INAHTA Brief

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Title ZAVICEFTA – A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/pprd_2983807/fr/zavicefta

Aim

Assessment of ZAVICEFTA (ceftazidime/avibactam) 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, including pyelonephritis
- Hospital-acquired pneumonia, including ventilator-associated pneumonia;

ZAVICEFTA is also indicated in the treatment of infections caused by Gram-negative aerobic bacteria in adult patients whose therapeutic options are limited.

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 few therapeutic alternatives.
◗ It is a last-resort treatment.
◗ ZAVICEFTA is likely to have an impact on public health.

Considering these elements, the Committee deems that the clinical benefit of ZAVICEFTA in the MA indications is:

- substantial only as a last resort for the treatment of patients with enterobacteria infections susceptible to ceftazidime/avibactam and for whom recourse to other beta-lactams and carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance, in particular via the production of KPC or OXA-48 carbapenemase;
- insufficient to justify its funding by the French national health insurance system in all other clinical situations.

Considering:

- its *in vitro* activity on *Pseudomonas aeruginosa* and Extended-Spectrum Beta-lactamase-Producing Enterobacteriaceae (ESBL-PE), particularly KPC and OXA-48,
- experience acquired with ceftazidime, a third-generation cephalosporin widely used in the treatment of severe nosocomial infections due to Gram-negative bacteria with high suspicion of *P. aeruginosa,*
- its demonstrated efficacy in moderate to mild complicated urinary tract infections (including pyelonephritis) and complicated intra-abdominal infections, particularly on ceftazidime-resistant strains; and in hospital-acquired pneumonia, including ventilator associated pneumonia,
- limited clinical data in severe forms and/or forms due to multi-drug resistant bacteria,
- the fact that the ceftazidime/avibactam combination is one of the few current antibiotics active on certain carbapenemase-producing enterobacteria,

ZAVICEFTA provides moderate clinical added value (CAV III) in the treatment of enterobacteria infections susceptible to ceftazidime/avibactam and for whom recourse to other beta-lactams and carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance.

Recommendations

The Transparency Committee issued its approval for the funding of ZAVICEFTA by the French national health insurance system in the MA indication only as a last resort for the treatment of patients with enterobacteria infections susceptible to ceftazidime/avibactam, and for whom recourse to other beta-lactams and carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance, in particular via the production of KPC or OXA-48 type carbapenemase.

Methods

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

Written by

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