

Integrated Impact Assessment Report for Clinical Commissioning Policies

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| Policy Reference Number | 1601 | | |
| Policy Title | Bortezomib for Relapsed/Refractory Waldenstrom's Macroglobulinaemia (WM) Proposal <u>not for routine commission</u> (ref A3.1) | | |
| Lead Commissioner | Lisa Jordan | Clinical Lead | Dermot Ball |
| Finance Lead | Jacqueline Low | Analytical Lead | Jacqueline Low |

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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

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| A1.1 Prevalence of the disease/condition. | WM has an age standardised incidence rate of 0.55 cases per 100,000 per year in the UK, leading to an estimated 304 new cases per year in England. WM is incurable and most patients will be considered 'Relapsed/Refractory' at some point. <i>Source: Policy Proposition section 6</i> |
| A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria. | 304 <i>Source: Policy Proposition section 6</i> |
| A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria. | <u>All ages</u> |
| A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria | The policy is proposed as an all ages policy. Therefore there is no difference between the age distribution of the patients diagnosed with WM and those impacted by the clinical criteria within the policy proposition. However, WM usually occurs in older adults, with a median age at presentation of over 70 years. WM has a male predominance. <i>Source: Policy Proposition section 6</i> |
| A1.5 How is the population currently distributed geographically? | <u>Evenly</u> <i>Source: Policy Proposition section 6</i> No geographic distribution issues can be found in the UK |

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

Prevalence increasing due to increasing survival

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?

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| YR2 +/- | 12 |
| YR3 +/- | 18 |
| YR4 +/- | 24 |
| YR5 +/- | 31 |
| YR10 +/- | 70 |

Source: Policy Proposition section 6

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 non-routine commissioning position of an additional new

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| | <u>treatment</u> |
| A3.2 What is the annual activity associated with the existing pathway for the eligible population? | 304 <i>Source: Policy Proposition section 6</i> |
| A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population? | Not applicable, this is a not for routine commissioning policy for a treatment that is not currently available. |
| 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. | 304 <i>Source: Policy Proposition section 6</i> |
| A4 Existing Patient Pathway | |
| A4.1 Existing pathway: Describe the relevant currently routinely commissioned: <ul style="list-style-type: none"> • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates. | A range of chemotherapy medicines are currently available to treat WM and some patients with a good functional status may have a stem cell transplant. Because the management of the condition is highly individualised, there is no clinical consensus as to the 'standard of care'. <i>Source: Policy Working Group</i> |
| 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: <ul style="list-style-type: none"> a) Be clinically assessed for treatment | If not known, please specify Click here to enter text. <ul style="list-style-type: none"> a) 100% |

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| b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment? | b) 100% c) 100% d) 100% e) 100% <i>Source: Policy Proposition</i> |
| 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? <i>If yes, describe relevant</i> <ul style="list-style-type: none"> <i>Treatment or intervention</i> <i>Patient pathway</i> <i>Actual or estimated eligibility and uptake</i> | <u>Yes - additional comparator not routinely commissioned</u> Relapsed/refractory WM may be treated with R-CHOP (rituximab with cyclophosphamide, daunorubicin, vincristine & prednisolone) or R-F (rituximab with fludarabine). <i>Source: Policy Working Group</i> |
| A5.2 What percentage of the total eligible population is estimated to: <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> a) 100% b) 0 c) 100% d) 100% e) 100% <i>Source: Policy Working Group</i> |

| A6 New Patient Pathway | |
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| <p>A6.1 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment? | Not applicable, this is a not for routine commissioning policy. Bortezomib is not currently available to treat this condition. |
| 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 |
| A7.3 Does the proposition require a change of delivery setting or capacity requirements? | Not applicable |

| A8 Coding | |
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| <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> | 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 |
| <p>A8.3 Identification Rules for Drugs: How are drug costs captured?</p> | <u>Not applicable</u> |
| <p>A8.4 Identification Rules for Devices: How are device costs captured?</p> | <u>Not applicable</u> |
| <p>A8.5 Identification Rules for Activity: How are activity costs captured?</p> | Not applicable, this is a not for routine commissioning policy |
| A9 Monitoring | |
| <p>A9.1 Contracts Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</p> | <u>None</u> |

