### Extracts from Guidance and Guidelines for the Pharmacological Management of Axial SpA (AS or Nr-axSpA) in the Presence of Peripheral Disease and EAMs

The following extracts are for consideration in the context of patients with severe axial SpA (AS or nr-axSpA).

This is a summary of the available guidelines and guidance, please refer to the full guidelines for complete information.

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<td>• 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 EAMs. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen (Recommendation 1.3)</td>
<td>• EAMs and patient choice should be considered when selecting a TNF-alpha inhibitor (Recommendation for choice of drug)</td>
<td>• The treatment of patients with axial SpA should be individualised according to the current signs and symptoms of the disease (axial, peripheral, EAMs) and the patient characteristics including comorbidities and psychosocial factors (Recommendation 1)</td>
<td>• In adults with active AS despite treatment with NSAIDs: ◦ Do not recommend any particular TNF-alpha inhibitor as the preferred choice, except for patients with concomitant IBD or recurrent iritis (PICO 5)</td>
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<td>Peripheral disease</td>
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<td>• In adults with AS and IBD: ◦ Do not recommend any particular NSAID as the preferred choice to decrease the risk of worsening of IBD symptoms (PICO 31, conditional recommendation)</td>
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<td>• 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 EAMs. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen (Recommendation 1.3)</td>
<td>• Glucocorticoid injections directed to the local site of musculoskeletal inflammation may be considered (Recommendation 7)</td>
<td>• Strongly recommend using treatment with TNF-alpha inhibitor monoclonal antibody over treatment with etanercept (PICO 32)</td>
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<td>• Sulfasalazine may be considered in patients with peripheral arthritis (Recommendation 8)</td>
<td>• In adults with AS and acute iritis: ◦ Strongly recommend treatment by an ophthalmologist to decrease the severity, duration, or complications of episodes (PICO 27)</td>
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<td>• In adults with AS and recurrent iritis: ◦ Conditionally recommend prescription over no prescription of topical glucocorticoids for prompt at-home use in the event of eye symptoms to decrease the severity, duration of iritis episode (PICO 28)</td>
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<td>• In adults with AS and IBD: ◦ Conditionally recommend treatment with infliximab or adalimumab over treatment with etanercept to decrease recurrences of iritis (PICO 29 &amp; 30)</td>
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<td>• ACR guidance makes no specific recommendations for active AS and psoriasis (as an EAM)</td>
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This resource is intended for UK healthcare professionals only.

1. © NICE [2016] TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis. Available from https://www.nice.org.uk/guidance/TA383 All rights reserved. Subject to Notice of Rights. NICE guidance is prepared for the National Health Service in England. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this product/publication.


This Back in Focus resource was developed in collaboration with the Back in Focus Steering Committee, for UK healthcare professionals only, organised and funded by AbbVie Ltd.
Humira (Adalimumab)
Prescribing Information (PI)

Humira (adalimumab) 20 mg, 40 mg and 80 mg solution for injection in pre-filled syringe; 40 mg and 80 mg solution for injection in pre-filled pen.

Presentation and method of administration: Each single dose 0.2 ml or 0.4 ml pre-filled syringe and each single dose 0.4 ml pre-filled syringe or 0.4 ml pre-filled pen contains 40 mg or 80 mg of adalimumab for subcutaneous injection. Each single dose 0.8 ml pre-filled syringe contains 80 mg of adalimumab for subcutaneous injection.

Indications and Dosage: refer to SmPC for full information.

Humira treatment should be initiated and supervised by medical staff with experience in the diagnosis and treatment of chronic inflammatory conditions for which Humira is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Humira (adalimumab) in patients with uveitis. Consult with an appropriate specialist before initiation of treatment in the diagnosis of central or peripheral nervous system demyelinating disorders because of the risk of malignancy.

Reintroduction of Humira after treatment interruption: 40 mg every 8 weeks. EOC (persistent benefit and the risk of long-term side effects) should be considered if treatment is interrupted for at least 6 months after the last treatment. Humira should be reinitiated for severe active AS or axSpA, adults: If ≥ 30 kg: 40 mg dose EOW in combination with MTX. Optional 80 mg dose EOW. If insufficient response, consider an increase in dosing frequency to 40 mg every week or 80 mg EOW. Treatment beyond 8 months should be reconsidered if no clinical response in that time.

Pediatric Crohn’s disease (CD), 6 years and above: For moderately to severely active CD with inadequate response, to intolerance or to infliximab, re-treatment with adalimumab (Humira) and a corticosteroid and/or an immunomodulator. Dosage: 80 mg EOW. Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg dose at Week 0, followed by 80 mg at Week 2. Maintenance: 80 mg EOW. If insufficient response, consider an increase in dosing frequency to 40 mg every week or 80 mg EOW. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Discontinue treatment and refer for evaluation in patients with a history of these disorders. Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders.

Pediatric ulcerative colitis (UC), adults: For moderately to severely active UC with inadequate response, to intolerance or to infliximab, re-treatment with adalimumab (Humira) and a corticosteroid and/or an immunomodulator. Dosage: 80 mg EOW. Induction: 80 mg dose at Week 0, followed by 40 mg at Week 2. For a more rapid response: 160 mg dose at Week 0, followed by 80 mg at Week 2. Maintenance: 80 mg EOW. If insufficient response, consider an increase in dosing frequency to 40 mg every week or 80 mg EOW. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Discontinue treatment and refer for evaluation in patients with a history of these disorders. Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders.

Other opportunistic infections: Opportunistic infections were observed in patients receiving Humira. Stop treatment in patients with signs and symptoms suggestive of a new or worsening opportunistic infection. Consult with an appropriate specialist before initiation of treatment in the diagnosis of central or peripheral nervous system demyelinating disorders because of the risk of malignancy.

Hypersensitivity to the active substance or to any excipients (see SmPC). Active tuberculosis (TB) or latent TB infection should be excluded prior to initiating treatment with Humira. For patients with active TB, treatment with anti-TB medication should be initiated prior to initiation of Humira treatment.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AbbVie UK on PVVendor@abbvie.com.

AbbVie on UK_PVVendor@abbvie.com

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Additional information: For full prescribing information refer to SmPC. Marketing authorisation numbers EU/1/03/256/017, EU/1/03/256/020, EU/1/03/256/021.

List price: Humira 20 mg £392.14 (for 24 syringes); Humira 40 mg £704.28 (for 2 syringes or 2 pens); Humira 80 mg £704.28 (for 1 syringe or 1 pen).

Legal category: POM. Responsible person: Marketing authorisation holders: EU: EU/1/03/256/017, EU/1/03/256/020, EU/1/03/256/021.

Fertility, pregnancy and lactation: Humira should only be used during pregnancy if clearly needed. Women of childbearing potential and those under 25 years old should consider the use of contraception during treatment with Humira and continue its use for at least 5 months after the last treatment. No administration of live vaccines (e.g. BCG) to infants exposed to Humira in utero for 5 months after the last treatment. No administration of live vaccines (e.g. BCG) to patients treated with Humira for 5 months after the last treatment.

Very common ≥ 1/10:

Common 1/10 to < 1/10:

Other less common and rarely reported adverse reactions are listed in the SmPC.

Date of revision: PI: November 2018, P NHPictured4/4