DORSET MEDICINES ADVISORY GROUP

COMMISSIONING STATEMENT ON THE USE OF GOLIMUMAB (SIMPONI®) FOR TREATING NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NICE TA497)

<table>
<tr><td colspan="2">SUMMARY
NHS Dorset Clinical Commissioning Group supports the use of Golimumab (Simponi®) for treating non-radiographic axial spondyloarthritis within NICE TA497.</td></tr>
<tr><td>BACKGROUND</td><td>Golimumab has a marketing authorisation in the UK for the treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

Golimumab is a human monoclonal antibody that forms high affinity, stable complexes with both the soluble and transmembrane bioactive forms of human TNF-α, which prevents the binding of TNF-α to its receptors.</td></tr>
<tr><td>RELEVANT NICE GUIDANCE</td><td>NICE TA 497 states:
1.1 Golimumab is recommended, within its marketing authorisation, as an option for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, nonsteroidal anti-inflammatory drugs.
1.2 If patients and their clinicians consider golimumab to be one of a range of suitable treatments, including adalimumab, etanercept and certolizumab pegol, the least expensive (taking into account administration costs and patient access schemes) should be chosen.
1.3 Assess the response to golimumab 12 weeks after the start of treatment. Continue treatment only if there is clear evidence of response, defined as:
a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and
a reduction in the spinal pain visual analogue scale (VAS) score by 2 cm or more.
1.4 When using BASDAI and spinal pain VAS scores, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the questionnaires, and make any adjustments they consider appropriate.</td></tr>
<tr><td>FORMULARY STATUS</td><td>Red</td></tr>
<tr><td>PBR STATUS</td><td>Excluded from PbR tariff</td></tr>
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COMMISSIONING IMPLICATIONS	Represents an additional option within the locally agreed pathway. NICE already recommends adalimumab, etanercept and certolizumab pegol for treating non-radiographic axial spondyloarthritis. An indirect comparison shows that golimumab provides similar overall health benefits to these drugs.
RELEVANT CLINICAL WORKING GROUP	Commissioned by MSK Right Care group/ Clinical Working Group of CCG
PATIENT PATHWAY IMPLICATIONS	Golimumab is recommended, within its marketing authorisation, as an option for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, nonsteroidal anti-inflammatory drugs If patients and their clinicians consider golimumab to be one of a range of suitable treatments, including adalimumab, etanercept and certolizumab pegol, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The local pathway will be updated to reflect the NICE TA.
SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS	Relevant evidence *considered* by NICE. The company presented a fixed-effects network meta-analysis, which compared the clinical effectiveness outcomes of golimumab with those of adalimumab, etanercept and certolizumab pegol (all assessed at 12 weeks). The network meta-analysis included the pivotal trial for golimumab (GO-AHEAD) and the same trials that were assessed for the NICE technology appraisal of adalimumab, etanercept and certolizumab pegol for the comparator treatments. The network meta-analysis showed a statistically significant benefit for golimumab compared with placebo for all outcomes (ASAS 20, ASAS 40 and BASDAI 50). The clinical effectiveness of golimumab was similar to adalimumab, etanercept and certolizumab pegol for Bath Ankylosing Spondylitis Functional Index (BASFI), BASDAI and Bath Ankylosing Spondylitis Metrology Index (BASMI) scores. Golimumab was statistically significantly superior to etanercept and adalimumab for change from baseline in BASFI score, etanercept for change from baseline in BASDAI score, and adalimumab for change from baseline in BASMI score. The ERG's view was that a random-effects network meta-analysis would have been more suitable for capturing variation between the trials. The point estimates in the ERG's random-effects network meta-analysis were similar to those in the company's submission, but had wider confidence intervals. The committee considered the impact of using 12-week outcomes for golimumab in the network meta-analysis (for consistency with the comparator treatments) compared with the 16-week outcomes reported in the GO-AHEAD trial. An additional analysis conducted by the ERG showed that the network meta-analysis results were robust regardless of whether 12- or 16-week outcomes were used. The committee concluded that the clinical effectiveness of golimumab was likely to be similar to those of the comparators

ASSESSMENT OF COST IMPLICATIONS	The list price of golimumab is £762.97 for a 50-mg pre-filled disposable injection and £1,525.94 for a 100-mg pre-filled disposable injection (excluding VAT; British national formulary [BNF] online [accessed September 2017]). Merck Sharp & Dohme has agreed a patient access scheme with the Department of Health. This will make the 100-mg dose of golimumab available to the NHS at the same cost as the 50-mg dose. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS. Assuming a patient has 50 mg every month, the annual cost of treatment with golimumab is estimated at £9,156. Because of the patient access scheme, this cost would remain the same for patients with a body weight greater than 100 kg whose disease does not respond adequately to 50 mg per month and who subsequently have monthly doses of 100 mg.NICE considered that NICE states "Golimumab meets the criteria for a successful cost comparison with the alternative agents. The committee therefore recommended golimumab as a cost-effective use of NHS resources for treating non-radiographic axial spondyloarthritis in adults." However, the manufacturer did not include biosimilar etanercept in this evaluation.
REFERENCES	NICE TA497 – Golimumab for treating non-radiographic axial spondyloarthritis SIMPONI® summary of product characteristics (accessed Jan 2018)
Date	January 2018
Review date	January 2020 or before in the light of new information
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