

### ● MONITORING REQUIREMENTS

- ▶ Manufacturer advises monitor for signs and symptoms of infection during and after treatment.
- ▶ Manufacturer advises periodic skin examination in patients at increased risk for skin cancer.
- ▶ Manufacturer advises monitor liver function routinely; monitor lipid profile 8 weeks after treatment initiation.
- ▶ Manufacturer advises monitor lymphocytes at baseline and every 3 months thereafter; neutrophils and haemoglobin should be monitored at baseline, after 4 to 8 weeks of treatment and every 3 months thereafter.

- **DIRECTIONS FOR ADMINISTRATION** Manufacturer advises tablets may be crushed and taken with water.

### ● NATIONAL FUNDING/ACCESS DECISIONS

#### NICE decisions

- ▶ **Tofacitinib for moderate-to-severe rheumatoid arthritis (October 2017)** NICE TA480  
Tofacitinib (*Xeljanz*<sup>®</sup>), 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 DMARDs, only if:

- disease is severe (a disease activity score [DAS28] of more than 5.1), **and**
- the manufacturer provides tofacitinib with the discount agreed in the patient access scheme.

Tofacitinib (*Xeljanz*<sup>®</sup>), 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 manufacturer provides tofacitinib with the discount agreed in the patient access scheme.

Tofacitinib can be used as monotherapy for adults who cannot take methotrexate because it is contra-indicated or because of intolerance, when the above criteria are met.

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.

Patients whose treatment was started within the NHS before this guidance was published should have the option to continue treatment, without change to their funding arrangements, until they and their NHS clinician consider it appropriate to stop.

[www.nice.org.uk/guidance/ta480](http://www.nice.org.uk/guidance/ta480)

- ▶ **Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs (October 2018)** NICE TA543  
Tofacitinib (*Xeljanz*<sup>®</sup>), with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults, only if:

- it is used as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (TA199 recommendations 1.1 and 1.2), **or**
- the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has not responded within the first 12 weeks or has stopped responding after 12 weeks, **or**
- TNF-alpha inhibitors are contra-indicated but would otherwise be considered (as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis).

Tofacitinib is only recommended if the manufacturer provides it according to the commercial arrangement.

Assess the response to treatment after 12 weeks. Treatment should only be continued if there is clear evidence of response, defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria

(PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria. People whose disease has a Psoriasis Area and Severity Index (PASI) 75 response but whose PsARC response does not justify continuing treatment should be assessed by a dermatologist.

Patients whose treatment was started within the NHS before this guidance was published should have the option to continue treatment, without change to their funding arrangements, until they and their NHS clinician consider it appropriate to stop.

[www.nice.org.uk/guidance/ta543](http://www.nice.org.uk/guidance/ta543)

- ▶ **Tofacitinib for moderately to severely active ulcerative colitis (November 2018)** NICE TA547

Tofacitinib (*Xeljanz*<sup>®</sup>) is recommended, within its marketing authorisation, as an option for treating moderately to severely active ulcerative colitis in adults when conventional therapy or a biological agent cannot be tolerated or the disease has responded inadequately or lost response to treatment. It is recommended only if the manufacturer provides tofacitinib with the discount agreed in the commercial arrangement.

[www.nice.org.uk/guidance/ta547](http://www.nice.org.uk/guidance/ta547)

### Scottish Medicines Consortium (SMC) decisions

SMC No. 1298/18

The *Scottish Medicines Consortium* has advised (February 2018) that tofacitinib citrate (*Xeljanz*<sup>®</sup>) is accepted for restricted use within NHS Scotland in combination with methotrexate in adults with severe active rheumatoid arthritis (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs. In patients with severe disease inadequately controlled by a tumour necrosis factor (TNF) antagonist it may be used in patients ineligible to receive rituximab.

This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

SMC No. 5MC2116

The *Scottish Medicines Consortium* has advised (January 2019) that tofacitinib (*Xeljanz*<sup>®</sup>) is accepted for restricted use within NHS Scotland in combination with methotrexate for the treatment of adults with psoriatic arthritis whose disease has not responded adequately to at least two conventional DMARDs, given either alone or in combination. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

SMC No. 5MC2122

The *Scottish Medicines Consortium* has advised (February 2019) that tofacitinib (*Xeljanz*<sup>®</sup>) is accepted for use within NHS Scotland for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

#### Tablet

- ▶ *Xeljanz* (Pfizer Ltd) ▼

**Tofacitinib (as Tofacitinib citrate) 5 mg** *Xeljanz* 5mg tablets | 56 tablet [POM] £690.03 (Hospital only)

**Tofacitinib (as Tofacitinib citrate) 10 mg** *Xeljanz* 10mg tablets | 56 tablet [POM] £1,380.06 (Hospital only)