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Title: Cost-Effectiveness of ibalizumab versus routine clinical care in heavily treatment experienced (HTE) people with HIV in the United States (US).

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Background: Ibalizumab is a monoclonal antibody approved in the United States (US) for heavily treatment experienced (HTE) people with HIV with ongoing viremia. Clinical evidence demonstrates that ibalizumab is effective in reducing and managing viral load (vL) in HTE people with HIV, which may have an economic benefit to US payers.

Objective: To estimate the cost-effectiveness of the addition of ibalizumab to routine clinical care (e.g optimised background regimens [OBR]) from a US payer perspective.

Methods: A Markov model estimated the cost per quality-adjusted life-year (QALY) gained following the addition of ibalizumab to OBR from a US payer perspective. The model considered HTE people with HIV as per ibalizumab's pivotal trials (TMB-201 and TMB-301/311). Model health states were: virally undetectable (vL<50 copies/ml), virally suppressed (50 ≤vL≤ 200 copies/ml), and virally unsuppressed (vL>200 copies/ml). Estimates of comparative effectiveness were derived through a standardized mortality rate (SMR)-weighting analysis of TMB-201 and TMB-301/311 data to non-IBA-containing regimens in routine clinical care from the OPERA® cohort. Costs were derived from appropriate US sources, and included treatment acquisition and administration, monitoring, adverse events, opportunistic infections, and terminal care. Mortality assumptions and health-state utility values were based on disease specific published literature and clinical trial data. Costs and outcomes were discounted at 3% per annum.

Results: Over a lifetime horizon, the addition of ibalizumab to OBR increased the time patients spent virally undetectable or suppressed and extended a patient's QALYs compared to OBR alone. A base-case incremental cost-effectiveness ratio (ICER) versus OBR of $169,103 was calculated. Deterministic and probabilistic scenario analyses indicated that the result was robust to changes to structural and parameter uncertainty.

Conclusions: The addition of ibalizumab to OBR resulted in increased costs and QALYs. The ICER fell within an acceptable cost-effectiveness range and demonstrates that the addition of ibalizumab to routine clinical care may provide payers with a cost-effective treatment option that can substantially improve outcomes for HTE people with HIV.

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