1 |
| YR10 +/- | 3 |

*Source: Service specification proposition section 3.1*

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.

Choose an item.

[Click here to enter text.](#)

| A3 Activity   |  |
|---|--|
| A3.1 What is the purpose of new policy?   | <p><b><u>Confirm routine commissioning position of an existing treatment</u></b></p> <p>Please specify<br/> <a href="#">Click here to enter text.</a></p>  |
| A3.2 What is the annual activity associated with the existing pathway for the eligible population?  | <p>81 patients are funded by NHS England, based on the funding arrangements in place prior to April 2016 <i>these patients will be included within the baselines for the London and North regions</i></p> <p><i>Source: required</i></p> <p>Please specify Clinical estimates</p> <p>The current population is made up of the patients who were previously able to access this drug before it was realised that there was no policy to support the commissioning of this drug.</p> |
| A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?   | <p>47 newly identified patients per year</p> <p><i>Source: based on exclusion of patients being treated currently and anticipated patients for year 1 of delivery</i></p> <p>Please specify<br/> <i>Financial modelling</i></p>  |
| A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4. | <p>enter number. Not applicable there is no comparator</p> <p><i>Source: required</i></p> <p>Please specify<br/> <a href="#">Click here to enter text.</a></p>   |
| A4 Existing Patient Pathway   |  |

|   |  |
|---|--|
| <p>A4.1 <b>Existing pathway:</b> Describe the relevant currently routinely commissioned:</p> <ul style="list-style-type: none"> <li>• Treatment or intervention</li> <li>• Patient pathway</li> <li>• Eligibility and/or uptake estimates.</li> </ul> | <p>The existing pathway for this cohort is a difficult one, there is not an effective treatment and patients are regularly seen at A&amp;E and have inpatient admissions to deal with the symptoms. A proportion (6% of adult FMF, 18% TRAPS patients and 18% of MKD patients) will go on to develop renal disease, requiring dialysis and kidney transplants, this number increases if patients are not able to access anakinra.</p> <p><i>Source: required</i></p>   |
| <p>A4.2. What are the current treatment access and stopping criteria?</p>   | <p>Patient eligibility criteria</p> <p><b>FMF</b> Anakinra may be used in patients who have: documented evidence of ongoing attacks characterised by intense bouts of debilitating abdominal and chest pain that can last 12 to 72 hours; and documented evidence of intolerance due to side effects or of disease unresponsive to effective doses of colchicine up to 3.0 mg/day (or equivalent paediatric age/ weight adjusted dosing regimen)</p> <p><b>HIDS/MKD</b> Anakinra may be used in patients who have documented evidence of at least three HIDS flares in a six-month period when not receiving treatment, and whose disease is poorly managed by first line treatments or who have documented significant adverse effects associated with first line treatments, provided that there is documented evidence of chronic or recurrent disease activity supported by substantially elevated acute phase markers (CRP and/or SAA)</p> <p><b>Schnitzler’s syndrome</b></p> <p>Anakinra may be used as a first line treatment in patients with a documented diagnosis of Schnitzler syndrome.</p> <p><b>TRAPS</b></p> <p>Anakinra may be used in patients who have severe flares, rash and tissue pain, periorbital edema and joint pain and whose disease is poorly managed by first line treatments or who have documented significant adverse effects associated with first line treatments, provided that there is documented evidence of chronic or recurrent disease activity supported by</p> |

