

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1607		
Policy Title	Bendamustine with rituximab for relapsed indolent non-Hodgkin's lymphoma (all ages) Proposal <u>not for routine commission</u> (ref A3.1)		
Lead Commissioner	Rupi Dev	Clinical Lead	Nisha Shaunak
Finance Lead	Jacque Low	Analytical Lead	Jacque Low

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

<p>A1.1 Prevalence of the disease/condition.</p>	<p>Non-Hodgkin’s lymphoma (NHL) is type of cancer that affects the lymphatic system. In 2015, there were 13,682 cases of NHL in the UK. Rates are significantly higher in males than females in most age groups, and on average more than a third (35%) of new cases were in people aged 75 years and over, with the highest rates in people aged 80 to 84 years.</p> <p>NHL is difficult to cure and most people with the condition will usually experience multiple episodes of treatment, remission and relapse. This policy proposition relates to relapsed NHL; this means that at least one prior treatment will have been given</p> <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>500</p> <p><i>Source: Policy Proposition, Section 6; Policy Working Group</i></p>
<p>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</p>	<p><u>All ages</u></p>
<p>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</p>	<p>NHL is more common in older people with more than a third (35%) of new cases were in people aged 75 years and over, and the highest rates in people aged 80 to 84 years.</p>

	<i>Source: Policy Proposition, Section 6</i>											
A1.5 How is the population currently distributed geographically?	<u>Evenly</u>											
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?	<u>Decreasing</u> Incidence rates for non-Hodgkin lymphoma are projected to fall by 2% in the UK between 2014 and 2035, to 26 cases per 100,000 people by 2035. <i>Source: Policy Proposition section 6</i>											
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<u>Yes</u> NHL is more common in older people with more than a third (35%) of new cases were in people aged 75 years and over, and the highest rates in people aged 80 to 84 years. <i>Source: Policy Proposition section 6</i>											
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?	<table border="1"> <tr> <td>YR2 +/-</td> <td>17</td> </tr> <tr> <td>YR3 +/-</td> <td>27</td> </tr> <tr> <td>YR4 +/-</td> <td>36</td> </tr> <tr> <td>YR5 +/-</td> <td>50</td> </tr> <tr> <td>YR10 +/-</td> <td>94</td> </tr> </table>		YR2 +/-	17	YR3 +/-	27	YR4 +/-	36	YR5 +/-	50	YR10 +/-	94
YR2 +/-	17											
YR3 +/-	27											
YR4 +/-	36											
YR5 +/-	50											
YR10 +/-	94											

<p>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</p>	<p><i>Source: Financial Model</i></p> <p><u>Yes</u></p>
<p>A3 Activity</p>	
<p>A3.1 What is the purpose of new policy?</p>	<p><u>Confirm non-routine commissioning position of an additional new treatment</u></p>
<p>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</p>	<p>500</p> <p><i>Source: Policy Proposition, Section 6; Policy Working Group</i></p>
<p>A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?</p>	<p>0</p> <p>This is a not for routine commissioning policy.</p> <p><i>Source: Policy Proposition</i></p>
<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>	<p>500</p> <p><i>Source: Policy Proposition</i></p>

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 for NHL and treatment aims to control the disease, relieve symptoms and complications and prolong life. There are a number of different chemotherapy medicines available, either given individually or in combination. Some patients may be suitable for a stem cell transplant but this is dependent on an individual patient's fitness.

Source: Policy Proposition, Section 3

A4.2. What are the current treatment access and stopping criteria?

Treatments are usually given sequentially and are continued until either the disease progresses or the side-effects of the chemotherapy treatment can no longer be tolerated. The most common combination regimen is called R-CHOP (rituximab with cyclophosphamide, doxorubicin hydrochloride, vincristine and prednisolone) and R-CVP (rituximab with cyclophosphamide, vincristine and prednisolone).

Source: Policy Proposition, Section 3

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?

- a) 100%
- b) 0%
- c) 100%
- d) 100%
- e) 100%

Source: Policy Proposition, Section 3

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*

Yes

The most common combination regimen is called R-CHOP (rituximab with cyclophosphamide, doxorubicin hydrochloride, vincristine and prednisolone) and R-CVP (rituximab with cyclophosphamide, vincristine and prednisolone).

Source: Policy Proposition, Section 3

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?

Total estimated eligible:

- a) 100%
- b) 0%
- c) 100%
- d) 100%
- e) 100%

Source: Policy Proposition, Section 3

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

Not applicable - this is a not for routine commissioning policy.

e) Complete treatment?	
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.	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:	Not applicable - this is a not for routine commissioning policy.

How are drug costs captured?	
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.	<u>None</u>
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.

<p>A9.5 Dashboard reporting Specify whether a dashboard exists for the proposed intervention?</p>	<p>Not applicable - this is a not for routine commissioning policy.</p>		
<p>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?</p>	<p>Not applicable - this is a not for routine commissioning policy.</p>		
<p>Section B - Service Impact</p>			
<p>B1 Service Organisation</p>			
<p>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</p>	<p>Chemotherapy can be prescribed and delivered at any provider commissioned by NHS England; this includes Cancer Centres, Teaching Hospitals and District General Hospitals.</p>		
<p>B1.2 Will the proposition change the way the commissioned service is organised?</p>	<p><u>No</u></p>		
<p>B1.3 Will the proposition require a new approach to the organisation of care?</p>	<p><u>No change to delivery of care</u></p>		
<p>B2 Geography & Access</p>			
<p>B2.1 Where do current referrals come from?</p>	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="1088 1286 1599 1347"> <tr> <td data-bbox="1088 1286 1509 1347">GP</td> <td data-bbox="1509 1286 1599 1347"><input type="checkbox"/></td> </tr> </table>	GP	<input type="checkbox"/>
GP	<input type="checkbox"/>		

	<table border="1"> <tr> <td data-bbox="1079 105 1503 161">Secondary care</td> <td data-bbox="1503 105 1599 161"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 161 1503 217">Tertiary care</td> <td data-bbox="1503 161 1599 217"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 217 1503 272">Other</td> <td data-bbox="1503 217 1599 272"><input type="checkbox"/></td> </tr> </table>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input checked="" type="checkbox"/>	Other	<input 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?	<u>No impact</u>							
B2.3 Is the new policy likely to improve equity of access?	<u>No impact</u> <i>Source: Equalities Impact Assessment</i>							
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	<u>No impact</u> There are a range of alternative treatments available for patients with relapsed indolent NHL. <i>Source: Equalities Impact Assessment</i>							
B3 Implementation								
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<u>No action required</u>							
B3.2 Time to implementation: Is a lead-in time required prior to implementation?	<u>No - go to B3.4</u>							

<p>B3.3 Time to implementation: If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p>	<p><u>No - go to B3.4</u></p>				
<p>B3.4 Is a change in provider physical infrastructure required?</p>	<p><u>No</u></p>				
<p>B3.5 Is a change in provider staffing required?</p>	<p><u>No</u></p>				
<p>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</p>	<p><u>No</u></p>				
<p>B3.7 Are there changes in the support services that need to be in place?</p>	<p><u>No</u></p>				
<p>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p>	<p><u>No</u></p>				
<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>	<p><u>No change</u></p>				
<p>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</p>	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="1088 1209 2000 1329"> <tr> <td data-bbox="1088 1209 1883 1268">Publication and notification of new policy</td> <td data-bbox="1883 1209 2000 1268"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1268 1883 1329">Market intervention required</td> <td data-bbox="1883 1268 2000 1329"><input type="checkbox"/></td> </tr> </table>	Publication and notification of new policy	<input checked="" type="checkbox"/>	Market intervention required	<input type="checkbox"/>
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 type="checkbox"/>
	National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>
	Procurement	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>

