Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	6th June 2017
Appraisal & Details	**Rituximab Biosimilars** The Northern (NHS) Treatment Advisory Group considered an appraisal of Rituximab Biosimilars for the following indication: Rheumatoid arthritis (RA) in adult patients.
Recommendation	**The Northern (NHS) Treatment Advisory Group recommends the use of rituximab biosimilars as an option for use in adults where the originator product (MabThera®) would normally be prescribed.** The group was satisfied that the data presented showed that biosimilarity had been demonstrated with regards to efficacy, safety and pharmaceutical quality. **The group agreed that a biosimilar product should be considered as a first line option in new patients suitable for treatment with rituximab. 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. It would also appear sensible to use the biosimilar product with lowest acquisition cost (with discount) and the easiest access scheme to manage.
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 the biosimilar Truxima® are comparable to those of MabThera®, the originator product. For the biosimilar Truxima®, in patients with RA, the clinical program consisted of a Phase 1 pharmacokinetic equivalence study between Truxima® and the EU reference product MabThera®, followed by a Phase 3 therapeutic equivalence study. In both studies efficacy in terms of DAS28 and ACR were shown to be comparable between the two products. In addition, PK equivalence was demonstrated in terms of all PK parameters across all comparisons. Limited data from 56-week open-label study showed that in patients who switched from MabThera to Truxima, efficacy was sustained, and comparable to those maintained on Truxima. However, this is a descriptive analysis and due to the small sample size no firm conclusions can be drawn.

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Safety	The overall safety profile of the two products appears broadly comparable although the incidences of AEs were generally lower for the originator product. The nature of TEAEs observed in clinical studies was in line with the well-characterised safety profile of MabThera® in RA populations. The majority of TEAEs were of mild to moderate severity, and no significant new safety signals were reported. Overall, a similar safety profile was observed between the maintenance and switch groups.
Patient Perspective	Patients may be concerned that a biosimilar may be less effective or less safe than the originator product. They can, however, be reassured that a comprehensive and state of the art comparability exercise has been performed for licensed biosimilars with the reference product MabThera®
Cost analysis summary	MabThera® has an NHS list price of £349.25 and £873.15 for 2 x 100mg, and 1 x 500mg vials, respectively. Currently only one biosimilar product (Truxima®) is available. This has a list price of £785.84 for 1 x 500mgvial, which is represents a discount of around 10% on the corresponding price of MabThera®. However, the actual cost of MabThera® and the biosimilar product may differ from list prices due to locally negotiated procurement discounts. As more rituximab biosimilars are approved, it would appear sensible to use the product with lowest acquisition cost (with discount) and the easiest access scheme to manage.
Financial impact **PbR: Excluded**	Rituximab 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.