Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1605		
Policy Title	Bendamustine with rituximab for first line treatment of advanced indolent non-Hodgkin's lymphoma Proposal **for routine commission** (ref A3.1)		
Lead Commissioner	Lisa Jordan	**Clinical Lead**	Susan Taylor
Finance Lead	Jacqui Low	**Analytical Lead**	Jacqui 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	
A1.1 Prevalence of the disease/condition.	The incidence of NHL in the UK in 2014 was 13,605 cases and there were 4,801 deaths (Cancer Research UK 2016). Age-specific incidence is seen to rise from 50-54 years onwards and median age at diagnosis is 70+ years. This policy relates to the first-line use of bendamustine with rituximab (BR) to treat advanced, indolent cases of NHL. BR is an un-licensed medicine for this indication which was previously made available for use in this indication through the Cancer Drugs Fund (CDF). The best source of likely activity related to this policy is the CDF (because registry data does not hold data on advanced, indolent cases), which indicates that approximately 933 patients per year are likely to be eligible for and receive treatment. *Source: Policy Proposition, Section 6 (taken from CDF Utilisation Data, 2016/17)*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	933 *Source: Policy Proposition, Section 6 (taken from CDF Utilisation Data, 2016/17)*
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**All ages**
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	Not applicable

<table>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Evenly</u></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>Increasing</u>

Incidence is stable yet prevalence is increasing due to increased survival.
The condition is more prevalent in adults aged over 50 years and therefore the activity growth assumptions for this policy reflect ONS average population growth for this age range (i.e 50 plus).

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></td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for treatment, according to the proposed policy commissioning criteria, per year in years 2-5 and 10?</td><td><table><tr><td>YR2 +/-</td><td>32</td></tr><tr><td>YR3 +/-</td><td>47</td></tr><tr><td>YR4 +/-</td><td>62</td></tr><tr><td>YR5 +/-</td><td>76</td></tr><tr><td>YR10 +/-</td><td>127</td></tr></table>
Source: Policy Proposition section 6/ other</td></tr>
</table>

A3 Activity	
A3.1 What is the purpose of new policy?	**<u>Confirm routine commissioning position of an additional new treatment</u>**
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	933 *Source:* Policy Proposition, Section 6 (taken from *CDF Utilisation Data, 2016/17)*
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	933 *Source:* Policy Proposition, Section 6 (taken from *CDF Utilisation Data, 2016/17)*
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.	933 *Source:* Policy Proposition, Section 6 (taken from *CDF Utilisation Data, 2016/17)*
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway	In most cases of advanced, indolent NHL treatment will only be started when symptoms develop or the disease begins to change. Where treatment is required, chemotherapy is the main option and this is usually given in combination. Most combination chemotherapy for this indication

• Eligibility and/or uptake estimates.	involves rituximab, with common combinations being: (i) R-CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone and rituximab); and (ii) R-CVP (cyclophosphamide, vincristine, prednisolone and rituximab). Chlorambucil ± rituximab may be given to people who are unsuitable for R-CHOP/R-CVP regimens. The clinical management of patients with advanced, indolent NHL is highly individualised and the choice of treatment available to each patient is dependent on a range of clinical factors including health status of the patient, grade and stage of the cancer and tolerability. BR is another potential first-line treatment for cases of advanced, indolent NHL which was previously available as an un-licensed treatment for this indication through the Cancer Drugs Fund. *Source:* Policy Proposition, Section 3
A4.2. What are the current treatment access and stopping criteria?	The decision to select the patient for treatment with BR must be made by either the haematology multi-disciplinary team or lymphoma multi-disciplinary team, and the patient. The first cycle must be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. No stopping criteria currently identified. *Source: Policy Proposition, Section 9*
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?	If not known, please specify Click here to enter text. a) 100% b) 0 c) 100% d) 100% e) 100% *Source: Policy Working Group*

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>Yes</u>** A range of treatments are currently available and are commissioned. Most combination chemotherapy for this indication involves rituximab, with common combinations being: (i) R-CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone and rituximab); and (ii) R-CVP (cyclophosphamide, vincristine, prednisolone and rituximab). Chlorambucil ± rituximab may be given to people who are unsuitable for R-CHOP/R-CVP regimens. The clinical management of patients with advanced, indolent NHL is highly individualised and the choice of treatment available to each patient is dependent on a range of clinical factors including health status of the patient, grade and stage of the cancer and tolerability. This means that there is not a single standard of care. *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?	a) 100% b) 0 c) 100% d) 100% e) 100% *Source: Policy Working Group*

