All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya®) film-coated tablet

Gilead Sciences Ltd

March 2018

Statement of Advice

In the absence of a submission from the holder of the marketing authorisation, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (Genvoya®) cannot be endorsed for use within NHS Wales for the treatment of human immunodeficiency virus-1 (HIV-1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir, in children aged from 6 years to 12 years and with body weight at least 25 kg for whom alternative regimens are unsuitable due to resistance or toxicities.

Advice context:
The All Wales Medicines Strategy Group (AWMSG) takes into account the National Institute for Health and Care Excellence (NICE) future work programme when considering whether a product will be appraised. To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intends to publish final technology appraisal guidance (STA/MTA/HST) for the same product and indication(s) within 12 months of the date of marketing authorisation. AWMSG guidance is interim to that of NICE, should NICE subsequently publish guidance.

The above medicine cannot be endorsed for use within NHS Wales as a technology appraisal by NICE or AWMSG has not been undertaken. The medicine should NOT be prescribed routinely within NHS Wales for the indication stated above.

In the absence of guidance issued by NICE or AWMSG, clinicians should continue to exercise their clinical judgement when providing care for an individual patient. This should be in consultation with the patient and/or guardian or carer, based on the best available evidence.

This statement will be removed on receipt of a submission (i.e. the full submission [Forms A and B] or limited submission [Forms A and C]), or updated when final NICE technology appraisal guidance becomes available.