1. **Treatment & Condition** *(Title)*

   Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of NICE technology appraisal guidance 196)

2. **Associated appraisal body** *(NICE/SMC/Other) & Summary of ruling* *(to include indication, restrictions, other relevant information)*

   NICE Technology Appraisal Guidance 326 (November 2014)

   Imatinib is recommended as an option as adjuvant treatment for up to 3 years for adults who are at high risk of relapse after surgery for KIT (CD117)-positive gastrointestinal stromal tumours, as defined by the Miettinen 2006 criteria (based on tumour size, location and mitotic rate).

   Note: This guidance replaces NICE Technology Appraisal guidance 196 issued in August 2010.

3. **Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)**

   Based on the costing information provided by NICE, 6 patients would be eligible for treatment with adjuvant imatinib annually in Northern Ireland.
   
   (2011 UK Census figures prorate)

4. **Patient Access Scheme availability**

   Not applicable

5. **Costs (before PAS if applicable)**

5.1 **Drug cost per patient per annum (for new and prevalent cases)**

   Imatinib (Glivec®) is given orally as tablets. The recommended dose is 400 mg/day for the adjuvant treatment of adult patients following resection of GIST. Optimal treatment duration is not yet established. Length of treatment in the clinical trial supporting this indication was 36 months.

   The NICE costing statement indicates a cost per patient of:

<table>
<thead>
<tr>
<th>Year</th>
<th>£</th>
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<tbody>
<tr>
<td>1</td>
<td>16,000</td>
</tr>
<tr>
<td>2</td>
<td>9,000</td>
</tr>
<tr>
<td>3</td>
<td>5,000</td>
</tr>
<tr>
<td>Total</td>
<td>30,000</td>
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</tbody>
</table>
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

Year 1 costs approximately £49k (6 patients come on during course of year)

5.4 Recurrent overall costs per annum (including additional costs)

Recurrent costs by year 3 £180k, phased as follows:

<table>
<thead>
<tr>
<th>Year</th>
<th>£</th>
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<tbody>
<tr>
<td>1</td>
<td>99,000</td>
</tr>
<tr>
<td>2</td>
<td>152,000</td>
</tr>
<tr>
<td>3</td>
<td>180,000</td>
</tr>
</tbody>
</table>

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 currently commissioned on a cost per case basis patients with high risk GIST following surgical resection for a treatment duration of up to 3 years. This was on the basis of a legacy NICaN Drugs and Therapeutics Committee business case Therefore, as this regime is already being commissioned as per the NICE recommendation, HSCB will now move to routine commissioning of this regime.

The legacy business case suggested that 8 patients per year in Northern Ireland would be suitable for treatment with Imatinib following resection of high risk GIST. A review of cost per case applications to date would suggest that this projection is in excess of actual requirements and that the NICE recommendation is more in line with requirements.

On this basis, HSCB will routinely commission Imatininib for 5 patients per year in line with the NICE guidance from 1 April 2015.

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.