SMC Scottish Medicines Consortium
Advising on new medicines for Scotland
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NHS SCOTLAND
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Product Update:

raltegravir 600mg film-coated tablets (Isentress®) SMC No 1280/17
Merck Sharp & Dohme Limited

6 October 2017

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

raltegravir 600mg film-coated tablets (Isentress®) are accepted for restricted use within NHS Scotland.

Indication under review: in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults and paediatric patients weighing at least 40kg.

SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions.

The 600mg tablet allows once daily dosing (1200mg once daily) at no additional cost compared with raltegravir 400mg tablets administered twice daily. Raltegravir 400mg tablets should not be used to administer the 1200mg once daily regimen.

SMC has previously accepted raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adolescents and children aged 2 to 17 years and in adult patients. In the original full submission the health economic case was made for a sub-population of patients within the licensed indication.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 16 August 2017.

Chairman, Scottish Medicines Consortium

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