Integrated Impact Assessment Report for Clinical Commissioning Policies	
Policy Reference Number	1748
Policy Title	Addition of rituximab to standard chemotherapy for newly diagnosed CD20 positive B-cell precursor Acute Lymphoblastic Leukaemia Proposal **not for routine commission** (ref A3.1)

Integrated Impact Assessment – Index		
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A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
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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.	ALL is a rare cancer. It can occur at any age, but is more prevalent among children then adults. In the UK, there were 832 reported new cases of ALL in 2015 and 300 of these were in adults (Cancer Research UK 2018) *Source: Policy Proposition, Section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	113 *Source: Policy Proposition, Section 6* B-ALL is the most common type of ALL, accounting for 75% of all cases in adults (Pui et al 2006). Although the majority of B cells express the CD20 antigen, it is only present (defined as > 20% leukaemic cells expressing CD20 as measured by immunohistochemistry) on 30-50% of B-cell precursor ALL blasts. As a result, it is estimated that between 68 to 113 patients would be eligible for the addition of rituximab to standard first line chemotherapy treatment.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Adults**
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	Although the condition is most common in children, teenagers and young adult, it can affect people of any age. It is estimated that approx. 300 adults are diagnosed with ALL per year. In adults, the presence of CD20 in the cancer cells is associated with disease relapse and poor prognosis.

A1.5 How is the population currently distributed geographically?	**Evenly**
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?	Not applicable - as this is a not for routine commissioning policy no modelling has been carried out.
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	Not applicable.
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? Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	Not applicable.
A3 Activity	
A3.1 What is the purpose of new policy?	**Confirm non-routine commissioning position of an additional new treatment**

A3.2 What is the annual activity associated with the existing pathway for the eligible population?	113
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	0 This policy is for not routine commissioning.
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.	Not applicable.
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Chemotherapy is the main treatment option, however, some people may also need treatment with a targeted cancer medicine and/or a stem cell transplant. The duration of treatment for the condition is around two to three years and consists of several months of intensive multi-drug chemotherapy, followed by low intensity maintenance therapy. *Source: Policy Proposition*
A4.2. What are the current treatment access and stopping criteria?	Access to treatment is through the haematology multi-disciplinary team at designated chemotherapy centres.
A4.3 What percentage of the total eligible population is expected to:	If not known, please specify Click here to enter text. a) 100%

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?	b) 100% c) 100% d) 100% e) 100% *Source: Policy Proposition*
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*	**<u>No</u>**
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?	Not applicable.

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?	Not applicable – this is a not for routine commissioning policy.
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	Not applicable – this is a not for routine commissioning policy
A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	Not applicable – this is a not for routine commissioning policy
A7.2 What is the current number of contracted providers for the eligible population by region?	Not applicable – this is a not for routine commissioning policy
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	Not applicable – this is a not for routine commissioning policy

A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	Not applicable – this is a not for routine commissioning policy
A8.2 Specify how the activity related to the new patient pathway will be identified.	Not applicable – this is a not for routine commissioning policy.
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	Not applicable – this is a not for routine commissioning policy.
A8.4 **Identification Rules for Devices:** How are device costs captured?	Not applicable.
A8.5 **Identification Rules for Activity:** How are activity costs captured?	Not applicable – this is a not for routine commissioning policy.
A9 Monitoring	
A9.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	Not applicable – this is a not for routine commissioning policy.

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.	Not applicable – this is a not for routine commissioning policy.
A9.3 **Business intelligence** Is there potential for duplicate reporting?	Not applicable – this is a not for routine commissioning policy
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	Not applicable – this is a not for routine commissioning policy
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	Not applicable – this is a not for routine commissioning policy.
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.)	Chemotherapy can be prescribed and delivered at any provider commissioned by NHS England; this includes Cancer Centres, Teaching Hospitals and District General Hospitals

<table>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>No</u></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></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></td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u></td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u></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></td></tr>
<tr><td colspan="2">B3 Implementation</td></tr>
</table>

B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required**
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4**
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**No - go to B3.4**
B3.4 Is a change in provider physical infrastructure required?	**No**
B3.5 Is a change in provider staffing required?	**No**
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No**
B3.7 Are there changes in the support services that need to be in place?	**No**
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No**
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	**No change**

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	☒

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	☐

<table>
<tr><td></td><td>
<table>
<tr><td></td><td>Excluded from tariff – pass through</td><td>☒</td></tr>
<tr><td></td><td>Excluded from tariff - other</td><td>☐</td></tr>
<tr><td rowspan="4">Devices</td><td>Not separately charged – part of local or national tariffs</td><td>☐</td></tr>
<tr><td>Excluded from tariff (excluding ZCM) – pass through</td><td>☐</td></tr>
<tr><td>Excluded from tariff (excluding ZCM) – other</td><td>☐</td></tr>
<tr><td>Via Zero Cost Model</td><td>☐</td></tr>
<tr><td rowspan="7">Activity</td><td>Paid entirely by National Tariffs</td><td>☒</td></tr>
<tr><td>Paid entirely by Local Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by National Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by Local Tariffs</td><td>☐</td></tr>
<tr><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr>
<tr><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>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.
NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>Not applicable – this policy is for not routine commissioning and the treatment is not currently commissioned. For this reason, no financial model has been developed.</td></tr>
<tr><td>C1.3 Device Costs</td><td>Not applicable.</td></tr>
</table>

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.	
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 %)	Not applicable – see section C1.2.
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.	Not applicable.
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	Not applicable.
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? Are there any changes expected in year 6-10 which would impact the model?	Not applicable – see section C1.2.
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 neutral**
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable.
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?	Not applicable.
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: **No impact on CCGs** Budget impact for providers: **No impact on providers**

C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost neutral**
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable.
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No**
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.	Not applicable – this policy is for not routine commissioning.
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?	Not applicable.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Not applicable.
C6.4 What scenario has been approved and why?	Not applicable.

<table>
<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 is mixed and it is uncertain whether the treatment is cost-effective</u></td></tr>
<tr><td>C7.2 Has other data been identified through the service specification 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></td></tr>
<tr><td colspan="2">C8 Cost Profile</td></tr>
<tr><td>C8.1 Are there non-recurrent capital or revenue costs associated with this policy?</td><td><u>No</u></td></tr>
</table>

C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable.

The full integrated impact assessment should be used for all clinical commissioning policies and for policy statements which are proposing a not for routine commissioning position. The rapid impact assessment template should be used for urgent policy statements and for policy statements which are proposing routine commissioning