

<p>1.</p>	<p>Treatment & Condition</p> <p>Filgotinib for treating moderate to severe rheumatoid arthritis</p>
<p>2.</p>	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA676 (February 2021)</p> <p>2.1 Filgotinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with 2 or more conventional disease-modifying antirheumatic drugs (DMARDs), only if:</p> <ul style="list-style-type: none"> • disease is <u>moderate or severe</u> (a disease activity score [DAS28] of 3.2 or more) and • the company provides filgotinib according to the commercial arrangement. <p>2.2 Filgotinib, 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:</p> <ul style="list-style-type: none"> • disease <u>is severe</u> (a DAS28 of more than 5.1) and • they cannot have rituximab and • the company provides filgotinib according to the commercial arrangement. <p>2.3 Filgotinib, 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:</p> <ul style="list-style-type: none"> • disease <u>is severe</u> (a DAS28 of more than 5.1) and • the company provides filgotinib according to the commercial arrangement. <p>2.4 Filgotinib can be used as monotherapy when methotrexate is contraindicated or if people cannot tolerate it, when the criteria in sections 2.1, 2.2 or 2.3 are met.</p>
<p>3.</p>	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>A number of advanced therapies (biological and targeted synthetic DMARDs) are currently available to people with severe rheumatoid arthritis (RA) whose disease had responded inadequately to 2 or more conventional DMARDs, or 1 or more biological DMARD. Implementation of this guidance offers an additional treatment option for treating severe rheumatoid arthritis. As such, implementation of this guidance is not expected to have an impact on resources deployed to treat severe RA. This is because filgotinib is a further treatment option for people with severe RA and is available at a similar price to the current treatment options.</p>

4.	<p>Patient Access Scheme Availability (Yes/No)</p> <p>The company (Gilead) has a commercial arrangement in place. This makes filgotinib available to the NHS with a discount. The size of the discount is commercial in confidence.</p>
5.	<p>Infrastructure Requirements</p> <p>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.</p>
6.	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p>Commissioning arrangements</p> <p>This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-care (CPC) basis.</p>
8.	<p>Monitoring arrangements</p> <p>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.</p> <p>All monitoring returns for biologics are reviewed by the specialist services commissioning team quarterly.</p>
9.	<p>DoH (NI) Legislative/Policy Caveats</p> <p>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.</p> <p>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.</p>