All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Final Appraisal Recommendation

Advice No: 4314 – December 2014

Infliximab (Remsima®▼) 100 mg powder for concentrate for solution for infusion

Submission by Celltrion Healthcare Ltd/Napp Pharmaceuticals Ltd

Recommendation of AWMSG

Infliximab (Remsima®▼) is recommended as an option for restricted use within NHS Wales.

Infliximab (Remsima®▼) should be prescribed within its licensed indications in accordance with NICE or AWMSG guidance for infliximab (Remicade®), the reference product.

Infliximab (Remsima®▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.
- Please refer to the NICE website for full guidance on NICE recommendations, including any specific restrictions on the use of the technology.
- In accordance with EMA guidance, the licence for the use of infliximab (Remsima®▼) in rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriatic arthritis and psoriasis was granted on the basis of assumed bioequivalence.
- Due to the potential for small differences between biosimilars from different manufacturers and/or the reference product infliximab (Remicade®), post-marketing pharmacovigilance is essential and will be facilitated by the Risk Management Plan.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2254), 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.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Celltrion Healthcare Ltd/Napp Pharmaceuticals Ltd
Date of first issue	December 2014
Last reviewed	March 2018