1. **Treatment & Condition**
   Lenvatinib and sorafenib for treating differentiated thyroid cancer after radioactive iodine

2. **Associated appraisal body & Summary of ruling**
   NICE Technology Appraisal guidance TA535 (August 2018)
   Lenvatinib (Lenvima®) and sorafenib (Nexavar®) are recommended as options for treating progressive, locally advanced or metastatic differentiated thyroid cancer (papillary, follicular or Hürthle cell) in adults whose disease does not respond to radioactive iodine, only if:
   - they have not had a tyrosine kinase inhibitor before or
   - they have had to stop taking a tyrosine kinase inhibitor within 3 months of starting it because of toxicity (specifically, toxicity that cannot be managed by dose delay or dose modification)

   Lenvatinib and sorafenib are recommended only if the companies provide them according to the commercial arrangements.

3. **Number of people in Northern Ireland expected to take up service/therapy**
   According to the Resource Impact Statement that accompanies NICE TA535, it is estimated that 5 people annually in Northern Ireland would be eligible for treatment with either lenvatinib or sorafenib in line with this guidance.

4. **Patient Access Scheme Availability**
   (Yes/No)
   The companies (Eisai and Bayer) each have a commercial arrangement that makes lenvatinib and sorafenib available to the NHS with a discount. The size of the discount is commercial in confidence.

5. **Infrastructure Requirements**
   Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process.

6. **Expected implementation period**
   There is no impediment to immediate implementation for new patients.

7. **Commissioning arrangements**
   This regimen will be formally commissioned by the HSCB/PHA via the Specialist
Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.

### 8. Monitoring arrangements

The HSCB cost per case process will generate quarterly reports on the number of applications.

HSCB currently routinely 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. DoH (NI) Legislative/Policy Caveats

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.