

## Integrated Impact Assessment Report for Clinical Commissioning Policies

|                                |  |                        |                 |
|--------------------------------|--|------------------------|-----------------|
| <b>Policy Reference Number</b> | 1630   |                        |                 |
| <b>Policy Title</b>            | Bendamustine and rituximab for first line mantle cell lymphoma (MCL)<br>Proposal <b><u>for routine commission</u></b> (ref A3.1) |                        |                 |
| <b>Lead Commissioner</b>       | Lisa Jordan  | <b>Clinical Lead</b>   | Rajinder Nijjar |
| <b>Finance Lead</b>            | Jacqui Low   | <b>Analytical Lead</b> | Jacqui Low      |

### Integrated Impact Assessment – Index

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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

|  |   |
|--|---|
| <p>A1.1 Prevalence of the disease/condition.</p>   | <p>Mantle cell lymphoma is a distinct non-Hodgkin's lymphoma (NHL) sub-type that accounts for 6% of patients with non-Hodgkin's Lymphoma. In 2013 there were 13,400 cases of NHL in the UK (Cancer Research UK 2015). In England, there were 11,392 (6186 males, 5206 females) cases of NHL (Cancer Registration Statistics England 2013). The estimated number of UK cases of MCL is 510 (Haematological Malignancy Research Network data, 2004-2014). The median survival time is approximately 4 years.</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>192</p> <p><i>Source: Policy Proposition, section 6</i></p>  |
| <p>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</p>                    | <p><b><u>All ages</u></b></p>   |
| <p>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</p>      | <p>MCL usually occurs in older adults and has a male predominance, with an estimated median age of 60.</p> <p><i>Source: Policy Proposition, section 6.</i></p>   |
| <p>A1.5 How is the population currently distributed geographically?</p>  | <p><b><u>Evenly</u></b></p>   |

**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**

*Source: Policy Proposition section 6*

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

**No**

*Source: Policy Proposition section 6/other*

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?

|          |     |
|----------|-----|
| YR2 +/-  | 200 |
| YR3 +/-  | 204 |
| YR4 +/-  | 208 |
| YR5 +/-  | 212 |
| YR10 +/- | 233 |

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

**Yes**

**A3 Activity**

A3.1 What is the purpose of new policy?

**Confirm routine commissioning position of an additional new treatment**

|   |   |
|---|---|
| A3.2 What is the annual activity associated with the existing pathway for the eligible population?  | 192   |
| A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?   | 192   |
| 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.                   | 192   |
| <b>A4 Existing Patient Pathway</b>  |   |
| <p>A4.1 <b>Existing pathway:</b> Describe the relevant currently routinely commissioned:</p> <ul style="list-style-type: none"> <li>• Treatment or intervention</li> <li>• Patient pathway</li> <li>• Eligibility and/or uptake estimates.</li> </ul> | <p>There is no standard treatment that is currently routinely commissioned for these patients although they are all likely to undergo some chemotherapy treatment. Patients will be under the care of a specialist following diagnosis and they will discuss the best available treatment options. Eligibility will depend on the stage of the disease and the fitness of the patient.</p> <p><i>Source: Policy Working Group</i></p> |
| A4.2. What are the current treatment access and stopping criteria?  | Not applicable.   |
| <p>A4.3 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> </ul>   | <p>If not known, please specify <a href="#">Click here to enter text.</a></p> <ul style="list-style-type: none"> <li>a) 100%</li> <li>b) 0%</li> </ul>  |

