Engagement Report

Topic details

Title of policy or policy statement:	Combination brentuximab vedotin and bendamustine for patients aged 8 years and above with relapsed or refractory classical Hodgkin lymphoma
Programme of Care:	Cancer
Clinical Reference Group:	Chemotherapy (and other anti-systemic cancer treatment)
URN:	2404

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

Classical Hodgkin lymphoma (cHL) is an uncommon blood cancer in which white blood cells start to grow in an uncontrolled way and form tumours in the lymph nodes and/or other parts of the body. Frontline therapy is highly effective and cures the majority of patients, but approximately 10-30% of patients will develop relapsed or refractory (R/R; resistant) disease. Clinicians will use the word ‘relapse’ if cancer returns following a period of remission. ‘Refractory’ does not respond well enough to initial treatment.

The first phase of treatment for R/R cHL is known as induction therapy. The aim is to eliminate as many cancer cells as possible to achieve remission (disappearance of lymphoma on scans). This usually consists of multi-drug chemotherapy initially (second-line treatment).

Once a patient achieves remission, they proceed to the second step known as consolidation treatment. The goal of consolidation therapy is to prevent cancer from returning. Consolidation treatment usually consists of stem cell transplant (SCT) and is potentially curative. This involves giving very high-dose chemotherapy to treat the lymphoma, then replenishing a patient’s blood stem cells to help them recover. Without SCT, treatment is considered palliative, and most patients will ultimately develop progressive disease.

However, to receive SCT, patients need to have an adequate response to induction chemotherapy. Only half of patients respond well enough to second-line chemotherapy. Of those who respond well, at least a quarter will relapse again and need further treatment. Therefore, most patients with R/R cHL require additional induction therapy (third-line treatment).

BV is an antibody-drug conjugate which is licenced and NICE approved for use in cHL (TA524). It works by binding to a protein on the cancer cell surface (CD30) and delivers a cytotoxic molecule to the cancer cells. This stops them from dividing and the cancer cell eventually dies.

Bendamustine is an alkylating chemotherapy drug. It works by inducing DNA damage and cross-linking DNA strands, which inhibits the ability of cancer cells to grow and survive. It has demonstrated clinical efficacy in several lymphoid malignancies, including non-Hodgkin lymphoma and cHL. However, its use in the treatment of R/R cHL, as well as in combination with BV, are off-label.

Recent studies have found high response rates and SCT rates with the combination of BV with bendamustine (BVB), much higher than reported with current third-line treatments, i.e. brentuximab or pembrolizumab alone. Treatment with BVB is also shorter than BV or pembrolizumab monotherapy and reduces the need for subsequent therapies.

3. Engagement

Following stakeholder testing feedback, the Programme of Care (PoC) has considered that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to ‘make arrangements’ to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition underwent a two-week stakeholder testing between the 5th June 2025 to 18th June 2025 with registered stakeholders from the following Clinical Reference Group:

- Chemotherapy (and other anti-systemic cancer treatment)

Respondents were asked the following consultation questions:

- Do you support the proposal for combination brentuximab vedotin and bendamustine to be available for patients aged 8 years and above with relapsed or refractory classical Hodgkin lymphoma through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you support the Equality and Health Inequalities Impact Assessment (EHIA)?

