Genomic Health

Genomic Health UK, Ltd.
[redacted]
Office: [redacted]
Fax: [redacted]
www.genomichealth.co.uk

12 November 2017

Via e-mail only to: donna.barnes@nice.org.uk, diagnostics@nice.org.uk

Donna Barnes
Project Manager – Diagnostics Assessment Programme
National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester M1 4BT

Re: Tumour Profiling Tests to Guide Adjuvant Chemotherapy Decisions in People with Breast Cancer (Update of DG 10) – Comments on the Diagnostic Assessment Report

Dear Donna,

Please find attached Genomic Health's comments on the Diagnostic Assessment Report (DAR).

We submit these comments to avoid missing the opportunity entirely to provide input into the assessment. However, for the reasons stated in Genomic Health's letters dated 3 November 2017, we have major concerns that the assessment procedure is fundamentally flawed and has indeed resulted in a DAR that is unbalanced and, for the reasons we explain in the comments, fails properly to take account of the purpose of tumour profiling tests.

To summarize our concerns:

- Authors of and contributors to the DAR have major conflicts of interest. One of the reference authors of the DAR was previously removed from the NICE Specialist Committee due to an acknowledged conflict of interest.
- The current assessment appears to be biased in favour of certain technologies under assessment.
- Principal data inputs for the cost-effectiveness model, identified in the Appendix to this letter, have not been disclosed to stakeholders, despite repeated requests, making it impossible for an effective and transparent consultation to take place.
- Several crucial assumptions used in the cost-effectiveness analysis are not supported by published evidence and have very limited clinical relevance.
- The time allowed for stakeholders to comment on the DAR was wholly insufficient given the volume and complexity of the report, rendering the consultation ineffective.

Based on the above considerations, we again respectfully request that NICE withdraw the current DAR altogether and commission a new assessment from independent and unbiased experts, which properly addresses the concerns identified above, in keeping with its obligations. To the extent that you are unwilling to agree to this request, we fully reserve our right to take such further action as may be appropriate.

Genomic Health UK, Ltd.
[redacted]
Office: [redacted]
Fax:
www.genomichealth.co.uk

We look forward to your prompt reply regarding this recommendation.

Yours truly

[redacted]

APPENDIX - INPUTS NECESSARY TO UNDERSTAND COST-EFFECTIVENESS MODEL
(LIST FROM TABLE 121 OF THE DAR)

- Risk classification probabilities for Oncotype DX, EPClin, Prosigna, IHC4+C
  - SOURCE: TransATAC bespoke data request.43 Analysed by subgroup (LN0 NPI≤3.4, LN0 NPI>3.4 and LN+ [1-3 nodes])
- Distant recurrence rates (10 years) conditional on test risk classification (Oncotype DX, EPClin, Prosigna, IHC4+C)
  - SOURCE: TransATAC bespoke data request.43 Analysed by subgroup (LN0 NPI≤3.4, LN0 NPI>3.4 and LN+ [1-3 nodes])
- Baseline probability of receiving adjuvant chemotherapy (current practice)
  - SOURCE: LN0 NPI≤3.4 subgroup NCRAS bespoke data request
  - SOURCE: LN0 NPI>3.4 subgroup: NHS England Access Scheme dataset
  - SOURCE: LN+ (1-3 nodes) subgroup: NCRAS bespoke data request
- Probability of receiving chemotherapy conditional on results of test (3-level tests – Oncotype DX, IHC4+C and Prosigna)
  - SOURCE: LN0 NPI>3.4 subgroup: NHS England Access Scheme dataset