|  |   |
|--|---|
| <p>c) Choose to initiate treatment<br/> d) Comply with treatment<br/> e) Complete treatment?</p>   | <p>c) 100%<br/> d) 100%<br/> e) 100%</p> <p><i>Source: Policy Proposition, section 6 / Policy Working Group</i></p>   |
| <p><b>A5 Comparator (next best alternative treatment) Patient Pathway</b><br/> (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)</p>   |   |
| <p><b>A5.1 Next best comparator:</b><br/> Is there another 'next best' alternative treatment which is a relevant comparator?<br/> <i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment or intervention</i></li> <li>• <i>Patient pathway</i></li> <li>• <i>Actual or estimated eligibility and uptake</i></li> </ul>             | <p><b><u>Yes - additional comparator not routinely commissioned</u></b></p> <p>The best known alternative treatment is Rituximab, cyclophosphamide, doxorubicin and vincristine (R-CHOP) delivered on a single day for up to 6 cycles.</p> <p><i>Source: Policy Working Group</i></p> |
| <p><b>A5.2</b> What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul> | <p>Total estimated eligible</p> <ul style="list-style-type: none"> <li>a) 100%</li> <li>b) 0%</li> <li>c) 100%</li> <li>d) 100%</li> <li>e) 100%</li> </ul> <p><i>Source: Policy Working Group</i></p>  |
|  |   |

## 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?

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

*Source: Policy Working Group*

A6.2 Specify the nature and duration of the proposed new treatment or intervention.

### **Time limited**

For time limited treatments, specify frequency and/or duration.

A dose of 90mg/m<sup>2</sup> bendamustine on two days every 28 days for up to 6 cycles and 375mg/m<sup>2</sup> rituximab on day 1 of each cycle.

*Source: Policy Proposition*

## A7 Treatment Setting

A7.1 How is this treatment delivered to the patient?

*Select all that apply:*

|                                  |                                     |
|----------------------------------|-------------------------------------|
| Emergency/Urgent care attendance | <input type="checkbox"/>            |
| Acute Trust: inpatient           | <input type="checkbox"/>            |
| Acute Trust: day patient         | <input checked="" type="checkbox"/> |
| Acute Trust: outpatient          | <input type="checkbox"/>            |

|  |   |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
|--|---|-----------------------------------|-------------------------------------|------------------------------------|--------------------------|-----------------------------|-------------------------------------|-------------------------------|--------------------------|-------|--------------------------|
|  | <table border="1"> <tr> <td data-bbox="1084 97 1637 156">Mental Health provider: inpatient</td> <td data-bbox="1637 97 1713 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 156 1637 215">Mental Health provider: outpatient</td> <td data-bbox="1637 156 1713 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 215 1637 274">Community setting</td> <td data-bbox="1637 215 1713 274"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 274 1637 333">Homecare</td> <td data-bbox="1637 274 1713 333"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 333 1637 392">Other</td> <td data-bbox="1637 333 1713 392"><input type="checkbox"/></td> </tr> </table> | Mental Health provider: inpatient | <input type="checkbox"/>            | Mental Health provider: outpatient | <input type="checkbox"/> | Community setting           | <input type="checkbox"/>            | Homecare                      | <input type="checkbox"/> | Other | <input type="checkbox"/> |
| Mental Health provider: inpatient  | <input type="checkbox"/>  |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| Mental Health provider: outpatient   | <input type="checkbox"/>  |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| Community setting  | <input type="checkbox"/>  |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| Homecare   | <input type="checkbox"/>  |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| Other  | <input type="checkbox"/>  |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| <p>A7.2 What is the current number of contracted providers for the eligible population by region?</p>  | <p>Not applicable – 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 service specification.</p>   |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| <p>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</p>  | <p><u>No</u></p>  |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| <p><b>A8 Coding</b></p>  |   |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| <p>A8.1 Specify the datasets used to record the new patient pathway activity.</p> <p>*expected to be populated for all commissioned activity</p> | <p><i>Select all that apply:</i></p> <table border="1"> <tr> <td data-bbox="1084 1121 1753 1181">Aggregate Contract Monitoring *</td> <td data-bbox="1753 1121 1848 1181"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 1181 1753 1240">Patient level contract monitoring</td> <td data-bbox="1753 1181 1848 1240"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 1240 1753 1299">Patient level drugs dataset</td> <td data-bbox="1753 1240 1848 1299"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 1299 1753 1358">Patient level devices dataset</td> <td data-bbox="1753 1299 1848 1358"><input type="checkbox"/></td> </tr> </table>                | Aggregate Contract Monitoring *   | <input checked="" type="checkbox"/> | Patient level contract monitoring  | <input type="checkbox"/> | Patient level drugs dataset | <input checked="" type="checkbox"/> | Patient level devices dataset | <input type="checkbox"/> |       |                          |
| Aggregate Contract Monitoring *  | <input checked="" type="checkbox"/>   |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| Patient level contract monitoring  | <input type="checkbox"/>  |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| Patient level drugs dataset  | <input checked="" type="checkbox"/>   |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |
| Patient level devices dataset  | <input type="checkbox"/>  |                                   |                                     |                                    |                          |                             |                                     |                               |                          |       |                          |

