EE428

Economic Value of a Novel Macrophage-Regulating Treatment for Diabetic Foot Ulcers from a Healthcare Sector Perspective

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Introduction

Diabetic foot ulcers (DFUs) incur enormous health and economic burdens to individual patients and healthcare systems. ON101 (Fespixon®), a novel macrophage-regulating drug, was recently demonstrated to accelerate the wound healing with superior healing rates among patients with DFUs in a phase 3 clinical trial (12-week treatment, 16-week follow-up).

Objective

This study aimed to determine the cost-effectiveness of ON101 versus general wound care (GWC) and further explore its cost-effectiveness among patient subgroups.

Methods

- Within-trial and model-based cost-effectiveness analyses (CEAs) and model-based CEA
- Perspective: Taiwan's healthcare sector perspective
- ON101's effectiveness: obtained from its phase 3 trial, estimated as the number needed to treat (NNT) to obtain one additional patient with complete healing in the within-trial CEA, and as quality-adjusted life years (QALYs) in the model-based CEA
- Costs (2022 US dollars): ON101 trial, published literature, and Taiwan's National Health Insurance program
- CEAs were further stratified by baseline patient characteristics (i.e., glycemic level, ulcer wound size, and smoking status).

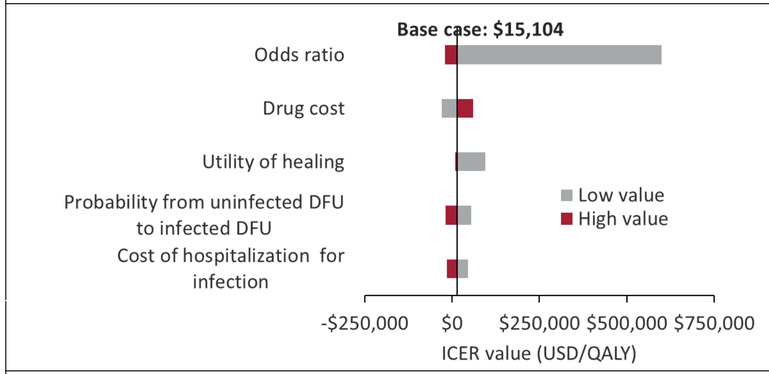
Results

Table 1. Within-trial cost-effectiveness analysis

Scenario setting	NNT	ΔC/person (US$)	Costs/complete healing gained (US$)
Base-case analysis	-5.33	3,967.42	21,127.73
HbA1c > 7%	-5.12	3,988.84	20,411.86
HbA1c ≤ 7%	-5.03	4,550.27	22,887.86
Ulcer > 5cm^2	-3.99	5,462.94	21,797.13
Ulcer ≤ 5cm^2	-6.44	3,656.11	23,545.35
Non-current smokers	-6.22	3,767.02	23,430.86

Abbreviations: ΔCost, difference in costs per subject between ON101 and general wound care over 28 weeks of study period; NNT, number needed to treat

Figure 1. One-way sensitivity analysis



Abbreviations: DFU, diabetic foot ulcer; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year

- Within a 28-week trial, the NNT was -5.33 of ON101 versus GWC to obtain a patient with complete healing at an extra cost of $3,967, resulting in $21,128 per complete-healing patient gained.
- Over a 5-year model simulation, ON101 versus GWC yielded a gain of 0.038 QALYs at an extra cost of $573, resulting in $15,104 per QALY gained.
- Against the pre-defined willingness-to-pay threshold ($32,788, one time the per capita gross domestic product of Taiwan), using ON101 was highly cost-effective versus GWC in both within-trial and model-based CEAs.
- Among overall DFU patients, and such favorable result was even more prominent among those with poor glycemic control, larger ulcer sizes, and current smokers.

Conclusion

ON101 represents good value for money, especially for patients with high risks of DFU progression, and therefore may be considered in future standard wound care.

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