NHS
Wakefield
Clinical Commissioning Group

Commissioning Statement

Treatment	Tocilizumab subcutaneous *RoActemra® (Roche)* 162mg/0.9ml subcutaneous injection in pre-filled syringe
For the treatment of	Rheumatoid Arthritis Active Systemic Juvenile Idiopathic Arthritis
Commissioning position	**Wakefield CCG commissions the use of subcutaneous (SC) tocilizumab in adults over the age of 18 years if the following conditions apply:** • **Route of administration is suitable, and the patient or their carer has been adequately trained in the administration technique.** • **The patient meets the specific clinical criteria set out below:** **Moderate – severe Rheumatoid Arthritis** ○ In combination with methotrexate in patients who have responded inadequately to 2 or more DMARDs (disease-modifying antirheumatic drugs), including methotrexate or TNF-inhibitor (tumour necrosis factor inhibitors) *OR* ○ The disease has responded inadequately to DMARDs and a TNF-inhibitor, and rituximab is contraindicated or not tolerated **AND** ○ Disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart **AND** ○ Procurement costs for subcutaneous tocilizumab are similar to intravenous tocilizumab (including patient access schemes) After initial response, treatment should be monitored no less frequently than 6-monthly intervals with assessment of DAS28. Treatment should be withdrawn if an adequate response (an improvement of 1.2 points or more in the DAS28 score) is not maintained. ***DAS28** = disease activity score (0 – 10); a composite score based on assessment of no. of swollen & tender joints (out of 28)* **Active Systemic Juvenile Idiopathic Arthritis (off label)**

	○ In patients whose disease has responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs), systemic corticosteroids and methotrexate **AND** ○ Procurement costs for subcutaneous tocilizumab are similar to intravenous tocilizumab (including patient access schemes) ○ Tocilizumab is **not routinely commissioned** for the treatment of systemic juvenile idiopathic arthritis whose disease continues to respond to methotrexate or who have not been treated with methotrexate After initial response, treatment should be monitored no less frequently than 6-monthly intervals. Treatment should be withdrawn if an adequate response is not maintained. The subcutaneous formulation of tocilizumab has been shown to be equivalent in efficacy and safety to the intravenous infusion route which is supported by current NICE Guidance. NHS England commissions treatment for children under the age of 18 years with Rheumatoid Arthritis and Juvenile Idiopathic Arthritis is **North Kirklees CCG / Greater Huddersfield CCG / Wakefield CCG / Calderdale CCG**
Date effective from	September 2014
Policy to be reviewed by	September 2017 (to be reviewed earlier if NICE issues more guidance at an earlier date)
Background information	**National Guidance:** NICE TA247 (Feb 2012) NICE recommends tocilizumab (only the intravenous (IV) route was considered in the guidance) in combination with methotrexate as an option for the treatment of **rheumatoid arthritis** in adults if: ○ it is used in accordance with the recommendations for other biological DMARDs in NICE TA130 (Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis) **or** ○ the disease has responded inadequately to DMARDs and a TNF inhibitor and the person cannot receive rituximab because of a contraindication to rituximab, or because rituximab is withdrawn because of an adverse event **and** ○ tocilizumab is used as described for TNF inhibitor treatments in NICE TA 195 (Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor) **or** ○ the disease has responded inadequately to one or more TNF inhibitor treatments and to rituximab **and** ○ the manufacturer provides tocilizumab with the discount agreed as part of the patient access scheme.

	NICE TA238 (Dec 2011) NICE recommends tocilizumab (only the IV route was considered in the guidance) for the treatment of systemic juvenile idiopathic arthritis *in children and young people aged 2 years and older* ○ whose disease has responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs), systemic corticosteroids and methotrexate **and** ○ the manufacturer makes tocilizumab available with the discount agreed as part of the patient access scheme. Tocilizumab is not recommended for the treatment of systemic juvenile idiopathic arthritis in children and young people aged 2 years and older whose disease continues to respond to methotrexate or who have not been treated with methotrexate. **Treatment pathway:** Tocilizumab SC would be used in the same position on the treatment pathway as tocilizumab IV, and in accordance with NICE Guidelines for biologic treatment of rheumatological conditions. IV treatment is normally given every four weeks as hospital day case, whereas subcutaneous tocilizumab is administered on a weekly basis. It is anticipated that most patients currently receiving tocilizumab via the intravenous (IV) infusion route will be switched to the subcutaneous (SC) route.
Summary of evidence/rationale	**Clinical effectiveness and Safety:** The SUMMACTA(1) study (a randomised, double-blind, parallel-group study of the safety and efficacy of subcutaneous tocilizumab versus intravenous tocilizumab, in combination with traditional DMARDs) looked at over 1200 patients with moderate to severe rheumatoid arthritis. It concluded that tocilizumab-SC 162 mg weekly demonstrated comparable efficacy to tocilizumab-IV 8 mg/kg. The safety profile of tocilizumab SC is consistent with the known and well-established safety profile of tocilizumab IV, with the exception of a higher incidence of ISR (injection site reactions), which were more common with tocilizumab SC administration. None of the ISRs were serious, and none required dose interruption or withdrawal. **Cost/resource impact:** The SC formulation is a fixed dose and cost, whereas the IV dose is dependent on body weight: • IV doses for patients weighing < 70kg are more cost-effective • SC doses are more cost-effective for patients weighing > 70kg (the majority of patients) ○ approx £400 per patient per annum saved The SC route will obviate the need for day care attendance • patients can administer their own doses

	• monthly hospital attendance/travel/car parking costs will be avoided • capacity within the rheumatology day care unit will be released Employing Homecare services will • reduce drug costs (saves aseptic preparation and VAT costs) • maintain the cold chain • ensure collection of clinical waste from patient homes **Equity of access** This policy is relevant to all patients whose disease activity fits the criteria above. *References:* *(1) A randomised, double-blind, parallel-group study of the safety and efficacy of subcutaneous tocilizumab versus intravenous tocilizumab in combination with traditional disease-modifying antirheumatic drugs in patients with moderate to severe rheumatoid arthritis (SUMMACTA study):* Burmester GR, et al. Ann Rheum Dis 2014;73:69–74.
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