|   |  |
|---|--|
|   | <p>substantially elevated acute phase markers (CRP and/or SAA).</p> <p><b>Stopping criteria</b></p> <p>The stopping criteria for all the four diseases are:</p> <ul style="list-style-type: none"> <li>• Inadequate clinical response to treatment</li> <li>• Adverse effects, including neutropenia; these may be managed by varying the dose or occasionally temporarily discontinuing the drug</li> </ul> <p>Patients who have a moderate response should continue for six months. If, at the end of that period the disease response achieved is below the threshold of moderate response, the treatment should be stopped.</p> <p>A moderate response is defined as an improvement in inflammatory disease activity equating to less than 50% greater than 20-50% improvement based on the blood markers of inflammation.</p> <p><i>Source: Policy Document</i></p> |
| <p>A4.3 What percentage of the total eligible population is expected to:</p> <ol style="list-style-type: none"> <li>Be clinically assessed for treatment</li> <li>Be considered to meet an exclusion criteria following assessment</li> <li>Choose to initiate treatment</li> <li>Comply with treatment</li> <li>Complete treatment?</li> </ol> | <p>If not known, please specify <a href="#">Click here to enter text.</a></p> <ol style="list-style-type: none"> <li>100% <i>the eligible population is defined as the cohort of patients for whom first line treatments are not effective</i></li> <li>0%</li> <li>100%</li> <li>100%</li> <li>Treatment is not curative so patients are unlikely to exit</li> </ol> <p><i>Source: required</i></p>   |
| <p><b>A5 Comparator (next best alternative treatment) Patient Pathway</b><br/> (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)</p>  |  |



|  |   |
|--|---|
| <p><b>A5.1 Next best comparator:</b><br/>Is there another 'next best' alternative treatment which is a relevant comparator?<br/><i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment or intervention</i></li> <li>• <i>Patient pathway</i></li> <li>• <i>Actual or estimated eligibility and uptake</i></li> </ul>               | <p><b><u>No</u></b><br/>If yes, <a href="#">Click here to enter text.</a><br/><i>Source: required</i></p>   |
| <p><b>A5.2</b> What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul> | <p>Total estimated eligible</p> <ul style="list-style-type: none"> <li>a) enter %</li> <li>b) enter %</li> <li>c) enter %</li> <li>d) enter %</li> <li>e)</li> </ul> <p><i>Source: required</i></p>   |
| <p><b>A6 New Patient Pathway</b></p>   |   |
| <p><b>A6.1</b> What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>  | <p>If not known, please specify <a href="#">Click here to enter text.</a></p> <ul style="list-style-type: none"> <li>a) 100%</li> <li>b) 0%</li> <li>c) 100%</li> <li>d) 100%</li> <li>e) 0% drug is not curative</li> </ul> <p><i>Source: required</i></p> |

A6.2 Specify the nature and duration of the proposed new treatment or intervention.

**Life long**

For time limited treatments, specify frequency and/or duration.

[Click here to enter text.](#)

*Source: required*

**A7 Treatment Setting**

A7.1 How is this treatment delivered to the patient?

*Select all that apply:*

|                                    |                                     |
|------------------------------------|-------------------------------------|
| Emergency/Urgent care attendance   | <input type="checkbox"/>            |
| Acute Trust: inpatient             | <input type="checkbox"/>            |
| Acute Trust: day patient           | <input checked="" type="checkbox"/> |
| Acute Trust: outpatient            | <input checked="" type="checkbox"/> |
| Mental Health provider: inpatient  | <input type="checkbox"/>            |
| Mental Health provider: outpatient | <input type="checkbox"/>            |
| Community setting                  | <input type="checkbox"/>            |
| Homecare                           | <input checked="" type="checkbox"/> |
| Other                              | <input type="checkbox"/>            |

Please specify:

[Click here to enter text.](#)

A7.2 What is the current number of contracted providers for the eligible population by region?

|                 |           |
|-----------------|-----------|
| NORTH           | Not known |
| MIDLANDS & EAST | Not known |
| LONDON          | Not known |

