Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1817		
Policy Title	Infliximab for Refractory or Progressive Neurosarcoidosis (Adults and post-pubescent children)		
Lead Commissioner	Jacquie Kemp	**Clinical Lead**	Desmond Kidd
Finance Lead	Justine Stalker-Booth	**Analytical Lead**	Click here to enter text.

Integrated Impact Assessment – Index

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.	Sarcoidosis can present in a variety of ways, ranging from a mild, acute self-limiting disease to chronic disease involving several organs and causing severe symptoms and functional impairment. It is characterised by the presence of lumps caused by clusters of inflammatory cells (non-caseating granulomas) in the organs. When the brain and central nervous system is affected, it is called neurosarcoidosis. Neurosarcoidosis is an uncommon but potentially serious manifestation of the disease, which occurs in approximately 5% of people with sarcoidosis. Approximately 100 people are diagnosed with neurosarcoidosis in the UK each year (Sarcoidosis UK, 2018). The majority of patients with neurosarcoidosis require treatment of some type, which may include steroids and oral immunosuppressants. In most cases this is all that is required to put patients into remission. However, in the invasive parenchymal form of neurosarcoidosis, these treatments have been shown to be ineffective.
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	20 new patients per year *Source: IIA* Please specify Click here to enter text.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Other** Please specify Adults and post-pubescent children

<table>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>Source: Policy section 1
Please specify
Adults and post-pubescent children</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Evenly</u>
If unevenly, estimate regional distribution by %:<table><tr><td>North</td><td>enter %</td></tr><tr><td>Midlands & East</td><td>enter %</td></tr><tr><td>London</td><td>enter %</td></tr><tr><td>South</td><td>enter %</td></tr></table>Source: Policy Proposition section 6
Please specify
Click here to enter text.</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>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?</td><td><u>Constant</u>

If other, Click here to enter text.
Source: Policy Proposition section 6</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>
Please specify
Click here to enter text.
Source: Policy Proposition section 6/other</td></tr>
</table>

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

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td><table>
<tr><td>YR2 +/-</td><td>0</td></tr>
<tr><td>YR3 +/-</td><td>0</td></tr>
<tr><td>YR4 +/-</td><td>0</td></tr>
<tr><td>YR5 +/-</td><td>0</td></tr>
<tr><td>YR10 +/-</td><td>1</td></tr>
</table>
Source: Policy proposition section 3.1

<u>Yes</u>
The incidence of progressive neurosarcoidosis has not increased however the incidence of use of IVIg and Plasma exchange for progressive neurosarcoidosis has increased. The population within this policy are expected to remain relatively constant.</td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Confirm routine commissioning position of an additional new treatment</u>
Please specify
Click here to enter text.</td></tr>
<tr><td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td><td>20
Source: Policy identifies 20 patients as fulfilling the criteria.
Please specify
Click here to enter text.</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>20 new patients</td></tr>
</table>

	Source: Policy Please specify Click here to enter text.
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.	20 *Source: Policy* Please specify These patients will continue to receive frequent (4-8 weekly) immunoglobulin infusions or plasma exchange
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Treatment options for progressive neurosarcoidosis include IVIg and plasma exchange, for which there is evidence of efficacy and ready access. Infiximab has been used when available and there is increasing evidence of its efficacy and cost-effectiveness. Implementing the use of infliximab would require that patients had been optimally managed with standard treatments. *Source: Policy proposition*
A4.2. What are the current treatment access and stopping criteria?	Most patients with sarcoidosis do not require treatment and often make a full recovery. Around a third have more serious disease involving different organs and require therapies such as steroids and drugs that suppress the immune system. The majority of patients with neurosarcoidosis require treatment of some type, which may include steroids and oral immunosuppressants. In most cases this is all that is required to put patients into remission. However, in the invasive parenchymal form of neurosarcoidosis, these treatments have been shown to be ineffective.

	Source: required
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?	These patients will be a cohort of the 666 patients receiving IVIg annually a) 100% b) 100% c) 100% d) 100% e) 100% *Source: Policy statement all eligible patients will be assessed at an MDT and are anticipated to complete treatment*
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** If yes, Click here to enter text. *Source:* PWG
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	a) 0% b) 0% c) 0% d) 0% e) 0%

<table>
<tr><td>e) Complete treatment?</td><td>Source: Click here to enter text.</td></tr>
<tr><td colspan="2">A6 New Patient Pathway</td></tr>
<tr><td>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?</td><td>Total estimated eligible will already have been assessed as eligible within an multi-disciplinary team (MDT)
a) 100%
b) 100%

c) 100%
d) 100%
e) 95%
Source: Policy</td></tr>
<tr><td>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</td><td><u>Time limited</u>

Source: IIA</td></tr>
<tr><td colspan="2">A7 Treatment Setting</td></tr>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td>Select all that apply:
<table><tr><td>Emergency/Urgent care attendance</td><td>☐</td></tr><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></table></td></tr>
</table>

	<table><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:
A7.2 What is the current number of contracted providers for the eligible population by region?	<table><tr><td>NORTH</td><td>8</td></tr><tr><td>MIDLANDS & EAST</td><td>5</td></tr><tr><td>LONDON</td><td>6</td></tr><tr><td>SOUTH</td><td>5</td></tr></table>
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** Please specify: Click here to enter text. *Source: DNR Policy*
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:* <table><tr><td>Aggregate Contract Monitoring *</td><td>☐</td></tr><tr><td>Patient level contract monitoring</td><td>☐</td></tr></table>

