NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 19 March 2025

Intervention: combination brentuximab vedotin and bendamustine

Indication: relapsed or refractory classical Hodgkin lymphoma (aged 8 years and above) URN: 2404

Gateway: 2, Round 1

Programme: Cancer

CRG: Chemotherapy

Information provided to the Panel

Policy Proposition

Change of Policy Title report

Evidence Reviews x2 completed by Solutions for Public Health – adults and children

Clinical Priorities Advisory Group (CPAG) Summary Report

Evidence to Decision (EtD) Summary

Equalities and Health Inequalities (EHIA) Assessment

Patient Impact Assessment

Blueteq® Form – Adults and Medicines for Children

Policy Working Group (PWG) Appendix

This Policy Proposition recommends the use of brentuximab vedotin (BV) and bendamustine (B) in relapsed and refractory classical Hodgkin lymphoma (cHL). 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, but approximately 10-30% of patients will develop relapsed or refractory (R/R; resistant) disease. BV is an antibody-drug conjugate which is licensed and NICE approved for use in cHL (TA524). Bendamustine is an alkylating chemotherapy drug. Current standard of care can include BV monotherapy, pembrolizumab or third line chemotherapy, with or without best supportive care. The use of bendamustine, in combination with BV, in this indication is off-label. Approximately 200 patients will be eligible for this treatment.

An evidence review was completed for the adult population which included seven papers – one single arm phase I and II trial, and six case series. An evidence review was also completed for the paediatric population which included two papers. No studies comparing BVB with other treatments were identified. No cost-effectiveness studies were identified for inclusion. Limitations of the studies were highlighted including the non-comparative, mainly retrospective nature of the studies with small sample sizes.

Outcomes that were considered critical and important to decision making were presented to Panel members. The evidence was graded of very low certainty. The evidence particularly within

the adult population demonstrated a very good response to treatment. Two-year overall survival ranged from 72 -82%, with one study reporting 93%, enabling patients to progress to a stem cell transplant, which only one third of patients on current treatment could access otherwise. Adverse events were noted with relatively very few patients having to discontinue treatment. Although fewer studies were identified in the paediatric population, the improvement demonstrated in overall survival was equally reported.

Panel members were informed of current treatments. BV is a licensed treatment and a third line option in this condition. Pembrolizumab is a licensed product in this treatment pathway.

The proposition and the supporting documentation were presented to Clinical Panel members.

Members were informed there are licensed medicines available as treatment options at the same point in the treatment pathway for this condition and that a legal view should be sought on off-label BVB being proposed as a treatment option against those.

EHIA – no amendments requested.
PIA – no amendments requested.

Recommendation

Clinical Panel recommends that this proposition progresses as a routine commissioning policy proposition, subject to the outcome of legal advice on the licensed products available as treatment options at the same point in the treatment pathway for this condition.

Why the panel made these recommendations

Panel members agreed that the evidence base, although of very low certainty, supported the proposition. Uncertainty in some of the evidence presented was considered carefully. Clinical Panel members considered that the evidence did demonstrate that clinical benefit was achieved in the population described.

Documentation amendments required Policy Proposition:

- Page 7 – patient pathway – pembrolizumab to be included in the treatment pathway.
- A legal view to be sought by the Pharmacy lead regarding off-label use of BVB where licensed treatment options are available.

Declarations of Interest of Panel Members: None received

Panel Chair: James Palmer, Medical Director, Specialised Services

Panel comments	Policy Working Group (PWG) response
Policy Proposition	
Page 7 – patient pathway – Pembrolizumab needs to be included as a licensed product as it is alternative 3rd line treatment.	The PWG acknowledge the need to make clinicians aware of alternative therapies including pembrolizumab. However, considering that nivolumab may also need to be present, PWG members were concerned that this was becoming more of a treatment algorithm than a patient pathway. They have therefore altered points in the pathway where the

	likes of pembrolizumab or nivolumab may be considered with the following: "*...consider alternative therapies in line with current commissioned policies and technology appraisals*". The policy proposition also links to the present available TAs and commissioned clinical policies in the 'Links and updates to other policies' section.
A legal view to be sought by the Pharmacy advisor regarding licensed treatment options as detailed.	Following obtaining a legal view, the PWG have actioned recommendation made in the report, adding a phrase in the 'What we've decided' section stating: "*This should not be relied upon as a statement of the effectiveness of any technology appraisal guidance published by NICE. Clinicians should ensure they keep up to date with evidence about available treatments.*"
N/A	'per annum' was added to the Epidemiology element of the policy proposition to add clarity to the eligible numbers.