|  |   |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
|--|---|-----------|---------------------------------|-------------------------------------|-----------------------------------|-------------------------------------|-----------------------------|--------------------------|-------------------------------|--------------------------|---|--------------------------|--------------------------------|--------------------------|--|--------------------------|-------------------|--------------------------|---------------------|--------------------------|---------|--------------------------|
|  | SOUTH   | Not known |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| <p>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</p>  | <p><b>No</b><br/> Please specify:<br/> Click here to enter text.<br/> Source: <i>required</i></p>   |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| <p><b>A8 Coding</b></p>  |   |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| <p>A8.1 Specify the datasets used to record the new patient pathway activity.</p> <p>*expected to be populated for all commissioned activity</p> | <p>Select all that apply:</p> <table border="1" data-bbox="1086 651 1848 1241"> <tr> <td>Aggregate Contract Monitoring *</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level contract monitoring</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level drugs dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level devices dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Devices supply chain reconciliation dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary Usage Service (SUS+)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health Services DataSet (MHSDS)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National Return**</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical Database**</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other**</td> <td><input type="checkbox"/></td> </tr> </table> <p>**If National Return, Clinical database or other selected, please specify:<br/> Click here to enter text.</p> |           | Aggregate Contract Monitoring * | <input checked="" type="checkbox"/> | Patient level contract monitoring | <input checked="" type="checkbox"/> | Patient level drugs dataset | <input type="checkbox"/> | Patient level devices dataset | <input type="checkbox"/> | Devices supply chain reconciliation dataset | <input type="checkbox"/> | Secondary Usage Service (SUS+) | <input type="checkbox"/> | Mental Health Services DataSet (MHSDS) | <input type="checkbox"/> | National Return** | <input type="checkbox"/> | Clinical Database** | <input type="checkbox"/> | Other** | <input type="checkbox"/> |
| Aggregate Contract Monitoring *  | <input checked="" type="checkbox"/>   |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| Patient level contract monitoring  | <input checked="" type="checkbox"/>   |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| Patient level drugs dataset  | <input type="checkbox"/>  |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| Patient level devices dataset  | <input type="checkbox"/>  |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| Devices supply chain reconciliation dataset  | <input type="checkbox"/>  |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| Secondary Usage Service (SUS+)   | <input type="checkbox"/>  |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| Mental Health Services DataSet (MHSDS)   | <input type="checkbox"/>  |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| National Return**  | <input type="checkbox"/>  |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| Clinical Database**  | <input type="checkbox"/>  |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |
| Other**  | <input type="checkbox"/>  |           |                                 |                                     |                                   |                                     |                             |                          |                               |                          |   |                          |                                |                          |  |                          |                   |                          |                     |                          |         |                          |

A8.2 Specify how the activity related to the new patient pathway will be identified.

Select all that apply

|   |                                     |
|---|-------------------------------------|
| OPCS v4.8   | <input type="checkbox"/>            |
| ICD10   | <input type="checkbox"/>            |
| Treatment function code   | <input type="checkbox"/>            |
| Main Speciality code  | <input type="checkbox"/>            |
| HRG   | <input type="checkbox"/>            |
| SNOMED  | <input type="checkbox"/>            |
| Clinical coding / terming methodology used by clinical profession | <input checked="" type="checkbox"/> |

**A8.3 Identification Rules for Drugs:**

How are drug costs captured?

Choose an item.  
 If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:  
 Anakinra is commissioned currently for a number of conditions  
 If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:  
 The coding of anakinra has been discussed with the pharmacy and Information lead for Specialised Commissioning

**A8.4 Identification Rules for Devices:**

How are device costs captured?

**Not applicable**  
 If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).  
[Click here to enter text.](#)  
 If the device is not excluded from Tariff **nor** covered within existing National or Local prices please specify details of action required and

|  |   |                     |                          |         |                                     |
|--|---|---------------------|--------------------------|---------|-------------------------------------|
|  | <p>confirm that this has been discussed with the HCTED team.<br/> <a href="#">Click here to enter text.</a></p>   |                     |                          |         |                                     |
| <p><b>A8.5 Identification Rules for Activity:</b><br/> How are activity costs captured?</p>  | <p><b><u>Not captured by an existing specialised service line</u></b><br/> If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).<br/> <a href="#">Click here to enter text.</a><br/> If activity costs are already captured please specify whether this service needs a separate code. <a href="#">Choose an item.</a><br/> If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team.<br/> <a href="#">Click here to enter text.</a><br/> If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. <a href="#">Choose an item.</a></p> |                     |                          |         |                                     |
| <p><b>A9 Monitoring</b></p>  |   |                     |                          |         |                                     |
| <p><b>A9.1 Contracts</b><br/> Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</p>  | <p><b><u>Yes - other</u></b><br/> Please specify<br/> Data will be collected by providers to inform a national audit meeting of the prescribing centres</p>   |                     |                          |         |                                     |
| <p><b>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)</b><br/> For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval</p> | <p><i>Select all that apply:</i></p> <table border="1" data-bbox="1086 1222 1599 1342"> <tr> <td data-bbox="1086 1222 1509 1283">Drugs or Device MDS</td> <td data-bbox="1509 1222 1599 1283"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1283 1509 1342">Blueteq</td> <td data-bbox="1509 1283 1599 1342"><input checked="" type="checkbox"/></td> </tr> </table>   | Drugs or Device MDS | <input type="checkbox"/> | Blueteq | <input checked="" type="checkbox"/> |
| Drugs or Device MDS  | <input type="checkbox"/>  |                     |                          |         |                                     |
| Blueteq  | <input checked="" type="checkbox"/>   |                     |                          |         |                                     |

