INAHTA Brief

Issue 2020/013

Title ERLEADA – A Health Technology Assessment

Agency HAS, French National Authority for Health (Haute Autorité de santé)
2 avenue du Stade de France – F 93218 La Plaine Cedex, France
Tel: +33 (0)1 55 93 70 00 – Fax: +33 (0)1 55 93 74 35, contact.sem@has-sante.fr, www.has-sante.fr

Reference link to full report in French
https://www.has-sante.fr/jcms/p_3144088/fr/erleada

Aim

Assessment of ERLEADA (apalutamide) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies in the indication treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).

Conclusions of Transparency Committee

Clinical Benefit

- Metastatic hormone-sensitive prostate cancer is a life-threatening disease.
- ERLEADA (apalutamide) in combination with androgen deprivation therapy (ADT) is a curative treatment.
- The efficacy/adverse effects ratio of ERLEADA, combined with ADT, is high.
- There are alternative medicinal products.
- It is a 1st line treatment.
- ERLEADA is unlikely to have an impact on public health.

Considering all of the above, the clinical benefit of ERLEADA is substantial in this MA indication extension.

Clinical Added Value
Considering:
- demonstration of the superiority of the apalutamide + ADT combination versus ADT alone, particularly in terms of overall survival (death: 16% vs. 22% in the comparator group, HR = 0.67; 95%CI [0.51; 0.89]) and radiographic progression-free survival (radiographic progression or death: 26% vs. 44% in the comparator group, HR = 0.48; 95%CI [0.39; 0.60]),
and despite:
- the absence of demonstration of an improvement in quality-of-life,
- the acceptable safety profile of ERLEADA + ADT but with a potential risk of ischaemic heart disease (4% vs. 2% with the placebo),
ERLEADA (apalutamide) in combination with ADT, as for ZYTIGA (abiraterone acetate), provides moderate Clinical Added Value (CAV III) versus ADT alone, in the indication "treatment of adult males with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT)".

Recommendations

The Transparency Committee issued its approval for the funding of ERLEADA (apalutamide) by the French national health insurance system (private practice and hospital) in the indication treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).

Methods

The assessment of ERLEADA (apalutamide) was founded on evidence-based medicine with a critical analysis of the clinical data.

Written by

HAS (Haute Autorité de santé), French National Authority for Health