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	<input type="checkbox"/>
	Excluded from tariff – pass through	<input checked="" type="checkbox"/>
	Excluded from tariff - other	<input type="checkbox"/>
Devices	Not separately charged – part of local or national tariffs	<input type="checkbox"/>

	<table border="1"> <tr> <td data-bbox="1086 97 1240 272"></td> <td data-bbox="1247 97 2056 156">Excluded from tariff (excluding ZCM) – pass through</td> <td data-bbox="2063 97 2143 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 97 1240 272"></td> <td data-bbox="1247 156 2056 215">Excluded from tariff (excluding ZCM) – other</td> <td data-bbox="2063 156 2143 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 97 1240 272"></td> <td data-bbox="1247 215 2056 272">Via Zero Cost Model</td> <td data-bbox="2063 215 2143 272"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 272 1240 687">Activity</td> <td data-bbox="1247 272 2056 331">Paid entirely by National Tariffs</td> <td data-bbox="2063 272 2143 331"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 272 1240 687"></td> <td data-bbox="1247 331 2056 391">Paid entirely by Local Tariffs</td> <td data-bbox="2063 331 2143 391"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 272 1240 687"></td> <td data-bbox="1247 391 2056 450">Partially paid by National Tariffs</td> <td data-bbox="2063 391 2143 450"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 272 1240 687"></td> <td data-bbox="1247 450 2056 509">Partially paid by Local Tariffs</td> <td data-bbox="2063 450 2143 509"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 272 1240 687"></td> <td data-bbox="1247 509 2056 568">Part/fully paid under a Block arrangement</td> <td data-bbox="2063 509 2143 568"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 272 1240 687"></td> <td data-bbox="1247 568 2056 627">Part/fully paid under Pass-Through arrangements</td> <td data-bbox="2063 568 2143 627"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 272 1240 687"></td> <td data-bbox="1247 627 2056 687">Part/fully paid under Other arrangements</td> <td data-bbox="2063 627 2143 687"><input type="checkbox"/></td> </tr> </table>		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"/>	Activity	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"/>
	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"/>																													
Activity	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>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.</p>	Not applicable, this is a not for routine commissioning policy.																														
<p>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.</p>	Not applicable.																														
<p>C1.4 Activity Costs covered by National Tariffs</p>	Not applicable, this is a not for routine commissioning policy.																														

List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)											
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?	<u>No</u>										
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?	<table border="1" data-bbox="1088 920 1599 1190"> <tr> <td>YR1</td> <td>£5,920</td> </tr> <tr> <td>YR2</td> <td>£5,920</td> </tr> <tr> <td>YR3</td> <td>£5,920</td> </tr> <tr> <td>YR4</td> <td>£5,920</td> </tr> <tr> <td>YR5</td> <td>£5,920</td> </tr> </table> <p data-bbox="1088 1230 1742 1265">Estimated cost per patient accessing R-CHOP</p> <p data-bbox="1088 1305 1128 1340">No</p>	YR1	£5,920	YR2	£5,920	YR3	£5,920	YR4	£5,920	YR5	£5,920
YR1	£5,920										
YR2	£5,920										
YR3	£5,920										
YR4	£5,920										
YR5	£5,920										

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.	<p><u>Cost saving</u></p> <p>Please specify: Year 1 -£503.0k Year 2 -£512.3k Year 5 -£544.8k</p>
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.	<p>Budget impact for CCGs: <u>No impact on CCGs</u></p> <p>Budget impact for providers: <u>No impact on providers</u></p>

C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<u>Cost saving</u> As per C3.1
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable - this is a not for routine commissioning policy.
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	<u>No</u>
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.
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	None identified.
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 - this is a not for routine commissioning policy.
C6.4 What scenario has been approved and why?	Not applicable - this is a not for routine commissioning policy.

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

C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?

Not applicable.

C8 Cost Profile

C8.1 Are there non-recurrent capital or revenue costs associated with this policy?

Not applicable.

C8.2 If yes, confirm the source of funds to meet these costs.

Not applicable.