<table>
<tr><th colspan="2">A6 New Patient Pathway</th></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>a) 100%
b) 0

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

6 cycles of 2 day treatments (day 1 + day 2 x 6 - Bendamustine + Rituximab on day 1 and Bendamustine on day 2)

Source: Policy Proposition, Section 7)</td></tr>
<tr><th colspan="2">A7 Treatment Setting</th></tr>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td><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>
<tr><td>Mental Health provider: inpatient</td><td>☐</td></tr>
<tr><td>Mental Health provider: outpatient</td><td>☐</td></tr>
</table></td></tr>
</table>

	Community setting ☐ Homecare ☐ Other ☐
A7.2 What is the current number of contracted providers for the eligible population by region?	Chemotherapy can be prescribed and delivered at any provider commissioned by NHS England; this includes Cancer Centres, Teaching Hospitals and District General Hospitals.
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** The additional activity required to be delivered is small and can be accommodated within Chemotherapy Unit capacity. The treatment has previously been available to patients through the CDF, so units are familiar with the treatment and the capacity required to deliver care. *Source: Policy Proposition Section 6*
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	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: SACT
A8.2 Specify how the activity related to the new patient pathway will be identified.	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?	**Already specified in current NHS England Drugs List document** Bendamustine – Cancer

<table>
<tr><td></td><td>Rituximab - Cancer</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>

NCBPS01C Chemotherapy</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><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>
</table>

A9.4 **Contract monitoring** Is this part of routine contract monitoring?	**Yes** : ACM and Drug MDS
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No** Not required.
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 in line with the policy proposition. *Source: Policy Proposition, Section 7*
B1.2 Will the proposition change the way the commissioned service is organised?	**No**
B1.3 Will the proposition require a new approach to the organisation of care?	**No change to delivery of care**

<table>
<tr><th colspan="2">B2 Geography & Access</th></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td><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>

Source: Policy Working Group</td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>Increase</u>

Source: Policy Working Group</td></tr>
<tr><td>B2.4 Is the new policy likely to improve equality of access and/or outcomes?</td><td><u>Increase</u>

Source: Policy Working Group</td></tr>
<tr><th colspan="2">B3 Implementation</th></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>
</table>

B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No**
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.	

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	

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 arrangment	☐
		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. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Rituximab (375mg/m2 day 1 of cycle) = £1,466.88 Bendamustine (90mg/m2 days 1 and 2 of cycle) = £53.70 Drug cost per cycle = £1,574.28 Treatment is delivered over 6 cycles. Drug cost over course of treatment (6 cycles) = £9,445.68		
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	Not applicable		

<table>
<tr><td>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.</td><td></td></tr>
<tr><td>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 %)</td><td>(NHSE) Chemotherapy Delivery 1st - SB13Z x 1 (£299 x 1) = £299
(NHSE) Chemotherapy Delivery Subsequent - SB15 x 11 (£299 x 11) = £3,289
(CCG) Outpatient Attendances - WF01A 303 x 6 (£109 x 6) = £654
= £4,242</td></tr>
<tr><td>C1.5 Will a prior approval mechanism be used to support implementation of the new policy that will require provider compliance to secure reimbursement?</td><td><u>No</u></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>13,392</td></tr><tr><td>YR2</td><td>13,392</td></tr><tr><td>YR3</td><td>13,392</td></tr><tr><td>YR4</td><td>13,392</td></tr><tr><td>YR5</td><td>13,392</td></tr></table>
If yes, please specify:
No</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
</table>

C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	**Cost pressure** Year 1 £1,843,556 Year 2 £1,874,246 Year 5 £1,957,545
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** : **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 pressure** Year 1 £1,843,556 Year 2 £1,874,246 Year 5 £1,957,545

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.	CPAG prioritisation reserve
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	There are no significant financial risks, robust financial modelling has been undertaken.
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?	Patient cohort numbers taken from CDF utilisation data for number of patients suitable for treatment. The number of patients could be higher if treatment has not been administered through CDF.
C6.4 What scenario has been approved and why?	See section C6.3.
C7 Value for Money	

<table>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td><u>There is no published evidence of cost-effectiveness</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>
<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>
<tr><td>C8.2 If yes, confirm the source of funds to meet these costs.</td><td>Not applicable</td></tr>
</table>