All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Human normal immunoglobulin (Aragam®)

For replacement therapy in primary immunodeficiency syndromes

Oxbridge Pharma Ltd

February 2012

Statement of Advice

ADVICE: in the absence of a submission from the holder of the marketing authorisation, human normal immunoglobulin (Aragam®) cannot be endorsed for use within NHS Wales for replacement therapy in primary immunodeficiency syndromes such as: congenital agammaglobulinemia and hypogammaglobulinemia; common variable immunodeficiency; severe combined immunodeficiency and Wiskott Aldrich syndrome; myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinemia and recurrent infections; children with congenital AIDS and recurrent infections; immunomodulation; idiopathic thrombocytopenic purpura; children or adults at high risk of bleeding or prior to surgery to correct the platelet count; Guillain Barré syndrome; Kawasaki disease; allogeneic bone marrow transplantation.

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Advice context:
The All Wales Medicines Strategy Group (AWMSG) takes into account the National Institute for Health and Clinical 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 intend to publish final advice for the same product within twelve months of the projected Form B submission date. 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 an 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 NICE guidance becomes available.