BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

SIVEXTRO (tedizolid), antibiotic of the oxazolidinone class

No clinical benefit demonstrated by comparison with linezolid.
A role in non-serious infections of staphylococcal aetiology that are resistant to methicillin

Main points

- SIVEXTRO has Marketing Authorisation in the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.
- It does not provide any therapeutic benefit by comparison with linezolid, since:
  - its in-vitro activity profile, efficacy and safety are comparable with that of linezolid;
  - and considering the insufficient documentation of clinical efficacy and safety in severe skin infections and/or skin infections caused by multidrug-resistant bacteria.
- It may be offered in infections regardless of severity for which a staphylococcal aetiology is proven or suspected (suppurative infections) and where resistance to methicillin is proven or strongly suspected.

Therapeutic use

- As a general rule, the choice of antibiotic should be based on the identified or probable bacteria and their level of resistance.
  In acute bacterial skin and skin structure infections, there are few available antibiotics for the treatment of infections caused by vancomycin-resistant enterococci, methicillin-resistant staphylococci and resistant gram-negative bacteria (Enterobacteria, Pseudomonas aeruginosa, Acinetobacter).
- Role of the medicinal product in the therapeutic strategy
  SIVEXTRO may be offered in infections not showing any signs of severity for which a staphylococcal aetiology is proven or suspected (suppurative infections) and where resistance to methicillin is proven or strongly suspected. It has the advantage that a 6-day course of once-daily dosing is equally effective as twice-daily dosing with linezolid for 10 days. However, in the case of severe acute bacterial skin and skin structure infections and/or infections caused by multidrug-resistant bacteria, the efficacy will potentially be lower than that of linezolid given the lower efficacy shown in studies in patients with proven methicillin-resistant staphylococcal infection and/or a vancomycin MIC > 1 µg/ml.
  Tedizolid is no less well tolerated than linezolid and does not necessitate monitoring of plasma concentrations and renal function.

Clinical data

- The efficacy of tedizolid (200 mg IV or orally once daily for 6 days) has been demonstrated in the treatment of acute bacterial skin and skin structure infections caused by gram-positive bacteria, mainly staphylococci.
- There are currently insufficient data for assessment of its therapeutic benefit in the treatment of severe skin and skin structure infections and/or skin and skin structure infections caused by multidrug-resistant gram-positive bacteria suitable for treatment with an antibiotic of the vancomycin or linezolid type. There is, moreover, a lack of data on use in concomitant infection with gram-positive and -negative bacteria, tedizolid being inactive against gram-negative bacteria.
Special prescribing conditions

- Medicine for hospital prescription.

Benefit of the medicinal product

- The actual benefit* of SIVEXTRO is substantial in the treatment of acute bacterial skin and skin structure infections only in adult patients with infections not showing any signs of severity for which a staphylococcal aetiology is proven or suspected (suppurative infections) and where resistance to methicillin is proven or strongly suspected.
- SIVEXTRO does not provide clinical added value** (CAV V) by comparison with linezolid in the treatment of acute bacterial skin and skin structure infections in adults.
- Recommends inclusion on the list of reimbursable products for hospital use in this indication.

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.

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