Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	8th September 2015 (updated)
Appraisal & Details	**Infliximab Biosimilars –Inflectra®▼ (Hospira), and Remsima®▼ (Napp).** The Northern (NHS) Treatment Advisory Group considered an appraisal of the two infliximab biosimilars for use in the following indications: Rheumatoid Arthritis (RA), Ankylosing spondylitis (AS), Psoriatic arthritis, Psoriasis, Crohn's disease and ulcerative colitis.
Recommendation	**The Northern (NHS) Treatment Advisory Group recommends the use of infliximab biosimilars as an option where the originator product (Remicade®) would normally be prescribed.** The group was satisfied that the data presented showed that bio similarity had been demonstrated for the infliximab biosimilar (CT-P13) with regards quality, non-clinical and clinical comparability. **The group agreed that infliximab biosimilars should be considered as a first line option in new patients suitable for treatment with infliximab. 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 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 CT-P13 (infliximab biosimilar) are comparable to those of Remicade®. The clinical trial program demonstrating bio similarity consisted of a phase III efficacy and safety study in patients with active rheumatoid arthritis (PLANETRA), and a phase I pharmacokinetic (PK) study in patients with ankylosing spondylitis (PLANETAS). Both studies showed that up to 54 weeks there were no clinically meaningful differences in the efficacy, safety or pharmacokinetic profile between CT-P13 and Remicade®. Preliminary data from 48-week open-label extensions showed that patients who switched from Remicade® to CT-P13, efficacy was sustained, and comparable to those maintained on just one product. Although clinical studies were only performed in patients with RA and AS, efficacy and safety for other indications is assumed from the demonstration of equivalence to the reference product in accordance with regulatory procedures. Based on the totality of evidence, the EMA concluded that similarity has been convincingly demonstrated enabling

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	extrapolation of CT-P13 approval to all other indications for which the reference product Remicade® is approved, including ulcerative colitis, Crohn's disease, psoriatic arthritis and psoriasis. It should also be noted that any biological product is likely to be modified several times over its lifecycle. In the case of Remicade® there have been 40 listed changes since its original authorisation.
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 Remicade®. A higher number of serious infections, including active TB were observed in the rheumatoid arthritis study, but the numbers involved are small and a thorough review of all available data by the EMA suggests that the observed difference was most likely due to chance. 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 infliximab biosimilar with the reference product Remicade®.
Cost analysis summary	Both Inflectra®▼ and Remsima®▼ have a NHS list price of £377.66 per 100 mg vial, which is 10% lower than the list price of Remicade® (£419.62 per 100 mg vial) However, the actual cost of Remicade® and the biosimilar products may differ from list prices due to locally negotiated procurement discounts. It would appear sensible to use the product with lowest acquisition cost (with discount) and the easiest access scheme to manage, bearing in mind that savings may not be seen immediately.
Financial impact **PbR: excluded**	Infliximab (Remicade®) 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.