DORSET MEDICINES ADVISORY GROUP

COMMISSIONING STATEMENT ON THE USE OF TNF-ALFA INHIBITORS FOR ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYOLARTHRITIS (NICE TA383)

SUMMARY

NHS Dorset Clinical Commissioning Group commissions the use of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs, and infliximab only if treatment is started with the least expensive infliximab product, and adalimumab, certolizumab pegol and etanercept as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Both indications are in accordance with TA383

BACKGROUND	This guidance replaces NICE technology appraisal guidance on adalimumab, etanercept and infliximab for ankylosing spondylitis (TA143) and golimumab for the treatment of ankylosing spondylitis (TA233). Adalimumab, certolizumab pegol, etanercept, golimumab, and infliximab inhibit the activity of tumour necrosis factor alpha (TNF-α). Ankylosing spondylitis and non-radiographic axial spondyloarthritis are part of a group of clinically heterogeneous inflammatory rheumatologic diseases known as spondyloarthritis. Conventional therapy for ankylosing spondylitis and non-radiographic axial spondyloarthritis includes non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy. Tumour necrosis factor (TNF) -alpha inhibitors (adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) are typically used when the disease has not responded adequately to conventional therapy.
RELEVANT NICE GUIDANCE	NICE TA383 states: • Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, (NSAIDs). • Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. • Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, (NSAIDs). The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or

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<tr><td></td><td>infliximab treatment should be assessed 12 weeks after the start of treatment.

Treatment should only be continued 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) by 2 cm or more.

Treatment with another tumour necrosis factor (TNF) -alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response.

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, specialist use only</td></tr>
<tr><td>PBR STATUS</td><td>Excluded from tariff</td></tr>
<tr><td>COMMISSIONING IMPLICATIONS</td><td>Local commissioned pathway already in existence for patients with ankylosing spondylitis, to be reviewed in the light of this TA.</td></tr>
<tr><td>RELEVANT CLINICAL WORKING GROUP</td><td>Planned and specialist clinical working group</td></tr>
<tr><td>PATIENT PATHWAY IMPLICATIONS</td><td>Local commissioned pathway already in existence, to be reviewed in the light of this TA. Likely to result in minimal change.</td></tr>
<tr><td>SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS</td><td>Summarised in ‘consideration of the evidence’ section of TA383

The BNF lists nausea, abdominal pain, worsening heart failure, hypersensitivity reactions, fever, headache, depression, antibody formation (including lupus erythematosus-like syndrome), pruritus, injection-site reactions, and blood disorders (including anaemia, leucopenia, thrombocytopenia, pancytopenia, and aplastic anaemia) as side effects of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab.

See individual SPCs for further information</td></tr>
<tr><td>ASSESSMENT OF COST IMPLICATIONS</td><td>
<table>
<tr><th>Product</th><th>Form, cost, annual cost, PAS</th><th>Dose</th></tr>
<tr><td>Adalimumab (Humira®) 40mg/0.8ml solution for injection</td><td>2 pre-filled disposable device, pre-filled syringes, £704.28
£9156 per year Local negotiated procurement discounts</td><td>S/C injection
40 mg every 2 weeks</td></tr>
<tr><td>Golimumab (Simponi®) 50mg/0.5ml solution for injection</td><td>50-mg prefilled pen or prefilled syringe = £762.97
£9156 per year. PAS - 100-mg dose available to the NHS at the same cost as the 50-mg dose.</td><td>S/C injection
50 mg once a month. Adults < 100 kg may require 100 mg once a month</td></tr>
<tr><td>Certolizumab pegol (Cimzia®) Injection 200mg/1ml solution for</td><td>2 pre-filled syringes = £715.00
£10,368 for 1st year (or with the PAS £6793)</td><td>S/C injection
400 mg at weeks 0, 2 and 4 then 200 mg</td></tr>
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	injection		every 2 weeks or 400 mg every 4 weeks.
	Etanercept (Enbrel®) Injection 25-mg prefilled syringe; 50-mg prefilled pen/prefilled syringe	25-mg prefilled syringe = £89.38; 50-mg prefilled pen or prefilled syringe = £178.75. *£9296 per year. Costs may vary because of negotiated procurement discounts.*	S/C injection 25 mg twice weekly. Alternatively 50 mg once weekly.
	Infliximab (Remicade®/ Inflectra®/Remsima®) 100mg powder for concentrate for solution for infusion vials	Remicade® 100mg vial = £419.62 *£16,785 - £13,428 per year* Inflectra®/Remsima® 100mg vial = £377.66	IV infusion Adult: 5 mg/kg, at weeks 0, 2 and 4 then every 6–8 weeks.
REFERENCES	NICE TA 383 TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis. Joint Formulary Committee. British National Formulary. London: BMJ Group and Pharmaceutical Press; Electronic edition. Accessed via http://www.medicinescomplete.com/		
Date	February 2016		
Review date	February 2018 or before in the light of new information		
Contact	Katie Taylor, Pharmacist, NHS Dorset CCG		