Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
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NHS SCOTLAND

Product Update:

tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®) (No. 905/13)

Gilead Sciences Ltd

09 August 2013

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

tenofovir disoproxil (Viread®) is accepted for restricted use within NHS Scotland.

Indication under review:
HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate.

Hepatitis B infection - for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.

SMC restriction: in patients <18 years, to be prescribed under the supervision of specialists in paediatric infectious diseases.

SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. SMC has previously accepted tenofovir disoproxil for use in the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis and in patients with decompensated liver disease.

Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of hepatitis B infection and HIV infection.

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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 13 June 2013.

Vice Chairman,
Scottish Medicines Consortium