

# Updating the National Genomic Test Directory

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# Background

1. The NHS Genomic Medicine Service (GMS) was established in October 2018 with the aim of providing consistent and equitable care to the country's 55 million population.
2. A central feature of the NHS GMS is the National Genomic Test Directory (Test Directory), which identifies the full range of genomic tests – from whole genome sequencing (WGS) to tests for single genes and molecular markers – that are commissioned by the NHS in England. The Test Directory sets out the technology by which tests are available and the patients who will be eligible to access a test.
3. Seven NHS Genomic Laboratory Hubs (GLHs) are responsible for delivering the testing outlined in the Test Directory across England.
4. The first version of the Test Directory was published in October 2018. It was developed from the existing provision of genomic testing in the NHS and was subject to extensive review by national clinical and scientific experts, existing genetic laboratory staff, patient and public representatives and organisations, and organisations including the British Society for Genetic Medicine and the Joint Committee for Genomics in Medicine.
5. An update to the Test Directory was published in March 2019 to simplify the format and make minor updates to testing criteria. A further minor update was made in September 2020 to ensure the Test Directory reflects new priorities and new technologies and to make further minor updates as appropriate.
6. From 2021/22, to update the Test Directory on an annual basis, NHS England and NHS Improvement will implement a structured, evidence-based process that allows for a wide group of stakeholders to contribute, supported by the Genomics Clinical Reference Group (CRG) and genomics test evaluation working groups. Through this process NHS England and NHS Improvement will continue to consider the potential costs and benefits of expanding or altering the genomic testing which it commissions, ensuring that this testing is available for all patients for whom it would be of clinical benefit.

7. The approach to updating the Test Directory will be effective from December 2020. NHS England and NHS Improvement will therefore follow the approach outlined in this document to update the Test Directory for 2021/22, and the timings will be amended. Instead of following the annual timescales presented in this document, NHS England and NHS Improvement will implement a bespoke application window for the 2021/22 update (see annex 1).
8. From April 2021 onwards, NHS England and NHS Improvement will follow the full approach and annual timescales to inform the update to the Test Directory to be published for April 2022 and annually thereafter.
9. The annual update to the Test Directory will achieve the following three aims:
  1. To systematically review all available genomic testing by condition to inform the definitive repertoire of tests commissioned by the NHS in England and ensure that the best value is achieved;
  2. To support ongoing evaluation of new tests and technologies to enable access to the most effective and affordable technology now and in the future, including replacing tests where appropriate; and
  3. To assess clinical utility of genomic tests and to understand the implications of the genomic testing on the end to end patient pathway.
10. This document sets out:
  1. The clinical oversight of updates to the Test Directory;
  2. The process for updating the Test Directory in response to in-year policy decisions (e.g. medicines approvals);
  3. The annual process for evaluating new genomic tests and applications to amend the Test Directory;
  4. The governance arrangements to sign off updated versions of the Test Directory; and
  5. How the process for updating the Test Directory will be reviewed.

# Clinical Oversight

## Genomics Clinical Reference Group

1. Updates to the Test Directory are overseen by the Genomics CRG.
2. The Genomics CRG<sup>1</sup> has been convened to support implementation of the NHS GMS. Through its professional, patient and public representation, the Genomics CRG carries out the following functions:
  1. Advising on clinical policy and strategy for genomics, including implementation of Long Term Plan commitments and future developments of the NHS GMS;
  2. Overseeing a clear and transparent process for annual review of the Test Directory; and
  3. Supporting activities to raise awareness and embedding genomics across all clinical specialties.
3. The Genomics CRG meets three times per year and reviews applications that are received on an ongoing basis. The CRG will make recommendations to NHS England and NHS Improvement's Genomics Programme Board on updates to the Test Directory once per year in line with the annual process.

## Genomic test evaluation working groups

4. To provide clinical and scientific support to the Test Directory updates, NHS England and NHS Improvement has recruited to three expert test evaluation working groups. The working groups report into the Genomics CRG and cover rare and inherited disease, cancer and pharmacogenomics.
5. Membership of the genomic test evaluation working groups include scientists, clinicians, health economists, and patient and public representatives.

