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

Health and Social Care Board

1	**Treatment & Condition** Lenalidomide for treating myelodysplastic syndromes (MDS) associated with an isolated deletion 5q cytogenetic abnormality.
2	**Associated appraisal body & Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE Technology Appraisal Guidance 322 (September 2014) Lenalidomide is recommended as an option, within its marketing authorisation, that is for treating transfusion-dependent anaemia caused by low or intermediate-1 risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate, with the following condition: • The drug cost of lenalidomide (excluding any related costs) for people who remain on treatment for more than 26 cycles (each of 28 days; normally a period of 2 years) will be met by the company.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* NICE suggest that the number of new people eligible for treatment with lenalidomide in Northern Ireland is around 5 per year. Engagement with local clinicians responsible for treating this cohort of patients would suggest that based on a recent review of the number of cases of MDS with isolated del (5q) and the average number of new cases was approximately two per year for the whole of Northern Ireland. There is currently one patient with MDS with isolated del (5q) who is being treated with Lenalidomide.
4	**Patient Access Scheme availability** The company (Celgene) has agreed a standard patient access scheme with the Department of Health, in which the NHS pays for lenalidomide treatment for up to 26 monthly cycles. The company subsequently provides free of charge lenalidomide for those people who receive more than 26 monthly cycles.
5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The summary of product characteristics recommends a starting dose of 10 mg orally, once daily, on days 1 to 21 of repeated 28 day cycles, with dose reductions (5.0 mg, 2.5 mg or 2.5 mg every other day) to manage adverse events. Dosage is

	continued or modified based on clinical and laboratory findings. The cost of a 28-day cycle of treatment with 10 mg of lenalidomide (excluding VAT) is £3780. The annual cost per patient treated with 10mg lenalidomide daily would be £49,275. Costs will vary with dosage modifications.
5.2	**Infrastructure costs per patient per annum** Given the small number of patients likely to be treated with this regime, no significant infrastructure costs are anticipated.
5.3	**Current in year costs** The in-year costs of implementing this regimen will be met via the CPC mechanism.
5.4	**Recurrent overall costs per annum** *(including additional costs)* Based on the NICE estimate, the number of new people eligible for treatment with lenalidomide in Northern Ireland is around 5 per year. The cost impact for treating these people is estimated to be approximately £176,184 for year 1 and £93,415 for year 2. Based on local knowledge, the number of new people eligible for treatment with lenalidomide in Northern Ireland is around 2 per year. The cost impact for treating these people is estimated to be approximately £70,472 for year 1 and £37,366 for year 2.
5.5	**Opportunities for cost savings and how these will be secured** The main treatment option currently available for people with low- or intermediate-1-risk MDS associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate is best supportive care, which involves regular red blood cell transfusions. Lenalidomide is associated with a statistically significant improvement in transfusion independence. Thus cost savings are expected with patients needing fewer blood transfusions.
6	**Expected implementation period** There is no impediment to immediate implementation.
7	**Commissioning arrangements** Given the small number of patients likely to require this treatment and the inability to predict if the patients will be treated at the cancer centre or units, this regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team on a CPC basis.

8	**Monitoring arrangements** The HSCB IFR process will generate quarterly reports on the number of Cost Per Case applications which will be reviewed formally by the Specialist Services Commissioning Team on a quarterly basis. HSCB currently reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units. The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.
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.