|   |   |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
|---|---|---|-------------------------------------|--------------------------------|-------------------------------------|--|--------------------------|----------------------|-------------------------------------|---------------------|--------------------------|---------|--------------------------|---|--------------------------|--|
|   | <table border="1"> <tr> <td>Devices supply chain reconciliation dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary Usage Service (SUS+)</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Mental Health Services DataSet (MHSDS)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National Return**</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Clinical Database**</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other**</td> <td><input type="checkbox"/></td> </tr> </table> <p>**If National Return, Clinical database or other selected, please specify:<br/>SACT database</p> | Devices supply chain reconciliation dataset | <input type="checkbox"/>            | Secondary Usage Service (SUS+) | <input checked="" type="checkbox"/> | Mental Health Services DataSet (MHSDS) | <input type="checkbox"/> | National Return**    | <input checked="" type="checkbox"/> | Clinical Database** | <input type="checkbox"/> | Other** | <input type="checkbox"/> |   |                          |  |
| Devices supply chain reconciliation dataset   | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| Secondary Usage Service (SUS+)  | <input checked="" type="checkbox"/>   |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| Mental Health Services DataSet (MHSDS)  | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| National Return**   | <input checked="" type="checkbox"/>   |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| Clinical Database**   | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| Other**   | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| <p>A8.2 Specify how the activity related to the new patient pathway will be identified.</p> | <p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>OPCS v4.8</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>ICD10</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Treatment function code</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Main Speciality code</td> <td><input type="checkbox"/></td> </tr> <tr> <td>HRG</td> <td><input type="checkbox"/></td> </tr> <tr> <td>SNOMED</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical coding / terming methodology used by clinical profession</td> <td><input type="checkbox"/></td> </tr> </table>                                | OPCS v4.8                                   | <input checked="" type="checkbox"/> | ICD10                          | <input checked="" type="checkbox"/> | Treatment function code                | <input type="checkbox"/> | Main Speciality code | <input type="checkbox"/>            | HRG                 | <input type="checkbox"/> | SNOMED  | <input type="checkbox"/> | Clinical coding / terming methodology used by clinical profession | <input type="checkbox"/> |  |
| OPCS v4.8   | <input checked="" type="checkbox"/>   |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| ICD10   | <input checked="" type="checkbox"/>   |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| Treatment function code   | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| Main Speciality code  | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| HRG   | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| SNOMED  | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| Clinical coding / terming methodology used by clinical profession                           | <input type="checkbox"/>  |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |
| <p><b>A8.3 Identification Rules for Drugs:</b><br/>How are drug costs captured?</p>         | <p><b><u>Already specified in current NHS England Drugs List document</u></b><br/>If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:<br/><a href="#">Click here to enter text.</a><br/>If the drug has NOT already been specified in the current NHS England</p>   |   |                                     |                                |                                     |  |                          |                      |                                     |                     |                          |         |                          |   |                          |  |

