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

Health and Social Care Board

1	**Treatment & Condition** Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed.
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance (TA375) January 2016. Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease‑modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in the above section are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* Each year in Northern Ireland the number of patients receiving biologic therapies for rheumatoid arthritis increases by around 500 across all five Trusts. At the end of March 2016, there were around 4,300 rheumatiod arthritis patients receiving biologic therapies. The projections for 2016/17 suggest that there will be a similar growth in patient numbers during the year.
4	**Patient Access Scheme availability** The manufacturers of certolizumab pegol, golimumab, abatacept and tocilizumab have agreed that these drugs will be available with a patient access scheme (PAS) discount. The level of discount is commercial in confidence.

5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Adalimumab is administered subcutaneously as a 40mg dose every other week. The net price of adalimumab is £352.14 per 40mg prefilled pen or prefilled syringe, or £352.14 per 40mg/0.8ml vial. Assuming 26 doses per year, the annual cost per patient of adalimumab is £9155.64. For adalimumab monotherapy, the dose may be increased up to 40 mg per week for people who have a decrease in response. Etanercept is administered subcutaneously as a 25mg dose twice weekly or alternatively as a 50mg dose every week. The net price of etanercept is £89.38 per 25mg prefilled syringe, or £178.75 per 50mg prefilled pen or prefilled syringe. Assuming 52 doses per year, the annual cost per patient of etanercept is £9295. Infliximab is administered as an intravenous infusion at a dose of 3mg/kg, with initial doses at 0, 2 and 6 weeks, and then every 8 weeks thereafter. For disease that has an inadequate response or loss of response after 12 weeks of treatment, consideration may be given to increasing the dose stepwise by approximately 1.5mg/kg up to a maximum of 7.5mg/kg every 8 weeks. Alternatively, administration of 3mg/kg as often as every 4 weeks may be considered. The NHS list price of originator infliximab (Remicade®) is £419.62 per 100mg vial. Assuming a weight per person of 70kg, vial wastage and 3 initial doses followed by treatment every 8 weeks, the cost in the first year is £10,070.88, and then £8812.02 per year. The NHS list price of infliximab biosimilars (Remsima®, Inflectra®) is £377.66 per 100mg vial. Assuming a weight per person of 70 kg, vial wastage, and 3 initial doses in the first year followed by treatment every 8 weeks, the cost in the first year is £9063.84, and then £7930.86 per patient per year. Certolizumab pegol is administered subcutaneously as initial 400mg doses at 0, 2 and 4 weeks, followed by maintenance doses of 200mg every 2 weeks. Alternatively, administration of 400mg every 4 weeks can be considered, once clinical response is confirmed. The net price of certolizumab pegol is £357.50 per 200mg prefilled syringe. Assuming 3 initial doses of 400 mg followed by maintenance doses every 2 weeks, the cost (without the patient access scheme) in the first year is £10,367.50, (or with the patient access scheme, £6793) and then £9295 per year. The company has agreed a patient access scheme with the Department of Health. In the scheme, the first 12 weeks of therapy (currently 10 pre-loaded syringes of 200mg each) with certolizumab pegol are free of charge. Golimumab is administered subcutaneously as a 50mg dose every month on the same day each month. For people weighing more than 100kg, a dose of 100mg may be considered if the disease has an inadequate clinical response after 3–4 doses. The net price of golimumab is £762.97 per 50mg prefilled pen or prefilled syringe. For people weighing less than 100kg and assuming 12 doses per year, the annual cost of golimumab is £9155.64 per patient. The company has agreed a patient access scheme with the Department of Health, in which the 100mg dose of golimumab will be available to the NHS at the same cost as the 50mg dose. Abatacept is given by subcutaneous injection at a dose of 125mg once weekly regardless of weight. Subcutaneous abatacept can be started with or without a single initial intravenous dose. The net price of abatacept for subcutaneous injection is £302.40 per 125mg prefilled syringe. Assuming a weight per person of 70kg, one

	intravenous loading dose followed by subcutaneous treatment doses every week, the cost (without the patient access scheme) of the initial intravenous dose is £907.20, and then £15,724.80 per patient per year. The company has agreed a patient access scheme with the Department of Health in which abatacept will be available with a discount. The level of discount is commercial in confidence. Tocilizumab is administered as a dose of 8mg/kg every 4 weeks. The net price of tocilizumab is £102.40 per 4ml (80mg) vial, £256.00 per 10ml (200mg) vial, or £512.00 per 20ml (400mg) vial. Assuming a weight per person of 70kg, vial wastage, and 13 doses each year, the annual cost per patient (without the patient access scheme) of tocilizumab is £9318.40. The company has agreed a patient access scheme with the Department of Health in which tocilizumab will be available with a discount. The level of discount is commercial in confidence.
5.2	**Infrastructure costs per patient per annum** The Resource Impact Report that accompanies TA375, estimates that the guidance will not result in a significant change in the pattern of resource use because it is considered that the recommendations are consistent with current clinical practice and existing NICE guidance. The HSC Board will work with Trusts to identify any infrastructure requirements.
5.3	**Current in year costs** The HSC Board financial plan for 2016/17 includes around £2.6m for the in-year costs of the projected growth of around 500 patients with rheumatoid arthritis on biologic treatments. The costs of implementing TA375 are included in these costs. NICE guidance indicates there will be no significant change in the pattern of resource use as the recommendations are considered to reflect current clinical practice and existing NICE guidance.
5.4	**Recurrent overall costs per annum** The projected recurrent costs of rheumatoid arthritis patients commenced on treatment in 2016/17 are £4.5m. The recurrent costs are included in the HSC Board financial plan for 2016/17. NICE believes that there will be no significant change in the level of resource required as a result of the guidance. This is because the recommendations are considered to reflect current clinical practice and existing NICE guidance.
5.5	**Opportunities for cost savings and how these will be secured** Cost savings are not anticipated.
6	**Expected implementation period** There is no barrier to immediate 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** HSCB currently reviews monthly monitoring information from all Trusts on all biologics used, number of patients treated, and number of patients waiting to commence treatment by banded waiting times. The Specialist Service Commissioning Team has a long established biologics sub group which meets on a bi-monthly basis. Service monitoring including the review of the monthly data returns is a key function of this group.
9	**DHSSPS Legislative/Policy Caveats** *(NICE guidance only)* 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.