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

Health and Social Care Board

1.	**Treatment & Condition** Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA715 (July 2021) 2.1 **Adalimumab, etanercept** and **infliximab**, all with methotrexate, are recommended as options for treating active rheumatoid arthritis in adults, only if: • intensive therapy with 2 or more conventional disease-modifying antirheumatic drugs (DMARDs) has not controlled the disease well enough and • disease is moderate (a disease activity score [DAS28] of 3.2 to 5.1) and • the companies provide adalimumab, etanercept and infliximab at the same or lower prices than those agreed with the Commercial Medicines Unit. 2.2 Adalimumab and etanercept can be used as monotherapy when methotrexate is contraindicated or not tolerated, when the criteria in 2.1 are met. 2.3 Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. If this initial response is not maintained, stop treatment. 2.4 If more than one treatment is suitable, start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may vary because of differences in how the drugs are used and treatment schedules. 2.5 Take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DAS28 and make any appropriate adjustments. 2.6 **Abatacept** with methotrexate is **not recommended**, within its marketing authorisation, for treating moderate active rheumatoid arthritis in adults when 1 or more DMARDs has not controlled the disease well enough
3.	**Number of people in Northern Ireland expected to take up service/therapy** The guidance is an update of the NICE technology appraisal guidance TA375 and it increases the population eligible for treatment to include people with ***moderate*** disease. Because there is no change in the guidance for people with severe disease, the resource impact assessment only considers costs associated with people with moderate disease. Until publication of this guidance, filgotinib was the only advanced treatment available for moderate rheumatoid arthritis. Filgotinib is a targeted disease modifying antirheumatic drug (tsDMARD). The technologies recommended for use

	in this guidance offer new advanced treatment options for moderate rheumatoid arthritis and are biologic DMARDs (bDMARDs). According to the Resource Impact Template that accompanies TA715, NICE estimate that, in Northern Ireland, 265 people with moderate RA will take up treatment with adalimumab, etanercept, infliximab or filgotinib by year 5.
4.	**Patient Access Scheme Availability** (**Yes**/No) The pharmaceutical companies responsible for these medicines have commercial arrangements in place. This makes these medicines available to the NHS with a discount. The size of these discounts is commercial in confidence.
5.	**Infrastructure Requirements** 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 immediate implementation for new patients.
7.	**Commissioning arrangements** These medicines will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-care (CPC) basis.
8.	**Monitoring arrangements** The HSC Board has robust arrangements in place for the quarterly monitoring of all biologic therapies (activity/cost 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 quarterly.
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. The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the act. The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the act.