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Title ZERBAXA – A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/pprd_2984003/fr/zerbaxa

Aim

Assessment of ZERBAXA (ceftolozane/tazobactam) with a view to funding by the French national health insurance system, and of its clinical contribution compared to other strategies in the treatment of the following infections in adults:

- Complicated intra-abdominal infections
- Complicated urinary tract infections
- Hospital-acquired pneumonia, including ventilator-associated pneumonia;

Conclusions of Transparency Committee

- The infections treated with this medicinal product are life-threatening to the patient, either immediately or as a result of complications.
- It is a curative treatment.
- The efficacy/adverse effects ratio is high.
- There are therapeutic alternatives.
- It is a last-resort treatment.
- ZERBAXA is likely to have an impact on public health.

Considering these elements, the Committee deems that the clinical benefit of ZERBAXA:

- remains substantial in the MA indications only as a last resort for the treatment of patients with *P. aeruginosa* infections susceptible to ceftolozane/tazobactam, and for whom recourse to other beta-lactams and/or carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance;
- becomes insufficient to justify its funding by the French national health insurance system in all other clinical situations.

Considering:

- its *in vitro* activity on extended-spectrum beta-lactamase-producing enterobacteriaceae, particularly *Pseudomonas aeruginosa,*
- its demonstrated efficacy in moderate to mild complicated urinary tract infections (including pyelonephritis) and complicated intra-abdominal infections; and in hospital-acquired pneumonia, including ventilator associated pneumonia,
- limited clinical data in severe forms and/or forms due to multi-drug resistant *Pseudomonas aeruginosa*,
- the fact that the ceftolozane/tazobactam combination is one of the few drugs currently active against *P. aeruginosa* resistant to other beta-lactams,

ZERBAXA provides moderate clinical added value (CAV III) in the treatment of *P. aeruginosa* infections susceptible to ceftolozane/tazobactam and for whom recourse to other beta-lactams and/or carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance.

Recommendations

The Transparency Committee issued its approval for the funding of ZERBAXA by the French national health insurance system in the MA indication only as a last resort for the treatment of patients with *P. aeruginosa* infections susceptible to ceftolozane/tazobactam, and for whom recourse to other beta-lactams and carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance.

Methods

The assessment of ZERBAXA was founded on evidence-based medicine with a critical analysis of the clinical data.

Written by

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