

QS 33

NICE quality standard for rheumatoid arthritis (QS33)

THE | COMMISSIONING
review

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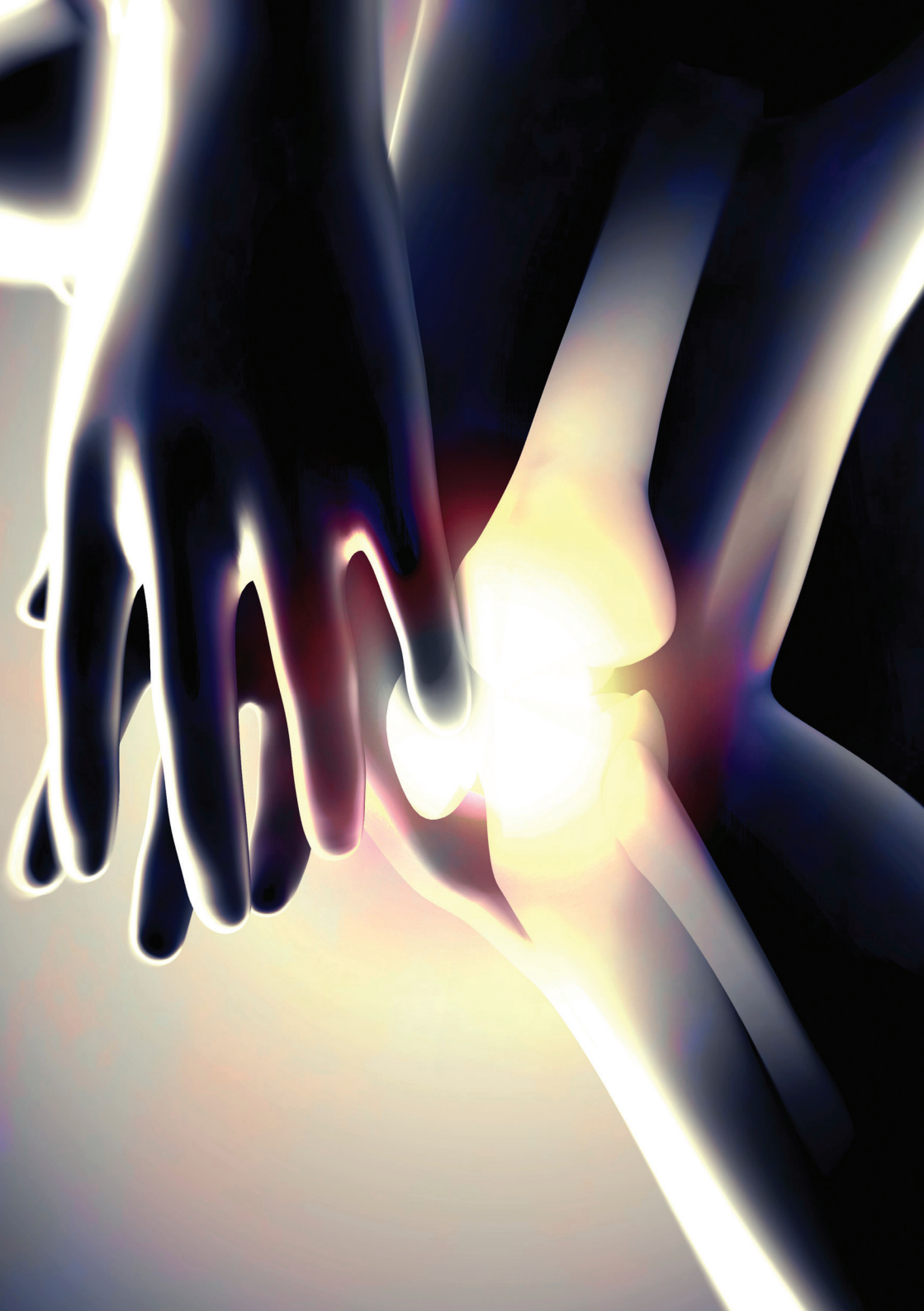
Bristol-Myers Squibb

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Introduction

In June 2013, NICE published a quality standard for the diagnosis and management of rheumatoid arthritis in adults (16 years and older). Rheumatoid arthritis is an inflammatory disease that typically affects the small joints of the hands and feet (but any joint can be affected). It is a systemic disease, which means that it does not just affect the musculoskeletal system but can affect the whole body, including the cardiovascular system, lungs, heart, eyes and small blood vessels (vasculitis). Medical management with drug therapy aims to relieve symptoms, modify the progress of the disease and the functional impairment associated with it, and reduce the risk of potential comorbidities.