<sup>1</sup> <https://www.england.nhs.uk/commissioning/spec-services/npc-crg/>

# In year updates to the Test Directory

## Funding decisions

1. Updates to the Test Directory may be mandated in year by policy decisions, such as medicine approvals by the National Institute for Health and Care Excellence (NICE), where a genomic test forms part of the access criteria for a drug, or urgent policy statements issued by NHS England and NHS Improvement Specialised Commissioning<sup>2</sup>, where NHS England and NHS Improvement needs to urgently implement a commissioning policy involving genomic tests.
2. Drugs and other treatments recommended by NICE through its technology appraisal programmes<sup>3</sup> must be funded by the NHS through the 'funding requirement'. In most cases, when the funding requirement is applied the NHS makes the treatment available within 90 days.
3. NHS England and NHS Improvement work closely with NICE to ensure the NHS is prepared for potential implementation of new genomic tests, and corresponding updates to the Test Directory.

## Horizon scanning

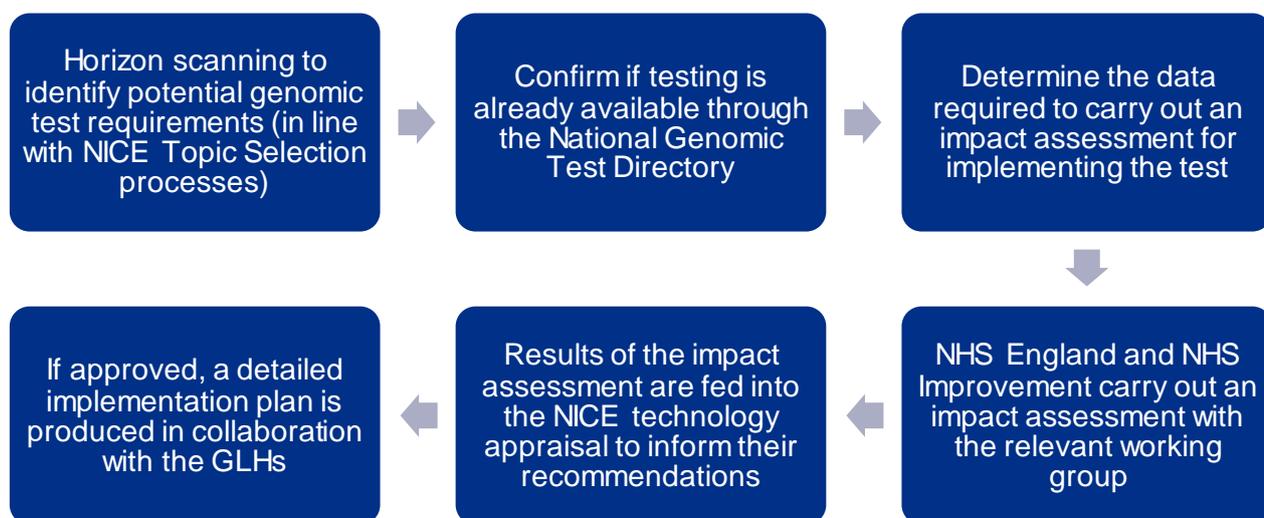
4. NHS England and NHS Improvement undertake ongoing horizon scanning to identify potential changes which may impact on or require a change to the Test Directory and take into consideration relevant policy changes and recommendations, for example, from NICE, European Medicine Agency (EMA, Medicines and Healthcare products Regulatory Agency (MHRA) and early access to medicines scheme (EAMS) recommendations.

<sup>2</sup> <https://www.england.nhs.uk/specialised-commissioning-document-library/policy-statements-urgent-policy-statements/>

<sup>3</sup> <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance>

- To support comprehensive horizon scanning, NHS England and NHS Improvement will work with stakeholders, including NICE, to gather the most up-to-date information. In addition, there is a notification form for stakeholders, including industry representatives, to notify NHS England and NHS Improvement of activity which may result in a proposed change to the Test Directory, e.g. the submission of a NICE Technology Appraisal by industry to NICE.

## Process for informing NICE Technology Appraisals



- NHS England and NHS Improvement are involved in the NICE Topic Selection process to identify medicines which may proceed through the NICE technology appraisal process and include a genomic test as part of the patient pathway. Where relevant medicines are identified, the impact of implementing the genomic testing element of the patient pathway will be included as part of the technology appraisal.
- In the first instance, NHS England and NHS Improvement will confirm whether the required genomic test is already listed within the Test Directory and therefore commissioned within England.
- If the genomic test is already commissioned, NHS England and NHS Improvement will work with the relevant test evaluation working group and the

GLHs to determine the impact which may occur as a result of the medicine being recommended, e.g. any increase in activity.

