

仑卡奈单抗治疗早期阿尔茨海默病的药物经济学评价^Δ

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摘要 目的 从全社会角度出发,对仑卡奈单抗治疗早期阿尔茨海默病(AD)进行药物经济学评价。方法 基于一项仑卡奈单抗治疗早期AD的全球多中心、随机、双盲、安慰剂对照研究(Clarity AD研究)的数据,根据AD的疾病发展进程建立Markov模型,循环周期为1个月,模拟至99%患者死亡。以质量调整生命年(QALY)和增量成本-效果比(ICER)为产出指标,以2倍我国2025年人均国内生产总值为意愿支付(WTP)阈值(199 330.00元/QALY),模拟在标准治疗(SoC)方案的基础上,仑卡奈单抗对比安慰剂治疗早期AD的经济性。采用单因素敏感性分析、概率敏感性分析和情境分析检验结果的稳健性。结果 在SoC方案的基础上,仑卡奈单抗方案相比于安慰剂方案的ICER为4 364 711.54元/QALY。单因素敏感性分析结果显示,疾病进展风险比、仑卡奈单抗单价、体重、轻度认知障碍月进展概率及折现率为模型稳健性的关键影响参数。概率敏感性分析结果显示,在上述WTP阈值下,仑卡奈单抗联合SoC方案具有经济性的概率为0。情境分析结果显示,仑卡奈单抗单价需要至少降低94.88%才能低于设定的WTP阈值。结论 在上述WTP阈值下,仑卡奈单抗联合SoC方案相较于安慰剂联合SoC方案治疗早期AD不具有经济性。

关键词 阿尔茨海默病;仑卡奈单抗;成本-效用分析;药物经济学

Cost-effectiveness of lecanemab for early Alzheimer disease

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ABSTRACT **OBJECTIVE** To evaluate the cost-effectiveness of lecanemab for early Alzheimer disease (AD) from a whole-society perspective. **METHODS** Based on data from the Clarity AD study, a global multicenter, randomized, double-blind, placebo-controlled study of lecanemab for early AD, a Markov model was developed according to the disease progression of AD, with a monthly cycle and a time horizon extending to 99% patient mortality. Quality-adjusted life year (QALY) and incremental cost-effectiveness ratio (ICER) were used as outcome indicators, with a willingness-to-pay (WTP) threshold set at twice China's per capita gross domestic product (GDP) for 2025 (199 330.00 yuan/QALY). The model simulated the cost-effectiveness of lecanemab plus standard of care (SoC) versus placebo plus SoC for early AD. One-way sensitivity analysis, probabilistic sensitivity analysis, and scenario analysis were employed to test the robustness of the results. **RESULTS** Compared with placebo plus SoC, the ICER for lecanemab plus SoC was 4 364 711.54 yuan/QALY. One-way sensitivity analysis showed that the hazard ratio for disease progression, the price of lecanemab, body weight, the monthly progression probability of mild cognitive impairment, and the discount rate were key parameters affecting model robustness. Results of the probabilistic sensitivity analysis showed that the probability of lecanemab being cost-effective was 0 at the current WTP threshold. Scenario analysis indicated that a price reduction of at least 94.88% would be required for lecanemab to fall below the WTP threshold. **CONCLUSIONS** At the current WTP threshold, lecanemab plus SoC is not cost-effective compared with placebo plus SoC for early AD.

KEYWORDS Alzheimer disease; lecanemab; cost-effectiveness; pharmacoeconomics

阿尔茨海默病(Alzheimer disease, AD)作为最常见的神经退行性疾病之一,以进行性认知功能减退为主要

临床特征,其患者需要长期维持治疗和护理,给社会和家庭带来沉重的经济负担^[1]。据报道,美国的AD相关年医疗成本已超过3 600亿美元,西班牙的中度AD患者的人均年直接非医疗成本达到了3.6万欧元^[2-3]。国内数据显示,AD的治疗成本呈现快速上升趋势,2019年达到了1 950亿美元,患者每次住院平均费用为14 755元^[4]。在仑卡奈单抗等生物靶向药物获批上市之前,AD标准治疗(standard of care, SoC)药物的作用以症状管理为

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