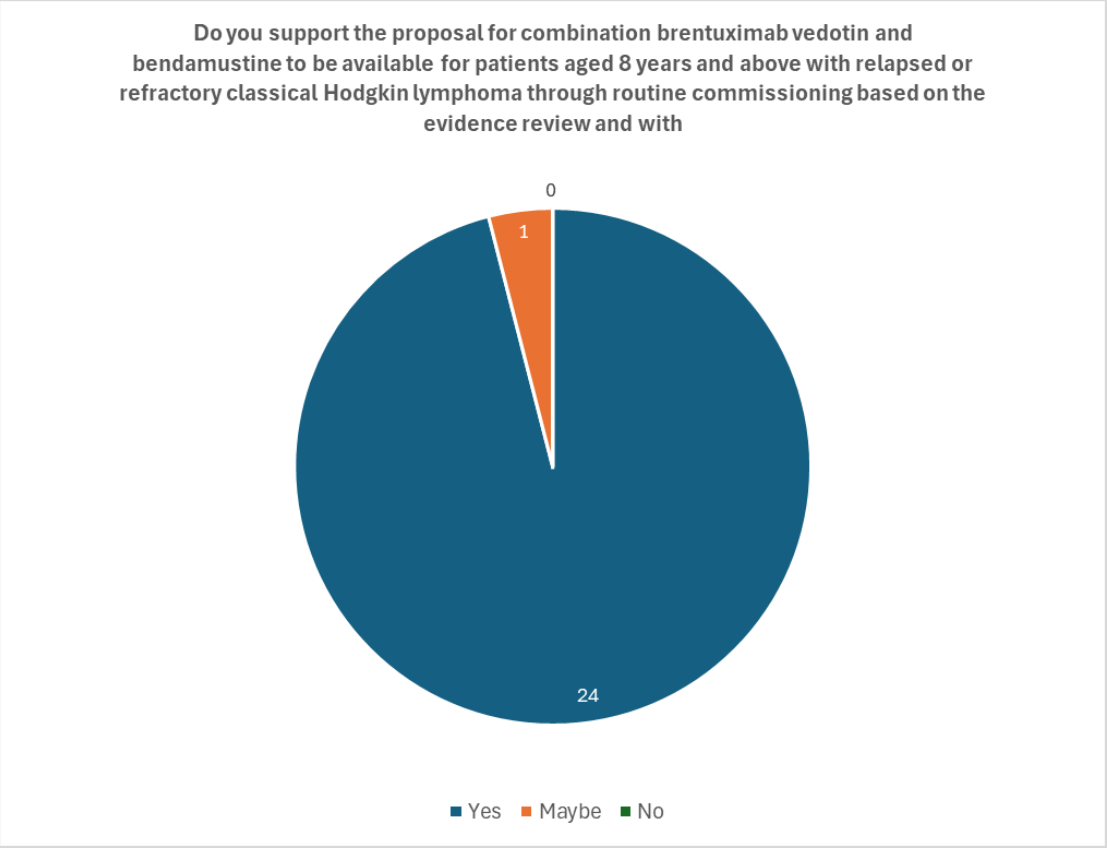
- Does the Patient Impact Assessment (PIA) present a true reflection of the patient and carers lived experience of this condition?
- Do you have any further comments on the policy proposal?
- Do you have any potential conflict of interest relating to this document or service area?

4. Engagement Results

Number stakeholders responded: 25

- 19 clinicians
- 2 patients
- 1 pharmacist
- 2 service providers
- 1 professional body

The majority of respondents were supportive of the policy proposal.



5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group (PWG) and the Cancer PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
Some respondents stated that the lower age limit of 8 was too restrictive citing EuroNet Paediatric guidelines.	The independent evidence review has not identified any peer reviewed papers, that meets the PICO criteria, providing data on individuals below the age of 8

	years old. NHS England cannot therefore determine the clinical efficacy or safety of this intervention for anyone below this age. The evidence submitted falls within the search strategy time period but would not have been included in the evidence review as it is a guideline.
One respondent shared concern over risks posed to patients whilst taking this intervention particularly for the older populations.	Following receipt of the evidence review through the evidence to decision document, the PWG determined that the benefits of allowing wider use outweighed the risks. Risks were mitigated through the 'Inclusion criteria' requiring individuals to be at a minimum performance status and the 'Stopping criteria' determining 'Unacceptable toxicity' as a reason for stopping treatment.
Impact Assessment	
Three respondents did not agree with the Patient Impact Assessment (PIA) as it did not describe a patient's experience whilst taking BVB.	The purpose of the PIA is to provide additional background information to Clinical Priorities Advisory Group (CPAG) on the impact of the medical condition for which the proposed treatment is indicated. It is the purpose of the Evidence to Decision document to determine the significance of the intervention.
Potential impact on equality and health inequalities	
One individual did not agree with the Equality and Health Inequality Assessment (EHIA) due to the restriction of the age limit.	As above.
Changes/addition to policy	
One respondent noted the lack of comparators offering three resources to emphasise the interventions impact.	The evidence review is collated using a PICO framework outlining the inclusion and exclusion criteria. The first referenced paper (Locatelli et al, 2018) would not have met the inclusion criteria as the participants only received brentuximab vedotin and not combination brentuximab vedotin and bendamustine therapy. The second and third references (McMillan et al, 2021; Abdelgawad et al, 2023) are a letter and poster respectively which would not meet the PICO criteria and so would not be included in the evidence review.
One respondent noted a few areas that they felt could help with the	The evidence review does include several international case series reflecting the efficacy and safety of

comprehensiveness and applicability of the policy: 1. Patient-reported outcomes and quality of life (QoL) measures 2. Real-world data or international case series 3. Long-term follow-up data 4. Health economic modelling by patient age group	combination BVB. Published health economics and QoL papers are considered as part of the evidence review. If any were available, they would have been identified in the searches and included in the evidence review. As outlined in the policy, all systemic anti-cancer treatments (SACT) must be recorded via the SACT portal as required within the NHS standard contract. There are no specific audit requirements, however data collection using case report forms (CRF) to facilitate a multicentre service evaluation is strongly encouraged. As part of the policy development process, financial modelling will take place to understand the cost-effectiveness of this intervention.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the policy proposition:

Nil

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

Nil