HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
19 FEBRUARY 2020

pomalidomide
IMNOVID 1 mg, 2 mg, 3 mg, 4 mg hard capsules

New indication

Key points

Favourable opinion for reimbursement in combination with bortezomib and dexamethasone in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

What therapeutic improvement?

No clinical added value compared to the bortezomib / dexamethasone combination.

Role in the care pathway?

There is no standard treatment for the first relapse or progression of multiple myeloma. The therapeutic decision depends on age, previous treatments, the duration of the first remission, the circumstances of the relapse, the general health status of patients and their comorbidities.

Role of the medicinal product in the care pathway

IMNOVID in combination with bortezomib and dexamethasone is a second line and later-line treatment for adult patients with relapsed or refractory multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

◗ Multiple myeloma is a serious blood disease that is life-threatening.
◗ IMNOVID (pomalidomide) is a specific curative treatment for multiple myeloma in patients who have already received at least one prior treatment regimen including lenalidomide.
◗ The efficacy/adverse reaction ratio of IMNOVID in combination with bortezomib and dexamethasone is high.
◗ The alternatives available at this stage of treatment are the medicinal products cited in section 04. "Clinically relevant comparators".
◗ It is a second and later-line treatment in patients with relapsed or refractory multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

Public health impact

Considering:
- the seriousness of multiple myeloma, particularly relapsed or refractory,
- its incidence,
- the partially met medical need in patients who have already received at least one prior treatment regimen including lenalidomide,
- the lack of demonstrated impact on mortality and quality of life,
- the absence of any demonstrated impact on the organisation of care,
- the lack of additional response to the identified need,

IMNOVID is not liable to have an additional impact on public health.

Considering all these elements, the Committee considers that the clinical benefit of IMNOVID (pomalidomide) is substantial in the MA indication "in combination with bortezomib and dexamethasone in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide".

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication "in combination with bortezomib and dexamethasone in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide" and at the MA dosages.

Clinical Added Value

Considering:
- **the superiority of IMNOVID (pomalidomide) in combination with bortezomib and dexamethasone compared to this same combination administered alone, in terms of progression-free survival (absolute increase of 4.1 months), in relapsed or lenalidomide-refractory patients,**
- **without any demonstrated improvement in overall survival, however,**
- **the absence of robust data on the patients' quality of life,**
- **and the partially met medical need,**

the Committee considers that IMNOVID, in combination with bortezomib and dexamethasone, provides no clinical added value (CAV V) compared to the bortezomib / dexamethasone combination, in patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.