	Patient level drugs dataset Blueteq ☒ 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: Click here to enter text.
A8.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:* OPCS v4.8 ☐ ICD10 ☐ Treatment function code ☐ Main Speciality code ☐ HRG ☐ SNOMED ☐ Clinical coding / terming methodology used by clinical profession ☐
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**<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:

<table>
<tr><td></td><td>Infliximab biosimilar</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).
NCBPS08O ADULT SPECIALIST NEUROSCIENCES SERVICES: NEUROLOGY</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>Yes - other</u>
Please specify
Blueteq reporting</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>Please specify: Not applicable</td></tr>
<tr><td>A9.3 Business intelligence</td><td><u>No</u></td></tr>
</table>

Is there potential for duplicate reporting?	
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	**Yes** If no, please specify contract monitoring requirement: Click here to enter text.
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No** If yes, specify how routine performance monitoring data will be used for dashboard reporting. Click here to enter text. If no, will one be developed? Click here to enter text.
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** If yes, specify how performance monitoring data will be used for this purpose. Click here to enter text.
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Tertiary centres *Source: required*
B1.2 Will the proposition change the way the commissioned service is organised?	**No** Please specify: Click here to enter text.

<table>
<tr><td></td><td>Source: required</td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>No change to delivery of care</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<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>Please specify:
Click here to enter text.</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:
Click here to enter text.</td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u>
Please specify:
Click here to enter text.
Source: Equalities Impact Assessment</td></tr>
</table>

B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**No impact** Please specify: Click here to enter text. *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required** Please specify: Click here to enter text.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4** If yes, specify the likely time to implementation: Enter text
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Choose an item. If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	**No** Please specify: Click here to enter text.
B3.5 Is a change in provider staffing required?	**No** Please specify: Click here to enter text.

<table>
<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:
Click here to enter text.</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:
Click here to enter text.</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>
Please specify:
Click here to enter text.</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><th>Region</th><th>Current no. of providers</th><th>Future
State expected range</th><th>Provisional or confirmed</th></tr>
<tr><td>North</td><td>8</td><td></td><td>select</td></tr>
<tr><td>Midlands & East</td><td>5</td><td></td><td>select</td></tr>
<tr><td>London</td><td>6</td><td></td><td>select</td></tr>
<tr><td>South</td><td>5</td><td></td><td>select</td></tr>
<tr><td>Total</td><td>24</td><td></td><td>select</td></tr>
</table>
Please specify:
Click here to enter text.</td></tr>
</table>

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: Click here to enter text.
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:

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	☐
	Part/fully paid under a Block arrangement	☐
	Part/fully paid under Pass-Through arrangements	☐
	Part/fully paid under Other arrangements	☐

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.

List Price per 100mg vial £377.00 excl VAT or £452.40 incl VAT
Dosage = 5mg per kg or 400mg based on an average weight of 80kg
Average cost per infusion = £452.40 x 4 = £1,809.60
Average number of infusions per patient = 13
Cost per patient per year at list price = £23,525

NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	The actual price charged to the NHS may be less than the list price.
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 %)	An infusion would group to the core HRG: DZ29 Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease 2019/20 National Tariffs Prices for a Day Case Infusion: DZ29H Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 5+ £783 DZ29J Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 2-4 £465 DZ29K Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 0-1 £425
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.	N/A

<table>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>N/A</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>No</u>
Please specify: Click here to enter text.</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?

Are there any changes expected in year 6-10 which would impact the model?</td><td><table>
<tr><td>YR1</td><td>£23,525</td></tr>
<tr><td>YR2</td><td>£23,525</td></tr>
<tr><td>YR3</td><td>£23,525</td></tr>
<tr><td>YR4</td><td>£23,525</td></tr>
<tr><td>YR5</td><td>£23,525</td></tr>
</table>
The cost represents the cost per patient, at list price, of the drug element only. Patients are expected on average to require treatment for 1 year.

If yes, please specify:
No</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost pressure</u>
Please specify:</td></tr>
</table>

	Based on the list price of £377+VAT, the cost would be £201.5k per year assuming there is no change in the number of infusions delivered. The actual cost pressure/saving will be less depending on any commercial in confidence discount offered to the NHS.
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?	N/A
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **Cost saving** Potential reduction in emergency admissions Budget impact for providers: **Cost neutral** Please specify:
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Please specify:

	At list price, there is expected to be a gross cost pressure of c£201.5k. There may be savings for CCGs from a reduction in emergency admissions for the patient cohort.
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Click here to enter text.
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** Please specify: Click here to enter text.
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.	Any net cost pressure would be funded from the CPAG Reserve.
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?	N/A
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	None -the cohort of patients is very small

<table>
<tr><td>C6.4 What scenario has been approved and why?</td><td>N/A</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td><u>Published evidence indicates the treatment is cost-effective</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>C7.2 Has other data been identified through the policy statement development relevant to the assessment of value for money?</td><td>Select all that apply:<table>
<tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☒</td></tr>
<tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☐</td></tr>
<tr><td>Other data has been identified</td><td>☐</td></tr>
<tr><td>No data has been identified</td><td>☐</td></tr>
<tr><td>The data supports a high level of certainty about the impact on value</td><td>☒</td></tr>
<tr><td>The data does not support a high level of certainty about the impact on value</td><td>☐</td></tr>
</table>Please specify:
Click here to enter text.</td></tr>
<tr><td colspan="2">C8 Cost Profile</td></tr>
</table>

C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No** If yes, specify type and range: Click here to enter text.
C8.2 If yes, confirm the source of funds to meet these costs.	Click here to enter text.