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

Health and Social Care Board

1	**Treatment & Condition** Ustekinumab for treating active psoriatic arthritis
2	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance 340 (June 2015) Ustekinumab is recommended as an option, alone or in combination with methotrexate, for treating active psoriatic arthritis in adults only when: • treatment with tumour necrosis factor (TNF) alpha inhibitors is contraindicated but would otherwise be considered (as described in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis and golimumab for the treatment of psoriatic arthritis) or • the person has had treatment with 1 or more TNF–alpha inhibitors. Ustekinumab is recommended only if the company provides the 90 mg dose of ustekinumab for people who weigh more than 100 kg at the same cost as the 45 mg dose, as agreed in the patient access scheme. Ustekinumab treatment should be stopped if the person's psoriatic arthritis has not shown an adequate response using the Psoriatic Arthritis Response Criteria (PsARC) at 24 weeks. An adequate response is defined as an improvement in at least 2 of the 4 criteria (1 of which must be joint tenderness or swelling score), with no worsening in any of the 4 criteria. As recommended in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis, people whose disease has a Psoriasis Area and Severity Index (PASI) 75 response but whose PsARC response does not justify continuing treatment should be assessed by a dermatologist to determine whether continuing treatment is appropriate on the basis of skin response (see NICE technology appraisal guidance on ustekinumab for the treatment of adults with moderate to severe psoriasis). When using the Psoriatic Arthritis Response Criteria (PsARC) healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect a person's responses to components of the PsARC and make any adjustments they consider appropriate.
3	**Number of people in Northern Ireland expected to take up service/therapy**

	Population %	Population numbers
Adult population of Northern Ireland		1,457,676
Estimated prevalence of psoriatic arthritis	0.65%	9,475
People with psoriatic arthritis eligible for treatment with TNF-alpha inhibitors	2.4%	227
People who stop taking their initial TNF-alpha inhibitor	24%	55

	Therefore it is estimated that approximately 55 people will be affected by this decision each year. Ustekinumab is an additional treatment option alongside current standard treatment options of golimumab, adalimumab, etanercept and infliximab, which are available at a similar cost.
4	**Patient Access Scheme availability** Ustekinumab is recommended only if the company provides the 90 mg dose of ustekinumab for people who weigh more than 100 kg at the same cost as the 45 mg dose, as agreed in the patient access scheme.
5	**Costs**
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The list price for ustekinumab is £2,147 per 45-mg vial. The recommended dose of ustekinumab is an initial dose of 45 mg, followed by a dose 4 weeks later and further doses every 12 weeks thereafter. A dose of 90 mg may be used in people with a body weight over 100 kg. The company has agreed a patient access scheme with the Department of Health, in which the company provides the 90-mg dose (2 vials) at the same cost as the 45-mg dose (1 vial), for people who weigh more than 100 kg and need the higher dose. The average annual acquisition cost for ustekinumab 45 mg is £10,735 in the first year and £9,304 per year thereafter.
5.2	**Infrastructure costs per patient per annum** It is recognised from the NICE guidance that there may be some infrastructure requirements associated with the introduction of this therapy. The HSC Board does not anticipate that this will be a significant resource and will work with Trusts to identify how the requirements compare to current infrastructure needs.
5.3	**Current in year costs** Ustekinumab is an additional treatment option alongside current standard treatment options. Any 2015/16 costs should be addressed by the funding made available to Trusts for the growth in the use of biologic therapies. Based on approvals to the end of August and the expected yearly uptake, there will be approximately 30 patients in year at a cost of approximately £150k
5.4	**Recurrent overall costs per annum** The recurrent costs of implementing this TA for 55 patients will be approximately £0.5m The recurrent costs will be included in the HSC Board financial planning assumptions for predicted growth in this area from 2016/17.

5.5	**Opportunities for cost savings and how these will be secured** It is not anticipated that there will be cost savings associated with the introduction of this treatment.
6	**Expected implementation period** This therapy is currently available in Northern Ireland on a cost per case basis. It is expected that this therapy will be formally commissioned during the fourth quarter of 2015/16. The introduction will be subject to confirmation of the level of funding available and submission of an IPT by Trusts for the overall drug cost requirements for treating patients with psoriatic arthritis. For patients being considered for drug treatment for psoriatic arthritis, it is expected that ustekinumab be considered as an option for treatment alongside the currently available therapies.
7	**Commissioning arrangements** This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. The treatment will be commissioned through the existing Investment Proposal Templates and subsequent negotiation process as part of the overall commissioning arrangements for psoriatic arthritis. An investment proposal template will be completed by each Trust and the final profile of resources and monitoring arrangements agreed.
8	**Monitoring arrangements** The current monthly monitoring return from Trusts (SDR5) will be amended to include patients on treatment with Ustekinumab.
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.