There are approximately 350,000 people aged 16 years or older with rheumatoid arthritis in England alone, suggesting there may be as many as 422,000 people affected in the whole of the UK. Around 2.5 men and 5.4 women per 10,000 people develop rheumatoid arthritis per year, which translates into approximately 17,500 people developing the condition per year in England, and about 21,000 across the UK. The overall occurrence of rheumatoid arthritis is 2 to 4 times greater in women than men. Onset generally occurs between the ages of 40 and 60 years, but people of all ages can develop the disease. Rheumatoid arthritis can result in a wide range of complications, and has a significant personal impact for people with the disease and their families and carers. It also has an economic impact on the NHS and society in general. Approximately one-third of people with rheumatoid arthritis stop work because of the disease within 2 years of onset, and this prevalence increases thereafter. The total costs of rheumatoid arthritis in the UK, including indirect costs and work-related disability, have been estimated at around £2.4 billion per year.

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. They draw on existing guidance, which provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement. The quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following frameworks:

- NHS Outcomes Framework 2013–14¹
- Improving outcomes and supporting transparency: Part 1: a public health outcomes framework for England, 2013–2016²
- The Adult Social Care Outcomes Framework, 2013–14³

The table below shows the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

QUALITY STANDARD

Quality statements

The adult social care outcomes framework 2013-14

Domain 1: Enhancing quality of life for people with care and support needs.

- Social care related quality of life.
- People manage their own support as much as they wish, so that are in control of what, how and when support is delivered to match their needs.
- Proportion of people who use services who have control over their daily life.

NHS outcomes framework 2013-14

Domain 2: Enhancing quality of life for people with long-term conditions.

- Health related quality of life for people with long term conditions.
- Ensuring people feel supported to manage their condition.
- Proportion of people feeling supported to manage their condition.
- Improving functional ability in people with long-term conditions.
- Employment of people with long-term conditions.

Domain 4: Ensuring that people have a positive experience of care.

- Patient experience of primary care.
- GP services.
- Improving people's experience of outpatient care.
- Patient experience of outpatient services.

Public health outcomes framework 2013-16

Domain 1: Improving the wider determinants of health.

- Improvements against wider factors that affect health and wellbeing and health inequalities.
- Employment for those with a long-term health condition including those with a learning difficulty/disability or mental illness.

List of quality statements

Statement 1. People with suspected persistent synovitis affecting the small joints of the hands or feet, or more than one joint, are referred to a rheumatology service within 3 working days of presentation.

Statement 2. People with suspected persistent synovitis are assessed in a rheumatology service within 3 weeks of referral.

Statement 3. People with newly diagnosed rheumatoid arthritis are offered short-term glucocorticoids and a combination of disease-modifying anti-rheumatic drugs by a rheumatology service within 6 weeks of referral.

Statement 4. People with rheumatoid arthritis are offered educational and self-management activities within 1 month of diagnosis.

Statement 5. People who have active rheumatoid arthritis are offered monthly treatment escalation until the



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disease is controlled to an agreed low disease activity target.

Statement 6. People with rheumatoid arthritis and disease flares or possible drug related side effects receive advice within 1 working day of contacting the rheumatology service.

Statement 7. People with rheumatoid arthritis have a comprehensive annual review that is coordinated by the rheumatology service.

To implement the quality standard, please refer to the full standard on the NICE website at: <http://www.nice.org.uk/qs33>

The NICE quality standard for rheumatoid arthritis in adults is based on the following NICE guidance:

National Institute for Health and Clinical Excellence (2009) Rheumatoid arthritis. NICE clinical guideline 79 available at: <http://guidance.nice.org.uk/CG79>

References

1. NHS Outcomes Framework 2013–14 - www.gov.uk/government/publications/nhs-outcomes-framework-2013-to-2014
2. Improving outcomes and supporting transparency:
Part 1: a public health outcomes framework for England, 2013–2016 - www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationPolicyAndGuidanceDH_132358
3. The Adult Social Care Outcomes Framework, 2013–14 www.dh.gov.uk/health/2012/11/ascof1314

ORENCIA® (abatacept) PRESCRIBING INFORMATION. See Summary of Product Characteristics before prescribing. **PRESENTATION:** 250 mg powder for concentrate for solution for IV infusion containing 250 mg abatacept per vial. Each ml contains 25 mg of abatacept, after reconstitution; 125 mg pre-filled syringe for SC injection. Each pre-filled syringe contains 125 mg of abatacept in 1 ml. **INDICATION: Rheumatoid arthritis (IV infusion and SC pre-filled syringe):** Treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a Tumour Necrosis Factor (TNF) -alpha inhibitor. A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate. See SmPC.

