

## Review of the health technology assessment process for antibiotics in Europe

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**Purpose:** To document the types of evidence and value considered by European health technology assessment agencies when making recommendations about antibiotics.

**Methods:** We studied five antibiotics that have gone through a health technology assessment process in at least one European country since 2010: fidaxomicin, aztreonam, ceftaroline fosamil, tigecycline, and colistimethate sodium. We selected the drugs to include a mix of new technologies and reformulations of older products. For each antibiotic, we identified every report from a health technology assessment body publicly available in English, Spanish, German, or Dutch. We systematically reviewed the reports to identify the evidence, sources of value, and other factors the agency considered in the health technology assessment. We supplemented this review by interviewing the pharmaceutical companies that developed the products to collect additional information about the health technology assessment process and its data and modelling requirements.

**Results:** We found health technology assessments from at least three countries for each product. Fidaxomicin was the most widely studied product with reports available from seven countries. The health technology assessments are based on clinical trial data and simple economic models that focus primarily on the direct treatment benefit of the drugs to patients. The threat of antibiotic resistance was mentioned irregularly. The assessments did not consider the value of antibiotics in enabling surgeries and other procedures, the insurance value of having an approved antibiotic ready when a new resistant outbreak emerges, or the diversity value of having multiple drugs with different modes of action available for a given infection.

**Conclusions:** Current health technology assessment practices do not encapsulate the full value of antibiotics. Ignoring the types of value unique to antibiotics may result in their being undervalued, which could make it less enticing for pharmaceutical companies to invest in research and development of new antibiotic products. There is a need for simple modelling frameworks that can better capture the true economic value of antibiotics.

Keywords: health technology assessment, Europe, antibiotics, systematic review

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