

CPAG Summary Report for Clinical Panel – 1605 Bendamustine with rituximab for first line treatment of advanced indolent non-Hodgkin's lymphoma (all ages)

| The Benefits of the Proposition | | | |
|--|---------------------------|---------------------------------|--|
| <i>No</i> | <i>Outcome measures</i> | <i>Grade of evidence</i> | <i>Summary from evidence review</i> |
| 1. | Survival | Not measured | There is insufficient data at this time to identify any difference between the treatments in overall survival. |
| 2. | Progression free survival | There is a survival benefit [B] | <p>Progression free survival is the time between the first treatment and one of the following; progressive disease, relapse after response or death from any cause.</p> <p>Bendamustine with rituximab (BR) has a superior effect on progression free survival (median 69.5 vs 31.2 months) compared to cyclophosphamide, doxorubicin, vincristine, prednisolone and rituximab (R-CHOP)</p> <p>This is likely to represent a benefit to patients although this evidence comes from an un-blinded study (a study where participants and/or researchers are aware of the intervention they receive).</p> |
| 3. | Mobility | Not measured | |
| 4. | Self-care | Not measured | |

| | | | |
|-----|--|-------------------------------|--|
| 5. | Usual activities | Not measured | |
| 6. | Pain | Not measured | |
| 7. | Anxiety / Depression | Not measured | |
| 8. | Replacement of more toxic treatment | Not measured | |
| 9. | Dependency on care giver / supporting independence | Not measured | |
| 10. | Safety | Adverse events identified [B] | <p>An adverse event (AE) is any untoward medical occurrence in a patient who has been given a treatment which does not necessarily have a causal relationship with this treatment.</p> <p>BR has a different side effect profile to R-CHOP/R-CVP (cyclophosphamide, vincristine, prednisolone and rituximab) greatly reducing the incidence of alopecia (hair loss) and peripheral neuropathy (nerve damage).</p> <p>BR caused less leukopenia (decreased number of white blood cells) and neutropenia (decreased number of neutrophils - white blood cells which helps with the immune system) but more lymphocytopenia (decreased number of lymphocytes – white blood cells which helps with the immune system).</p> <p>BR has a higher risk of drug</p> |

| | | | |
|-----|--------------------------|--------------|--|
| | | | <p>hypersensitivity and skin rash.</p> <p>The risk of secondary malignancies for B-R and R-CHOP/R-CVP does not appear to be different.</p> |
| 11. | Delivery of intervention | Not measured | |

| Other health outcome measures determined by the evidence review | | | |
|---|-------------------|-------------------|---|
| No | Outcome measure | Grade of evidence | Summary from evidence review |
| 1. | Complete response | Grade B | <p>A complete response (CR) is when there is no detectable disease following a course of treatment. It does not always mean the disease has been cured but is the best result that can be reported and that there is no evidence of disease.</p> <p>There was no significant difference in CR when patients were treated with BR compared to R-CHOP/R-CVP. In terms of initial outcome to induction treatment, patients on either treatment would be expected to experience a similar level of effectiveness.</p> |
| 2. | Overall response | Grade B | <p>The overall response rate (ORR) to a treatment is the percentage of patients with either a complete response or partial response (PR) following treatment. Where CR is as described above and PR is a</p> |

| | | | |
|----|-----------------|---------|--|
| | | | <p>decrease in tumour size or the amount of cancer detected in the body following treatment.</p> <p>Overall response rate to BR was greater than R-CHOP/R-CVP, these rates were: BR = 97%, R-CHOP/R-CVP = 91% (p = 0.0102).</p> <p>These data from a double blinded study indicate a statistical difference but one that in clinical terms may be small.</p> |
| 3. | Quality of Life | Grade C | <p>BR showed some advantages in Quality of Life compared to R-CHOP/R-CVP but the clinical significance of the benefits was small, and the differences between the groups were not statistically significant at all points in time.</p> |