Service Notification in response to DHSSPS endorsed NICE Technology Appraisals

Health and Social Care Board

NICE TA 251: Dasatinib, nilotinib and standard-dose imatinib for the first-line treatment of chronic myeloid leukaemia (part review of technology appraisal guidance 70)

1	**Name of Commissioning Team** Specialist Services Commissioning Team
2	**Summary of NICE TA 251** This guidance should be read in conjunction with the NICE technology appraisal guidance 70 (TA70) Guidance on the use of imatinib for chronic myeloid leukaemia (published October 2003). This guidance partially updates NICE TA70. • Standard-dose imatinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive chronic myeloid leukaemia (CML). • Nilotinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive CML if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme. • Dasatinib is **not** recommended for the first-line treatment of chronic phase Philadelphia-chromosome-positive CML. • People currently receiving dasatinib that is not recommended according to this guidance should be able to continue treatment until they and their clinician consider it appropriate to stop.
3	**Number of people in Northern Ireland expected to take up service/therapy (new cases per year)** The number of patients in Northern Ireland likely to start treatment for CML is 10-12 annually. The current standard of care for CML first-line is standard-dose imatinib (as recommended in TA70).
4	**Outcomes**
4.1	**Additional life expectancy gain / progress improvement** Following the introduction of imatinib into routine practice a number of years ago, 5-year relative survival increased from 27.1% in 1990-1992 to 48.7% in 2002-2004.
4.2	**Reduction in morbidity** CML has three phases: 1. The initial chronic phase – duration may be several years, symptoms are mild and non-specific. Around 90% of CML cases are diagnosed in this

phase.

2. The accelerated phase – disease progression is more rapid and symptoms (bruising, bleeding, and infections) become more problematic.
3. The blast-crisis phase – when this phase is reached CML is often fatal within 3-6 months.

Drugs such as dasatinib, nilotinib or imatinib slow progression of the disease. They increase the time taken for patients to reach the blast-crisis phase.

4.3 Cost per patient per annum

Annual treatment costs[1]		
Drug	**Regimen**	**Annual cost per patient (£)**
Dasatinib	100mg once daily	30,477
Imatinib	400mg once daily	20,980
Nilotinib[2]	300mg twice daily	31,714

1. Drug acquisition costs were taken from the BNF 63
2. The cost of nilotinib is lower than that indicated as nilotinib is available at a discount.

The NICE Costing Statement that accompanies TA241indicates that implementation of this guidance "is unlikely to result in a significant change in resource use in the NHS. This is because dasatinib is not recommended and standard dose imatinib is already recommended by NICE. In addition, the manufacturer of nilotinib has agreed a patient access scheme with the Department of Health that makes nilotinib available with a discount. Details of the patient access scheme are commercial-in-confidence.

In summary, all eligible patients with this condition receive treatment with Imatinib. TA 251 now supports treatment with Nilotinib as an alternative to Imatinib. As Nilotinib is available within a discount scheme it is not anticipated that there will be any additional costs associated with the availability of this regime.

4.4 In year cost per patient per annum (for new and prevalent cases)

There are unlikely to be any in-year costs as patients are already being treated with imatinib. Nilotinib will be an alternative therapy to that which is already offered. The patient access scheme results in imatinib and nilotinib being priced similarly.

4.5 Any cost savings and how these will be secured

Implementation of this TA is unlikely to result in a significant change in resource use. Cost savings are not anticipated.

4.6 Recurrent overall cost

Not anticipated to generate any additional overall recurrent cost.

4.7	**Cost per QALY** In their cost effectiveness analyses, NICE used a model of four different scenarios in their economic analysis to work through the main disease phases and the different possible treatments in each phase. Nilotinib ICER per QALY gained = £26,000 to £36,000 Dasatinib ICER per QALY gained >£300,000 NICE noted that the ICER for nilotinib was on the border of cost effectiveness.
4.8	**Other treatments available for this condition** Interferon-alpha, hydroxycarbamide or best supportive care. For many people interferon-alpha or hydroxycarbamide are considered to be little better than best supportive care. Bone marrow stem cell transplantation could be used, although it carries high risks and is restricted to fit, younger patients.
4.9	**Readiness to implement** It is expected that treatment could be implemented without delay.
5	**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.
6	**What will Commissioning Team do to secure funding for the implementation of this TA including any proposals for disinvestment** Not applicable as no additional costs are expected.
7	**Commissioning arrangements** The Trust will be advised of the support of the HSCB in commissioning this regime and activity will be monitored via the existing chemotherapy pharmacy monitoring arrangements. As it is not anticipated that the change in regime will require any additional resource and is in keeping with NICE endorsed guidance the commissioning team would agree this as a priority development.
8	**Monitoring arrangements** Normally monitoring arrangements would involve production of an implementation plan within three months by the Trusts. However the number of patients who receive nilotinib instead of imatinib will be a sub set of the 10 to 12 patients who

	commence treatment annually. As the HSCB already has a system in place which provides quarterly monitoring information on all regimes in use across all Trusts, it is proposed to use this mechanism to track and monitor usage. The monitoring pro forma will be adapted to capture the specific information in respect of this regimen and this group of patients. SSCT has a long-established working relationship with NICaN D&T committee, which meets on a bi-monthly basis. Service monitoring including the review of the quarterly monitoring of data returns is a key function of this group.