NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

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

Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD)

Definitions:

Consultees – Organisations that accept an invitation to participate in the appraisal including the manufacturer or sponsor of the technology, national professional organisations, national patient organisations, the Department of Health and the Welsh Assembly Government and relevant NHS organisations in England. Consultee organisations are invited to submit evidence and/or statements and respond to consultations. They are also have right to appeal against the Final Appraisal Determination (FAD). Consultee organisations representing patients/carers and professionals can nominate clinical specialists and patient experts to present their personal views to the Appraisal Committee.

Clinical specialists and patient experts – Nominated specialists/experts have the opportunity to make comments on the ACD separately from the organisations that nominated them. They do not have the right of appeal against the FAD other than through the nominating organisation.

Commentators – Organisations that engage in the appraisal process but that are not asked to prepare an evidence submission or statement. They are invited to respond to consultations but, unlike consultees, they do not have the right of appeal against the FAD. These organisations include manufacturers of comparator technologies, NHS Quality Improvement Scotland, the relevant National Collaborating Centre (a group commissioned by the Institute to develop clinical guidelines), other related research groups where appropriate (for example, the Medical Research Council and National Cancer Research Institute); other groups (for example, the NHS Confederation, NHS Information Authority and NHS Purchasing and Supplies Agency, and the *British National Formulary*).

Public – Members of the public have the opportunity to comment on the ACD when it is posted on the Institute's web site 5 days after it is sent to consultees and commentators. These comments are usually presented to the appraisal committee in full, but may be summarised by the Institute secretariat – for example when many letters, emails and web site comments are received and recurring themes can be identified.

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comments received from consultees

Consultee	Comment	Response
Novartis	Novartis are pleased that the Committee have given a positive preliminary recommendation to approve imatinib as an adjuvant treatment for gastro-intestinal stromal tumours in patients at high-risk of disease recurrence. The ACD provides both a balanced assessment of the evidence submitted, and an accurate representation of the discussions from the first Appraisal Committee meeting.	Comment noted.
Royal College of Nursing	This is to inform you that the Royal College of Nursing have no comments to submit to inform on the ACD of the Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of TA196) [ID696] appraisal. Thank you for the opportunity to review this document.	Comment noted.
Joint response from Sarcoma UK and the British Sarcoma Group	**1. Has all of the relevant evidence been taken into account?** We are not aware of other evidence within the scope of the appraisal.	Comment noted.
Joint response from Sarcoma UK and the British Sarcoma Group	**2. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** We think the clinical and cost effectiveness summaries and conclusions are appropriate.	Comment noted.

Consultee	Comment	Response
Joint response from Sarcoma UK and the British Sarcoma Group	**3. Are the provisional recommendations sound and a suitable basis for guidance to the NHS?** The recommendations are a suitable base for guidance to the NHS. We believe that the adoption of the Meittenen & Lasota model for analysing patients at high risk is currently appropriate but further research is underway and may develop a more accurate future alternative. We would like to see the Committee's final recommendations include the suggestion that potential and advising commissioners consult a professional consensus meeting as a route forward for modifying the choice of risk assessment model. Sarcoma UK and the British Sarcoma Group would be prepared to organise and fund such a meeting to ensure its independence. We would take the advice of our recognised GIST specialist professional members on timing such a move	Comment noted. Guidance is developed after considering the current evidence base. However, please note that guidance may be reviewed before the suggested review time when there is significant new evidence that is likely to change the recommendations (as described in section 4.3 of the FAD). See 'Guide to the processes of technology appraisal' for further details' of how to make NICE aware of new evidence.
Joint response from Sarcoma UK and the British Sarcoma Group	**4. Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** None of which we are aware.	Comment noted.
Department of Health	Thank you for the opportunity to comment on the appraisal consultation document for the above single technology appraisal. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Comment noted.

Comments received from clinical specialists and patient experts

None

Comments received from commentators

None

Comments received from members of the public

None