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Cladribine Tablets Are a Cost-Effective and Cost-Saving Treatment Strategy for High Disease Activity Relapsing Multiple Sclerosis Patients in Iran.

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Background: Cladribine tablets, hypothesized to act as an immune reconstitution therapy, are the first oral treatment for high disease activity relapsing multiple sclerosis (HDA-RMS).

Objective(s): This study was conducted to assess the cost-effectiveness of cladribine tablets in comparison to natalizumab in HDA-RMS patients and also its budget impact in Iranian setting.

Method(s): Cost-utility analysis (CUA): A Markov cohort model, with 21 expanded disability status scale (EDSS)-based health states was developed to compare cladribine tablets to natalizumab in a 5-year time horizon, from a societal perspective, in the context of Iran. Demographic and utility data were extracted from the CLARITY trial. Annual relapse rate and confirmed disability progression were extracted from a network meta-analysis, due to a lack of head-to-head trials. Mortality covariant such as age, sex and health states were also included. Effectiveness was assessed using quality adjusted life years (QALYs). Costs, which were identified through previous studies and expert opinion, were measured in Iranian Rial rates and converted to 2019 USD. Discount rates were 3.5% and 7.2% for QALY and costs, respectively. Probabilistic and deterministic sensitivity analyses (P/DSA) were conducted to assess robustness of the model.

Budget impact analysis (BIA): Markov-based static BIA was designed to compare total budgetary cost of two scenarios, with and without cladribine tablets, used in second-line treatment of RMS in a 10-year horizon. The Model was populated with the 2018 local MS pharmaceuticals usage data and included all available comparators (interferons, glatiramer acetate, dimethyl fumarate, teriflunomide, fingolimod and natalizumab). Key cost inputs included drug acquisition, administration and monitoring costs. CUA: Cladribine tablets was superior to natalizumab and was associated with cost savings of 6.607 USD and increased QALY of 0.003 per patient, over a 5-year time horizon. Drug acquisition was the major cost component (92% in both arms). Results were robust in DSA and PSA (57.5% probability of cost-effectiveness at a willingness-to-pay threshold of 2,709 USD). BIA: Considering a cohort of 35,667 patients, inclusion of cladribine tablets as a second-line RMS treatment will yield -0.33% savings in budget (7,856,019 USD), over a 10-year horizon.

Result(s): Results indicated that use of cladribine tablets in HDA-RMS is a cost-effective and also cost-saving strategy in Iran.