Commissioning Statement

NHS Calderdale Clinical Commissioning Group

Treatment	**Tocilizumab** subcutaneous 162mg/0.9ml subcutaneous injection in pre-filled syringe or pen
For the treatment of	Rheumatoid arthritis
Commissioning position	Calderdale 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:** o has severe rheumatoid arthritis (DAS28 greater than 5.1) and tocilizumab SC is: o used in combination with methotrexate, or as monotherapy if patient cannot take methotrexate due to contra-indication or intolerance, in patients who have responded inadequately to intensive treatment with a combination of conventional disease-modifying anti-rheumatic drugs (DMARDs). ***OR*** o the disease has responded inadequately to DMARDs and a tumour necrosis factor (TNF)-inhibitor, and rituximab is not tolerated or contraindicated. **AND** o procurement costs for subcutaneous tocilizumab are similar to intravenous tocilizumab (including patient access schemes). Treatment is continued only if there is a moderate response using EULAR criteria 6 months after starting treatment. After an initial response within 6 months, treatment is withdrawn if moderate EULAR response is not maintained. ***DAS28*** *= disease activity score (0 – 10); a composite score based on assessment of no. of swollen & tender joints (out of 28)* ***EULAR*** *– European League Against Rheumatism* NHS England commissions treatment for children under the age of 18 years with rheumatoid arthritis and juvenile idiopathic arthritis.

Date effective from	March 2019
Policy to be reviewed by	March 2022 (to be reviewed earlier if NICE issues more guidance at an earlier date)
Background information	**National Guidance:** NICE TA247 (Feb 2012) has been partially replaced by NICE TA Guidance 375 (January 2016) on adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed. NICE TA247 states that tocilizumab (in combination with methotrexate) is an option for the treatment of **rheumatoid arthritis** in adults if: • 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 TA375 states that tocilizumab, alone or with methotrexate, is an option if: • the patient has severe rheumatoid arthritis (DAS28 greater than 5.1) **AND** • has responded inadequately to intensive treatment with a combination of conventional DMARDs **AND** • the manufacturer provides tocilizumab with the discount agreed as part of the patient access scheme. **Treatment pathway:** Tocilizumab SC would be used in the same position in 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 a hospital day case, whereas subcutaneous tocilizumab is administered on a weekly

	basis.
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 1,200 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 (1). **Cost/resource impact:** The SC formulation is a fixed dose and cost, whereas the IV dose is dependent on body weight. 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 patients' homes. **Equity of access** This policy is relevant to all patients whose disease activity fits the criteria above. **<u>References:</u>** (1) NICE. Tocilizumab for the treatment of rheumatoid arthritis TA247(February 2012) https://www.nice.org.uk/guidance/ta247 Accessed on: 18.05.2018 (2) NICE. Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed TA375 (January 2016) https://www.nice.org.uk/guidance/ta375

	Accessed on: 18.05.2018 (3) NICE. Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor (August 2010) https://www.nice.org.uk/guidance/ta195 Accessed on: 18.05.2018 (4) 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. https://www.ncbi.nlm.nih.gov/pubmed/23904473 Accessed 18.05.2018
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