

## Fidaxomicin for the Treatment of Clostridium difficile Infection in Egypt

### Health Technology Appraisal

*Issued: August 2014*

• بيانات المستحضر محل الدراسة:

<b>Intervention</b>	Fidaxomicin
<b>Company name</b>	1-Mash for Biomed for pharmaceutical industries (Clostridax 200mg tablets) 2-Copad pharma (Diaventox 200mg film coated tablets) 3-EGPI for Advance pharma (Fidcarmicin 200mg tablets) 4-Medizen pharmaceutical industries (Fidoclostid 200mg film coated tablets)
<b>Comparator</b>	Vancomycin

• الهدف:

تقييم الفعالية لقاء التكلفة لمستحضر Fidaxomicin في علاج حالات حالات Clostridium Difficile Infections . وذلك لضمان أفضل النتائج العلاجية بالنسبة للمريض وبأقل تكلفة ممكنة من خلال الإلتزام بالخطوط العلاجية الاستراتيجية الاستراتيجية العالمية وفي ضوء الممارسة الإكلينيكية المحلية.

• توصية لجنة اقتصاديات الدواء:

بناء على الطلب المحول من إدارة التسعيرة لعمل دراسة "Pharmacoeconomics" للتأكد من وجود فائدة إضافية لمستحضر Fidaxomicin مقارنة بمستحضر vancomycin وذلك بعد تظلم الشركة بمقارنة مستحضرها بمادة Vancomycin إذ ترى الشركة أن كل الدراسات الإكلينيكية التي تم إجرائها للمستحضر مقارنة بمادة Vancomycin تثبت تفوق مادة Fidaxomicin.

وعليه فقد تبين من الدراسة التي قامت بها وحدة اقتصاديات الدواء (scenario analysis) الي ان مادة Fidaxomicin 200mg هي الأكفأ من حيث الفعالية مقابل التكلفة (Cost Effective) وذلك مقارنة بمستحضر vancomycin 125 mg tablet وذلك عندما تم احتساب سعر المستحضر ما بين ٣٠٠ الي ٤٠٠ جنيه مصري كحد اقصى .

- علما ان الدراسة التي قامت باجرائها وحدة اقتصاديات الدواء شملت بيانات التكلفة الخاصة بالمستحضرات التي تم تجميعها من إدارة التسعيرة بالاضافة إلى باقي التكلفة المرتبطة بالإقامة بالمستشفى والأدوية والتبعات المحتملة عن علاج الحالات الغير مستجيبة. كما تم تجميع البيانات الخاصة بالقيمة العلاجية الناتجة عن جودة الحياة المعيشية للمريض ونسبة الحالات المستجيبة للعلاج من الدراسات المنشورة عالميًا .

*English Summary:*

**Cost-Effectiveness Analysis of Fidaxomicin versus Oral Vancomycin for the Treatment of Clostridium difficile Infection in Egypt**

• **Introduction**

Clostridium difficile infection is a serious diarrheal illness associated with substantial morbidity and mortality, C. difficile infections have become more frequent, more severe, more difficult to treat, and more likely to recur after initial treatment. Although most people become infected with C. difficile in the hospital, the infection has also become more common in patients who have not been hospitalized or through community-acquired infection, An oral antibiotic is usually recommended to treat people who are infected with C. difficile.(1)

Vancomycin is one of the primary antibiotics used in the treatment of C difficile infection, The current recommended treatment regimens for Clostridium difficile-associated diarrhea (CDAD) have not changed in almost 25 years and include metronidazole and vancomycin depending on disease severity, Metronidazole is recommended as initial treatment for mild to moderate disease. Vancomycin is generally reserved for more severe cases of C. difficile, or if metronidazole is ineffective at curing disease.(2)

Fidaxomicin, an exceedingly narrow spectrum macrolide antibiotic, was recently approved for the treatment of Clostridium difficile-associated diarrhea (CDAD). In phase III clinical trials, fidaxomicin was noninferior to vancomycin in achieving clinical cure of CDAD. Furthermore, fidaxomicin was associated with fewer recurrences of CDAD compared with vancomycin in clinical trials. These results, combined with the ease of administration and a good safety profile, make fidaxomicin an attractive treatment option for treating CDAD.(3)

The study was primarily conducted to assess the cost-effectiveness for treating Clostridium difficile-associated diarrhea (CDAD) based on the Egyptian current clinical practice.