9. Where the relevant genomic testing is not already commissioned, NHS England and NHS Improvement will work with the genomic test evaluation working groups and the GLHs to determine the impact of implementing the testing if the medicine is recommended by NICE. Patient and Public Voice (PPV) representatives on the Genomics CRG and test evaluation working groups will ensure that the patient view is captured at this stage.
10. The outcome of the NHS England and NHS Improvement impact assessment should be submitted as per the requirements of the NICE technology appraisal guidance development process. If the impact assessment identifies that implementation within 90 days would be unachievable, an extension to the funding requirement may be requested as per the technology appraisal process<sup>3</sup>. In these cases, NHS England and NHS Improvement will set out how long the extension is requested for and detail plans for implementation during the extended period for agreement by NICE.
11. NHS England and NHS Improvement will work closely with GLHs to develop and follow a detailed implementation plan to ensure that testing is available within the appropriate time scale, following the NICE recommendation of the medicine for commissioning.
12. NHS England and NHS Improvement will not duplicate the robust clinical and scientific evidence review undertaken by the technology appraisal process but will review and impact assess recommendations in relation to the operational, workforce and financial implications of implementing the proposed amendment to the Test Directory.

## NICE Diagnostics Assessment Programme Guidance

13. Updates may also be required as a result of the publication of NICE Diagnostics Assessment Programme (DAP) guidance. The NICE DAP advise on the formulation of NICE's guidance on diagnostic technologies and matters related to the evaluation of diagnostic technologies. The DAP develop recommendations for the NHS in accordance with NICE's published methods and processes for developing guidance on diagnostic technologies.

14. DAP guidance is developed via the diagnostics assessment process<sup>4</sup>, involving professional and lay specialist committee members with expert knowledge of the subject under consideration. As part of the diagnostics assessment process, all guidance undergoes robust evidence review and stakeholder consultation.
15. NHS England and NHS Improvement will work with the NICE Diagnostics programme to ensure that relevant DAP guidance involving recommendations for genomics is further reviewed and impact assessed as part of the process for updates to the Test Directory.
16. NHS England and NHS Improvement will not duplicate the robust clinical and scientific evidence review undertaken by the DAP but will review and impact assess published DAP guidance in relation to the operational, workforce and financial implications of implementing the proposed amendment to the Test Directory as outlined in the process for updates to the Test Directory.

## Process for NHS England and NHS Improvement urgent policy statements



<sup>4</sup> <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-diagnostics-guidance>

17. In circumstances when NHS England and NHS Improvement needs to urgently implement a commissioning policy, a policy statement or urgent policy statement will be developed. Policy statements will go through the standard development process for all policies, including evidence review, impact analysis and decision by the Clinical Priorities Advisory Group (CPAG)<sup>5</sup>.
18. For any policies which involve or require genomic testing, the NHS England and NHS Improvement will be notified of the policy.
19. In the first instance, NHS England and NHS Improvement will confirm whether the required genomic test is already listed within the Test Directory and therefore commissioned within England.
20. If the genomic test is already commissioned, NHS England and NHS Improvement will work with the relevant test evaluation working group and the GLHs to determine the impact which may occur as a result of the introduction of the policy, for example any increase in activity.
21. Where the relevant genomic testing is not already commissioned, NHS England and NHS Improvement will work with the genomic test evaluation working groups and the GLHs to determine the impact of implementing the testing. PPV representatives on the Genomics CRG and test evaluation working groups will ensure that the patient view is captured at this stage. The outcome of the NHS England and NHS Improvement impact assessment will inform the NHS England and NHS Improvement policy implementation.
22. NHS England and NHS Improvement will work closely with GLHs to develop and follow a detailed implementation plan to ensure that testing is available within the appropriate time scale, following policy approval.

