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Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1604		
Policy Title	Bendamustine and rituximab for relapsed mantle cell lymphoma (MCL)		
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Finance Lead	Jacqui Low	**Analytical Lead**	Jacqui Low

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Sections A - C	
Theme / Questions: Each section is divided into themes. Each theme sets out a number of questions.	**Responses / Comments:** All questions are answered by selecting a drop down option or including free text in line with the specified word limit. 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.	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). There are currently 670 patients in England and Wales diagnosed with mantle cell lymphoma (MCL) per year. The median survival time is approximately 4 years. *Source: Policy Proposition*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	Of the 670 patients diagnosed per year, approximately 370 patients will have relapsed disease and qualify for the treatment. *Source: Policy Proposition*

<table>
<tr><td>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</td><td><u>All ages</u></td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>MCL usually occurs in older adults and has a male predominance, with an estimated median age of 60.</td></tr>
<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>Constant</u>

Source: Policy Proposition section 6/ Policy Working Group</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>

Source: Policy Proposition section 6/other</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>385</td></tr><tr><td>YR3 +/-</td><td>393</td></tr><tr><td>YR4 +/-</td><td>401</td></tr><tr><td>YR5 +/-</td><td>409</td></tr><tr><td>YR10 +/-</td><td>452</td></tr></table>
Source: Policy Working Group</td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Confirm routine commissioning position of an additional new treatment</u></td></tr>
</table>

A3.2 What is the annual activity associated with the existing pathway for the eligible population?	370 *Source: Policy Working Group*
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	370 *Source:* Policy Working Group
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population?	370 *Source: Policy Working Group*
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	There is no standard agreed treatment for relapsed MCL, patients are likely to receive chemotherapy. ASCT may also be considered. *Source: European Society for Medical Oncology*
A4.2. What are the current treatment access and stopping criteria?	See section A4.1
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 Working Group/ European Society for Medical Oncology*

A5 Comparator (next best alternative treatment) Patient Pathway	
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 - additional comparator not routinely commissioned</u>** The best known alternative treatment for MCL is of Rituximab, cyclophosphamide, doxorubicin and vincristine (R-CHOP). This is delivered on a single day for up to 6 cycles. *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*.
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.	**<u>Time limited</u>** When used in this indication it is administered by intravenous

	infusion at a dose of 90mg/m2 on two days every 28 days for up to 6 cycles. Rituximab is administered at a dose of 375mg/m2 on day 1 of the cycle (administered 6 times in total). . *Source: Policy Proposition*

A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	**Acute Trust: day case**
A7.2 What is the current number of contracted providers for the eligible population by region?	NORTH: number MIDLANDS & EAST: number LONDON: number SOUTH: number 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.
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No**

A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	*Select all that apply:* 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, list here: SACT database
A8.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:* OPCS v4.8 | ☒ ICD10 | ☒ Treatment function code | ☐ Main Speciality code | ☐ HRG | ☐ SNOMED | ☐ Clinical coding / terming methodology used by clinical profession | ☐
A8.3 Does the service require the creation of a new specialised service line?	**No**

<table>
<tr><th colspan="2">A9 Monitoring</th></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
For treatments which are tariff excluded drugs, specify the pharmacy monitoring required, for example reporting or use of prior approval systems.</td><td>Select all that apply:<table><tr><td>Drugs 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
Specify analytical information, monitoring and reporting requirements, including validation requirements, to ensure activity is not double charged through existing routes.</td><td>Monitoring will occur through the SACT dataset</td></tr>
<tr><td>A9.4 Contract monitoring
Specify contract monitoring to be undertaken by supplier managers, and any changes from current arrangements.</td><td>Monitoring will occur through the SACT dataset</td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u>

If no, will one be developed?
Not applicable.</td></tr>
<tr><td>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?</td><td><u>No</u></td></tr>
<tr><th colspan="2">Section B - Service Impact</th></tr>
</table>

<table>
<tr><th colspan="2">B1 Service Organisation</th></tr>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc)</td><td>Chemotherapy can be prescribed and delivered at any provider commissioned by NHS England; this includes Cancer Centres, Teaching Hospitals and District General Hospitals.</td></tr>
<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>Not applicable</u></td></tr>
<tr><th colspan="2">B2 Geography & Access</th></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>Increase</u>

Source: Equalities Impact Assessment</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: Equalities Impact Assessment</td></tr>
</table>

B3 Implementation	
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?	**Not applicable.**
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 Is this treatment paid under national prices?	**Yes** If yes, specify HRG and tariff: First attendance SB13Z £299 Subsequent attendance SB15Z £299

