HAUTE AUTORITÉ DE SANTÉ

# TRANSPARENCY COMMITTEE
## SUMMARY
## 09 SEPTEMBER 2020
*The legally binding text is the original French opinion version*

***ixazomib***
**NINLARO strength, pharmaceutical form**

**Reevaluation**

### Key points

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

### What therapeutic improvement ?

No clinical added value compared to the lenalidomide/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**

NINLARO (ixazomib) in combination with lenalidomide and dexamethasone remains a therapeutic option in the treatment of patients with multiple myeloma who have received at least one prior treatment.

## COMMITTEE'S CONCLUSIONS

### Clinical benefit

◗ Multiple myeloma is a serious disease that is life-threatening.
◗ NINLARO (ixazomib) is a curative treatment for multiple myeloma.
◗ The efficacy/adverse effects ratio is moderate given the level of evidence of the efficacy demonstration (see paragraph 8.5).
◗ There are alternatives (see paragraph 5).
◗ NINLARO (ixazomib) in combination with lenalidomide and dexamethasone remains a therapeutic option in the treatment of patients with multiple myeloma who have received at least one prior treatment (see paragraph 9).

**Public health impact**

On the basis of currently available data, the previous assessment of the PHI is not modified: NINLARO (ixazomib) is unlikely to have an impact on public health.

**Given all these elements, the Committee deems that the clinical benefit of NINLARO remains substantial in the MA indication.**

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

### Clinical Added Value

**Considering :**

- **previous data having enabled only a not very robust demonstration of a difference in progression-free survival in favour of NINLARO in combination with lenalidomide and dexamethasone compared to this same combination administered alone, observed on assessment by the independent review committee, and an absence of difference according to the assessment conducted by the investigators,**
- **new medium and long-term safety data that have not revealed any new signals,**
- **immature new efficacy data concerning overall survival that do not enable any conclusions to be drawn for this endpoint,**

**the Committee considers that NINLARO, in combination with lenalidomide and dexamethasone, provides no clinical added value (CAV V) compared to the lenalidomide and dexamethasone combination, in patients with multiple myeloma having already received at least one treatment line.**