All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Final Appraisal Recommendation

Advice No: 3515 – November 2015

Raltegravir (Isentress®) 100 mg granules for oral suspension

Limited submission by Merck Sharp & Dohme Ltd

Recommendation of AWMSG

Raltegravir (Isentress®) 100 mg granules for oral suspension, in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents, children, toddlers and infants from the age of four weeks are recommended as an option for restricted use within NHS Wales.

Raltegravir (Isentress®) 100 mg granules for oral suspension should be restricted for use in patients who are resistant or intolerant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs), or for whom these options are compromised due to drug–drug interactions.

Additional note(s):

- Prescribers should consider switching from granules for oral suspension to chewable tablets when patient weight is ≥ 11 kg. Refer to the Summary of Product Characteristics (SPC) for further information on the dosing of raltegravir (Isentress®).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2366), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by the Minister for Health and Social Services and will be considered for review every three years.