TRANSPARENCY COMMITTEE

SUMMARY

3 MARCH 2021

The legally binding text is the original French opinion version

carmustine

**CARMUSTINE OBVIUS 100 mg powder and solvent for concentrate for solution
for infusion**

New indication

► Key points

Unfavourable opinion for reimbursement in the new MA indication.

► What therapeutic improvement?

No clinical added value in the therapeutic strategy for conditioning prior to autologous haematopoietic stem cell transplantation (HSCT) in malignant haematological diseases (Hodgkin's disease/Non-hodgkin's lymphoma).

COMMITTEE'S CONCLUSIONS

Clinical benefit

- ▶ Malignant haematological diseases (Hodgkin's disease/Non-hodgkin's lymphoma) requiring conventional haematopoietic stem cell transplantation are life-threatening.
- ▶ This is a preparatory (conditioning) treatment prior to curative haematopoietic stem cell transplantation.
- ▶ The efficacy/adverse effects ratio is high.
- ▶ There are medicinal alternatives (see section 05 of this opinion).
- ▶ The proprietary medicinal product CARMUSTINE OBVIUS is a first-line treatment.

- ▶ Public health impact

Considering:

- the seriousness of malignant haematological diseases (Hodgkin's disease/Non-hodgkin's lymphoma),
- their incidence,
- the partially met medical need,
- the lack of additional response to the identified need due to:
- limited data from the literature in combination with other anti-cancer treatments, in particular as part of the BEAM protocol,
- the lack of quality of life data,
- the lack of data on a potential impact on the organisation of care,
- CARMUSTINE OBVIUS is unlikely to have an additional impact on public health.

Given all these elements, the Committee deems that the clinical benefit of CARMUSTINE OBVIUS 100 mg is substantial in the new MA indication.

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the new indication and at the MA dosages.

Clinical Added Value

This medicinal product is a eurogeneric that provides no clinical added value (CAV V) in the therapeutic strategy for conditioning prior to autologous haematopoietic stem cell transplantation (HSCT) in malignant haematological diseases (Hodgkin's disease/Non-hodgkin's lymphoma).