|   |   |
|---|---|
| systems.  | <div style="border: 1px solid black; display: inline-block; padding: 2px;">Other prior approval</div> <input type="checkbox"/> <p>Please specify: <a href="#">Click here to enter text.</a></p>       |
| <b>A9.3 Business intelligence</b><br>Is there potential for duplicate reporting?  | <b><u>No</u></b><br>If yes, please specify mitigation:<br><a href="#">Click here to enter text.</a>   |
| <b>A9.4 Contract monitoring</b><br>Is this part of routine contract monitoring?   | <b><u>Yes</u></b><br>If yes, please specify contract monitoring requirement:<br><a href="#">Click here to enter text.</a>   |
| <b>A9.5 Dashboard reporting</b><br>Specify whether a dashboard exists for the proposed intervention?  | <b><u>No</u></b><br>If yes, specify how routine performance monitoring data will be used for dashboard reporting.<br><a href="#">Click here to enter text.</a><br>If no, will one be developed?<br>No |
| <b>A9.6 NICE reporting</b><br>Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy? | <b><u>No</u></b><br>If yes, specify how performance monitoring data will be used for this purpose.<br><a href="#">Click here to enter text.</a>   |
| <b>Section B - Service Impact</b>   |   |
| <b>B1 Service Organisation</b>  |   |
| B1.1 Describe how the service is currently organised? (i.e. tertiary  | The service is provided by a small number of tertiary specialist  |

|   |   |    |                                     |                |                                     |               |                                     |       |                          |
|---|---|----|-------------------------------------|----------------|-------------------------------------|---------------|-------------------------------------|-------|--------------------------|
| centres, networked provision etc.)  | immunology and paediatric rheumatology providers<br><i>Source: required</i>   |    |                                     |                |                                     |               |                                     |       |                          |
| B1.2 Will the proposition change the way the commissioned service is organised? | <b>Yes</b><br>Please specify:<br>Prescribing will be limited to providers that are members or affiliates of the RITA ERN for immunodeficiency, autoinflammatory and autoimmune diseases<br><i>Source: required</i>  |    |                                     |                |                                     |               |                                     |       |                          |
| B1.3 Will the proposition require a new approach to the organisation of care?   | <b><u>No change to delivery of care</u></b><br>Please specify:<br><a href="#">Click here to enter text.</a>   |    |                                     |                |                                     |               |                                     |       |                          |
| <b>B2 Geography &amp; Access</b>  |   |    |                                     |                |                                     |               |                                     |       |                          |
| B2.1 Where do current referrals come from?                                      | <p><i>Select all that apply:</i></p> <table border="1" data-bbox="1086 903 1597 1139"> <tr> <td data-bbox="1086 903 1509 963">GP</td> <td data-bbox="1509 903 1597 963"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 963 1509 1024">Secondary care</td> <td data-bbox="1509 963 1597 1024"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1024 1509 1085">Tertiary care</td> <td data-bbox="1509 1024 1597 1085"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1085 1509 1139">Other</td> <td data-bbox="1509 1085 1597 1139"><input type="checkbox"/></td> </tr> </table> <p>Please specify:<br/><a href="#">Click here to enter text.</a></p> | GP | <input checked="" type="checkbox"/> | Secondary care | <input checked="" type="checkbox"/> | Tertiary care | <input checked="" type="checkbox"/> | Other | <input type="checkbox"/> |
| GP  | <input checked="" type="checkbox"/>   |    |                                     |                |                                     |               |                                     |       |                          |
| Secondary care  | <input checked="" type="checkbox"/>   |    |                                     |                |                                     |               |                                     |       |                          |
| Tertiary care   | <input checked="" type="checkbox"/>   |    |                                     |                |                                     |               |                                     |       |                          |
| Other   | <input type="checkbox"/>  |    |                                     |                |                                     |               |                                     |       |                          |
| B2.2 What impact will the new policy have on the sources of referral?           | <b><u>No impact</u></b><br>Please specify:  |    |                                     |                |                                     |               |                                     |       |                          |

