COST-EFFECTIVENESS ANALYSIS OF DELAYED-RELEASE DIMETHYL-FUMARATE IN THE TREATMENT OF RELAPSE-REMITTING MULTIPLE SCLEROSIS IN ITALY
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OBJECTIVES: To compare cost-effectiveness of delayed-release dimethyl fumarate (DMF) - also known as gastro-resistant DMF - vs. pharmaceutical alternatives indicated for the first-line treatment of relapsing-remitting multiple sclerosis (RRMS), adopting the perspective of the Italian National Healthcare Service (NHS).

METHODS: A cost-effectiveness model was used to evaluate costs and outcomes of patients treated with DMF vs. interferon beta-1a intramuscular (IFN beta-1a, IM), interferon beta-1a subcutaneous, at two different doses (IFN beta-1a, SC 225 IU, and IFN beta-1a SC 440 IU) vs. beta-1a subcutaneous (IFN beta-1a SC 440 IU), interferon gamma aceta-subcutaneous (GA), and oral teriflunomide (T). The Markov model used for the analysis evaluated the effects of disability progression, relapses, and treatment-related adverse events, on direct healthcare costs and quality adjusted life years (QALYs) gained. Sensitivity analysis conducted on both clinical and economic data showed that like-

Mean change in clinical variables was HbA1c -0.5% (±0.3%), weight +0.8g (+1.6 g) and hypoglycaemia events/week -3.6 (+0.9). A baseline cohort was projected over a lifetime using published IFN beta-1a (<0.005) and published DMF disutility (0.0141) and without treatment effects applied to cal-


tulate life expectancy (LE) and QALYs associated with the treatment and post-switch policies predicted a QALYs gain of 19.50 (LYs) and 6.55 (QALYs). The incre-

A Markov decision-analytic model was used to simulate cohorts with preventive stratified treatment in high-risk (FRS>20%) individuals (ATPIII guideline). This treatment threshold was incrementally lowered to T=0.1%. The predictions indicated the distribution of individuals over the low (<0.5%), intermediate (0.5%-7%), and high (>7%) risk category and corresponding observed CHD-risks were calculated. The Net Health Benefit (NHB) (yielding to a QALY gain) was used to calculate the incremental cost-effectiveness of the alternative treatment. The NHB was then assessed with probabilistic sensitivity analysis. The NHB for each 0.5% risk category was calculated to assess the impact of risk prediction uncertainty on associ-

Conclusions: This study used the CORE Diabetes Model (CDM) and published audit data for patients with type 1 diabetes switching to insulin degludec (ID) from either insulin glargin or detemir (ID). Mean (±SD) baseline profiles were age 35.0 years (± 11.4), diabetes duration: 18.2 years (± 7.5), HbA1c 9.4% (± 0.8), weight 77.0 g (± 14.0). DMF were non-inferior in their effectiveness and safety data used in the model were derived from a mixed treatment contrast. All unit tariffs and costs were adapted to the Italian setting. RESULTS: Lifetime direct healthcare costs associated with DMF were €276,500 per patient-vel,

yielding to 19.50 life-years (LYs) and 6.55 quality-adjusted LYs (QALYs). The incre-

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