NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Dimethyl fumarate for treating relapsing-remitting multiple sclerosis

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name [redacted]

Name of your organisation: Royal College of Pathologists
Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? **No**

- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? **A specialist in the scientific evidence base that support the use of the technology in this medical condition.**

- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)? **No**

- other? (please specify): **Consultant Immunologist**

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Innovation:
NICE has responded to Sir Ian Kennedy's report 'Appraising the value of innovation'. Please therefore provide your response to the following three questions in your submissions:
-Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Dimethyl fumarate is innovative. It is an oral therapy with a novel mechanism of action. Dimethyl fumarate has a dual immunomodulatory; anti-inflammatory and neuroprotective mechanism.

Dimethyl fumarate (Fumaderm) has been used for the oral treatment of psoriasis for more than 50 years. Observational studies following patients for up to 14 years do NOT indicate that Fumaderm® is associated with serious or permanent adverse effect. Raised serum creatinine and liver enzymes levels occur rarely and resolve with continued treatment or on dose reduction. Reversible leucopenia, lymphopenia and transient eosinophilia are frequently observed.

-Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the quality-adjusted life years (QALY) calculation?

I can't comment on the QALY, but I believe with being an oral treatment, it is easier to administer.

-Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

There is a long term experience with the use of Dimethyl fumarate in patients with Psoriasis, which can help in addressing the long term safety of the drug. Reference: Roll A, Reich K, Boer A. Use of Fumaric acid easters in Psoriasis. Indian J Dermatol Venereol Leprol 2007; 73:133-7.