SUMMARY

dalbavancin

XYDALBA 500 mg

powder for concentrate for solution for infusion

Indication extension

Original French opinion adopted by the Transparency Committee on 3 July 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement only in patients aged from 3 months to 17 years with acute bacterial skin and skin structure infections (ABSSSI), of a certain degree of seriousness, for whom a staphylococcal aetiology and methicillin resistance are demonstrated or strongly suspected.

Transparency Committee's conclusions

Clinical Benefit

- Skin and skin structure infections are composed of a very varied range of clinical entities, for which the development conditions, treatment and prognosis are variable, from ulcers, infected wounds, abscesses, erysipelas and diabetic foot ulcers through to the most serious forms, including bacterial cellulitis and necrotising fasciitis.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high in non-serious infections (erysipelas/non-necrotising cellulitis, infected wounds and major skin abscesses), primarily caused by Staphylococcus, including MRSA.

  In more serious forms requiring critical or intensive care treatment and/or due to multi-drug resistant bacteria, the efficacy/adverse effects ratio is yet to be specified.
- This is a last-resort treatment in view of the therapies available.

Public health benefit

Considering:

- the 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, due to the possibility of its use in certain situations, but limited efficacy data in terms of transposability of the results in severe and/or multi-drug resistant infections, which require a glycopeptide or linezolid antibiotic, and limited safety data in terms of toxicity for reproduction and development,
- the lack of evidence of an impact of XYDALBA (dalbavancin) on quality of life and the organisation of care,

XYDALBA (dalbavancin) 500 mg powder for concentrate for solution for infusion is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of XYDALBA (dalbavancin) 500 mg powder for concentrate for solution for infusion is:

- **substantial in the treatment of acute bacterial skin and skin structure infections (ABSSSI), only in patients aged from 3 months to 17 years with infections of a certain degree of seriousness, for whom a staphylococcal aetiology and methicillin resistance are demonstrated or strongly suspected;**
- **insufficient to justify public funding cover in the other MA situations.**

The Committee issues the following opinions:

- **a favourable opinion for inclusion of XYDALBA (dalbavancin) 500 mg powder for concentrate for solution for infusion in the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages;**
- **an unfavourable opinion for inclusion of XYDALBA (dalbavancin) 500 mg powder for concentrate for solution for infusion in the list of covered drugs for outpatients and/or the list of covered drugs for inpatients approved for use in the other situations covered by the MA indication.**

Clinical Added Value

Considering:

- **simplification of the dosing regimen due to its long half-life,**
- **in vitro activity data, and pharmacokinetic/pharmacodynamic data enabling extrapolation of the efficacy and safety to paediatric patients in the MA indications,**
- **inadequate documentation of its clinical efficacy and safety in severe skin infections and/or those due to multi-drug resistant bacteria,**

as in adults, the Committee deems that XYDALBA (dalbavancin) provides no clinical added value (CAV V) compared to vancomycin in the last-resort treatment of paediatric patients aged from 3 months to 17 years with ABSSSI of a certain degree of seriousness, for whom a staphylococcal aetiology and methicillin resistance are demonstrated or strongly suspected.

The Committee highlights the importance of consulting an antibiotic expert when making the therapeutic decision in view of persistent uncertainties in terms of resistance.