Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	ID-012		
Policy Title	Canakinumab for periodic fever syndromes Proposal **for routine commission** (ref A3.1)		
Lead Commissioner	Joan Ward	**Clinical Lead**	Dr Philip Hawkins
Finance Lead	Jacqueline Low	**Analytical Lead**	Richard Diaz

Integrated Impact Assessment – Index		
Section A – Activity	**Section B - Service**	**Section C – Finance**
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this Policy to NHS England
A4 Existing Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this policy to the NHS as a whole
A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
A6 New Patient Pathway		C6 Financial Risks Associated with Implementing this Policy
A7 Treatment Setting		C7 Value for Money
A8 Coding		C8 Cost Profile
A9 Monitoring		

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.

	Familial Mediterranean fever (FMF)	Tumour necrosis factor receptor associated periodic syndrome (TRAPS)	Hyperimmunoglobulin D syndrome / mevalonate Kinase deficiency (HIDS/MKD)	Total
Children 2-17 Prevalence	8	12	8	28
Children 2-17 Incidence	2	1	2	5
Adults Prevalence	27	72	26	125
Adults Incidence	3	5	2	10
Total	40	90	38	168

Source: PWG Clinical expert opinion based on the euro fever submission

A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.

168

Source: Clinical experts on the PWG

Please specify

	All 168 people would be eligible for treatment with canakinumab, however expert opinion is that only around 80% would start the treatment and the remaining people would remain on their existing treatment options. Expert clinical opinion is that, although anakinra is commissioned by NHS England because it isn't licensed, canakinumab, which is a licensed indication, will be offered to all people currently on anakinra irrespective of the starting criteria.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Other** Please specify From 2 years old and onwards
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	33 children (age 2 -17) 135 adults *Source Clinical experts PWG*
A1.5 How is the population currently distributed geographically?	**unknown** The population is mainly treated in 2 sites in London with centres also in Leeds and Newcastle.
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** – Clinical expert opinion is that the population will increase by around a third over the next ten years due to better diagnostics and awareness. *Source: PWG Clinical expert opinion*

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

Not known

Source: Clinical experts PWG

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?

	FMF	TRAPS	HIDS/MKD
YR2 +/-	+3	+12	+2
YR3 +/-	+4	+18	+3
YR4 +/-	+5	+24	+5
YR5 +/-	+7	+30	+6
YR10 +/-	+13	+60	+14

Source: Clinical experts PWG

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

No

The clinical experts have stated that there has been an increase in the eligible population because of improved diagnostics and testing as well as greater awareness of the conditions. Therefore growth is estimated above the level of general population growth.

A3 Activity

A3.1 What is the purpose of new policy?

Confirm routine commissioning position of an additional new treatment

Please specify

At present there are a small number of people being treated with canakinumab on compassionate grounds after being on the drug as part of a trial. The policy looks at all eligible people including this group and

<table>
<tr><td></td><td>whether canakinumab should be made available to the whole eligible population as an additional treatment option.</td></tr>
<tr><td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td><td>Current numbers of patients on Canakinumab
<table>
<tr><td></td><td>FMF</td><td>TRAPS</td><td>HIDS/MKD</td></tr>
<tr><td>YR2</td><td>0</td><td>6</td><td>3</td></tr>
<tr><td>YR3</td><td>0</td><td>6</td><td>3</td></tr>
<tr><td>YR4</td><td>0</td><td>6</td><td>3</td></tr>
<tr><td>YR5</td><td>0</td><td>6</td><td>3</td></tr>
<tr><td>YR10</td><td>0</td><td>8</td><td>5</td></tr>
</table>
Source: PWG Clinical experts
Please specify
A total of 168 known people have a periodic fever syndrome and we expect this number to grow by around a third in the period. There are currently 8 people on Canakinumab, shown in year 0.</td></tr>
<tr><td>A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?</td><td>It is expected that 80% of the 168 people with the condition (as detailed in A1.1) would be eligible for treatment.</td></tr>
<tr><td>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.</td><td>There is currently a range of different treatments available for the different types of periodic fever syndrome.
Source: PWG Clinical experts</td></tr>
<tr><td colspan="2">A4 Existing Patient Pathway</td></tr>
</table>