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| A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model) For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems. | Not applicable, this is a not for routine commissioning policy |
| A9.3 Business intelligence Is there potential for duplicate reporting? | Not applicable, this is a not for routine commissioning policy |
| A9.4 Contract monitoring Is this part of routine contract monitoring? | Not applicable, this is a not for routine commissioning policy |
| A9.5 Dashboard reporting Specify whether a dashboard exists for the proposed intervention? | Not applicable, this is a not for routine commissioning policy |
| A9.6 NICE reporting Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy? | <u>No</u> |
| 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 |

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| B1.2 Will the proposition change the way the commissioned service is organised? | <u>No</u> | | | | | | | | |
| B1.3 Will the proposition require a new approach to the organisation of care? | <u>No change to delivery of care</u> | | | | | | | | |
| B2 Geography & Access | | | | | | | | | |
| B2.1 Where do current referrals come from? | <p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>GP</td><td><input type="checkbox"/></td></tr> <tr> <td>Secondary care</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Tertiary care</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Other</td><td><input type="checkbox"/></td></tr> </table> <p>Please specify: Click here to enter text.</p> | GP | <input type="checkbox"/> | Secondary care | <input checked="" type="checkbox"/> | Tertiary care | <input checked="" type="checkbox"/> | Other | <input type="checkbox"/> |
| 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? | <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> | | | | | | | | |

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| B2.4 Is the new policy likely to improve equality of access and/or outcomes? | <u>No impact</u> <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> |
| B3.3 Time to implementation: If lead-in time is required prior to implementation, will an interim plan for implementation be required? | <u>No - go to B3.4</u> |
| B3.4 Is a change in provider physical infrastructure required? | <u>No</u> |
| B3.5 Is a change in provider staffing required? | <u>No</u> |
| B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place? | <u>No</u> |
| B3.7 Are there changes in the support services that need to be in place? | <u>No</u> |

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| B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor) | <u>No</u> | | | | | | | | | | | | | | | | | |
| 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 | <u>No change</u> | | | | | | | | | | | | | | | | | |
| B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner. | <p><i>Select all that apply:</i></p> <table border="1"> <tr> <td data-bbox="1090 547 1883 603">Publication and notification of new policy</td> <td data-bbox="1890 547 1998 603"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1090 608 1883 663">Market intervention required</td> <td data-bbox="1890 608 1998 663"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1090 668 1883 756">Competitive selection process to secure increase or decrease provider configuration</td> <td data-bbox="1890 668 1998 756"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1090 761 1883 849">Price-based selection process to maximise cost effectiveness</td> <td data-bbox="1890 761 1998 849"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1090 853 1883 909">Any qualified provider</td> <td data-bbox="1890 853 1998 909"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1090 914 1883 970">National Commercial Agreements e.g. drugs, devices</td> <td data-bbox="1890 914 1998 970"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1090 975 1883 1031">Procurement</td> <td data-bbox="1890 975 1998 1031"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1090 1035 1883 1091">Other</td> <td data-bbox="1890 1035 1998 1091"><input type="checkbox"/></td> </tr> </table> | | Publication and notification of new policy | <input 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"/> |
| Publication and notification of new policy | <input 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 | <u>No</u> | | | | | | | | | | | | | | | | | |

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| commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs) | | |
| Section C - Finance Impact | | |
| C1 Tariff/Pricing | | |
| <p>C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway</p> | <i>Select all that apply:</i> | |
| | Drugs | Not separately charged – part of local or national tariffs <input type="checkbox"/> |
| | | Excluded from tariff – pass through <input type="checkbox"/> |
| | | Excluded from tariff - other <input type="checkbox"/> |
| | Devices | 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"/> |
| | Activity | Paid entirely by National Tariffs <input 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"/> |
| | | |
| C1.2 Drug Costs | | |
| Not applicable, this is a not for routine commissioning policy. | | |

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| 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. | This treatment was previously included within the Cancer Drugs Fund, and was removed on the 12 th of March 2015. There is currently no legacy/continuous treatment relating to this policy. |
| 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. | Not applicable |
| C1.4 Activity Costs covered by National Tariffs List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %) | Not applicable |
| 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 it 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> |

| 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 neutral</u></p> <p>This treatment was removed from the CDF in March 2015, at which point NHS England issued a non-routine commissioning policy. There currently exists no legacy treatment relating to this policy and therefore the decision to not routinely commission this treatment will be cost neutral.</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 neutral</u> |
| C4.3 Where the budget impact is unknown set out the reasons why | Not Applicable |

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| this cannot be measured | |
| 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 |
| 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 | |

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