<sup>5</sup> <https://www.england.nhs.uk/commissioning/cpag/>

# Annual updates to the Test Directory

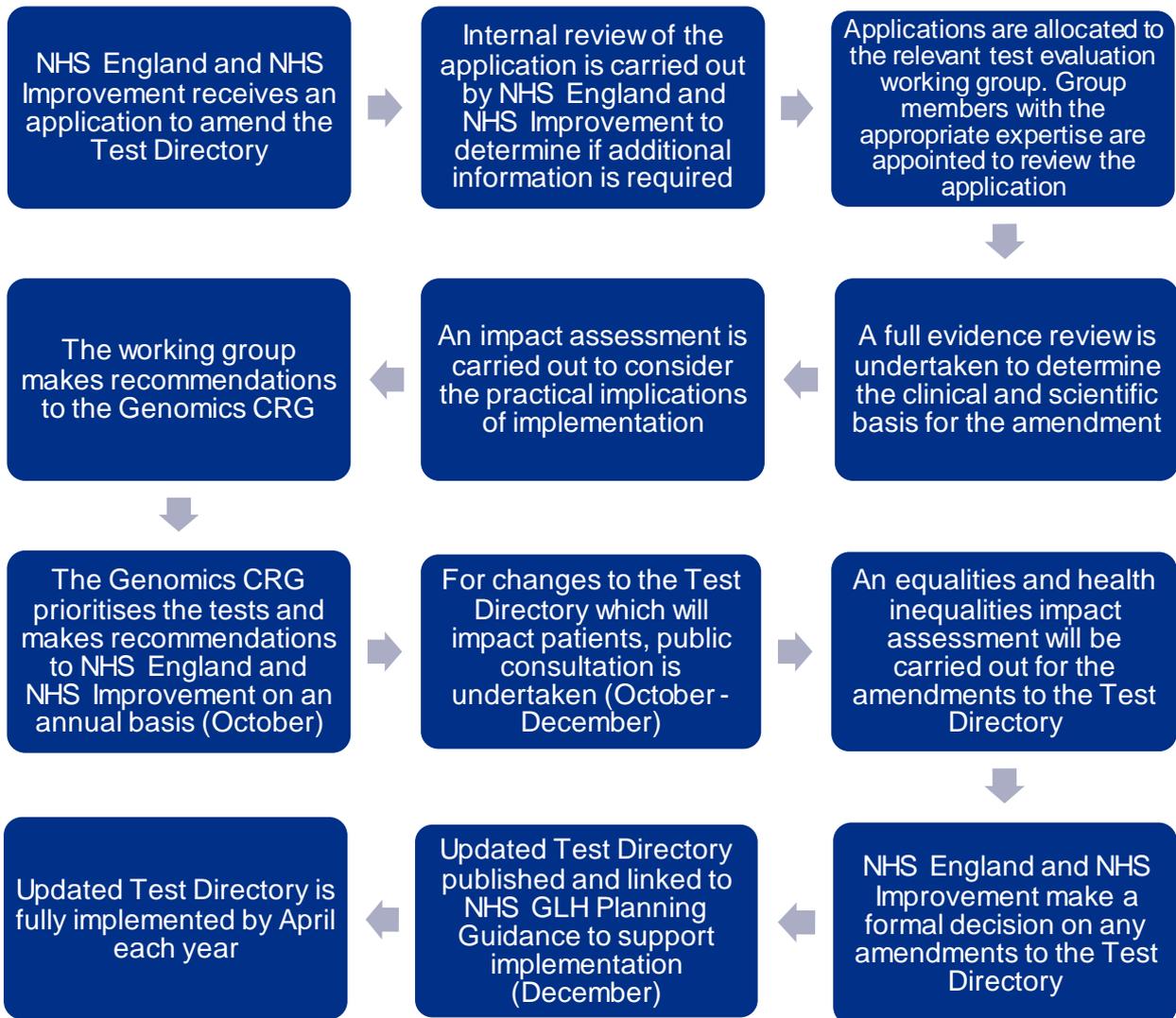
## Annual test evaluation

1. Any proposed amendments to the Test Directory which are not mandated by a policy decision will go through an annual evaluation process to ensure that NHS commissioning of genomic tests in England is supported by the most up-to-date scientific, clinical and economic evidence.
2. The test evaluation process is overseen by the Genomics CRG and supported by three genomic test evaluation working groups for cancer, rare and inherited disease and pharmacogenomics.
3. The test evaluation process is triggered upon receipt of an application to amend the Test Directory. Applications may seek to:
  1. Add new clinical indications to the Test Directory;
  2. Amend the eligibility criteria, requesting specialities, constituent tests, test targets or technologies for existing clinical indications;
  3. Amend the content of NHS GMS gene panels;
  4. Decommission a test where it is obsolete or no longer supported by the clinical scientific or economic evidence;
  5. Move a clinical indication to whole genome sequencing (once this technology becomes more widely available).
4. Applications are not restricted and will be accepted from any stakeholder that wishes to propose an amendment to the Test Directory.
5. The Test Directory will be updated on an annual basis. The annual update to the Test Directory will provide stability and clarity for the NHS GMS in implementing genomic testing and will be linked to the appropriate annual funding and commissioning processes.