|   |   |
|---|---|
|   | Click here to enter text.   |
| B2.3 Is the new policy likely to improve equity of access?  | <p><b><u>Increase</u></b><br/> Please specify:<br/> There is currently a funded patient cohort, and unfunded patient cohort. This policy will ensure equality of access.<br/> Source: <i>Equalities Impact Assessment</i></p> |
| B2.4 Is the new policy likely to improve equality of access and/or outcomes?  | <p><b><u>Increase</u></b><br/> Please specify:<br/> See above, patients symptoms resolve whilst on treatment<br/> Source: <i>Equalities Impact Assessment</i></p>   |
| <b>B3 Implementation</b>  |   |
| B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?  | <p><b><u>Contract action</u></b><br/> Please specify: Trusts will need to declare that they are a member or an affiliate member of RITA ERN.<br/> Click here to enter text.</p>   |
| <p><b>B3.2 Time to implementation:</b><br/> Is a lead-in time required prior to implementation?</p>   | <p><b><u>No - go to B3.4</u></b><br/> If yes, specify the likely time to implementation: Enter text</p>   |
| <p><b>B3.3 Time to implementation:</b><br/> If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p> | <p>Choose an item.<br/> If yes, outline the plan:<br/> Click here to enter text.</p>  |



| B3.4 Is a change in provider physical infrastructure required?   | <p><b>No</b><br/>Please specify:<br/><a href="#">Click here to enter text.</a></p>  |                             |                          |                             |                          |       |  |  |        |
|--|---|-----------------------------|--------------------------|-----------------------------|--------------------------|-------|--|--|--------|
| B3.5 Is a change in provider staffing required?  | <p><b>No</b><br/>Please specify:<br/><a href="#">Click here to enter text.</a></p>  |                             |                          |                             |                          |       |  |  |        |
| B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?   | <p><b>No</b><br/>Please specify:<br/><a href="#">Click here to enter text.</a></p>  |                             |                          |                             |                          |       |  |  |        |
| B3.7 Are there changes in the support services that need to be in place?   | <p><b>No</b><br/>Please specify:<br/><a href="#">Click here to enter text.</a></p>  |                             |                          |                             |                          |       |  |  |        |
| B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)   | <p><b>Yes</b> The Providers will have to meet annually to audit the activity and outcomes<br/>Please specify:<br/><a href="#">Click here to enter text.</a></p>   |                             |                          |                             |                          |       |  |  |        |
| B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region | <p><b>Not yet known</b> no providers are currently commissioned to provide this service<br/><i>Please complete table:</i></p> <table border="1" data-bbox="1086 1182 2013 1374"> <thead> <tr> <th data-bbox="1086 1182 1281 1321">Region</th> <th data-bbox="1281 1182 1525 1321">Current no. of providers</th> <th data-bbox="1525 1182 1830 1321">Future State expected range</th> <th data-bbox="1830 1182 2013 1321">Provisional or confirmed</th> </tr> </thead> <tbody> <tr> <td data-bbox="1086 1321 1281 1374">North</td> <td data-bbox="1281 1321 1525 1374"></td> <td data-bbox="1525 1321 1830 1374"></td> <td data-bbox="1830 1321 2013 1374">select</td> </tr> </tbody> </table> | Region                      | Current no. of providers | Future State expected range | Provisional or confirmed | North |  |  | select |
| Region   | Current no. of providers  | Future State expected range | Provisional or confirmed |                             |                          |       |  |  |        |
| North  |   |                             | select                   |                             |                          |       |  |  |        |

|  |                 |  |  |        |
|--|-----------------|--|--|--------|
|  | Midlands & East |  |  | select |
|  | London          |  |  | select |
|  | South           |  |  | select |
|  | Total           |  |  | select |

