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

Health and Social Care Board

1.	**Treatment & Condition** Upadacitinib (Rinvoq®) for treating severe rheumatoid arthritis.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA665 (December 2020) **2.1** Upadacitinib, 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 upadacitinib according to the commercial arrangement. **2.2** Upadacitinib, 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 upadacitinib according to the commercial arrangement. **2.3** Upadacitinib, 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 upadacitinib according to the commercial arrangement. **2.4** Upadacitinib can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in 2.1, 2.2 and 2.3 above are met. **2.5** 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, stop treatment if at least a moderate EULAR response is not maintained.
3.	**Number of people in Northern Ireland expected to take up service/therapy** Implementation of this guidance offers an additional treatment option for treating severe rheumatoid arthritis The NICE resource impact statement indicates that the guidance is not expected to have an impact on resources. This is because the technology is a further treatment option and is available at a similar price to the current treatment options.

4.	**Patient Access Scheme Availability** (**Yes**/No) The company (AbbVie) has a commercial arrangement. This makes upadacitinib available to the NHS with a discount. The size of the discount is commercial in confidence.
5.	**Infrastructure Requirements** 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 immediate implementation for new patients.
7.	**Commissioning arrangements** This drug will be formally commissioned by HSCB/PHA via the Specialist Services Commissioning Team.
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.