6. Applications for amendments to the Test Directory must be submitted using the required application form to [ENGLAND.testevaluation@nhs.net](mailto:ENGLAND.testevaluation@nhs.net). Applications can be submitted at any point in the year.
7. Each year NHS England and NHS Improvement will publish the timelines for the annual process, which include defined “cut off” dates at which;
  1. Applications submitted prior to the date would be considered for the annual update to the Test Directory occurring within the annual cycle;
  2. Applications submitted after the date would be accepted but may not be able to be fully evaluated within the current annual cycle and would be progressed in line with the next available update to the Test Directory.
8. The setting of these dates allows for sufficient time to comprehensively evaluate the proposed updates and ensure stakeholders are involved and engaged in decision making.

## Process for annual updates

Please note that the process outlined in this section does not apply to proposed amendments to the content of NHS GMS virtual gene panels. For amendments to the content of NHS GMS virtual gene panels see “NHS GMS virtual gene panel content”.



9. NHS England and NHS Improvement will carry out initial review of all applications and will request further information or clarifications where necessary. The application will then be passed to the relevant genomics test evaluation working group who will carry out a full evidence review to assess the clinical and scientific basis for the proposed amendment. If the working group supports the proposed amendment at this stage, they will proceed to impact assessment.

10. An impact assessment will be carried out in collaboration with the GLHs to consider the operational, workforce and financial implications of implementing the proposed amendment to the Test Directory, including (but not limited to):
  1. Clinical utility and analytical validity;
  2. Cost effectiveness; and
  3. Workforce required to deliver testing.
11. Evidence reviews and impact assessments will take place between April and September each year.
12. An assessment will be carried out of the impact of proposed changes to the Test Directory on patients and the public in accordance with NHS England and NHS Improvement's legal duties to involve the public in decisions around healthcare commissioning. We will follow the principles and processes outlined in the Framework for patient and public participation in specialised commissioning<sup>6</sup>. Where a proposed amendment is identified to have a significant impact on patients, early engagement will be carried out with relevant patient groups to ensure that their views are taken into consideration in advance of recommendations being produced.
13. Based on the evidence review, impact assessment and early patient and public engagement, the test evaluation working group will make recommendations to the Genomics CRG to support or not to support the proposed amendment to the Test Directory.
14. The proposed amendments will be collated by NHS England and NHS Improvement and a formal decision through the appropriate governance will be made on the level of patient and public consultation which will be required to support prioritisation. Where amendments are limited to technical updates, a formal consultation may not be required. However, where the proposed amendments are likely to have a significant impact on patients, NHS England and NHS Improvement may consider a 30, 60, or 90-day public consultation.
15. The Genomics CRG will receive the outputs from any public consultation, along with the recommendations from the test evaluation working groups. After confirming that all processes have been followed correctly, the

<sup>6</sup> [www.england.nhs.uk/wp-content/uploads/2017/01/specialised-participation-frmwrk.pdf](http://www.england.nhs.uk/wp-content/uploads/2017/01/specialised-participation-frmwrk.pdf)

Genomics CRG will prioritise the proposals to develop recommendations on how the budget for updating the Test Directory should be spent.

16. The process for prioritising amendments to the Test Directory will be developed in collaboration with the Genomics CRG and will be based on the following principles:
  1. Proposed amendments are evaluated by test evaluation working groups based on across several domains (see annex 2 for further details of evaluation and scoring), including:
    - (1) Evidence of patient benefit and clinical utility, including if the amendment meets an unmet clinical need;
    - (2) Strength of scientific and clinical evidence supporting the amendment;
    - (3) Financial implication of implementation (cost saving, cost neutral, cost pressure, level of investment required);
    - (4) GLH resource required to implement the amendment and technical feasibility of implementation;
    - (5) Confidence that overall benefits to patients and/or clinical pathways would be realised upon implementation; and
    - (6) Alignment to an NHS England and NHS Improvement clinical priority area
  2. Evaluation and scoring informs test evaluation working groups holistic review, discussion and decision on each proposed amendment, allowing recommendations made; and
  3. Clear and transparent process for allocating NHS spending. Funding will be allocated based on the recommendations from the test evaluation working groups following evaluation.
17. An equalities and health inequalities impact assessment will be carried out for the prioritised amendments to the Test Directory and published annually with the updated Test Directory in accordance with NHS England and NHS Improvement's legal duties to give due regard or regard to addressing health inequalities and advancing equality of opportunity<sup>7</sup>.

<sup>7</sup> Health and Social Care Act 2012, section 13G - National Health Service Act 2006 as amended

18. The Genomics CRG will make recommendations to the Genomics Programme Board in November each year.
19. In December each year, the updated Test Directory will be published and linked to the NHS GLH Planning Guidance to support implementation of the amendments. The updated Test Directory will be fully implemented annually by April.

## NHS GMS virtual gene panel content

20. NHS England and NHS Improvement will undertake a quarterly review and update of NHS GMS virtual gene panel content. Proposed amendments to the content of NHS GMS virtual gene panels should be submitted as evidence reviews via the Genomics England PanelApp platform<sup>8</sup>.
21. NHS England and NHS Improvement will review all evidence reviews associated with NHS GMS virtual gene panels submitted via PanelApp on a quarterly basis, and each year will publish the dates at which quarterly reviews will take place.
22. This process does not apply to any NHS GMS panels which are not virtual (e.g. wet lab panels) as amendments to these will require further impact assessment as per the annual process. Any amendments to NHS GMS panels which are not virtual should be submitted via the relevant application form as per the annual process (see “Process for annual updates”).

## Fast track process

23. A “fast track” process for applications to amend the Test Directory is provided to support amendments that may be identified as requiring implementation more urgently than through the annual update to the Test Directory.
24. If a “fast track” amendment is identified, a “fast track” cover sheet to outline the rationale for requiring the amendment outside of the annual update should be completed and provided in addition to the required application form for the proposal of the amendment.

<sup>8</sup> <https://panelapp.genomicsengland.co.uk>

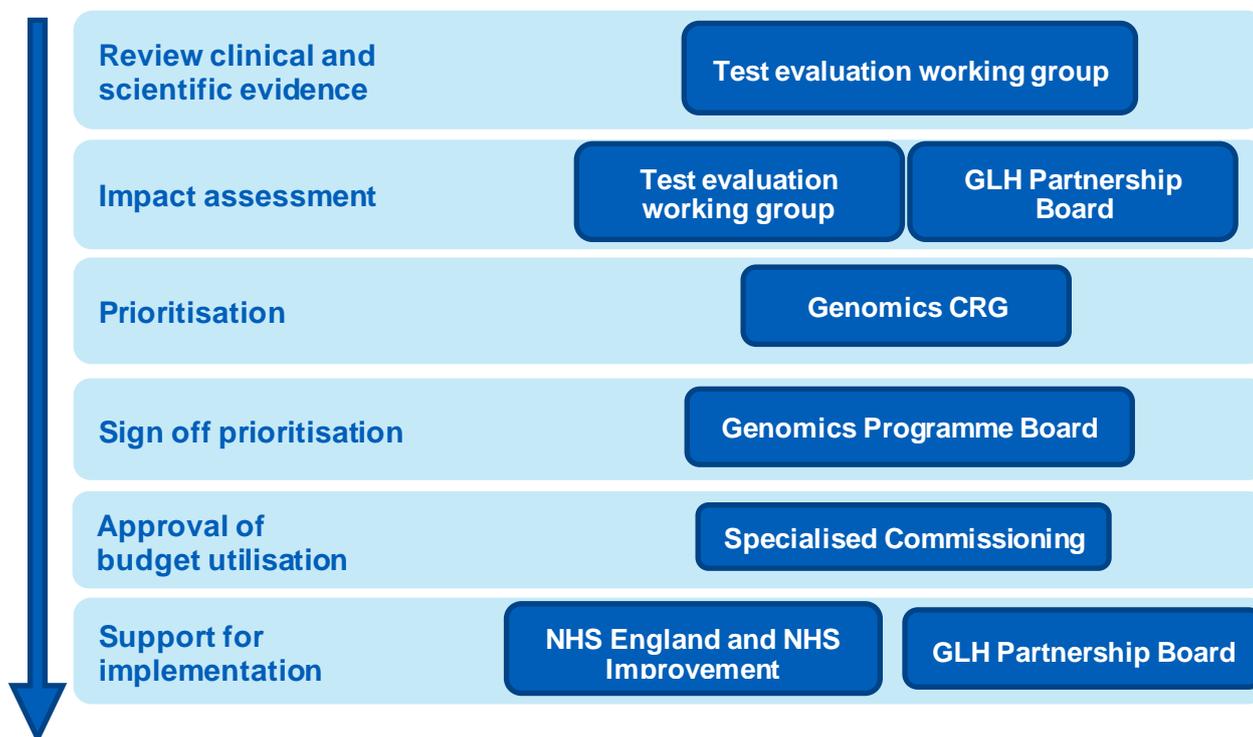
25. Fast Track updates will be considered for implementation outside of the annual update if they meet one of the following criteria; Fast Track updates will be considered if they meet one of the following criteria;
1. An error is identified that needs to be corrected to ensure correct delivery of testing
  2. An urgent change is needed to address an unmet patient need that has limited financial impact
  3. An urgent change is needed to benefit operational implementation in the NHS Genomic Medicine Service that has limited financial impact
  4. Newly emerged guidance or clinical policy mandates the amendment (including NICE guidance)
  5. An urgent change is needed as a result of the COVID-19 response

## Resubmission of applications

26. If an application is either;
1. submitted to the process but deemed insufficient during initial triage, or
  2. evaluated through the process and is not accepted as an amendment to the Test Directory,
- NHS England and NHS Improvement will contact the submitter confirming why the application was not accepted.
27. Applications to the process can be resubmitted at any time, for example, following the provision of further information to support the evaluation of the application.

# Governance and funding

1. NHS England and NHS improvement will set aside a portion of its budget each year to pay for implementation of changes to the Test Directory. The total funding envelope for updating the Test Directory will be determined on an annual basis, utilising the spending from the previous year as a baseline, and taking into account other spending commitments within the year.
2. All funding decisions will be made at the end of the evaluation process against all amendments recommended by the test evaluation working groups, when no further applications are being considered for the relevant year (funding decisions will not be made on a first come first served basis). The funding envelope will be allocated to the proposed amendments based on the recommendations from the test evaluation working groups.
3. Genomics CRG will prioritise tests and make recommendations to the Genomics Programme Board who confirm that the correct process has been followed and confirm their support for the Genomic CRG's recommendations.
4. Approval to utilise the Test Directory updates budget will be acquired through annual Specialised Commissioning planning processes.



# Future development of the Test Directory

1. The Genomics CRG and genomics test evaluation working groups will assess the operation of the approach to updating the Test Directory. Particular areas for review will include (but not be limited to):
  1. Whether the annual process was successful in supporting development of an update version of the Test Directory, including (but not limited to):
    - (1) The effectiveness of the open application process
    - (2) The time allocated for each stage of the review process and whether this was appropriate or should be revised and the effectiveness of the overall timelines of the process;
    - (3) The approach to governance and funding, and scoring and evaluation in supporting decision-making;
  2. Whether the implementation of in-year updates has been effective
  3. Whether any aspects of the process should be amended to ensure that it runs smoothly.
2. Any potential changes to the annual review process will be considered by the Genomics CRG in collaboration with NHS England and NHS Improvement.
3. NHS England and NHS Improvement will ensure that appropriate stakeholder engagement and consultation is undertaken as part of the review of the process.
4. The Genomics CRG and genomic test evaluation working groups will continue to assess the success of the annual review process each year to ensure that the process continues to support development of a Test Directory which reflects the most recent scientific, clinical and economic evidence.

# Annex 1 - Updates to the Test Directory for 2021/22

1. NHS England and NHS Improvement will accept applications to update the Test Directory for 2021/22 from the date of publication of this consultation response until 11.59pm on 31<sup>st</sup> January 2021.
2. Amendments must be submitted by completing the relevant application form and submitted via email to [ENGLAND.testevaluation@nhs.net](mailto:ENGLAND.testevaluation@nhs.net) no later than 11.59pm on 31<sup>st</sup> January. Stakeholders are encouraged to submit applications as soon as possible in advance of the deadline to support the timely evaluation of applications prior to the 2021/22 publication of the Test Directory in April 2021.
3. All information regarding the process to update the Test Directory for 2021/22 and all documentation can be access via the NHS England and NHS Improvement website<sup>9</sup>

<sup>9</sup> <https://www.england.nhs.uk/genomics/the-national-genomic-test-directory/>

# Annex 2 - Evaluation and scoring of amendments to the Test Directory

- Scoring alone does not determine the outcome of an application but is indicative to guide the test evaluation working groups in their holistic review, discussions and decisions on each proposed amendment. The test evaluation working groups will use their expertise and experience to assess each application with the relative evidence provided to provide their recommendation on the proposed amendment. Each application will be considered in its own context, for example, patient population size, evidence base, disease area etc.

