SEL Area Prescribing Committee
Biosimilar Infliximab – Position Statement, September 2015

Reference	**PS-001**
Intervention:	**Biosimilar infliximab (CT-P13) - manufactured by Celltrion and marketed in the UK as Inflectra® (Hospira) or Remsima® (Napp).** *The therapeutic indications, dosing regimen, pharmaceutical form (powder for concentrate for solution for infusion) and strength (100mg infliximab per vial) of Inflectra® and Remsima® are the same as those of Remicade® - for use in ankylosing spondylitis, rheumatoid and psoriatic arthritis, psoriasis and inflammatory bowel disease (Crohn's disease and ulcerative colitis).*
Date of Decision	**March 2015**
Date of Issue:	**March 2015 - updated June 2015 and September 2015**
Recommendation:	**RED – suitable for prescribing and supply by hospital only**
Further Information	1. Inflectra® or Remsima® may be used, when indicated according to the current guidelines and pathways for ankylosing spondylitis, rheumatoid and psoriatic arthritis, psoriasis and inflammatory bowel disease (Crohn's disease and ulcerative colitis**) for patients who are infliximab naive.** 2. Any proposed unlicensed use should be covered by Trust unlicensed use policies, as for Remicade®. 3. Inflectra® or Remsima® are cost effective options if infliximab therapy is required in line with pathways and should be considered as an option by clinicians, also considering patient preference. 4. The APC has agreed that certain groups of patients under the care of gastroenterology, rheumatology and dermatology who are established on Remicade® therapy may be considered for a switch to biosimilar infliximab. 5. Trusts will use the brand name when prescribing infliximab, to ensure that substitution of a biosimilar product does not occur when the medicine is dispensed by the pharmacist (MHRA advice[2]). 6. Use is restricted to specialist consultants and is subject to inclusion in an approved Trust Biologics Clinical Guideline. 7. It is recommended that Trusts collaborate locally to maximise good practice and knowledge to manage this change.
Cost Impact for agreed patient group	Infliximab is expensive and the biosimilars are a cost-saving alternative; those marketed are currently 5-20% cheaper than the originator products. However this does not change the position of infliximab in pathways as the intravenous infusion route of administration is still more expensive than biologics which are available for subcutaneous administration. *Trusts have highlighted the need for further collaboration with CCGs regarding implementation resource*.
Usage Monitoring & Impact Assessment	Acute Trusts: Safety, efficacy monitoring via biologics database. Audit. CCGs: Monitor monthly high cost drugs data submitted by Trusts– via South East CSU.
Evidence reviewed	**Key References** 1. London Medicines Evaluation Network Review - Answers to commonly asked questions about biosimilar versions of infliximab, February 2015, accessed 18.02.15 2. MHRA Drug Safety Update: Biosimilar products, February 2008, accessed 18.02.15

NOTES:

a) Area Prescribing Committee recommendations, position statements and minutes are available publicly on member CCG websites.

b) This Area Prescribing Committee position statement has been made on the cost effectiveness, patient outcome and safety data available at the time. The position statement will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS