Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	5th April 2016
Appraisal & Details	**Etanercept Biosimilar 50mg (Benepali®▼, Biogen)** The Northern (NHS) Treatment Advisory Group considered an appraisal of Benepali® for the following indications: Rheumatoid arthritis (RA), Axial spondylitis (AS), Psoriatic arthritis and Plaque psoriasis (adults only)
Recommendation	**The Northern (NHS) Treatment Advisory Group recommends the use of etanercept biosimilar Benepali® as an option for use in adults where the originator product (Enbrel®) would normally be prescribed.** The group was satisfied that the data presented showed that bio similarity had been demonstrated for Benepali® with regards quality, non-clinical and clinical comparability. **The group agreed that the etanercept biosimilar should be considered as a first line option in new patients suitable for treatment with etanercept. For existing patients consideration should be given to switching where it is clinically appropriate and as part of a clinician led management programme which has appropriate monitoring in place.** If localities are considering a managed therapeutic switch programme the group recommends that this is done in agreement with local Trusts and Specialists, ensuring a full discussion with the patient prior to any switch. If this approach is taken it is recommended that this is co-ordinated via the regional contracting arrangement to ensure consistency throughout the NTAG region. Further data on how to manage a biosimilar switch appropriately are outlined within the NICE health technologies appraisal support document published on 31st July 2015.
Clinical evidence summary	To gain approval in the EU, biosimilar medicines must demonstrate that they are as safe and as effective as the reference medicine, and have the same quality characteristics. In an extensive comparability exercise it was shown that all major physicochemical characteristics and biological activities of Benepali® (etanercept biosimilar) are comparable to those of Enbrel®, the originator product. The clinical trial program demonstrating bio similarity consisted of a phase III efficacy and safety study in patients with active rheumatoid arthritis and a phase I pharmacokinetic (PK) study in healthy volunteers. The phase III study was carried out in those patients with moderate to severe RA despite methotrexate therapy. Benepali® was shown to have equivalent efficacy to that of Enbrel® in the primary outcome of ACR20 response at week 24. Secondary efficacy outcomes at week 24 also support the primary findings and response rates were sustained to a similar degree in both treatment groups up to week 52. Based on the totality of evidence, the EMA concluded that similarity has been convincingly demonstrated enabling extrapolation of Benepali® approval to all other indications for which the reference product Enbrel® is approved, except the paediatric indications due to the dose available.

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Safety	The type and incidence of treatment-emergent adverse events observed in the clinical studies was generally similar between the two treatment groups and were in line with the well-characterised safety profile of Enbrel®. The majority of adverse events were mild to moderate in severity with no significant new safety signals reported. There were no marked differences in the immunogenicity profile and the impact of antibodies on efficacy and safety was comparable between treatment arms.
Patient Perspective	Patients may be concerned about the use of a biosimilar however they can be reassured that a comprehensive and state of the art comparability exercise has been performed for the Benepali® biosimilar with the reference product Enbrel®. The administration devices differ in that the Benepali® pen is an auto injector device whereas the Enbrel® pen requires the patient to press a button to inject the dose. The Benepali® needle sheath is latex free.
Cost analysis summary	Benepali® has a NHS list price of £656 for 4x 50mg which is 10% lower than the list price of Enbrel® (£715 for 4x50mg) However, the actual cost of Enbrel® and the biosimilar product may differ from list prices due to locally negotiated procurement discounts.
Financial impact **PbR: excluded**	Etanercept is a high-cost medicine and represents a significant expenditure for the NHS. The use of a biosimilar will free up limited resources to reinvest in other services. This recommendation is expected to be cost saving.