NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology Appraisals and Guidance Information Services

Static List Review (SLR)

Title and TA publication number of static topic:	TA179 Sunitinib for the treatment of gastrointestinal stromal tumours
Final decision:	The guidance will remain on the 'static guidance list'

1. Publication date:	2009
2. Date added to static list:	January 2012
3. Date the last searches were run:	May 2011
4. Current guidance:	1.1 Sunitinib is recommended, within its licensed indication, as a treatment option for people with unresectable and/or metastatic malignant gastrointestinal stromal tumours if: • imatinib treatment has failed because of resistance or intolerance, and

	• the drug cost of sunitinib (excluding any related costs) for the first treatment cycle will be met by the manufacturer. 1.2 The use of sunitinib should be supervised by cancer specialists with experience in treating people with unresectable and/or metastatic malignant gastrointestinal stromal tumours after failure of imatinib treatment because of resistance or intolerance.
5. Research recommendations from original guidance:	6.1 A trial comparing 37.5 mg sunitinib with 800 mg imatinib is currently recruiting participants. *This is trial A6181112, also called NCT00372567. "The study prematurely discontinued on July 27, 2009 due to poor recruitment and operational futility as a result of changes in clinical practice. There were no safety or efficacy concerns regarding the study in the decision to terminate the trial." The trial record has some results.* 6.2 The Committee considered that rigorous data collection is needed on the life-extending benefits of sunitinib. *One phase IV study of 60 participants was found, completed in 2014, (NCT00793871) which had a secondary outcome measure of overall survival. The trial record has some results.* *There is an active registry, which started in 2013 and has an estimated primary completion date of December 2019: NCT00700258 "Star-tor - Registry For The Evaluation Of The Safety, Tolerability And Efficacy Of Temsirolimus (Torisel®), Sunitinib (Sutent®), And Axitnib (Inlyta®) For The Treatment Of Subjects With Advanced Renal Cell Carcinoma (Mrcc), Mantle Cell Lymphoma (Mcl), And Gastro-intestinal Stroma Tumor (Gist)". Overall survival is a primary outcome measure.*

6. Current cost of technology/ technologies:	The NHS indicative price in eBNF (May 17) for 28 capsules of 50mg is £3138.80 (the same as TA179).
7. Cost information from the TA (if available):	The recommended dosage is 50 mg once daily, for 4 consecutive weeks, followed by a 2-week rest period (that is, a complete treatment cycle of 6 weeks). The dose may be adjusted in steps of 12.5 mg according to tolerability (within the dose range 25–75 mg). The price for a pack of 50-mg capsules (28 per pack) is £3138.80 (excluding VAT; 'British national formulary' [BNF] edition 56). The manufacturer of sunitinib has agreed a patient access scheme with the Department of Health for GIST, in which the first treatment cycle of sunitinib is free to the NHS.
8. Alternative company(ies):	No relevant information was found.
9. Changes to the original indication:	There are no changes for the GIST component: TA179 - for the treatment of people with unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesilate treatment due to resistance or intolerance. Current eMC - for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.
10. New relevant trials:	There is a phase I/II trial in progress of sunitinib for people aged 6 – 18 with GIST: NCT01396148.
11. Relevant NICE guidance (published or in progress):	For the technology: • Neuroendocrine tumours (metastatic, unresectable) - everolimus, lutetium-177 and sunitinib. NICE technology appraisal guidance [ID858]. Publication expected July 2017

	• Renal cell carcinoma – sunitinib. NICE technology appraisal guidance [ID1076]. Publication expected April 2018 For the indication: • Regorafenib for treating advanced gastrointestinal stromal tumours. NICE technology appraisal guidance [ID1056]. Publication expected November 2017
12. Relevant safety issues:	Although there have been revisions of the SPC based on post marketing pharmacovigilance, no safety alerts were found. In November 2016 it was concluded that "Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Sutent in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity."
13. Any other additional relevant information or comments:	None
14. Technical Lead comments and recommendation:	There is limited new evidence available and one new trial in progress that includes children and young people (6 to 20 years) with GIST. This trial is due to complete in 2019. There have not been any changes to the cost of sunitinib (or anticipated changes to the PAS for this indication), therefore TA179 should remain on the static list.

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Appendix 1 – explanation of options

Options	Consequence	Selected – 'Yes/No'
The guidance will remain on the 'static guidance list'	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes
The decision to review the guidance will be deferred	NICE will consider whether a review is necessary at the specified date. NICE will actively monitor the evidence available to ascertain when a consideration of a review is more suitable.	No
A full consideration of a review will be carried out through the Review Proposal Process	There is evidence that could warrant a review of the guidance. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No
The guidance will be withdrawn	The guidance is no longer relevant and an update of the existing recommendations would not add value to the NHS. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No

The guidance should be updated in an on-going clinical guideline.	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No