C1.2 Is this treatment excluded from national prices?	**No**
C1.3 Is this covered under a local price arrangement? NB: Local pricing may be subject to commercial confidentiality and must not be disclosed.	**No**
C1.4 Is a new price proposed?	**No**
C1.5 If VAT is payable, is it included in the proposed price?	**Yes payable - included in price**
C1.6 Will a prior approval mechanism be used to support implementation of the new policy that will require provider compliance to secure reimbursement?	**No**
C2 Average Cost per Patient	
C2.1 What is the estimated net cost per patient to NHS England, in years 1-5, including follow-up where required? NB: Net cost takes account of the impact of the new proposal compared to the existing pathway and any comparators. A4 sets out the existing pathway. A5 sets out any relevant comparator pathway. A6.2 sets out the nature of the proposed treatment (one off / ongoing etc). Inputs summary sets out key input assumptions.	YR1 £2,192 YR2 £2,192 YR3 £2,192 YR4 £2,192 YR5 £2,192
C3 Overall Cost Impact of this Policy to NHS England	
C3.1 Specify the budget impact of the	**Cost pressure**

proposal on NHS England.	
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 agreed, and calculated?	Not applicable.
C3.4 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, are CCGs aware of the values to be transferred?	**No**
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **Cost neutral** Budget impact for providers: **Cost neutral**
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure**
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.	There are no known sources of funds beyond the amount being made available against which to prioritise investments in specialised

	commissioning services.
C6 Financial Risks Associated with Implementing this Policy	
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.
C7 Value for Money	
C7.1 What evidence is available that the treatment is cost effective?	**No published evidence available**
C7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	Not applicable.
C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No**
C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable.

SUMMARY: INPUTS (BASED ON POLICY PROPOSITION AND IMPACT ASSESSMENT) TO BE USED FOR CALCULATION OF COST PER PATIENT AND BUDGET IMPACT

INPUT ASSUMPTIONS	Yr 1	Yr2	Yr 3	Yr 4	Yr5
1. Patients eligible	377	385	393	401	409
2. Uptake	100%	100%	100%	100%	100%
3. Treatment duration	6 cycles of 2 day treatments (day 1 + day 2 x 6 - Bendamustine + Rituximab on day 1 and Bendamustine on day 2) followed by a haematology follow up appointment after each cycle.				
4. Treatment regimen factors (dosing, discontinuation etc)	When used in this indication it is administered by intravenous infusion at a dose of 90mg/m2 on two days every 28 days for up to 6 cycles. Rituximab is administered at a dose of 375mg/m2 on day 1 of the cycle (administered 6 times in total).				
5. Treatment effectiveness	Treatment required only once.				
6. Number needed to treat to achieve primary outcome (from published evidence)	Not applicable.				
7. Treatment price (list price used where commercially confidential discounts available)	**Drug costs (per patient, per cycle):** Rituximab (375mg/m^2 day 1 of cycle) = £1,466.88 Bendamustine (90mg/m^2 on days 1 and 2 of cycle) = £53.70 **Drugs Sub-Total = £1,520.58** **Delivery costs (per patient, per cycle):** Complex Chemotherapy at first attendance, SB13Z = £299 X 1 Chemotherapy at subsequent attendance, SB15Z = £299 X 11 **Delivery Sub-Total = £3,588** **Grand total (per patient, per cycle) - £5,108.58**				
8. Care cost associated with proposal (tariff price or range used where commercially confidential prices in place)	Outpatient attendances (per patient): £ Haematology Follow-up WF01A 109 **Total cost (per patient, per cycle) = £109**				
9. Costs of existing or alternative pathway which the proposal will offset (deaths / morbidity / healthcare utilisation avoided, other treatments reduced or avoided))	The best known alternative treatment for MCL is of Rituximab, cyclophosphamide, doxorubicin and vincristine (R-CHOP). This is delivered on a single day for up to 6 cycles. **Drugs Sub-Total (per patient, per cycle):** Rituximab 375mg/m2 day 1 of cycle = £1,466.88 Doxorubicin 50mg/m2 day 1 of cycle = £26.36 Vincristine 1.4mg/m2 day 1 of cycle = £13.20 Cyclophosphamide 750mg/m2 day 1 of cycle = £31.39 **Drugs Sub-Total = £1,537.83**				

	<u>Delivery costs (per patient, per cycle):</u> Complex Chemotherapy at first attendance, SB13Z = £299 X 1 Chemotherapy at subsequent attendance, SB15Z = £299 X 5 **Delivery Sub-Total = £1,794** **<u>Care costs (per patient, per cycle):</u>** Haematology Follow-up (WF01A) = £109 **Care Sub-Total = £109** **Total cost (per patient, per cycle) = £3,440.83**