HEALTH CARE DECISION-MAKERS’ ATTITUDE TOWARDS ON HEALTH ECONOMICS RESEARCH

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OBJECTIVE: To assess lifetime cost-effectiveness of glatiramer acetate (GA) compared to natalizumab (NZ) in patients diagnosed with relapsing-remitting multiple sclerosis (RRMS) in the presence of long-term clinical evidence. METHODS: A literature-based Markov model was developed with patients transitioning through health-states based on Kurtzke expanded disability status scale (EDSS). Patients in the model are ≥21 years of age with RRMS and start in any of the health-states at diagnosis. Patients with an EDSS score below 6.0 receive treatment. Treatment effects for relapse and disease progression were obtained from clinical trials and long-term clinical evidence where available. Transition rates were estimated by applying a percent reduction of treatment effects of therapies to natural history rates of relapse and disease progression. Rates were adjusted for treatment discontinuation and persistent NZ antibodies. Patients incurred drug, other medical and lost worker productivity costs. Patients on NZ incurred additional costs for monitoring, diagnosis, and treatment of progressive multifocal leukoencephalopathy (PML), a possible serious adverse event for patients on NZ. Utility weights for each health-state were taken from clinical trials and long-term clinical evidence.

RESULTS: Thirty-four of 64 CDR submissions recommended ‘no listing’, 17 ‘list with criteria’, and 13 ‘list or list in similar manner as other drugs in the same category’. Of the 64 appraisals, 41 were recommended to conduct further research to either collect specific items of data (n = 28), conduct subgroup analysis (n = 13), or collect data using a more appropriate study design (n = 19). The most commonly requested item was long-term adverse events or safety data (16/28), and this observation is consistent with the fact that, to date, most post-launch studies are safety surveillance studies. In addition, 11 of 28 recommended the collection of clinically important outcomes, long-term effectiveness (7/28). Similarly, 41 of 48 NICE appraisals recommended further research to collect real-world data, including treatment pathways, effectiveness, and long-term effectiveness or adverse events. CONCLUSION: This review suggests that recommendations for post-launch research from CDR and NICE appear to be similar. This highlights the inherent weakness of regulatory trials as a piece of evidence in informing reimbursement decisions.