Please specify:

[Click here to enter text.](#)

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

*Select all that apply:*

|   |                                     |
|---|-------------------------------------|
| Publication and notification of new policy  | <input checked="" type="checkbox"/> |
| Market intervention required  | <input type="checkbox"/>            |
| Competitive selection process to secure increase or decrease provider configuration | <input type="checkbox"/>            |
| Price-based selection process to maximise cost effectiveness                        | <input type="checkbox"/>            |
| Any qualified provider  | <input checked="" type="checkbox"/> |
| National Commercial Agreements e.g. drugs, devices                                  | <input type="checkbox"/>            |
| Procurement   | <input type="checkbox"/>            |
| Other   | <input checked="" type="checkbox"/> |

Please specify:

Any qualified provider means one who is a member of the RITA ERN

#### B4 Place-based Commissioning

B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)

**No**

Please specify:

[Click here to enter text.](#)

### Section C - Finance Impact

#### C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?  
Only specify for the relevant section of the patient pathway

*Select all that apply:*

|                 |  |                                     |
|-----------------|--|-------------------------------------|
| <b>Drugs</b>    | Not separately charged – part of local or national tariffs | <input type="checkbox"/>            |
|                 | Excluded from tariff – pass through                        | <input checked="" type="checkbox"/> |
|                 | Excluded from tariff - other                               | <input type="checkbox"/>            |
| <b>Devices</b>  | Not separately charged – part of local or national tariffs | <input type="checkbox"/>            |
|                 | Excluded from tariff (excluding ZCM) – pass through        | <input type="checkbox"/>            |
|                 | Excluded from tariff (excluding ZCM) – other               | <input type="checkbox"/>            |
|                 | Via Zero Cost Model  | <input type="checkbox"/>            |
| <b>Activity</b> | Paid entirely by National Tariffs                          | <input checked="" type="checkbox"/> |
|                 | Paid entirely by Local Tariffs                             | <input type="checkbox"/>            |
|                 | Partially paid by National Tariffs                         | <input type="checkbox"/>            |
|                 | Partially paid by Local Tariffs                            | <input type="checkbox"/>            |
|                 | Part/fully paid under a Block arrangement                  | <input type="checkbox"/>            |
|                 | Part/fully paid under Pass-Through arrangements            | <input type="checkbox"/>            |
|                 | Part/fully paid under Other arrangements                   | <input type="checkbox"/>            |

|   |  |
|---|--|
| <p><b>C1.2 Drug Costs</b><br/>Where not included in national or local tariffs, list each drug or combination, dosage, quantity, <b>list</b> price including VAT if applicable and any other key information e.g. Chemotherapy Regime.<br/>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p> | <p>Anakinra annual cost for delivery in a hospital setting is £11,489 to provide 100mg per day to each patient this value includes VAT at the standard 20% rate, the cost of the drug is reduced by delivery in a homecare setting to £9,850 which is inclusive of delivery and administration charges. The charge can also be further reduced by delivery through an outsourced pharmacy to £9,574 which excludes a delivery charge.</p>  |
| <p><b>C1.3 Device Costs</b><br/>Where not included in national or local tariff, list each element of the excluded device, quantity, <b>list or expected</b> price including VAT if applicable and any other key information.<br/>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>         | <p>NA</p>  |
| <p><b>C1.4 Activity Costs covered by National Tariffs</b><br/>List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</p>   | <p>A&amp;E attendances priced at an average of Type 1 &amp; 2 departments at £158 per attendance (VB01Z – VB99Z)<br/>OP attendances are priced at Rheumatology OP rates against WF01B single professional first attendance £246 and WF01A single professional follow up £111.<br/>Inpatient attendances are costed using an average rate of adults £2,798 against HRG`s WJ07A – WJ07D, Paediatric patients are an average £800 using HRG`s PW20A – PW20C, dependent upon complication and comorbidity score<br/>MFF is then applied at 8.075%.</p> |
| <p><b>C1.5 Activity Costs covered by Local Tariff</b><br/>List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.</p>  | <p>N/A</p>   |



|  |   |
|--|---|
| C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.   | N/A   |
| C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated? | NA  |
| <b>C4 Overall cost impact of this policy to the NHS as a whole</b>   |   |
| C4.1 Specify the budget impact of the proposal on other parts of the NHS.  | <p>Budget impact for CCGs:<br/><b><u>Cost neutral</u></b></p> <p>Budget impact for providers:<br/><b><u>Cost neutral</u></b></p> <p>Please specify:<br/><a href="#">Click here to enter text.</a></p>                             |
| C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.  | <p><b><u>Cost saving</u></b></p> <p>Please specify:<br/><a href="#">Click here to enter text.</a></p>   |
| C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured  | NA  |
| C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?   | <p><b><u>Yes</u></b></p> <p>Please specify: Patients will be able to lead normal lives, to go to work and school, to pay taxes and not be reliant on state financial support</p> <p><a href="#">Click here to enter text.</a></p> |

**C5 Funding**

C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.

There will be an initial cost pressure of £377,530 to meet the drug costs of patients who would become eligible under this policy *this value is already within the baselines of the London and North regions*

**C6 Financial Risks Associated with Implementing this Policy**

C6.1 What are the material financial risks to implementing this policy?

None

C6.2 How can these risks be mitigated?

NA

C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?

The impact of the disease over 10 years has been modelled for patients who are treated with Anakinra, and those not treated with Anakinra but following the current pathway of A&E and regular IP stays to treat the conditions .

C6.4 What scenario has been approved and why?

[Click here to enter text.](#) It is more cost effective to treat these patients with anakinra then to leave them untreated and using other NHS resources for symptom alleviation, which is less effective and more expensive.

**C7 Value for Money**

C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?

**There is no published evidence of cost-effectiveness**

Please specify:

|  |  |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
|--|--|---|--------------------------|--|-------------------------------------|--|--------------------------|--------------------------------|--------------------------|-----------------------------|--------------------------|---|-------------------------------------|---|--------------------------|
|  | Click here to enter text.  |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money? | <p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other data has been identified</td> <td><input type="checkbox"/></td> </tr> <tr> <td>No data has been identified</td> <td><input type="checkbox"/></td> </tr> <tr> <td>The data supports a high level of certainty about the impact on value</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>The data does not support a high level of certainty about the impact on value</td> <td><input type="checkbox"/></td> </tr> </table> <p>Please specify:<br/>Click here to enter text.</p> | Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment | <input type="checkbox"/> | Available pricing data suggests the treatment is lower cost compared to current/comparator treatment | <input checked="" type="checkbox"/> | Available clinical practice data suggests the new treatment has the potential to improve value for money | <input type="checkbox"/> | Other data has been identified | <input type="checkbox"/> | No data has been identified | <input type="checkbox"/> | The data supports a high level of certainty about the impact on value | <input checked="" type="checkbox"/> | The data does not support a high level of certainty about the impact on value | <input type="checkbox"/> |
| Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment                        | <input type="checkbox"/>   |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| Available pricing data suggests the treatment is lower cost compared to current/comparator treatment                             | <input checked="" type="checkbox"/>  |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| Available clinical practice data suggests the new treatment has the potential to improve value for money                         | <input type="checkbox"/>   |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| Other data has been identified   | <input type="checkbox"/>   |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| No data has been identified  | <input type="checkbox"/>   |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| The data supports a high level of certainty about the impact on value  | <input checked="" type="checkbox"/>  |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| The data does not support a high level of certainty about the impact on value  | <input type="checkbox"/>   |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| <b>C8 Cost Profile</b>   |  |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| C8.1 Are there non-recurrent capital or revenue costs associated with this policy?   | <p><b>No</b></p> <p>If yes, specify type and range:<br/>Click here to enter text.</p>  |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |
| C8.2 If yes, confirm the source of funds to meet these costs.  | Click here to enter text.  |   |                          |  |                                     |  |                          |                                |                          |                             |                          |   |                                     |   |                          |



Draft for consultation