A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	TRAPS, HIDS/MKD and FMF are rare conditions with limited treatment options. Current clinical treatment for all conditions include non-steroidal anti-inflammatory drugs (NSAIDs) and short-term high doses of glucocorticoids (for TRAPS and HIDS/MKD only). These help to manage fever, inflammation and pain associated with the conditions. However, these treatments do not control the underlying cause of the symptoms or reduce the frequency of attacks. Continued use of glucocorticoids and NSAIDs are associated with adverse effects such as osteoporosis and increased risk of gastrointestinal and cardiovascular events, respectively. Colchicine is also used in people with FMF to control fever attacks and to prevent secondary amyloidosis. However, colchicine is associated with adverse effects of diarrhoea and transient elevation of transaminases (liver enzymes) and the rare adverse effects of liver dysfunction, leukopenia (low white blood cells), and neuromyopathy (disease affecting nerves and muscles). People with FMF who do not respond to or are intolerant to colchicine have very few treatment options (EPAR: Canakinumab). At present we estimate that current practice for people who are FMF colchine resistant is that all 10 children with the condition are treated with anakinra and of the 30 adults with the condition, 27 receive standard care (steroids or NSAIDS) and 3 are treated with anakinra. We estimate that current practice for people with TRAPS is that of the 13 children with the condition, 12 are treated with anakinra and 1 is treated with etanercept. We estimate that of the 77 adults with the condition, 25 receive standard care (steroids or NSAIDS), 40 are treated with anakinra, 4 are treated with etanercept and 5 are treated with canakinumab. We estimate that current practice for people with HIDS is that of the 10 children with the condition, 8 are treated with anakinra and 2 are treated with canakinumab. We estimate that of the 28 adults with the condition, 6

	receive standard care (steroids or NSAIDS), 20 are treated with anakinra, 1 is treated with tocilizumab and 1 is treated with canakinumab. *Source: Policy proposition/Resource impact assessment using data provided by the clinicians on the policy working group*
A4.2. What are the current treatment access and stopping criteria?	Not applicable
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Please see resource template for breakdown. *Source: PWG Clinical experts*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**No** *Source: Policy Working Group*

A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	N/A
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify a) 100% b) 0% c) 80% d) 100% e) 97% *Source:* PWG Clinical experts
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Life long** *Source: Company Submission*
A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	*Select all that apply:* Emergency/Urgent care attendance ☐

	<table><tr><td>Acute Trust: inpatient</td><td>☐</td></tr><tr><td>Acute Trust: day patient</td><td>☐</td></tr><tr><td>Acute Trust: outpatient</td><td>☒</td></tr><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr><tr><td>Homecare</td><td>☐</td></tr><tr><td>Other</td><td>☐</td></tr></table> Please specify: Canakinumab can only be prescribed for people with TRAPS, HIDS/MKD and FMF by providers who have an NHS England contract and are compliant with the service specification for specialised immunology (all ages) B09/S/a, paediatric medicine and rheumatology E03/S/b.
A7.2 What is the current number of contracted providers for the eligible population by region?	<table><tr><td>NORTH</td><td>2</td></tr><tr><td>MIDLANDS & EAST</td><td>0</td></tr><tr><td>LONDON</td><td>2</td></tr><tr><td>SOUTH</td><td>0</td></tr></table>

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** Please specify: No changes required *Source: Policy Working Group*
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	*Select all that apply:* Aggregate Contract Monitoring * ☒ Patient level contract monitoring ☐ Patient level drugs dataset ☐ Patient level devices dataset ☐ Devices supply chain reconciliation dataset ☐ Secondary Usage Service (SUS+) ☐ Mental Health Services DataSet (MHSDS) ☐ National Return** ☐ Clinical Database** ☐ Other** ☐ **If National Return, Clinical database or other selected, please specify:
A8.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:* OPCS v4.8 ☐

<table>
<tr><td></td><td>
<table>
<tr><td>ICD10</td><td>☒</td></tr>
<tr><td>Treatment function code</td><td>☐</td></tr>
<tr><td>Main Speciality code</td><td>☐</td></tr>
<tr><td>HRG</td><td>☐</td></tr>
<tr><td>SNOMED</td><td>☐</td></tr>
<tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>A8.3 Identification Rules for Drugs:
How are drug costs captured?</td><td><u>Already specified in current NHS England Drugs List document</u>
If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:
Canakinumab for Cryopyrin associated periodic syndrome (CAPS)</td></tr>
<tr><td>A8.4 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not applicable</u></td></tr>
<tr><td>A8.5 Identification Rules for Activity:
How are activity costs captured?</td><td><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u>
If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).
NCBPS16Z Immunology / NCBPS23W – Children’s Services – Rheumatology
If activity costs are already captured please specify whether this service needs a separate code. <u>No</u>
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.</td></tr>
</table>

