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

1	**Treatment & Condition** *(Title)* Nintedanib for previously treated locally advanced, metastatic, or locally recurrent non-small-cell lung cancer.
2	**Associated appraisal body & Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE technology appraisal guidance 347 (July 2015) Nintedanib in combination with docetaxel is recommended, within its marketing authorisation, as an option for treating locally advanced, metastatic or locally recurrent non-small-cell lung cancer (NSCLC) of adenocarcinoma histology that has progressed after first-line chemotherapy, only if the company provides nintedanib with the discount agreed in the patient access scheme.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* By a pro rata calculation from the figures in the Costing Statement that accompanies TA347, it is estimated that the population eligible for treatment is approximately 24 patients per year in Northern Ireland and that 100% uptake is unlikely to be reached prior to yr 4. Local knowledge would suggest that likely patient numbers may be approximately 30 patients per year and that 100% uptake will be achieved by year 3. It is understood that this variance is due to the rising rate of adenocarcinoma in NI and therefore the number of patients receiving 2nd line therapy for adenocarcinoma is higher than the NICE estimate. HSCB would wish to commission this regime on the basis of the advice received by local clinicians. On this basis, patient numbers would be estimated as follows: **Yr 1** : 50% - 15 patients **Yr 2:** 75% - 23 patients **Yr 3:** 100% - 30 patients
4	**Patient Access Scheme availability** The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of nintedanib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.
5	**Costs** *(before PAS if applicable)*
5.1	**Drug cost per patient per annum (for new and prevalent cases)** The recommended dose of nintedanib in this condition is 200 mg twice daily. This can be reduced to 150 mg or 100 mg twice daily in patients who experience adverse events.

	Nintedanib costs £2151.10 for a 30-day pack of 150 mg or 100 mg capsules for oral use. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of nintedanib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.
5.2	**Infrastructure costs per patient per annum** As this is an oral treatment, infrastructure costs are not anticipated to be significant. The regional service impact process will assess the infrastructure costs for this regime with reference to the wider consideration of introducing the regime to include management of toxicity etc.
5.3	**Current in year costs** The additional cost per patient is about £3k. This will be funded as cases are approved on a cost per case basis.
5.4	**Recurrent overall costs per annum** *(including additional costs)* Based on local knowledge, it is estimated that the population eligible for treatment is about 30 patients per year in Northern Ireland. It is therefore estimated that the annual cost (without the discount from the patient access scheme) of implementing this technology for the population of Northern Ireland will be £103k.
5.5	**Opportunities for cost savings and how these will be secured** Cost-savings are not anticipated
6	**Expected implementation period** There is no impediment to immediate implementation.
7	**Commissioning arrangements** At present, this regime is commissioned on a cost per case basis. This was on the basis of a recommendation by NICE through a Final Appraisal Determination (FAD) in June 2015. HSCB will now move to identifying a recurrent funding source to support this regime.
8	**Monitoring arrangements** 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.