INTRODUCTION

• Patients with relapsing multiple sclerosis (RMS) experiencing frequent relapses can be described as having high disease activity (HDA).
• Disease-modifying drugs (DMDs) available as treatment options for patients with HDA have distinct efficacy and safety profiles. Consequently, benefit-risk balance is a key consideration for physicians when selecting effective treatments for these patients.
• Increasingly, structured decision making and treatment choice from alternatives offering different potential benefits or risks employs Multi-Criteria Decision Analysis (MCDA) methods.

OBJECTIVES

• To apply MCDA to a structured, blinded, benefit-risk assessment of cladribine tablets and newer approved DMDs for patients with HDA.

METHODS

• Decision conferencing with expert clinical neurologists as the decision makers was used to create an MCDA model incorporating available evidence and clinical judgements about the relevance of that evidence.
• This followed a group workshop approach guided by the ‘OAC-ACT-URL’ (Problem formulation, Objectives, Alternatives, Consequences, Trade-offs, benchmark, Risk attitude, and Linked decision) framework. Benefit-risk assessments were conducted for DMDs in RMS and HDA (defined as 2 relapses in the previous year – also described as high relapse activity (HRA)).
• Treatments options included in the model were cladribine tablets and recently approved DMDs available in the EU countries at the time of assessment (December 2015): alemtuzumab, dimethyl fumarate, fingolimod, mitoxantrone, and teriflunomide.
• DMDs were independently agreed on 7 favorable effects and 11 unfavorable effects based on study endpoints, posology, and established or potential risks of DMDs (Figure 1).

RESULTS

• Cladribine tablets had the highest overall weighted preference value for patients with HDA (indicating that it was the most preferred option in the model followed by interferon beta, mitoxantrone, and fingolimod). Table 2: Differences in Weighted Preference Values Between Cladribine Tablets and Alternatives

CONCLUSIONS

• Using MCDA with decisions from blinded expert physicians, the benefit-risk profile of cladribine tablets in HDA patients (2 relapses in the previous year; HRA) was favorable compared to the other DMDs included in the model.

REFERENCES

• This study was presented by EMD Serono, Inc., a business of Merck KGaA, Darmstadt, Germany (in the EU), and Merck Serono SA – Geneva, an affiliate of Merck KGaA, Darmstadt, Germany (outside of the EU).
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DISCLOSURES

• PV has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. BV has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. RF has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. ML has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. EM has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. RS has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. MS has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. PM has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. CL has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. SA has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. LK has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. RS has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. RF has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. EM has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. MS has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. PM has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. CL has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. SA has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. RS has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. RF has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. EM has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. MS has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme. PM has received honoraria at congress meetings from Biogen, Sanofi-Aventis, Janssen-Cilag, and Genzyme.