HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
18 MARCH 2020

lenalidomide
REVLIMID 5 mg, 7.5 mg, 10 mg and 15 mg hard capsules

New indication

Key points

Favourable opinion for reimbursement as monotherapy in the maintenance treatment of adult patients with previously untreated multiple myeloma who have undergone autologous stem cell transplantation.

What therapeutic improvement?

No clinical added value compared to no therapy.

Role in the care pathway?

In symptomatic patients with previously untreated multiple myeloma, the first-line treatment depends on eligibility for intensive chemotherapy combined with autologous stem cell transplantation.

In eligible patients, having received intensive chemotherapy combined with autologous stem cell transplantation, post-transplant consolidation treatment may be considered with the aim of improving the quality and extent of the response. Post-transplant maintenance therapy aimed at delaying the first relapse is one of the treatment options that may be proposed in the first-line treatment strategy for multiple myeloma.

Role of the REVLIMID (lenalidomide) in the care pathway?

REVLIMID (lenalidomide) is a maintenance treatment following autologous stem cell transplantation.

As a precaution, the Committee recommends that REVLIMID (lenalidomide) be administered for a maximum period of two years and not until disease progression, in the absence of data supporting the optimal duration of this treatment.

01 COMMITTEE'S CONCLUSIONS

01.1 Clinical benefit

◗ Multiple myeloma is a serious disease that is life-threatening.
◗ REVLIMID (lenalidomide) can be incorporated in the curative treatment of multiple myeloma.
◗ The efficacy/adverse effects ratio of REVLIMID (lenalidomide) as monotherapy in the maintenance treatment of adult patients with previously untreated multiple myeloma who have undergone autologous stem cell transplantation is modest due to:

- demonstration of an increase in progression-free survival time (absolute increase of 15 months or 18 months depending on the study considered) without robust demonstration of an increase in overall survival time in a context in which a potentially negative impact on the success of subsequent treatment following relapse cannot be excluded in a patient demonstrating disease progression during maintenance treatment with REVLIMID (lenalidomide),
- potentially serious haematological and infectious adverse events that may occur during maintenance treatment with REVLIMID (lenalidomide),
- the additional risk of secondary cancers associated with the use of REVLIMID (lenalidomide),
- the absence of assessment of quality of life during REVLIMID (lenalidomide) maintenance treatment in comparison with no therapy in the two clinical trials.

◗ There is no therapeutic alternative with an MA or recommended in the maintenance treatment of adult patients with previously untreated multiple myeloma who have undergone autologous stem cell transplantation. No therapy is a non-medicinal alternative.
◗ REVLIMID (lenalidomide) is a maintenance treatment following autologous haematopoietic stem cell transplantation.

Public health impact:

Considering:

- the seriousness of multiple myeloma, a progressive, life-threatening disease,
- the number of incident cases of multiple myeloma, estimated to be around 5,442 patients in France in 2018,
- the partially met medical need in multiple myeloma given the risk of relapse after a first line of treatment including intensive chemotherapy and autologous stem cell transplantation for eligible patients,
- the lack of additional response to the identified partially met medical need,
- the lack of elements supporting the absence of a deterioration in the care and/or life pathway in the absence of data demonstrating maintenance of the quality of life of patients treated with REVLIMID (lenalidomide) in comparison with no therapy, in view of the potentially serious events that can occur and the regular laboratory monitoring required during treatment with REVLIMID (lenalidomide),
- the absence of any demonstrated impact on the organisation of care,

REVLIMID (lenalidomide) is unlikely to have an additional impact on public health in this indication.

Considering all these elements, the Committee deems that the clinical benefit of REVLIMID (lenalidomide) is low in the indication "as monotherapy in the maintenance treatment of adult patients with previously untreated multiple myeloma who have undergone autologous stem cell transplantation".

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the indication "as monotherapy in the maintenance treatment of adult patients with previously untreated multiple myeloma who have undergone autologous stem cell transplantation" and at the MA dosages.

01.2 Clinical Added Value

Considering:

- **demonstration of the superiority of REVLIMID (lenalidomide) compared to placebo in two clinical trials in terms of progression-free survival time (absolute increase of 15 months or 18 months depending on the study considered) without robust demonstration of an increase in overall survival time,**
- **the potentially serious haematological and infectious adverse events that may occur during maintenance treatment with REVLIMID (lenalidomide),**
- **the additional risk of the development of secondary cancers,**
- **the absence of data demonstrating maintenance of the quality of life of patients treated with REVLIMID (lenalidomide) in comparison with no therapy, in view of the potentially serious events and the regular laboratory monitoring required during treatment with REVLIMID (lenalidomide), whereas no therapy gives patients a period without active treatment during their disease,**

the Committee considers that REVLIMID (lenalidomide), as a maintenance treatment following autologous transplantation, provides no clinical added value (CAV V) compared to no therapy, in adult patients with previously untreated multiple myeloma who have undergone autologous stem cell transplantation.