• **Objective:**

The aim of this study was to estimate the cost-effectiveness of oral fidaxomicin versus oral vancomycin for the treatment of clostridium difficile infections (CDIs) in patients aged 16 years or older based on the Egyptian current clinical practice.

• **Economic evaluation Key Features:[4]**

<b>Key Features:</b>	
<b>Year of the document</b>	August 2014
<b>Affiliation of authors</b>	Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs
<b>Purpose of the document</b>	To assess the cost-effectiveness of fidaxomicin with oral vancomycin for treatment of CDAD based on Egyptian clinical practice
<b>Standard reporting format included</b>	yes
<b>Disclosure</b>	yes
<b>Target audience of funding/ author's interests</b>	Public payers
<b>Perspective</b>	public
<b>Indication</b>	Treatment of Clostridium difficile–Associated Diarrhea (CDAD).
<b>Target population</b>	Those who are insured & uninsured by the Egyptian health care system.
<b>Subgroup analysis</b>	Not done
<b>Choice of comparator</b>	vancomycin is the routinely used intervention for this indication in such patients
<b>Time horizon</b>	Four weeks after treatment when outcomes are measured and compared
<b>Assumptions required</b>	yes
<b>Analytical technique</b>	CUA
<b>Costs to be included</b>	Direct medical costs
<b>Source of costs</b>	Official sources of unit cost data for resources
<b>Modeling</b>	A decision-tree model
<b>Systematic review of evidences</b>	yes
<b>Preference for effectiveness over efficacy</b>	yes
<b>Outcome measure</b>	The primary outcome was the rate of clinical cure, The

	secondary end point was recurrence of C. difficile infection during the 4-week period after treatment.
<b>Method to derive utility</b>	The direct use of EQ-5D
<b>Equity issues stated</b>	All lives, life years, or QALYs should be valued equally, regardless of age, gender, or socioeconomic status of individuals in the population.
<b>Discounting costs</b>	No discounting
<b>Discounting outcomes</b>	No discounting
<b>Sensitivity analysis-parameters and range</b>	Critical component(s) in the calculation is varied through a relevant range or from worst case to best case
<b>Sensitivity analysis-methods</b>	PSA
<b>Presenting results</b>	fidaxomicin is a cost effective alternative to vancomycin
<b>Incremental analysis</b>	yes
<b>Total costs vs effectiveness (cost/effectiveness ratio)</b>	yes
<b>Portability of results (Generalizability)</b>	The generalizability and extent to which the clinical efficacy data and the economic data are representative is identified

#### • Committee Discussion

It is important to identify the most cost-effective treatment in patients with Clostridium difficile-associated diarrhea (CDAD) based on the Egyptian current clinical practice,

Decision analysis is a quantitative method for synthesizing data from numerous sources for the evaluation of treatment alternatives and was developed to determine the cost-effectiveness of fidaxomicin as an important treatment option for treating CDAD based on the Egyptian current clinical practice.

Our results demonstrate that use of fidaxomicin as an important treatment option for treating CDAD versus oral vancomycin resulted in an incremental cost-effectiveness ratio (ICER) EGP 4684 /QALY, Results from PSA indicate that the fidaxomicin had a 99% chance of being cost-effective at our EGP 70,000 per QALY.

• **Conclusion**

Compared with commonly accepted willingness-to-pay threshold in Egypt, the results of the model showed that fidaxomicin is cost effective option for the treatment of CDIs when compared with oral vancomycin .

• **Declaration of interest**

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

• **Appraisal Committee members**

Each technology appraisal is appraised by the PE Committee, which is one of CAPA's standing advisory committees and consist of members who represent different specialties such as statistics, clinical evidence, economics, medicine, clinical pharmacy and pharmacoeconomics. A list of the Committee members who took part in the discussions for this appraisal appears below:

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**Dr. Gihan Hamdy**, Head of Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs, Ministry of Health.

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• **References:**

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- [2] Paul M. Stranges, PharmD, David W. Hutton, et al. Cost-Effectiveness Analysis Evaluating Fidaxomicin versus Oral Vancomycin for the Treatment of Clostridium difficile Infection in the United States, VALUE IN HEALTH 16(2013)297–304.
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