DORSET MEDICINES ADVISORY GROUP

Commissioning statement on the use of infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy, NICE TA 329 (including a review of TA140 and TA262)

SUMMARY

- NHS Dorset Clinical Commissioning Group recommends the use of infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy in accordance with NICE TA 329.

BACKGROUND	Ulcerative colitis is a chronic condition in which inflammation develops in the large intestine. Its exact cause is unknown although hereditary, infectious and immunological factors have been proposed as possible causes. The modified Truelove and Witts severity index is widely used to classify the severity of ulcerative colitis. It defines moderate ulcerative colitis as more than 4 daily bowel movements but the patient is not systemically ill and severe ulcerative colitis as more than 6 bowel movements daily and the patient is also systemically ill (as shown by tachycardia, fever, anaemia or a raised erythrocyte sedimentation rate). Severe ulcerative colitis, as defined by the Truelove and Witts severity index, is potentially life threatening and normally requires hospitalisation and emergency care. This is aligned with the UK definition of 'acute severe ulcerative colitis', NICE TA 163 applies in this situation. TA 329 includes moderately to severely active ulcerative colitis but not acute severe ulcerative colitis (that is, severe ulcerative colitis according to the Truelove and Witts severity index). Treatment for ulcerative colitis aims to relieve symptoms during a flare-up and then to maintain remission. The management of moderately to severely active ulcerative colitis involves treatment with oral or topical aminosalicylates (sulfasalazine, mesalazine, balsalazide or olsalazine), or with corticosteroids if aminosalicylates are contraindicated or not tolerated. Oral corticosteroids or drugs that affect the immune response can also be added if the disease does not respond to aminosalicylates. Colectomy is a treatment option if symptoms are inadequately controlled or if the patient has a poor quality of life on conventional therapy.
RELEVANT NICE GUIDANCE	NICE TA 329 states: 1.1 Infliximab, adalimumab and golimumab are recommended, within their marketing authorisations, as options for treating moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies.

	Golimumab is recommended only if the company provides the 100 mg dose of golimumab at the same cost as the 50 mg dose, as agreed in the patient access scheme. The choice of treatment between infliximab, adalimumab or golimumab should be made on an individual basis after discussion between the responsible clinician and the patient about the advantages and disadvantages of the treatments available. This should take into consideration therapeutic need and whether or not the patient is likely to adhere to treatment. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose). 1.2 Infliximab is recommended, within its marketing authorisation, as an option for treating severely active ulcerative colitis in children and young people aged 6–17 years whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. 1.3 Infliximab, adalimumab or golimumab should be given as a planned course of treatment until treatment fails (including the need for surgery) or until 12 months after starting treatment, whichever is shorter. Specialists should then discuss the risks and benefits of continued treatment with the patient, and their parent or carer if appropriate: • They should continue treatment only if there is clear evidence of response as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. People who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. • They should consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People whose disease relapses after treatment is stopped should have the option to start treatment again.
FORMULARY STATUS	Red
PBR STATUS	Excluded from PbR tariff
COMMISSIONING IMPLICATIONS	This is an extension of the adult patient cohort who may receive treatment with these agents. As such this is a commissioning development which will require additional funding. Commissioned by NHS England for paediatric indications (where adult TA available).

RELEVANT CLINICAL WORKING GROUP	Commissioned by Planned and Specialist Clinical Working Group of CCG
PATIENT PATHWAY IMPLICATIONS	The use of biologics in patients with moderate to severe disease following conventional therapy provides patients with an additional therapeutic option before they may need to consider surgery.
SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS	Summarised in NICE TA 329: http://www.nice.org.uk/guidance/ta329/chapter/4-evidence-and-interpretation
ASSESSMENT OF COST IMPLICATIONS	The costing statement from NICE in 2015 suggests that for the Dorset population the drug cost implication may be up to £1.2million. Locally, the actual drug costs in 2020 are less than this figure due to patent expiries and an increase in biologic treatments available.
REFERENCES	http://www.nice.org.uk/guidance/ta329/chapter/1-guidance
Date Written	March 2015
Reviewed by Gastroenterology Working Group	July 2020
Approved at DMAG	September 2020
Next Review	September 2022 or before, in light of new information
Contact for this Policy	Gastroenterology Working Group Medicine.question@dorsetccg.nhs.uk