<table>
<tr><td></td><td>N/A
If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. Choose an item.</td></tr>
<tr><td colspan="2">A9 Monitoring</td></tr>
<tr><td>A9.1 Contracts
Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td><u>None</u></td></tr>
<tr><td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)
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 systems.</td><td>Select all that apply:<table><tr><td>Drugs or Device MDS</td><td>☐</td></tr><tr><td>Blueteq</td><td>☒</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table></td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u></td></tr>
<tr><td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td><td><u>No</u></td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u>
If no, will one be developed?</td></tr>
</table>

	No
A9.6 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	**No**
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	NHS England contract and are compliant with the service specification for specialised immunology (all ages) B09/S/a, paediatric medicine and rheumatology E03/S/b. *Source: Policy proposition section 10*
B1.2 Will the proposition change the way the commissioned service is organised?	**No** Please specify: See B.1.1 *Source: Policy proposition section 10*
B1.3 Will the proposition require a new approach to the organisation of care?	**No change to delivery of care** Please specify: No change in services is required.
B2 Geography & Access	

<table>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:<table><tr><td>GP</td><td>☒</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u>
Please specify:
The treatment will not lead to a change in referrals, however there may be an increase in the number of referrals.</td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u>
Source: Equalities Impact Assessment</td></tr>
<tr><td>B2.4 Is the new policy likely to improve equality of access and/or outcomes?</td><td><u>No impact</u>
Source: Equalities Impact Assessment</td></tr>
<tr><td colspan="2">B3 Implementation</td></tr>
<tr><td>B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?</td><td><u>No action required</u></td></tr>
<tr><td>B3.2 Time to implementation:
Is a lead-in time required prior to implementation?</td><td><u>No - go to B3.4</u></td></tr>
</table>

<table>
<tr><td>B3.3 Time to implementation:
If lead-in time is required prior to implementation, will an interim plan for implementation be required?</td><td><u>No - go to B3.4</u></td></tr>
<tr><td>B3.4 Is a change in provider physical infrastructure required?</td><td><u>No</u>
Please specify:
No physical infrastructure changes will be required.</td></tr>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>No</u></td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td><u>No</u>
Please specify:
No changes required.</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u>
Please specify:
No changes required, monitoring and tests are roughly in line with current arrangements.</td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u></td></tr>
<tr><td>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</td><td><u>No change</u>
Please complete table:
<table>
<tr><td>Region</td><td>Current no. of providers</td><td>Future
State expected range</td><td>Provisional or confirmed</td></tr>
</table>
</td></tr>
</table>

North	2		**C**
Midlands & East			
London	2		**C**
South			
Total	4		**C**

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	☐
Market intervention required	☐
Competitive selection process to secure increase or decrease provider configuration	☐
Price-based selection process to maximise cost effectiveness	☐
Any qualified provider	☐
National Commercial Agreements e.g. drugs, devices	☐
Procurement	☐
Other	☒

Please specify:

NHS England contract and are compliant with the service specification for specialised immunology (all ages) B09/S/a, paediatric medicine and rheumatology E03/S/b.

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**

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:

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☒
	Excluded from tariff - other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☐
	Paid entirely by Local Tariffs	☒
	Partially paid by National Tariffs	☐
	Partially paid by Local Tariffs	☐

	<table><tr><td></td><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr><tr><td></td><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr><tr><td></td><td>Part/fully paid under Other arrangements</td><td>☐</td></tr></table>
C1.2 **Drug Costs** Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price including VAT if applicable and any other key information e.g. Chemotherapy Regime.	The list price of canakinumab 150mg per 1ml is £9,927.80 excluding VAT £11,913.36 including VAT 1 vial for injection Source BNF
C1.3 **Device Costs** Where not included in national or local tariff, list each element of the excluded device, quantity, **list or expected** price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	N/A
C1.4 **Activity Costs covered by National Tariffs** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	<table><tr><th>**Description**</th><th>**National Tariff 18/19 (£)**</th><th>**National Tariff 18/19 with MFF Average of 1.1**</th></tr><tr><td>Emergency Medicine, Category 2 Investigation with Category 4 Treatment (VB04Z)</td><td>196</td><td>216</td></tr><tr><td>Follow up outpatient appointment</td><td>131</td><td>144</td></tr></table>

	paediatrics (420) (WF01A)		
	Follow up outpatient appointment adults nephrology (361) (WF01A)	115	127
	6 Monthly assessment at the National Amyloidosis Centre	1,025	1,128
	Inborn Errors of Metabolism with CC Score 3+ (KC04A)	3,123	3,435
	Paediatric Other Gastrointestinal Disorders with CC Score 4+ (PF26A)	2,144	2,358

C1.5 **Activity Costs covered by Local Tariff** 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.	**Description**	**National Tariff 18/19 (£)**	**National Tariff 18/19 with MFF Average of 1.1**
	Average of dialysis in reference cost 16/17 for adults	151	167
	Tariffs LD01A – LD10A.		
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	N/A		
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**No**		

C2 Average Cost per Patient

C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?

