HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
05 MAY 2021

The legally binding text is the original French opinion version

olaparib
LYNPARZA (100 mg, 150 mg) tablets

New indication

Key points

Favourable opinion for reimbursement in the indication “as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent”.

What therapeutic improvement?

Therapeutic improvement compared to treatment with a new hormonal agent: abiraterone acetate or enzalutamide.

Role in the care pathway?

According to the Oncology Committee of the French Urology Association (CCAFU), the care pathway in metastatic castration-resistant prostate cancer (mCRPC) is based on new hormonal agents or "NHAs" (abiraterone acetate and enzalutamide) or taxane-based chemotherapy (docetaxel or cabazitaxel). Cabazitaxel, in combination with prednisone or prednisolone, is indicated in patients previously treated with docetaxel.

Hence the management of mCRPC in France consists in alternating the two treatment options, i.e., NHAs and chemotherapies. There is no consensus as to the optimal treatment sequence. The choice between these different therapies takes into account prior therapies, the patient's response to these therapies, along with their general condition, age, clinical profile and preferences. For patients in whom the disease has progressed under an NHA, the treatment options remain identical to those for mCRPC in general.

The use of cabazitaxel may be of therapeutic benefit compared to an NHA in a subpopulation of patients having demonstrated rapid disease progression (<12 months) under an NHA and having previously received docetaxel.

Role of LYNPARZA (olaparib) in the care pathway:

LYNPARZA (olaparib) is a third-line treatment for patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy with enzalutamide or abiraterone acetate. In the absence of available data, its role compared to docetaxel or cabazitaxel is not known.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

- Prostate cancer is a serious, life-threatening disease.
- This is a curative treatment.
- The efficacy/adverse effects ratio is high.
- There are medicinal alternatives at this stage of the disease.
- LYNPARZA (olaparib) is a third-line treatment.

- **Public health impact**:

Considering:

- the seriousness of advanced prostate cancer,
- the low incidence of prostate cancer with BRCA1/2 mutation, estimated to be less than 900 new cases per year for this indication,
- the partially met medical need in this disease,
- the impossibility of quantifying the impact in the MA population given the identified limitations, the absence of demonstration of an impact in terms of quality of life,

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

Considering all these elements, the Committee deems that the clinical benefit of LYNPARZA (olaparib) is substantial in this 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 "as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent" and at the MA dosages.

- **Recommended reimbursement rate: 100%**

Clinical Added Value

Considering, on the one hand:

- **demonstration of a superiority of olaparib (LYNPARZA) compared to enzalutamide or abiraterone acetate in cohort A including three mutations (BRCA1, BRCA2 and ATM) of the phase 3 open-label PROFOUND study, with an increase in median radiological progression-free survival of +3.84 months (7.39 months versus 3.55 months) and an increase of +4.40 months for overall survival (19.09 months versus 14.69 months),**

and, on the other hand:

- **the absence of comparative data versus docetaxel chemotherapy for patients eligible for this treatment,**
- **the increased toxicity under olaparib versus the comparator group, particularly in terms of the frequency of grade ≥ 3 adverse events, reported in 52% of patients in the olaparib group and 40% in the comparator group),**
- **the lack of demonstrated impact on quality of life,**

the Committee considers that LYNPARZA (olaparib) provides a minor clinical added value (CAV IV) compared to hormone therapy with abiraterone acetate of enzalutamide, in the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent.