GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Policy Position PP184

Genomic Testing

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Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission Genomic Testing in accordance with the criteria outlined in this document.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy position statement.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy position statement.

1. Introduction

This Policy Position has been developed for the planning and delivery of genomic testing for people resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain language summary

Genomic testing, which is sometimes called genetic testing, finds changes in genes that can cause health problems. It is mainly used to diagnose rare and inherited health conditions and some cancers.

A genomic test can:

- help to diagnose a rare health condition in a child
- help you understand whether an inherited health condition may affect you, your child or another family member, and help you decide whether to have children
- show if you are at higher risk of getting certain health conditions, including some types of cancer
- guide doctors in deciding what medicine or treatment to give you
- guide doctors on whether you're able to join a clinical trial[1]

1.2 Background

For the last 15 years the UK Genetic Testing Network[2] (UKGTN) has provided leadership in this area by publishing the NHS Directory of Genetic Disorders/Genes for Diagnostic Testing, which evaluated and recommended genetic tests for rare and inherited disorders for the NHS across the UK. However, there was not an equivalent for cancer genomic testing. Instead the testing that has been offered within the NHS has evolved over time, in-part driven by NICE medicine assessments and the identification of companion diagnostics.

The National Genomic Test Directory specifies which genomic tests are commissioned by the NHS in England, the technology by which they are available, and the patients who will be eligible to access a test. Over time, as the evidence develops, the Test Directory will also include other functional genomic tests for example RNA based technologies and proteomics.

[1] Genetic and genomic testing - NHS
[2] UK Genetic Testing Network - Supporting Genetic Testing in the NHS

What does this mean for patients in Wales?

In response to NHS England's ongoing reorganisation and investment in genomic services in England to deliver the Test Directories, WHSSC allocated funding[3] to ensure equity of services across the UK and enable rapid investment and expansion of genomic testing in Wales.

Implementation of these tests is being clinically prioritised in collaboration with a range of clinicians. Please refer to the All Wales Medical Genetics Service website for details of availability.

How was the content of the Test Directory developed?

NHS England established two expert groups to develop and agree the final lists of tests for rare and inherited disorders and for cancer to be included in the test directory. The groups included the following brought together clinicians, scientists, health economists, policy experts, public representatives and patient organisations. The Test Directory builds on the evaluation work that has been undertaken by the UK Genetic Testing Network and through a detailed process combining national and international evaluation approaches, emerging evidence and findings from research and the 100,000 Genomes Project and an analysis of current NHS testing activity.

Who is eligible for testing?

The Test Directory sets out the clinical indications where there is clear evidence for the value of genomic testing for patients. This is primarily in cancer and rare and inherited disorders. Each clinical indication included in the Test Directory has a set of testing criteria that sets out which patients qualify for testing. For some clinical indications, these will focus testing on cases where the likelihood of an inherited condition and clinically actionable findings is higher than is currently required by some local practice.

As the evidence base develops then the scope of the Test Directory is likely to expand to cover other areas, such as pharmacogenomics (how patients' genomic variation affects how they respond to the medicines they are given).

How will the directory be kept up to date?

The Test Directory will be updated on an annual basis by NHS England supported by a Clinical and Scientific Expert Panel. The Expert Panel will create a clear and transparent process for the future evaluation of new genomic tests in order to determine which tests are available, and any tests that will be retired or replaced by more modern technology, such as whole genome sequencing.

[3] Funding was allocated by WHSSC in February 2019

The UK approach to evaluating genomic tests will be published and NHS England will also publish a policy outlining the approach to commissioning and funding the tests.

The contents, structure and format of the Test Directory is copyrighted by NHS England and therefore the content is owned, controlled and maintained by NHS England. The Test Directory may only be amended pursuant to a robust and evidence based process conducted and approved by NHS England.

1.3 Aims and Objectives

This Policy Position Statement aims to define the commissioning position of WHSSC on the use of genomic testing.

The objectives of this policy are to:

- ensure commissioning for the use of genomic testing is evidence based
- ensure equitable access to genetic testing
- define criteria for people to access treatment
- improve outcomes for people with cancer and rare and inherited diseases.

1.4 What NHS Wales has decided

WHSSC has carefully reviewed the relevant guidance issued by NHS England. We have concluded that there is enough evidence to fund genomic testing, within the criteria set out in section 2.1.

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of genomic testing in line with the criteria identified in the policy.

2.1 Inclusion Criteria

- Tests as defined in the National Genomic Test Directory for cancer.
- Tests as defined in the National Genomic Test Directory for rare and inherited disease.
- Certain additional tests not included in the above directories; details of these tests are available on the All Wales Medical Genetics Service website

Eligibility criteria are specific for each individual test, please refer to the National Genomic Test Directories for information.

2.2 Exclusion Criteria

Implementation of tests is being clinically prioritised in collaboration with a range of clinicians. Please refer to the All Wales Medical Genetics Service website for details of availability.

2.3 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.4 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

2.5 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner. Performance against key performance indicators will be monitored on a quarterly basis. These KPIs will be the nationally agreed turnaround times which have been set by the Association for Clinical Genomic Science.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young adults.

2.6 Responsibilities

Referrers should:

- inform the patient that genomic testing is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

3. Documents which have informed this policy

The following documents have been used to inform this policy:

- Welsh Government, Genomics for Precision Medicine Strategy, July 2017
- NHS England, 2019/2020 National Genomic Test Directory
- Association for Clinical Genomic Science, General Genetic Laboratory Reporting Recommendations, 2015
- NHS England National Genomic Test Directories

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

4. Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

5. Putting Things Right:

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

6. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Annex i Abbreviations and Glossary

Abbreviations

AWMGS All Wales Medical Genomics Services

IPFR Individual Patient Funding Request

UKGTN United Kingdom Genetic Testing Network

WHSSC Welsh Health Specialised Services Committee

Glossary

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.