Service Notification in response to DHSSPS endorsed NICE Technology Appraisals

Health and Social Care Board

NICE TA 241: Dasatinib, high dose imatinib and nilotinib for the treatment of imatinib-resistant chronic myeloid leukaemia (CML)

1	**Name of Commissioning Team** Specialist Services Commissioning Team
2	**Summary of NICE TA 241** This guidance should be read in conjunction with the NICE technology appraisal TA70 - Guidance on the use of imatinib for chronic myeloid leukaemia (published by NICE in October 2003). This guidance partially updates NICE TA 70. Nilotinib is recommended for the treatment of chronic or accelerated phase Philadelphia-chromosome-positive chronic myeloid leukaemia (CML) in adults: • whose CML is resistant to treatment with standard-dose imatinib; **or** • who have imatinib intolerance; **and** • if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme. Dasatinib is **not** recommended for the treatment of chronic, accelerated or blast-crisis phase CML in adults with imatinib intolerance or whose CML is resistant to treatment with standard-dose imatinib. High-dose imatinib is **not** recommended for the treatment of chronic, accelerated or blast-crisis phase Philadelphia-chromosome-positive CML that is resistant to standard-dose imatinib. People who are currently receiving dasatinib or high-dose imatinib for the treatment of CML should have the option to continue treatment until they and their clinicians consider it appropriate to stop. **As dasatinib and high dose imatinib are NOT RECOMMENDED, these regimes will not be routinely commissioned. Thus, this commissioning plan relates only to nilotinib.**
3	**Number of people in Northern Ireland expected to take up service/therapy (new cases per year)** There were an estimated 19 people newly diagnosed with CML in NI in 2009. It is anticipated that approximately 8-9 patients will be eligible for treatment with Nilotinib.

4	**Outcomes**
4.1	**Additional life expectancy gain / progress improvement** Nilotinib is better tolerated than imatinib, and other treatments. Nilotinib is also associated with a lower rate of progression and thus a reduction in cost of managing disease progression.
4.2	**Reduction in morbidity** As outlined above Nilotinib is associated with lower rate of progression. In the blast crisis phase of CML, life expectancy is short (about 3-6 months). The available evidence on life extension in the blast crisis phase is too weak and is not considered to be robust. A local Business Case is awaited via NICaN D and T committee.
4.3	**Cost per patient per annum** Local Business Case awaited via NICaN D and T committee, however resource implications are expected to be small as Nilotinib will replace Dasatinib and it is cheaper.
4.4	**In year cost per patient per annum (for new and prevalent cases)** As local Business Case is still awaited, costs are yet to be confirmed. However, it is anticipated that in year costs will be addressed via the offset in the use Dasatinib.
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. This is because the number of people involved is small and the treatment cost of currently used options as recommended in 'Guidance on the use of imatinib for chronic myeloid leukaemia' (TA70) is not significantly different to that of nilotinib. In addition, the manufacturer of nilotinib has agreed a patient access scheme with the DoH that makes Nilotinib available with a discount.
4.6	**Recurrent overall cost** To be confirmed on approval of local business case by NICaN D and T committee.
4.7	**Cost per QALY** NICE viewed the Novaritis' adjusted ICER of £22,800 per QALY gained as too optimistic, however agreed, with the patient access scheme in place, the use of nilotinib for the treatment of imatinib-resistant CML could be regarded as a cost effective use of NHS resources.

4.8	**Other treatments available for this condition** There are other treatment alternatives however with lesser outcomes.
4.9	**Readiness to implement** Awaiting designated business case from NICaN D and T committee.
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** The SSCT will review local business care once prioritised by NICaN D and T committee, to inform local requirements for implementation. A funding source with in specialist drugs allocation will then be identified to support this regime.
7	**Commissioning arrangements** The treatment will be commissioned on the approved business case and subsequent negotiation process as part of the over all commissioning arrangements for the full suite of NICE approved cancer therapies.
8	**Monitoring arrangements** Normally monitoring arrangements would involve production of an implementation plan within 3 months by the Trust. HSCB currently reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across cancer centre and other units. The monitoring pro forma will be adapted to capture information in respect of this regime and this group of patients. The Specialist Service Commissioning Team has a long established working relationship with NICaN Drugs and Therapeutics Committee, which meets on a monthly basis. Service monitoring including the review of the quarterly monitoring of data returns is a key function of this group.