|   |  |                     |                                     |         |                          |                      |                          |
|---|--|---------------------|-------------------------------------|---------|--------------------------|----------------------|--------------------------|
|   | <p>Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:<br/> <a href="#">Click here to enter text.</a></p>  |                     |                                     |         |                          |                      |                          |
| <p><b>A8.4 Identification Rules for Devices:</b><br/> How are device costs captured?</p>  | <p><b><u>Not applicable</u></b></p>  |                     |                                     |         |                          |                      |                          |
| <p><b>A8.5 Identification Rules for Activity:</b><br/> How are activity costs captured?</p>   | <p><b><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u></b></p> <p>NCBPS01C Chemotherapy</p>  |                     |                                     |         |                          |                      |                          |
| <p><b>A9 Monitoring</b></p>   |  |                     |                                     |         |                          |                      |                          |
| <p><b>A9.1 Contracts</b><br/> Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</p>   | <p><b><u>None</u></b></p>  |                     |                                     |         |                          |                      |                          |
| <p><b>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)</b><br/> 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.</p> | <p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Drugs or Device MDS</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Blueteq</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other prior approval</td> <td><input type="checkbox"/></td> </tr> </table> | Drugs or Device MDS | <input checked="" type="checkbox"/> | Blueteq | <input type="checkbox"/> | Other prior approval | <input type="checkbox"/> |
| Drugs or Device MDS   | <input checked="" type="checkbox"/>  |                     |                                     |         |                          |                      |                          |
| Blueteq   | <input type="checkbox"/>   |                     |                                     |         |                          |                      |                          |
| Other prior approval  | <input type="checkbox"/>   |                     |                                     |         |                          |                      |                          |
| <p><b>A9.3 Business intelligence</b></p>  | <p><b><u>No</u></b></p>  |                     |                                     |         |                          |                      |                          |

|   |  |
|---|--|
| Is there potential for duplicate reporting?   |  |
| <b>A9.4 Contract monitoring</b><br>Is this part of routine contract monitoring?   | <b><u>Yes</u></b><br>If yes, please specify contract monitoring requirement:<br>Monitored through SACT database.   |
| <b>A9.5 Dashboard reporting</b><br>Specify whether a dashboard exists for the proposed intervention?  | <b><u>No</u></b>   |
| <b>A9.6 NICE reporting</b><br>Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy? | <b><u>No</u></b>   |
| <b>Section B - Service Impact</b>   |  |
| <b>B1 Service Organisation</b>  |  |
| 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. |
| B1.2 Will the proposition change the way the commissioned service is organised?   | <b><u>No</u></b>   |
| B1.3 Will the proposition require a new approach to the organisation of care?   | <b><u>No change to delivery of care</u></b>  |

## B2 Geography & Access

B2.1 Where do current referrals come from?

Select all that apply:

|                |                                     |
|----------------|-------------------------------------|
| GP             | <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?

**No impact**

B2.3 Is the new policy likely to improve equity of access?

**Increase**

*Source: Equalities Impact Assessment*

B2.4 Is the new policy likely to improve equality of access and/or outcomes?

**Increase**

*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**

|  |                                      |
|--|--------------------------------------|
| <p><b>B3.2 Time to implementation:</b><br/>Is a lead-in time required prior to implementation?</p>   | <p><b><u>No - go to B3.4</u></b></p> |
| <p><b>B3.3 Time to implementation:</b><br/>If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p>   | <p><b><u>Not applicable.</u></b></p> |
| <p><b>B3.4</b> Is a change in provider physical infrastructure required?</p>   | <p><b><u>No</u></b></p>              |
| <p><b>B3.5</b> Is a change in provider staffing required?</p>  | <p><b><u>No</u></b></p>              |
| <p><b>B3.6</b> Are there new clinical dependency and/or adjacency requirements that would need to be in place?</p>   | <p><b><u>No</u></b></p>              |
| <p><b>B3.7</b> Are there changes in the support services that need to be in place?</p>   | <p><b><u>No</u></b></p>              |
| <p><b>B3.8</b> Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p>   | <p><b><u>No</u></b></p>              |
| <p><b>B3.9</b> 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><b><u>No change</u></b></p>       |

