SUMMARY

olaparib

LYNPARZA 100 mg and 150 mg,

film-coated tablet

Reassessment at manufacturer's request

Original French opinion adopted by the Transparency Committee on 17 January 2024

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Advanced high-grade ovarian, fallopian tube or primary peritoneal epithelial cancer is a life-threatening cancer.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- Medicinal alternatives are available.
- This is a first-line treatment option in view of the therapies available.

- **Public health benefit**

In view of:

- the seriousness of the condition and its incidence,
- the partially met medical need,
- the partial response to the identified need considering the improvement in progression-free survival, with no evidence of improvement in overall survival or quality of life,
- the lack of data allowing an assessment of the additional impact on delivery of care.

LYNPARZA (olaparib), monotherapy is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of LYNPARZA (olaparib), monotherapy, remains substantial in the MA indication.

The Committee approves continued inclusion of LYNPARZA (olaparib), monotherapy, in the list of drugs covered for outpatients and in the list of drugs covered for inpatients in the indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%**

Clinical Added Value

In view of:

- the evidence of the superiority of olaparib monotherapy versus placebo, in a randomised double-blind study, in terms of investigator-assessed progression-free survival: HR=0.30 [95%CI: 0.23-0.41], with a median progression-free survival not reached in the olaparib group and of 13.8 months in the placebo group,
- the lack of evidence of superiority on overall survival, despite the new data submitted,
- the lack of formal conclusion that can be drawn from the quality-of-life findings,
- the safety profile of olaparib, with in particular the onset of myelodysplastic syndromes/acute myeloid leukaemia,

the Committee deems that LYNPARZA (olaparib) monotherapy provides minor clinical added value (CAV IV) in the therapeutic strategy.