1. **Treatment & Condition**

Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs

2. **Associated appraisal body & Summary of ruling**

NICE Technology Appraisal guidance TA543 (October 2018)

Tofacitinib (Xeljanz®), 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 (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 contraindicated 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 company provides it according to the commercial arrangement.

Assess the response to tofacitinib after 12 weeks of treatment. Only continue treatment 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, to determine whether continuing treatment is appropriate based on skin response (as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis, recommendation 1.3).

When using the PsARC healthcare professionals should take into account any physical, sensory or learning disabilities or communication difficulties that could affect a person’s responses to components of the PsARC and make any adjustments they consider appropriate.

When using the PASI, healthcare professionals should take into account skin colour and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.

3. **Number of people in Northern Ireland expected to take up service/therapy**

Implementation of this guidance offers an additional treatment option for treating psoriatic arthritis. The guidance is not expected to have an impact on resources. This is because the technology is an option alongside current standard treatment
4. **Patient Access Scheme Availability**
   
   *(Yes/No)*

   The company (Pfizer) has a commercial arrangement. This makes tofacitinib available to the NHS with a discount. The size of the discount is commercial in confidence.

5. **Infrastructure Requirements**

   Any additional infrastructure costs associated with the introduction of this medicine for this indication will be dealt with as part of the routine commissioning process.

6. **Expected implementation period**

   There is no impediment to implementation of this guidance.

7. **Commissioning arrangements**

   This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost per case basis.

8. **Monitoring arrangements**

   The HSC Board has robust arrangements in place for the monitoring of all biologic therapies (patient numbers and waiting times), and this regime will be included within the routinely provided return.

   All monitoring returns for biologics are reviewed by the specialist services commissioning team.

9. **DoH (NI) Legislative/Policy Caveats**

   This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.