Polyarticular Juvenile Idiopathic Arthritis (pJIA) {IV infusion only:} Orenzia 250 mg powder for concentrate for solution for infusion is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor. **DOSAGE and ADMINISTRATION:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. Orenzia 250 mg powder for concentrate for solution for IV infusion **Adults and elderly:** Patients weighing < 60 kg: 500 mg (2 vials). Patients weighing ≥ 60 kg to ≤ 100 kg: 750 mg (3 vials). Patients weighing > 100 kg: 1000 mg (4 vials). **Treatment of pJIA:** Paediatric patients, 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg paediatric patients weighing 75 kg or more: to be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, Orenzia should be given at 2 and 4 weeks, then every 4 weeks thereafter. **Children:** Use in children below 6 years of age is not recommended. Orenzia 125 mg solution for injection (SC pre-filled syringe) **Adults and elderly:** Treatment should be initiated with a loading dose using an intravenous infusion. Following this loading dose, the first 125 mg subcutaneous injection of Orenzia should be given within a day, then 125 mg subcutaneous injections once weekly. Patients who are unable to receive an infusion may initiate weekly injections of subcutaneous Orenzia without an intravenous loading dose. Patients transitioning from Orenzia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. **Children:** Administration in children below 18 years of age is not recommended. The continuation of treatment with abatacept should be reassessed if patients do not respond within 6 months. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections. **WARNINGS AND PRECAUTIONS: Allergic Reactions:** Caution in patients with a history of allergic reactions. Anaphylaxis or anaphylactoid reactions can occur and can be life threatening. Orenzia should be discontinued permanently if a patient develops serious allergic or anaphylactic reaction. **Infections:** Caution should be exercised when considering the use in patients with a history of frequent infections, or underlying conditions which may prompt to infection. Treatment with Orenzia should not be initiated with patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and Orenzia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to Orenzia. Co-administration of Orenzia with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). Orenzia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. **Malignancies:** The potential role of Orenzia in the development of malignancies is unknown, see SmPC. **Elderly:** Caution should be used when treating elderly patients due to a higher incidence of infections and malignancies in this patient group. **Autoimmune processes:** Theoretical risk of deterioration in autoimmune disease. **Immunisation:** Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orenzia. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orenzia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orenzia in combination with sulfasalazine, hydroxychloroquine or leflunomide. **PREGNANCY AND LACTATION:** Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment. **UNDESIRABLE EFFECTS:** In adult placebo-controlled trials the following adverse drug reactions were reported. Very Common (≥ 1/10): upper respiratory tract infection including tracheitis, nasopharyngitis. Common (≥ 1/100 to < 1/10): Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes infections (including herpes simplex, oral herpes and herpes zoster), rhinitis, pneumonia, influenza, leukopenia, headache, dizziness, paraesthesia, conjunctivitis, hypertension, flushing, blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), alopecia, pruritus, pain in extremity, fatigue, asthenia, injection site reactions. Uncommon (≥ 1/1,000 to < 1/100): Tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, pelvic inflammatory disease, basal cell and squamous cell carcinoma, skin papilloma, thrombocytopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, hot flush, vasculitis, blood pressure decreased, bronchospasm, wheezing, dyspnea, gastritis, increased tendency to bruise, dry skin, urticaria, psoriasis, erythema, hyperhidrosis, arthralgia, amenorrhea, menorrhagia, influenza like illness, weight increased. Rare (≥ 1/10,000 to < 1/1,000): Tuberculosis, bacteraemia, gastrointestinal infection, lymphoma, lung neoplasm, malignant, throat tightness. See SmPC for further details. **LEGAL CATEGORY:** POM. **MARKETING AUTHORISATION NUMBER AND BASIC NHS PRICE:** Orenzia 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack: £302.40 Orenzia 125 mg solution for injection - EU/1/07/389/008, 4 pre-filled syringes with needle guard: £1209.60. **MARKETING AUTHORISATION HOLDER:** Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH. Tel: 0800-731-1736. **DATE OF PREPARATION:** April 2013. Job No: 427UK13PRQ3910

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 Bristol-Myers Squibb Pharmaceuticals Ltd
 Medical Information on 0800 731 1736 or medical.information@bms.com.

ACHIEVE BALANCE FROM YOUR RA* BIOLOGIC THERAPY¹⁻³

EFFICACY SAFETY

 Bristol-Myers Squibb

 **ORENCIA**
(abatacept)

* RA: Rheumatoid arthritis. References: 1. Bristol-Myers Squibb. ORENCIA® (abatacept) SmPC 2012. 2. Weinblatt ME, Schiff M, Valente R, *et al. Arthritis Rheum.* 2013;65(1):28-38. 3. Thaler KJ, Gartlehner G, Kien C, *et al. Drug Class Review: Targeted Immune Modulators: Final Update 3 Report* [Internet]. Portland (OR): Oregon Health & Science University. 2012 Mar. 4. Choy EH. *Clin Exp Rheumatol.* 2009;27(3):510-518. 5. Moreland LW, Alten R, Van den Bosch F, *et al. Arthritis Rheum.* 2002;46(6):1470-1479. 6. Emery P. *Expert Opin Investig Drugs.* 2003;12(4):673-681. 7. Weisman MH, Durez P, Hallegua D, *et al. J Rheumatol.* 2006;33(11):2162-2166.
427UK13PR05315-01 Date of Preparation: September 2013 UKOC-138730-01

The first and only
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