

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	25 th November 2014
Appraisal & Details	<p>Biologic drugs for treatment-refractory moderate to severely active ulcerative colitis in younger patients (to avoid colectomy)</p> <p>The Northern (NHS) Treatment Advisory Group considered an appraisal of adalimumab, golimumab, infliximab and vedolizumab for the treatment of moderate to severely active ulcerative colitis in younger patients to avoid a colectomy.</p>
Recommendation	<p>The Northern (NHS) Treatment Advisory Group does not recommend the use of biologic drugs for treatment refractory moderate to severely active ulcerative colitis in younger patients to avoid colectomy.</p> <p>The group did not support use due to an absence of supporting clinical and cost effectiveness data for this specific patient population. <i>However the group recognised that there may be certain individuals in exceptional circumstances for whom these treatments may be considered. Such cases must be referred via local individual funding request mechanisms.</i></p>
Clinical evidence summary	<p>In the NICE assessment, for those patients for whom it was an option, colectomy dominated all of the treatments under evaluation including conventional therapy. For patients for whom colectomy is not an option, adalimumab was likely to be the most cost-effective option; however the cost per QALY was above the level considered to represent cost-effective use of NHS resources. There is no signal to suggest that the newer agent vedolizumab may have any advantages over the TNF inhibitors.</p> <p>The potential impact of surgery on fertility or on younger patients has not been fully assessed as this data is not available. It is also not clear if treatment with biologic agents would just delay rather than negate the need for a colectomy.</p>
Safety	<p>Safety issues identified in the adalimumab, golimumab and infliximab trials were consistent with those previously identified for TNFi drugs. In the vedolizumab trial, adverse events were reported to be similar across treatment groups, with no important differences between placebo groups and vedolizumab-treated group.</p>
Patient Perspective	<p>Patients with UC that is poorly controlled despite optimum use of standard therapies and who are reluctant to or determined not to undergo surgery despite clinical advice currently have few options other than to tolerate their symptoms, the adverse effects of medication (possibly including long-term effects of exposure to corticosteroids), the increased risks of colorectal cancer and the regular endoscopic surveillance that this entails.</p>
Cost analysis summary	<p>NICE estimate that average costs of treatment for moderately to severely active UC with the TNF inhibitors (based on 8 weeks of induction therapy followed by 26 weeks of maintenance therapy) range from £4,622 (adalimumab) to £14,530 (golimumab for patients weighing \geq 80 kg).</p>
Financial impact PbR: Excluded	<p>Studies have suggested that almost 10% of patients with UC experience chronic continuous disease activity. This would equate to approximately 775 patients across the NTAG footprint. It would, therefore, cost approximately £3.5 million to treat 775 patients with adalimumab, the most cost-effective TNFi identified via the NICE appraisal process.</p> <p>The financial impact of this recommendation is expected to be nil.</p>