Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	2nd June 2020 (updated August 2020, reviewed 8th June 2021, reviewed 22nd February 2022 & no changes made)
Appraisal & Details	The Northern (NHS) Treatment Advisory Group considered an appraisal of **Infliximab subcutaneous injection (Remsima SC ®)**
Recommendation	**The Northern (NHS) Treatment Advisory Group recommends Remsima SC® be available as additional treatment option during the COVID-19 pandemic for both licensed and off-label uses as part of individual hospital Trust management strategies to reduce hospital day case admissions, and keep immunosuppressed people out of hospital during the COVID-19 pandemic. Remsima SC® could be considered as an option where the patient would otherwise get the intravenous Remsima® formulation of Infliximab. This recommendation is subject to any off-label use of Remsima SC® being considered and approved via individual hospital trust governance processes (including clinical governance) for the use of unlicensed/off-label drugs.** In June 2021 NTAG reviewed this recommendation after 12 months as agreed. NTAG agreed at this time to make no changes to the recommendation due to the ongoing COVID-19 pandemic and to review the position again in a further six months' time. In February 2022 NTAG reviewed this recommendation again after a further six months as agreed. NTAG agreed at this time to make no changes to the recommendation due to the current uncertainty around future ICS commissioning structures, and the uncertainty around future NHS tariff arrangements for high cost drugs. NTAG agreed to review this recommendation when ICS commissioning structures are more established and there is clarity on the ICS funding arrangements for high cost drugs. If localities are considering a managed therapeutic switch programme from Infliximab IV to Infliximab SC this should be done in agreement with Trusts and Commissioners, coordinated via regional procurement to ensure consistency across regions, and to support national constraints around homecare capacity at this time. Commissioners should be fully involved in discussions to move to this temporary arrangement, and providers and patients should be aware that post COVID-19 pandemic this service provision may be revised. There are currently constraints around homecare capacity nationally, so the preferred supply route at this time is through hospital pharmacy departments dispensing on an outpatient basis. If supplied via the hospital pharmacy, ancillaries and sharps bins should be supplied where required.
Clinical evidence summary	Infliximab subcutaneous (Remsima SC®) was originally only licensed for Rheumatoid arthritis (RA), and a license extension for the treatment of adult patients with ankylosing spondylitis, Crohn's disease, ulcerative colitis, psoriatic arthritis and psoriasis was granted on the 24th July 2020. Marketing authorisation for the subcutaneous formulation was granted based on the data from an initial (part 1) 54-week phase 1 / phase 3 study and the subsequent randomised controlled trial (part 2), demonstrating non-inferiority of the subcutaneous preparation of CT-P13 compared to the intravenous

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	preparation over a period of 30 weeks in patients with active RA. The license extension is based on data from a pivotal study comparing the pharmacokinetics, efficacy and safety of the subcutaneous (SC) and intravenous (IV) formulations of Remsima® in people with active Crohn's disease and ulcerative colitis, throughout a 1-year treatment period. There is no data available on switching from a different brand of intravenous Infliximab other than Remsima® to Remsima SC®. NICE have published NG167 - COVID-19 rapid guideline: rheumatological autoimmune, inflammatory and metabolic bone disorders on 3rd April 2020 and updated on the 2nd July 2020. This recommends assessing whether patients having intravenous treatment can be switched to the same treatment in subcutaneous form. If this is not possible, discuss with the patient an alternative subcutaneous treatment. NICE have published an evidence summary ES29: Remsima (infliximab biosimilar) for subcutaneous injection for managing rheumatoid arthritis on the 21st July 2020.
Safety	The type and incidence of treatment-emergent adverse events observed in the clinical studies was generally similar between intravenous Remsima® and subcutaneous Remsima®, and were in line with the well-characterised safety profile of infliximab.
Patient Perspective	The use of infliximab subcutaneous will give patients an additional option for infliximab. Infliximab can be self-administered at home and could help reduce local capacity issues, plus keep immunosuppressed people out of hospital during the COVID-19 pandemic. Infliximab is only one of a wide range of biologics (from different therapeutic classes) licensed and recommended by NICE, some of which are administered via intravenous infusion, some via subcutaneous injection and some orally. The recommendations on individual agents in RA and IBD have been summarised in NICE guidelines.
Cost analysis summary	Remsima SC® has an NHS list price of £377.66 per 120mg pre-filled syringe or pen. For comparison IV infliximab biosimilars all have an NHS list price of £377.66 per 100 mg vial, which is 10% lower than the list price of the originator product Remicade® (£419.62 per 100 mg vial). However, the actual cost of Remicade and the biosimilar products (including Remsima SC®) may differ from list prices due to locally negotiated procurement discounts. Based on a 75kg adult, and using NHS list prices (excl VAT), the cost of SC vs. IV infliximab is as follows: • Remsima SC® (all indications) 120mg maintenance dose every 2 weeks = £1,510.64 over 8 week period (not including homecare costs) • Infliximab IV (biosimilar) for RA 3mg/kg every 8 weeks maintenance dose = £1,132.98 (not including administration and day case attendance costs) • Infliximab IV (biosimilar) for all other indications 5mg/kg every 8 weeks maintenance dose = £1,510.64 (not including administration and day case attendance costs) (N.B. VAT will have to be applied to items dispensed by hospital inpatient pharmacies)

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Financial impact **PbR: excluded**	Infliximab is a high-cost medicine and represents a significant expenditure for the NHS. The use of infliximab subcutaneous will not produce savings to local budgets and will be a cost pressure, but will give patients an additional option of a product that can be self-administered at home and could help reduce local capacity issues, plus keep immunosuppressed people out of hospital during the COVID-19 pandemic. The introduction of a subcutaneous version of Infliximab is unlikely to dramatically change the initial choice of anti-TNF.