HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE

SUMMARY

22 JULY 2020

The legally binding text is the original French opinion version

daratumumab

DARZALEX 1,800 mg solution for injection

First assessment

Key points

Favourable opinion for reimbursement in the treatment of multiple myeloma (for more details, see MA).

What therapeutic improvement?

No clinical added value compared to DARZALEX 20 mg/mL concentrate for solution for infusion.

Role in the care pathway?

The role of DARZALEX 1,800 mg solution for subcutaneous injection (daratumumab) is identical to that of DARZALEX 20 mg/mL concentrate for solution for infusion. It is a first or second-line treatment for multiple myeloma, used in combination with various treatment regimens. Its role as monotherapy from the third line of treatment for multiple myeloma remains to be defined.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ Multiple myeloma is a serious blood disease that is life-threatening.
◗ DARZALEX (daratumumab) is a specific curative treatment for multiple myeloma.
◗ The efficacy/adverse effects ratio of DARZALEX (daratumumab) is substantial in all its indications.
◗ There are medicinal alternatives, in particular DARZALEX 20 mg/mL concentrate for solution for infusion (daratumumab) (see chapter 05. Clinically relevant comparators).
◗ DARZALEX (daratumumab) is a first or second-line treatment for multiple myeloma, used in combination with various treatment regimens. Its role as monotherapy from the third line of treatment remains to be defined, in the absence of comparison with the other treatments available at this stage in the care pathway (see chapter 08. Role in the care pathway).

Public health impact
Considering:
- the seriousness of multiple myeloma,
- its prevalence and incidence,
- the partially met medical need as first, second and third-line treatment,
- the absence of any demonstrated additional impact on morbidity and mortality compared to DARZALEX (daratumumab) by the IV route,
- the lack of a demonstrated impact on the patient's care and/or life pathway, due to quality of life data that are not very robust or not available depending on the indication, and despite a subcutaneous administration regimen compared to IV infusion and a reduction in the frequency of infusion-related reactions (13% versus 35% with the IV route),
- the expected impact on the organisation of care given the short administration time of the SC route (less than 5 min) compared to the IV route (several hours), but which may fluctuate depending on the combined protocols, and which has nonetheless not been demonstrated due to a lack of data,
- the lack of additional response to the identified need,

DARZALEX 1,800 mg solution for injection (daratumumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of DARZALEX 1,800 mg solution for injection (daratumumab) is substantial in the MA indications.

The Committee issues a favourable opinion for inclusion of DARZALEX 1,800 mg solution for injection (daratumumab) in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indications and dosages.

Clinical Added Value

Considering:
- **demonstration of the non-inferiority of daratumumab as monotherapy by the subcutaneous route compared to administration by the IV route, in terms of overall response rate and pharmacokinetics, demonstrated in an open-label study in patients with relapsed or refractory multiple myeloma, and the methodological reservations raised,**
- **the absence of demonstrated improvement in terms of progression-free survival and overall survival in patients with relapsed or refractory multiple myeloma and the absence of data concerning these criteria in the other indications of DARZALEX (daratumumab),**

- **the similar safety profile between the two administration routes, apart from the superiority of SC administration of daratumumab compared to IV administration in terms of infusion-related reactions, demonstrated in this same study,**
- **the absence of a demonstrated impact in terms of improvement of quality of life in patients with relapsed or refractory multiple myeloma due to a lack of robust data, and the absence of data concerning this criterion in the other indications of DARZALEX (daratumumab), and despite a subcutaneous administration regimen compared to IV infusion,**

the Transparency Committee considers that DARZALEX 1,800 mg solution for injection (daratumumab) provides no clinical added value (CAV V) compared to DARZALEX 20 mg/mL concentrate for solution for infusion.