

Golimumab for treating non-radiographic axial spondyloarthritis

Technology appraisal guidance

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Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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1 Recommendations

- 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.

Why the committee made these recommendations

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. The acquisition costs of golimumab are the same as or less than those of adalimumab and etanercept, and in the longer term, would be similar to those of certolizumab pegol.

Because it has similar overall health benefits and costs to adalimumab, etanercept and certolizumab pegol, golimumab is recommended for treating non-radiographic axial

spondyloarthritis in the NHS.

2 The technology

Marketing authorisation

- 2.1 Golimumab ((Simponi, Merck Sharp & Dohme) is indicated 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)'.

Recommended dose and schedule

- 2.2 Golimumab is administered by subcutaneous injection. The recommended dosage is 50 mg once a month, on the same date each month. The summary of product characteristics recommends that continued golimumab therapy should be reconsidered if there is no evidence of therapeutic benefit within 12 to 14 weeks of starting treatment (that is, after 3 to 4 doses). For patients with a body weight greater than 100 kg whose disease does not respond adequately after 3 or 4 doses (50 mg each), the summary of product characteristics states that increasing the dosage of golimumab to 100 mg once a month may be considered. If there is still no evidence of therapeutic benefit after 3 to 4 additional doses of 100 mg, continued golimumab therapy should be reconsidered.

Price

- 2.3 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.

3 Committee discussion

The appraisal committee ([section 5](#)) considered evidence submitted by Merck Sharp & Dohme and a review of this submission by the evidence review group (ERG). See the [committee papers](#) for full details of the evidence.

Comparators

The comparison of golimumab with adalimumab, etanercept and certolizumab pegol is appropriate

3.1 [NICE has already produced technology appraisal guidance on adalimumab, etanercept and certolizumab pegol](#) for non-radiographic axial spondyloarthritis, which recommends that if more than one treatment is suitable then the least expensive treatment (taking into consideration costs and patient access schemes) should be used. The company presented a cost comparison case, in which it proposed that:

- the overall health benefits associated with golimumab are similar to or greater than those associated with adalimumab, etanercept and certolizumab pegol
- the acquisition cost of golimumab is similar to or lower than those associated with adalimumab, etanercept and certolizumab pegol.

The committee understood that treatment with adalimumab, etanercept and certolizumab pegol is standard for non-radiographic axial spondyloarthritis in the NHS. The committee concluded that it was appropriate for the company to compare golimumab with adalimumab, etanercept and certolizumab pegol.

Clinical effectiveness

Golimumab is clinically effective compared with placebo

3.2 The company presented results of the GO-AHEAD trial which compared golimumab with placebo in 198 people with non-radiographic axial

spondyloarthritis. Golimumab showed statistically significant improvement in all outcomes at 16 weeks (Assessment in Spondyloarthritis International Society [ASAS] 20, ASAS 40, Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] 50 and ASAS partial response) compared with placebo in the full analysis set and in the population with objective markers of active disease (abnormal MRI and/or elevated C-reactive protein [CRP] at baseline). The committee agreed that golimumab is a clinically effective treatment compared with placebo.

Golimumab has similar clinical effectiveness to adalimumab, etanercept and certolizumab pegol

3.3 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.

Adverse events

Adverse events with golimumab are likely to be similar to those with adalimumab, etanercept and certolizumab pegol

3.4 The adverse event profile for golimumab is well established and is similar to those of adalimumab, etanercept and certolizumab pegol. Patients receiving the 100-mg dose of golimumab may or may not have a greater risk of adverse events than those receiving the 50-mg dose. The committee concluded that the adverse events associated with golimumab were likely to be similar to those associated with adalimumab, etanercept and certolizumab pegol when treating non-radiographic axial spondyloarthritis.

Overall health benefits

Golimumab provides similar overall health benefits to adalimumab, etanercept and certolizumab pegol

3.5 The committee agreed that the network meta-analysis provided by the company was suitable for the purpose of decision-making. It considered the clinical effectiveness and adverse event profiles of golimumab to be similar to those of the comparator treatments and that, therefore, golimumab was likely to provide similar overall health benefits.

Resource use

It is appropriate to assume that all resource use and costs other than drug acquisition costs are identical across golimumab and the comparators

3.6 The company assumed that resource use and costs including drug administration, treatment initiation and monitoring, management of adverse events and long-term disease management are identical across golimumab and the comparators. The committee agreed with the company's assumption.

Cost comparison results

Golimumab meets the criteria for a successful cost comparison

3.7 The company presented results of a cost comparison analysis for the first and subsequent years of treatment. It showed that the acquisition cost of golimumab is the same as that of adalimumab in the first and subsequent years of treatment (£9,156), and lower than the cost of etanercept in the first and subsequent years (£9,295). The acquisition cost of certolizumab pegol in the first year (£5,720) is lower than that of golimumab because of a patient access scheme which provides the first 10 vials of certolizumab pegol at no cost, but its cost in subsequent years (£9,295) is higher than that of golimumab. The committee concluded that the criteria for a positive cost comparison were met, because:

- the overall health benefits of golimumab are similar to those of adalimumab, etanercept and certolizumab pegol
- the acquisition costs of golimumab are similar to or lower than those of adalimumab, etanercept and certolizumab pegol (taking into account that although certolizumab pegol is approximately half the cost of golimumab in the first year, the subsequent annual cost in the long term is higher than that of golimumab).

The committee therefore recommended golimumab as a cost-effective use of NHS resources for treating non-radiographic axial spondyloarthritis in adults.

4 Implementation

- 4.1 Section 7(6) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication. Because golimumab has been recommended through the fast track appraisal process, NHS England and commissioning groups have committed to providing funding to implement this guidance 30 days after publication.
- 4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal determination.
- 4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has non-radiographic axial spondyloarthritis and the doctor responsible for their care thinks that golimumab is the right treatment, it should be available for use, in line with NICE's recommendations.
- 4.4 The Department of Health and Merck, Sharp & Dohme have agreed that golimumab will be available to the NHS with a patient access scheme which makes it available with a discount. This will make the 100-mg dose of golimumab available to the NHS at the same cost as the 50-mg dose. Any enquiries from NHS organisations about the patient access scheme should be directed to keiron.hughes@merck.com.

5 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by [committee A](#).

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The [minutes of each appraisal committee meeting](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

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