## Evaluation and scoring of amendments to existing clinical indications

| Evaluation Criteria   |                                       |          |
|---|---------------------------------------|----------|
| Criteria  | Score (1-5)                           | Comments |
| Positive impact on clinical management or outcomes  | --select--                            |          |
| Benefit to patient  | --select--                            |          |
| Minimal impact on existing testing pathways   | --select--                            |          |
| Minimal impact on existing clinical pathways  | --select--                            |          |
| Low impact on existing activity figures/testing volumes   | --select--                            |          |
| Low financial impact  | --select--                            |          |
| Limited laboratory operational impact   | --select--                            |          |
| <b>Total Score</b>  | 0                                     |          |
| Outcomes  | Test Evaluation Group Member Response |          |
| Change accepted?  | --select--                            |          |
| Recommended for discussion at Test Evaluation Group?  | --select--                            |          |
| Reason for discussion at Test Evaluation Group (e.g. new area not currently included in the Test Directory, emerging scientific evidence)         |                                       |          |
| If appropriate, please note any legal, ethical or social implications of this application you would like the Test Evaluation Group to be aware of |                                       |          |
| Other comments  |                                       |          |

| Test Evaluation for an Amendment to an Existing Clinical Indication - Scoring                  |          |
|--|----------|
| The following scoring system is in place for Test Evaluation Working Group member evaluations: |          |
| <b>SCORING (1-5):</b>  |          |
| 5 - strong evidence for implementation provided  |          |
| 4 - relatively strong evidence for implementation provided                                     |          |
| 3 - moderate evidence for implementation provided  |          |
| 2 - relatively weak evidence for implementation provided                                       |          |
| 1 - weak evidence for implementation provided  |          |
| <b>OUTCOMES (max. score 30):</b>   |          |
| Weak overall case for implementation   | <15      |
| Moderate overall case for implementation   | 15 to 20 |
| Strong overall case for implementation   | >20      |

## Evaluation and scoring of new clinical indications proposed to be added to the Test Directory

| Evaluation Criteria   |  |                 |
|---|--|-----------------|
| <b>Clinical Utility</b>   | <b>Score (1-5)</b>                           | <b>Comments</b> |
| Evidence of clinical utility  | --select--                                   |                 |
| Benefit to patient  | --select--                                   |                 |
| Evidence of unmet diagnostic need   | --select--                                   |                 |
| Strength of scientific evidence base  | --select--                                   |                 |
| Evidence of appropriate diagnostic yield  | --select--                                   |                 |
| <b>Health Economic Case</b>   |  |                 |
| <b>Health Economic Case</b>   | <b>Score (1-5)</b>                           | <b>Comments</b> |
| Low level of additional investment required   | --select--                                   |                 |
| Cost effectiveness  | --select--                                   |                 |
| <b>NHS Implementation</b>   |  |                 |
| <b>NHS Implementation</b>   | <b>Score (1-5)</b>                           | <b>Comments</b> |
| Aligns to an NHS England and NHS Improvement clinical priority  | --select--                                   |                 |
| Practicality of implementation in the GMS   | --select--                                   |                 |
| Technical feasibility   | --select--                                   |                 |
| <b>Overall Score:</b>   | 0  |                 |
| <b>Test method</b>  |  |                 |
| <b>Test method</b>  | <b>Select</b>                                | <b>Comments</b> |
| Proposed use of the test  | --select--                                   |                 |
| Do you have any concerns over the test method proposed in the application?<br>If yes, please provide details                                      | --select--                                   |                 |
| Are there opportunities for the generation of further evidence to support commissioning decisions? (e.g. WGS for high cost)                       | --select--                                   |                 |
| <b>Evaluation Outcomes</b>  |  |                 |
| <b>Evaluation Outcomes</b>  | <b>Test Evaluation Group Member Response</b> |                 |
| Recommended for GMS implementation?   | --select--                                   |                 |
| Proposed eligibility criteria accepted?   | --select--                                   |                 |
| Recommended for discussion at Test Evaluation Group?  | --select--                                   |                 |
| Reason for discussion at Test Evaluation Group  |  |                 |
| If appropriate, please note any legal, ethical or social implications of this application you would like the Test Evaluation Group to be aware of |  |                 |
| Other comments  |  |                 |

| Test Evaluation for a New Clinical Indication - Scoring  |          |
|--|----------|
| The following scoring system is in place for Test Evaluation Working Group member evaluations: |          |
| <b>SCORING (1-5):</b>  |          |
| 5 - strong evidence for implementation provided  |          |
| 4 - relatively strong evidence for implementation provided                                     |          |
| 3 - moderate evidence for implementation provided  |          |
| 2 - relatively weak evidence for implementation provided                                       |          |
| 1 - weak evidence for implementation provided  |          |
| <b>OUTCOMES (max. score 45):</b>   |          |
| Weak overall case for implementation   | 0 to 20  |
| Moderate overall case for implementation   | 21 to 30 |
| Strong overall case for implementation   | >31      |