SUMMARY

dalbavancin

XYDALBA 500 mg,

powder for solution for dilution for infusion,

Reassessment at Transparency Committee's request

Original French opinion adopted by the Transparency Committee on 6 December 2023

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Considering all of this information and after discussion and a vote, the Committee deems that within the scope of the assessment: the new data submitted are not likely to change the Committee's previous conclusions within the scope of the MA on account of its pharmacokinetic properties (long half-life of 372 hours) and its foreseeable off-label use documented by the data from the post-registration study (DAL-REG01-FRA) showing predominant use in osteoarticular infections (55%), endocarditis and infectious arthritis (15%) and multisite infections (15%).

Clinical Benefit

- Skin and soft tissue infections are made up of very different clinical entities, of which the conditions of onset, therapeutic management and outcomes vary from ulcers, infected wounds, abscesses, erysipelas and diabetic foot to the severest forms of bacterial dermohypodermitis and necrotising fasciitis.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio remains high for less serious infections (erysipelas/non-necrotising cellulitis, infected wounds and major skin abscesses), primarily from staphylococci, including methicillin-resistant staphylococci.

  In more serious forms requiring admission to intensive care or resuscitation units and/or caused by multiresistant bacteria, the efficacy/adverse effects ratio has yet to be specified.
- This is a treatment of last resort in view of the therapies available.

➔ Public health benefit

XYDALBA (dalbavancin) is unlikely to have an additional impact on public health in the MA indication.

Considering all of these elements, the Committee deems that the clinical benefit of XYDALBA (dalbavancin) remains substantial for adult patients with ABSSTIs of a certain degree of severity, with an established or suspected staphylococcal cause and for which methicillin resistance has been established or is strongly suspected.

The Committee approves the continued inclusion of XYDALBA (dalbavancin) in the list of covered drugs for inpatients only within the selected scope of the MA and at the MA dosages.

Clinical Added Value

In view of:

- the new real-life data, showing off-label use,
- a simplification of the administration schedule in the light of its long half-life,
- its *in vitro* activity, efficacy and safety profile comparable to that of vancomycin in the marketing authorisation indications,
- the insufficient documentation of clinical efficacy and safety in severe and/or multi-resistant bacteria-induced skin infections.

the Committee deems that XYDALBA (dalbavancin) provides no clinical added value (CAV V) in relation to vancomycin in the treatment of ABSSTIs in adults with infections of a certain degree of severity, with an established or suspected staphylococcal cause and for which methicillin resistance has been established or is strongly suspected.