All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Human normal immunoglobulin (Panzyga®) solution for infusion

Octapharma AG

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Statement of Advice

In the absence of a submission from the holder of the marketing authorisation, human normal immunoglobulin (Panzyga®) cannot be endorsed for use within NHS Wales as replacement therapy in adults, and children and adolescents in: primary immunodeficiency syndromes with impaired antibody production; hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia, in whom prophylactic antibiotics have failed; hypogammaglobulinaemia and recurrent bacterial infections in plateau phase multiple myeloma patients who have failed to respond to pneumococcal immunisation; hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation; congenital AIDS with recurrent bacterial infections. Immunomodulation in adults, and children and adolescents in: primary immune thrombocytopenia, in patients at high risk of bleeding or prior to surgery to correct the platelet count; Guillain Barré syndrome; Kawasaki disease.

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 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 guidance from NICE becomes available.