South East London Area Prescribing Committee
Formulary recommendation

Reference	**075**
Intervention:	**Golimumab injection at a dose of 100 mg for the treatment of ulcerative colitis in adult patients weighing <80kg** (Golimumab is a human monoclonal antibody that inhibits tumour necrosis factor alpha [TNF-α]).
Date of Decision:	**August 2017**
Date of Issue:	**September 2017**
Recommendation:	**Red – suitable for prescribing and supply by the hospital only**
Further Information:	• Golimumab is accepted for use at a higher maintenance dose of 100mg every 4 weeks for the treatment of ulcerative colitis in adult patients weighing less than 80kg. • The higher dose may be considered as an option for patients who have had a partial response or secondary loss of response to golimumab 50mg every four weeks. • The place in therapy should be in line with the SEL IBD pathway, and NICE technology appraisal guidance 329. The SEL IBD pathway will be updated to reflect this recommendation. • **Note:** at the time of writing, golimumab is not licensed for use at a dose of 100mg every 4 weeks in patients weighing less than 80kg with ulcerative colitis. This should be communicated to the patient in line with the organisation's usual consent processes.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• Golimumab is a tariff excluded drug. CCGs are the responsible commissioners when golimumab is used for the treatment of ulcerative colitis in adult patients. • The manufacturers supply golimumab 100 mg under a patient access scheme for the same price as the 50 mg dose, and hence a dose increase would not come at an extra cost to the NHS.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor usage and report back to the APC when required. • Audit use as required by commissioners to ensure use is in line with this recommendation, this includes auditing against the IBD monitoring framework.
	CCGs: • Monitor monthly tariff excluded high cost drugs invoicing submitted by Trusts to the NEL CSU.

Evidence reviewed	References (from evidence review)
	1. Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy. NICE Technology Appraisal 329 (Feb 2015). Available online at: https://www.nice.org.uk/guidance/ta329 (access 13/07/2017). 2. Vedolizumab for treating moderately to severely active ulcerative colitis. NICE Technology Appraisal 342 (Jun 2015). Available online at: https://www.nice.org.uk/guidance/ta342/ (access 13/07/2017). 3. South East London Area Prescribing Committee: Primary & Secondary Care Inflammatory Bowel Disease Pathway May 2017. Available online at: http://www.lambethccg.nhs.uk/news-and-publications/meeting-papers/south-east-london-area-prescribing-committee/Documents/Clinical%20guidelines%20and%20pathways/IBD%20pathways%20May%202017.pdf (accessed 13/07/2017) 4. Simponi (Golimumab) Summary of Product Characterisitics. Available onlione at: https://www.medicines.org.uk/emc/medicine/23766 (accessed 13/07/2017) 5. Simponi (Golimumab) – label (US FDA). Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125289s0064lbl.pdf (accessed 13/07/2017) 6. Sandborn W, Feagan B, Marano C et al. Subcutaneous golimumab induces clinical response and remission in patients with modeate to sever ulcerative colitis. Gastroenterology 2014 146 p85-95 7. Sandborn W, Feagan B, Marano C et al. Subcutaneous golimumab maintains clinical response in patients with moderate to severe ulcerative colitis. Gastroenterology 2014 146 p96-109 8. Simponi EPAR (variation) Jul 2013. Available online at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_Report_-_Variation/human/000992/WC500152828.pdf (accessed 14/07/2017) 9. MSD. Personal communication, June 2017.

NOTES:

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

b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation 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.**