National Institute for Health and Clinical Excellence

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PRESS RELEASE

NICE recommends new drug for rheumatoid arthritis

In **final** guidance, published today (22 June), the National Institute for Health and Clinical Excellence (NICE) recommends golimumab (Simponi) as an option for treating rheumatoid arthritis in specific circumstances where previous treatments haven't worked.

Golimumab in combination with methotrexate is recommended for adults whose rheumatoid arthritis has responded inadequately to conventional disease-modifying antirheumatic drugs (DMARDs) only, including methotrexate. In this case, golimumab is an option if it is used as described for other tumour necrosis factor (TNF) inhibitor treatments – adalimumab, etanercept and infliximab – covered by NICE technology appraisal 130, **and** the manufacturer provides the 100 mg dose of golimumab at the same cost as the 50 mg dose.

For adults whose rheumatoid arthritis has responded inadequately to other DMARDs, including a TNF inhibitor, golimumab in combination with methotrexate is also recommended as a treatment option. In this situation golimumab can be used only as described for other TNF inhibitor treatments in NICE technology appraisal guidance 195 (which covers the use of adalimumab, etanercept, infliximab, rituximab and abatacept after the failure of a TNF inhibitor), **and** the manufacturer provides the 100 mg dose of golimumab at the same cost as the 50 mg dose.

Dr Carole Longson, Health Technology Evaluation Centre Director at NICE said: "This final guidance sets out the circumstances where golimumab can now be offered by the NHS as a treatment option for people with rheumatoid arthritis for whom previous treatments have not worked. Rheumatoid arthritis treatments help to relieve pain, improve mobility and reduce the long-term damage often experienced by people with this condition. NICE has already recommended seven treatment

options for patients living with this very disabling disease; now golimumab is another option."

The NICE guidance 'Golimumab for the treatment of rheumatoid arthritis after failure of previous disease-modifying anti-rheumatic drugs' is available at: http://guidance.nice.org.uk/TA225 .

NICE has also published a piece of terminated guidance on golimumab for the treatment of rheumatoid arthritis in people who have not previously been treated with methotrexate. The manufacturer did not make an evidence submission so NICE is unable to recommend the use of golimumab for the treatment of methotrexate-naive rheumatoid arthritis in the NHS. When evidence is not submitted by the manufacturer, NICE issues advice to the NHS setting out the situation and explaining why the appraisal has been terminated, and highlights the standard national advice on local decision making when NICE guidance is not available.

Ends

Notes to Editors

About the guidance 'Golimumab for the treatment of rheumatoid arthritis after failure of previous disease-modifying anti-rheumatic drugs'

1. The NICE guidance 'Golimumab for the treatment of rheumatoid arthritis after failure of previous disease-modifying anti-rheumatic drugs' is available at http://guidance.nice.org.uk/TA225.
2. NICE currently recommends a range of treatments for rheumatoid arthritis: adalimumab, etanercept, infliximab, rituximab, abatacept, tocilizumab and certolizumab pegol. More information is at: http://www.nice.org.uk/newsroom/pressreleases/NICERecommendsTreatmentsForRheumatoidArthritis.jsp and http://guidance.nice.org.uk/TA186.
3. NICE technology appraisal guidance 130 recommends adalimumab, etanercept and infliximab as possible treatments for people with rheumatoid arthritis who
   - have already tried methotrexate and another disease-modifying anti-rheumatic drug (DMARD), and
   - Have 'active' rheumatoid arthritis, as assessed by a rheumatologist on two separate occasions. People who are treated with adalimumab, etanercept or infliximab should normally also be given methotrexate. If methotrexate does not suit them, they may be given adalimumab or etanercept on its own.

   Further information is at http://www.nice.org.uk/guidance/TA130.
4. NICE technology appraisal guidance 195 recommends rituximab in combination with methotrexate as an option for the treatment of adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor.
   - If rituximab is contraindicated or withdrawn, adalimumab, etanercept, infliximab and abatacept, each in combination with methotrexate, are now recommended as treatment options.

- If rituximab therapy cannot be given because methotrexate is contraindicated or withdrawn because of an adverse event, adalimumab and etanercept, each as monotherapy, are now recommended as treatment options.

For further information, visit: http://www.nice.org.uk/guidance/TA195.

5. The manufacturer of golimumab (Simponi) is Schering-Plough, part of Merck Sharp and Dohme.
6. Golimumab is a treatment for moderate to severe active rheumatoid arthritis in adults where the response to DMARD therapy including methotrexate has been inadequate. Golimumab is a human monoclonal antibody that prevents the binding of TNF to its receptors, thereby neutralising its activity. Golimumab is injected subcutaneously via a pre-filled injection pen. The recommended dosage is 50 mg given once a month, on the same date each month. The SPC states that in people who weigh more than 100 kg whose rheumatoid arthritis does not show an adequate clinical response after three or four doses, the dosage may be increased to 100 mg once a month. The cost of golimumab is £774.58 for a 50 mg vial (MIMS) and the annual cost is £9295. Costs may vary in different settings because of negotiated procurement discounts. The manufacturer has agreed a patient access scheme with the Department of Health, in which the 100 mg dose of golimumab will be available to the NHS at the same cost as the 50 mg dose.
7. NICE recently approved golimumab for psoriatic arthritis (guidance published 27 April, http://www.nice.org.uk/newsroom/pressreleases/GolimumabForPsoriaticArthritis.jsp) and is currently also appraising golimumab for use in treating ankylosing spondylitis (http://guidance.nice.org.uk/TA/Wave19/48).

About the terminated guidance 'Golimumab for the treatment of methotrexate-naive rheumatoid arthritis'

8. Golimumab is also licensed as a treatment for severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. The manufacturer of golimumab (Schering-Plough, part of Merck Sharpe and Dohme) was invited to submit evidence for this single technology appraisal (STA) in November 2010. The manufacturer didn't submit evidence because current clinical practice and existing NICE guidance does not support the use of any TNF-α inhibitor for patients with severe, active and progressive rheumatoid arthritis who were not previously treated with methotrexate. The manufacturer has indicated a willingness to submit evidence for this indication when clinical guidance indicates that this would be appropriate. NICE will review the position at any point if the manufacturer indicates that it wishes to make a full submission.

   If, after taking into account the reasons why the manufacturer did not make an evidence submission, NHS organisations still wish to consider the local use of golimumab for the treatment of methotrexate-naive rheumatoid arthritis, they should follow the advice set out in the Department of Health document, 'Good practice guidance on managing the introduction of new healthcare interventions and links to NICE technology appraisal guidance', (www.dh.gov.uk/en/DH_064983).

   The terminated guidance, 'Golimumab for the treatment of methotrexate-naive rheumatoid arthritis', is available at http://guidance.nice.org.uk/TA224 .

About NICE

9. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance and standards on the promotion of good health and the prevention and treatment of ill health
10. NICE produces guidance in three areas of health:

- **public health –** guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
- **health technologies –** guidance on the use of new and existing medicines, treatments, medical technologies (including devices and diagnostics) and procedures within the NHS
- **clinical practice –** guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

11. NICE produces standards for patient care:
    - **quality standards –** these reflect the very best in high quality patient care, to help healthcare practitioners and commissioners of care deliver excellent services
    - **Quality and Outcomes Framework –** NICE develops the clinical and health improvement indicators in the QOF, the Department of Health scheme which rewards GPs for how well they care for patients
12. NICE provides advice and support on putting NICE guidance and standards into practice through its **implementation** programme, and it collates and accredits high quality health guidance, research and information to help health professionals deliver the best patient care through **NHS Evidence**.