



## 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

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### 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:
    - o limited data from the literature in combination with other anti-cancer treatments, in particular as part of the BEAM protocol,
    - o 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).**