

# **AWMSG ADVICE SUPERSEDED BY NICE GUIDANCE (TA729)**

**NICE GUIDANCE ISSUED SEPTEMBER 2021**

(Refer to NICE website for full guidance on NICE recommendations, including any specific restrictions on the use of the technology)

**Sapropterin (Kuvan®) tablets**

**Merck Serono Ltd**

**October 2015**

## **Statement of Advice**

**In the absence of a submission from the holder of the marketing authorisation, sapropterin (Kuvan®) cannot be endorsed for use within NHS Wales for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria (PKU) who have been shown to be responsive to such treatment; or for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with tetrahydrobiopterin (BH4) deficiency who have been shown to be responsive to such treatment.**

### **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 advice (STA/MTA/HST) for the same product and indication(s) within 12 months of the date of marketing authorisation. AWMSG advice 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 when final technology appraisal advice from NICE becomes available.