DORSET MEDICINES ADVISORY GROUP

COMMISSIONING STATEMENT ON THE USE OF SARILUMAB (KEVZARA®) FOR TREATING MODERATE TO SEVERE RHEUMATOID ARTHRITIS (NICE TA485)

SUMMARY

- NHS Dorset Clinical Commissioning Group supports the use of Sarilumab (Kevzara®) for treating moderate to severe rheumatoid arthritis within NICE TA485.

BACKGROUND	Sarilumab has a marketing authorisation in the UK for the 'treatment of moderately to severely active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs. Sarilumab can be given as monotherapy or in combination with methotrexate. Sarilumab is a human monoclonal antibody (IgG1 subtype) that specifically binds to both soluble and membrane-bound IL-6 receptors (IL-6Rα), and inhibits IL-6-mediated signalling.
RELEVANT NICE GUIDANCE	NICE TA 485 states: 1.1 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs), only if: disease is severe (a disease activity score [DAS28] of more than 5.1) and the company provides sarilumab with the discount agreed in the patient access scheme. 1.2 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if: disease is severe (a DAS28 of more than 5.1) and they cannot have rituximab and the company provides sarilumab with the discount agreed in the patient access scheme. 1.3 Sarilumab, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to rituximab and at least 1 biological DMARD, only if: disease is severe (a DAS28 of more than 5.1) and the company provides sarilumab with the discount agreed in the patient access scheme. 1.4 Sarilumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in sections 1.1 and 1.2 are met. 1.5 Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.

FORMULARY STATUS	Red
PBR STATUS	Excluded from PbR tariff
COMMISSIONING IMPLICATIONS	Represents an additional option with a potential benefit compared to tocilizumab that sarilumab has a longer shelf-life when kept out of the fridge and therefore having a treatment that lasts 14 days rather than a number of hours is an important practical factor for people, especially those who travel. As an alternative to tocilizumab it may represent a more cost effective option.
RELEVANT CLINICAL WORKING GROUP	Commissioned by MSK Right Care group/Planned and Specialist Clinical Working Group of CCG
PATIENT PATHWAY IMPLICATIONS	Sarilumab's marketing authorisation and the company submission to NICE covers its use at 5 points in the treatment pathway, specifically in adults with: • moderate, active rheumatoid arthritis that has not responded adequately to conventional disease-modifying antirheumatic drugs (DMARDs) • severe, active rheumatoid arthritis that has not responded adequately to conventional DMARDs • severe, active rheumatoid arthritis that has not responded adequately to biological DMARDs • severe, active rheumatoid arthritis that has not responded adequately to biological DMARDs, when rituximab is contraindicated or withdrawn because of adverse events • severe, active rheumatoid arthritis that has not responded adequately to rituximab and biological DMARDs. These indications includes the use of sarilumab alone or with methotrexate.
SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS	Relevant evidence *considered* by NICE. MONARCH, a phase III trial which included people whose disease responded inadequately or who were intolerant to methotrexate. Sarilumab 200 mg plus placebo was given once every 2 weeks and the comparator was adalimumab plus placebo. The primary outcome was the change from baseline in disease activity score 28 – erythrocyte sedimentation rate (DAS28-ESR) at week 24. Sarilumab 200 mg administered as monotherapy was superior to adalimumab 40 mg monotherapy as demonstrated by the primary endpoint of change from baseline in 28-joint disease activity score (DAS28)-erythrocyte sedimentation rate (ESR) (LSM difference: −1.077; p <0.0001), with no unexpected safety signals Because the only direct evidence available on the comparative effectiveness of sarilumab and the biological DMARDs was with

	adalimumab, the company did a network meta-analyses for the NICE evaluation.
ASSESSMENT OF COST IMPLICATIONS	The recommended dose of sarilumab is 200 mg administered once every 2 weeks. A reduction in dose from 200 mg once every 2 weeks to 150 mg once every 2 weeks is recommended for management of neutropenia, thrombocytopenia and liver enzyme elevations. Sarilumab is administered subcutaneously using a pre-filled pen or syringe The list price per pre-filled pen or syringe of 150 mg or 200 mg of sarilumab is £456.13. The average cost per patient per year is estimated at £11,900 based on the list price. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of sarilumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS.
REFERENCES	NICE TA485 – Sarilumab for moderate to severe rheumatoid arthritis KEVZARA® summary of product characteristics (accessed 21/12/2017) BNF (accessed 21/12/2017)
Date	December 2017
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Contact for this Policy	Michelle Trevett, Senior Pharmacist, NHS Dorset CCG