SUMMARY

eravacycline

XERAVA 100 mg

powder for concentrate for solution for infusion

Initial inclusion

Original French opinion adopted by the Transparency Committee on 31 January 2024

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- The conditions concerned by this proprietary medicinal product are life-threatening for the patient in the immediate term or following complications.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high in mild or moderate forms. In severe infections and/or those due to drug-resistant bacteria, the efficacy/adverse effects ratio is still to be specified in the absence of data.
- There are alternatives, including for multi-drug resistant bacteria.
- This is a treatment option when the therapeutic alternatives are deemed to be inappropriate.

Public health benefit

Considering:

- the frequency and seriousness of the infections concerned,
- the medical need to have access to new antibiotics in order to respond to the spread of resistance to the antibiotics currently recommended in the treatment of these infections,
- the partial response to the identified need, but given:
  - the absence of a demonstrated additional impact on the reduction of morbidity and mortality compared to the treatments used in current practice, in the event of severe infections and/or those due to drug-resistant bacteria,
  - the lack of a demonstrated additional impact on the care and life pathway and the organisation of care,

XERAVA (eravacycline) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of XERAVA (eravacycline) is:

- **substantial in the treatment of complicated intra-abdominal infections only in the event of infection with eravacycline-susceptible microorganisms and when the therapeutic alternatives are deemed to be inappropriate,**
- **insufficient to justify public funding in the other MA situations.**

The Committee issues a favourable opinion for inclusion of XERAVA (eravacycline) in the list of covered drugs for inpatients approved for use in the treatment of complicated intra-abdominal infections only in the event of infection with eravacycline-susceptible microorganisms and when the therapeutic alternatives are deemed to be inappropriate.

The Committee issues an unfavourable opinion for inclusion of XERAVA (eravacycline) in the list of covered drugs for inpatients approved for use in the other situations.

Clinical Added Value

Considering:

- its broad-spectrum in vitro activity against Gram-positive or negative bacteria and anaerobic bacteria, some of which are resistant to carbapenems and other antibiotics;
- demonstration of the non-inferiority of eravacycline compared to ertapenem and meropenem on the percentage of clinical recoveries, in patients with non-severe complicated intra-abdominal infections;
- the medical need partially met by the existence of alternatives having demonstrated an efficacy in the event of infections with multi-drug resistant bacteria;

but:

- the lack of data in more severe patients or those with infections due to multi-drug resistant bacteria, who have not been included in clinical studies;
- the difficulty of transposing experimental data given that the patients included in the trials are not representative of those likely to be given eravacycline in clinical practice;
- the absence of comparative data versus tigecycline in patients with an infection due to multi-drug resistant bacteria, despite this comparison being possible;

the Transparency Committee deems that XERAVA (eravacycline) concentrate for solution for infusion provides no clinical added value (CAV V) in the treatment of complicated intra-abdominal infections.

Other Committee recommendations

➔ Special recommendations in view of the quality and safety of care requirements related to the medicinal product

Given the product characteristics and the need to restrict its use exclusively to situations when the alternatives are deemed to be inappropriate, **the therapeutic decision should be taken with the help of an antibiotic expert**, with systematic reassessment 48 hours after the start of treatment.