HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1.	**Treatment & Condition** Tofacitinib for moderate to severe rheumatoid arthritis
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA480 (October 2017) Tofacitinib, 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: • the disease is severe (a disease activity score [DAS28] of more than 5.1) and; • the company provides tofacitinib with the discount agreed in the patient access scheme Tofacitinib, 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 one biological DMARD, only if: • the disease is severe (a DAS28 of more than 5.1) and • the patient cannot have rituximab and; • the company 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 contraindicated or because of intolerance, when the criteria in the above two paragraphs are met. Continue treatment only if there is at least 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.
3.	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* Implementation of this guidance offers an additional treatment option for treating active rheumatoid arthritis in adults. The NICE resource impact statement indicates that the guidance is not expected to have an impact on resources. This is because the technology is an option alongside current standard treatment options.
4.	**Patient Access Scheme Availability** **(<u>Yes</u>/No)** The company (Pfizer) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of tofacitinib, with

	the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.
5.	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The recommended dose of tofacitinib is 5 mg twice daily. The list price of a 56 tablet pack of 5mg tofacitinib is £690 (excluding VAT). Hence, the annual cost per patient, at the list price, is £8,995 (excluding VAT).
5.2	**Infrastructure costs per annum** It is anticipated that infrastructure requirements will be minimal. Infrastructure requirements for the delivery of all biologics are reviewed annually as part of the routine commissioning arrangements for supporting growth in the provision of these therapies.
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.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the monthly 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 monthly.
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 applicable in their case.