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  | <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 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:

|              |  |                          |
|--------------|--|--------------------------|
| <b>Drugs</b> | 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"/>                                   |                                     |
|  | <b>Devices</b>  |   | Not separately charged – part of local or national tariffs | <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"/>            |
|  |                 |   |  |                                     |
|  | <b>Activity</b> |   | 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"/>            |
| <b>C1.2 Drug Costs</b>   |                 |   |  |                                     |
| Where not included in national or local tariffs, list each drug or combination, dosage, quantity, <b>list</b> price including VAT if applicable and any other key information e.g. Chemotherapy Regime.<br>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<br>Bendamustine 90mg/m2 days 1 and 2 of cycle - £53.70<br><br>Activity delivered over 6 cycles.<br><br>Total cost per patient over 6 cycles - £9,123.48 |  |                                     |
| <b>C1.3 Device Costs</b>   |                 |   |  |                                     |
| Where not included in national or local tariff, list each element of the excluded device, quantity, <b>list or expected</b> price including VAT if   |                 | Not applicable.   |  |                                     |

|   |   |
|---|---|
| <p>applicable and any other key information.</p> <p>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>  |   |
| <p><b>C1.4 Activity Costs covered by National Tariffs</b></p> <p>List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</p>  | <p>Activity covered under national tariffs.</p> <p>SB13Z - £299; SB15Z - £299; and WF01A - £109</p> |
| <p><b>C1.5 Activity Costs covered by Local Tariff</b></p> <p>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 it has been derived, validated and tested.</p> | <p>Not applicable.</p>  |
| <p><b>C1.6 Other Activity Costs not covered by National or Local Tariff</b></p> <p>Include descriptions and estimates of all key costs.</p>   | <p>Not applicable.</p>  |
| <p>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</p>   | <p><b><u>No</u></b></p>   |
| <p><b>C1.6 Other Activity Costs not covered by National or Local Tariff</b></p> <p>Include descriptions and estimates of all key costs.</p>   | <p>Click</p>  |
| <p>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</p>   | <p><b><u>No</u></b></p>   |
| <p><b>C3 Overall Cost Impact of this Policy to NHS England</b></p>  |   |

|  |   |
|--|---|
| C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.   | <p><b><u>Cost pressure</u></b></p> <p>Net cost per patient treated – £2,192</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.   |
| <p><b>C4 Overall cost impact of this policy to the NHS as a whole</b></p>  |   |
| C4.1 Specify the budget impact of the proposal on other parts of the NHS.  | <p>Budget impact for CCGs:<br/> <b><u>No impact on CCGs</u></b><br/> Budget impact for providers:<br/> <b><u>No impact on providers</u></b></p> |
| C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.  | <p><b><u>Cost pressure</u></b></p> <p>See section C3.1.</p>   |
| 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   | <b><u>No</u></b>  |

|   |   |
|---|---|
| commissioners and/or public sector funders?   |   |
| <b>C5 Funding</b>   |   |
| 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. | There are no known sources of funds beyond the amount being made available against which to prioritise investments in specialised commissioning services. |
| <b>C6 Financial Risks Associated with Implementing this Policy</b>  |   |
| C6.1 What are the material financial risks to implementing this policy?   | There are not expected to be any material financial risks associated with implementing this policy.   |
| 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.   |
| <b>C7 Value for Money</b>   |   |
| C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?   | <b><u>There is no published evidence of cost-effectiveness</u></b>  |

|  |   |                                     |
|--|---|-------------------------------------|
| C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money? | <i>Select all that apply:</i>   |                                     |
|  | Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment | <input type="checkbox"/>            |
|  | Available pricing data suggests the treatment is lower cost compared to current/comparator treatment      | <input type="checkbox"/>            |
|  | Available clinical practice data suggests the new treatment has the potential to improve value for money  | <input type="checkbox"/>            |
|  | Other data has been identified  | <input type="checkbox"/>            |
|  | No data has been identified   | <input checked="" type="checkbox"/> |
|  | The data supports a high level of certainty about the impact on value                                     | <input type="checkbox"/>            |
|  | The data does not support a high level of certainty about the impact on value                             | <input type="checkbox"/>            |

**C8 Cost Profile**

|  |                  |
|--|------------------|
| C8.1 Are there non-recurrent capital or revenue costs associated with this policy? | <b><u>No</u></b> |
| C8.2 If yes, confirm the source of funds to meet these costs.                      | Not applicable.  |