Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 0519 – April 2019

Blinatumomab (Blincyto®) 38.5 micrograms powder for concentrate and solution for solution for infusion

Limited submission by Amgen Ltd

Recommendation of the All Wales Medicines Strategy Group

Blinatumomab (Blincyto®) is recommended as an option for use within NHS Wales as monotherapy for the treatment of paediatric patients aged 1 year or older with Philadelphia chromosome negative CD19 positive B-cell precursor acute lymphoblastic leukaemia (ALL) which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic haematopoietic stem cell transplantation.

This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent to or lower than the PAS price.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.
- AWMSG considered that blinatumomab (Blincyto®) satisfied the AWMSG criteria for ultra-orphan status.
- AWMSG considered that the AWMSG criteria for appraising life-extending, end-of-life medicines applied to blinatumomab (Blincyto®) for the indication under consideration.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3769), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

The All Wales Therapeutics and Toxicology Centre (AWTTC) reviewed this appraisal recommendation in June 2022. It will be reviewed again in three years.