SUMMARY

olaparib

LYNPARZA 100 mg and 150 mg,

film-coated tablet

New indication

Original French opinion adopted by the Transparency Committee on 5 April 2023

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Seriousness of the condition: metastatic castration-resistant prostate cancer is a serious life-threatening condition.
- The proprietary medicinal product LYNPARZA (olaparib) is a curative medicinal product.
- The efficacy/adverse effects ratio of LYPARZA (olaparib) is high.
- Availability of an alternative: there are therapeutic alternatives (see Clinically relevant comparators).
- The proprietary medicinal product LYNPARZA (olaparib) is a second-line treatment i.e. after castration resistance (androgen suppression being the first-line treatment).

Public health benefit

In view of:

- the seriousness of the condition and its incidence;
- the insufficiently met medical need;
- the partial response to the identified need, with:
  - an established additional impact of LYNPARZA (olaparib) in association with abiraterone only compared to abiraterone alone on morbidity in terms of radiographic progression-free survival;
  - the lack of evidence of an impact on mortality;
  - the lack of evidence of an impact on quality of life;
  - a presumed expected simplification of the care pathway with LYNPARZA (olaparib) given that there is no test prior to setting up treatment (BRCA 1/2).

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

Considering all of these elements, the Committee deems that the clinical benefit (CB) of LYNPARZA (olaparib) in association with abiraterone and with prednisone or with prednisolone is substantial in the MA indication extension.

The Committee approves inclusion in the list of covered drugs for outpatients and in the list of covered drugs for inpatients for the indication extension 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 superiority in the PROpel phase III study of the association of olaparib + abiraterone versus placebo + abiraterone, in terms of radiographic progression-free survival (with a point estimation of an absolute difference in median rPFS of 8.2 months where HR=0.66; 95% CI [0.54; 0.81], p<0.0001);

and despite:

- the lack of evidence of superiority of the association of olaparib + abiraterone versus placebo + abiraterone on overall survival,
- an additional toxicity primarily concerning grade ≥ 3 adverse events, with 52.8% in the olaparib group and 40.4% in the placebo group,
- the risk of myelodysplastic syndrome (MDS) or acute myeloid leukaemia (AML), identified as a substantial potential risk in the Risk Management Plan (RMP) and in a context of treatment at an advanced stage of the disease,
- the lack of formal conclusion that can be drawn on quality of life (exploratory outcome measure),

The Committee deems that LYNPARZA (olaparib) in association with abiraterone and with prednisone or with prednisolone provides minor clinical added value (CAV IV) versus abiraterone in association with prednisone or with prednisolone for the treatment of adult metastatic castration-resistant prostate cancer (mCRPC) patients for whom chemotherapy is not clinically indicated.

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