Our Ref:
001559

NHS England and NHS Improvement
NHS England
Skipton House
80 London Road
London
SE1 6LH

NHS Genomic Laboratory Hubs
NHS Genomic Medicine Centres
Cc NHS Clinical Genetics Services
Genomics England Limited

26 March 2020

Dear Colleague

Re: Guidance to the NHS Genomic Medicine Service in response to COVID-19

We are writing to provide additional advice for the NHS Genomic Medicine Service to assist with the prioritisation of work.

During this period our priority is to ensure the continued delivery of urgent and essential genomic testing and to enable the release of genomic laboratory capacity to support COVID-19 testing where needed. In recognition of these pressures, we have worked with laboratory teams to develop a prioritisation for genomic testing services as per the table in Appendix 1.

Services should be directed to those groups of patients with urgent needs. This will include:

- pregnant women undergoing prenatal diagnosis;
- patients needing urgent advice on carrier testing relating to pregnancy examples include cystic fibrosis, thalassaemia;
- those faced with abnormal fetal scans; critically ill neonates and children requiring assessment and those for whom the rapid PICU/NICU WES is appropriate;
- conditions where rapid genetic testing may alter clinical treatment or decision making; and
- patients requiring urgent testing, for example BRCA testing, to inform chemotherapy options.

Medical, genetic counsellor, laboratory and nursing staff in genomic medicine have significant transferable skills and may be required to be redeployed to support or provide other clinical services.

For the period 1 April to 31 July, funding for genomic services will be managed in line with all other NHS services. During this period, NHS Trusts will be funded a block amount to cover all NHS services, this block includes genomic services.

The block figures will be based on the average monthly expenditure implied by the provider figures in the M9 Agreement of Balances return plus an uplift to recognise the impact of pay uplifts and other cost increases.

Arrangements for pass through drugs and devices costs (this includes 6+1 molecular diagnostics) will continue to operate as currently on a cost and volume basis.

A retrospective top-up will be provided to providers to reflect the difference between actual costs and the block funding.

For the Genomic Laboratory Hubs (GLH) and NHS Genomic Medicine Centres (NHS GMCs), this means that:

- There will be no separate arrangement for funding or contracting for services. All funding will be issued and managed through the national process; and
- Funding will flow directly to the provider delivering the service – i.e. Lead Contractors and Local Genomic Laboratories should record expenditure relating to the provision of their services only in their expenditure submissions to NHS England and NHS Improvement. All organisations will therefore be funded directly by NHS England and NHS Improvement through the block funding and top-up process.

Where services have changed since 2019/20 and changes in cost base are not included in the M9 Agreement of Balances submission, the top-up reconciliation process will address changes in cost, e.g. transfers of activity between laboratories and any other changes in a Trust's cost base as a consequence of changes in service provision.

For the process to operate fairly for all Trusts and ensure that Trusts are reimbursed for appropriate spend only, all GLH and NHS GMCs will require formal approval from NHS England and NHS Improvement for all service changes from 1 April 2020, including investment in GLH infrastructure.

We are continuing to work with colleagues to confirm the position regarding provider-to-provider billing for this period and we will provide an update once this has been confirmed.

We were scheduled to hold the Q4 GLH assurance meetings over the coming weeks. The Q4 assurance meetings will not take place as currently planned, and GLHs will not be required to complete any materials or updates at this time. GLHs can still request 30 minutes to 1 hour of the currently allocated slot to talk to us about your service or to ask any questions.

In areas where GLHs are in a position to continue with planned service changes (i.e. mobilisation of geographical boundaries/specialist testing/investment in laboratory infrastructure related to mobilisation of the NHS GMS) we will support you to do this but formal approval from NHS England and NHS Improvement will be required to ensure that resources are being managed appropriately during this period and that we can support the changes on a recurrent basis once the financial regime measures end.

Where GLHs have identified there is available capacity, testing of the informatics platform to support the ordering of whole genome sequencing will continue on a best endeavours basis. This position will be reviewed on an ongoing basis. We will work with Genomics England to make the testing process more accessible for remote working. At this stage, plans to begin User Acceptance Testing and enter phased clinical implementation have been paused.

The return of primary findings from the 100,000 Genomics Project should continue if there is capacity in the system to do so.

In recognition of the pressures on the service, the return of additional findings will not begin as planned from May 2020. When it is appropriate to do so, NHS England and NHS Improvement will work with representatives from the NHS GMCs and GLHs to develop a revised implementation timeline.

NHS England and NHS Improvement will work with Genomics England to develop a communication to notify the 100,000 Genomes Project participants.

The GMS Alliance provider selection process has been suspended at this time. In recognition of the significant work that has already been made to develop the submissions, all areas who wish to do so can still submit their draft proposals using the online portal. We will review and then provide any feedback on the plans so far.

In the meantime, the funding arrangements for the continuation of the NHS GMCs will be in line with all other NHS services, as set out above.

If you have any questions about this guidance, then please do contact us at england.genomics@nhs.net.

The response to COVID-19 is rapidly changing and we will provide updates to this guidance when required.

Finally, I would like to take this opportunity to thank all of you for your incredibly hard work. I wish you all well as you and your teams continue to go above and beyond to respond to the unprecedented challenge that COVID 19 is bringing and to help ensure genomic testing remains available to those who need it.

With our very best wishes.

Yours sincerely,

Professor Dame Sue Hill DBE FMedSci FRSB FRCP(Hon) FRCPath (Hon) FHCS
Chief Scientific Officer and SRO for Genomics
NHS England

Appendix 1 – Prioritisation of genomic testing during COVID-19 pandemic

Key to RAG rating			
Green	Continue		
Amber	Partial stop		
Red	Only continue if there is laboratory resource available over and above that required to support COVID-19 testing		
Cancer somatic genomic services	**RAG rating for pandemic**	**Rationale for RAG**	**Further details**
All clinically appropriate testing to inform diagnosis	Green	Urgent cancer service	
All clinically appropriate testing to inform therapy choice and patient management	Green	Urgent cancer service	
Urgent minimum residual disease monitoring e.g. acute leukaemias	Green	Urgent cancer service	
Other minimum residual disease monitoring e.g. non urgent chronic myeloid leukaemia	Amber	Cancer service	When clinically safe to do so, consider reducing frequency of testing or extending turnaround times
Chimerism testing for stem cell transplant monitoring	Amber	Cancer service	
Testing for myeloproliferative neoplasms	Amber	Cancer service	When clinically safe to do so, consider extending turnaround times
Rare disease genomic services	**RAG rating for pandemic**	**Rationale for RAG**	**Further details**
All prenatal diagnosis	Green	Urgent diagnostic service	
Urgent carrier testing relating to pregnancy; e.g. cystic fibrosis, thalassaemia etc.	Green	Urgent diagnostic service	
Testing to inform urgent management, transplantation or therapy e.g. neonatal diabetes and congenital hyperinsulinism testing, BRCA testing to inform chemotherapy options etc.	Green	Urgent diagnostic service	
Rapid exome sequencing for NICU/PICU	Green	Urgent diagnostic service	
Genomic testing to support New Born Screening Programme e.g. cystic fibrosis, MCADD	Green	Urgent diagnostic service	
All other rare disease testing	Red	Diagnostic service	Any samples received should be processed and stored appropriately for testing at a later date.