	FMF	TRAPS	HIDS/MKD
YR1	£19,751	£7,021	£20,843
YR2	£69,837	£48,458	£80,610
YR3	£61,855	£64,749	£105,250
YR4	£62523	£62,734	£106,470
YR5	£60,132	£61,433	£109,793

Are there any changes expected in year 6-10 which would impact the model?

If yes, please specify:

It is assumed that there will be further growth in total patient numbers over this period.

C3 Overall Cost Impact of this Policy to NHS England

C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.

Cost pressure

Please specify:

	FMF	TRAPS	HIDS/MKD	Total
Year 1 (£m)	£0.6	£0.5	£0.7	£1.8
Year 2 (£m)	£2.2	£4.4	£3.2	£9.8
Year 5 (£m)	£2.8	£6.5	£4.8	£14.1
Year 10 (£m)	£3.6	£6.9	£5.6	£16.1

<table>
<tr><td></td><td></td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>Not applicable</td></tr>
<tr><td>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?</td><td>Not applicable</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</td></tr>
<tr><td>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</td><td>Budget impact for CCGs:
<u>Cost saving</u>
Budget impact for providers:
<u>Cost neutral</u>
Please specify:
We are assuming that CCG’s will benefit through reduced outpatient treatments, A&E attendances, inpatients spells etc. The effect on providers will be cost neutral as the reduced activity should lead to an offsetting of both associated income and costs.</td></tr>
<tr><td>C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.</td><td><u>Cost pressure</u>
Please specify:
<table><tr><td></td><td>FMF</td><td>TRAPS</td><td>HIDS/MKD</td><td>Total</td></tr><tr><td>Year 1 (£m)</td><td>£0.8</td><td>£0.7</td><td>0.8</td><td>£2.3</td></tr><tr><td>Year 2 (£m)</td><td>£3.0</td><td>£4.9</td><td>£3.6</td><td>£11.5</td></tr></table></td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td>Year 5 (£m)</td><td>£4.0</td><td>£7.3</td><td>£5.3</td><td>£16.6</td></tr>
<tr><td>Year 10 (£m)</td><td>£4.9</td><td>£7.8</td><td>£6.3</td><td>£19.0</td></tr>
</table>
</td></tr>
<tr><td>C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured</td><td>Not applicable</td></tr>
<tr><td>C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?</td><td><u>Unknown</u></td></tr>
<tr><td colspan="2">C5 Funding</td></tr>
<tr><td>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.</td><td>CPAG prioritisation reserve.</td></tr>
<tr><td colspan="2">C6 Financial Risks Associated with Implementing this Policy</td></tr>
<tr><td>C6.1 What are the material financial risks to implementing this policy?</td><td>The financial risk is that there could potentially be a high budget impact.</td></tr>
<tr><td>C6.2 How can these risks be mitigated?</td><td>We have looked at the worst case scenario for the uptake of canakinumab. Expert clinical opinion is that there is uncertainty around what the uptake of canakinumab will be and therefore the uptake may be lower which would reduce the financial risk.</td></tr>
</table>

C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	We have assumed that because the comparator treatment for canakinumab is unlicensed, that canakinumab will be offered to everybody. We have assumed that 80% of people will accept the offer of treatment with canakinumab.
C6.4 What scenario has been approved and why?	The scenario of 80% uptake has been approved because the clinicians on the PWG thought that was a reasonable estimate based on their experience with the drug for another condition. From a legal standing everybody should be offered the licensed treatment.
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**<u>There is no published evidence of cost-effectiveness</u>** Please specify: The clinical evidence review for this technology found no studies relating to cost effectiveness.
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	*Select all that apply:* Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment ☐ Available pricing data suggests the treatment is lower cost compared to current/comparator treatment ☐ Available clinical practice data suggests the new treatment has the potential to improve value for money ☐ Other data has been identified ☐ No data has been identified ☒

	The data supports a high level of certainty about the impact on value ☐ The data does not support a high level of certainty about the impact on value ☐ Please specify: Click here to enter text.
C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No** No non-recurrent capital / set up costs required.
C8.2 If yes, confirm the source of funds to meet these costs.	N/A