Innovation Brief

Medical Technology Innovation Dynamic Purchasing System - Genedrive® CYP2C19 ID Kit supplied by Genedrive Diagnostics Ltd.

Summary

Disruptive innovation

This briefing introduces a disruptive innovation newly available via NHS Supply Chain: The CYP2C19 diagnostic test. Reviewed by clinical specialists and supported by key stakeholders, this device offers a novel approach for genotype testing to guide clopidogrel use after ischaemic stroke or transient ischaemic attack.

Introduction

This document is intended to inform clinical stakeholders and procurement teams about innovative products that have undergone a clinical review and are now accessible through NHS Supply Chain.

Products featured in this brief may be classified as:

- Disruptive innovations
  - A disruptive innovation is novel.
  - It should offer improvements compared to the existing provision of care.
  - The proposed format should not exist elsewhere (either within or beyond the health and care sector).

Note: While robust evidence or validated savings may not yet be available, early data and clinical insights support the potential for patient and system-level improvements.

Departments / stakeholders for engagement

- NHS procurement teams
- Emergency departments
- Stroke
- Pathology

Opportunity

Individual level impact

- Informs treatment to prevent secondary events (for example stroke or myocardial infarction).
- Informs treatment to reduce risk of disability, improves life outcomes.
- Informs treatment to reduce emotional and psychological burden on families.
- Empowers clinicians with genetic insight within 69 minutes.

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Product overview

The Genedrive System is a point-of-care gene amplification device used for qualitative in vitro molecular diagnostic tests. The company states that the test can detect the *2, *3, *4, *8, *17 and *35 alleles.

Clopidogrel is an antiplatelet drug used after ischaemic stroke or TIA (sometimes called a 'mini stroke') to reduce the risk of blood clots that can cause further strokes. Clopidogrel is metabolised into its active form by an enzyme encoded by a gene called CYP2C19.

In some people CYP2C19 has variations that reduce the enzyme's function (known as 'loss-of-function' variants or alleles). This means clopidogrel does not work as well in these people. Testing for these alleles is known as CYP2C19 genotype testing. It aims to identify people with CYP2C19 loss-of-function alleles so they can be offered alternative antiplatelet drugs to lower their risk of blood clots.

Testing can be done in a laboratory or at the point of care (for example, on a stroke ward). There is good clinical evidence that people with loss-of-function CYP2C19 alleles who have clopidogrel are more likely to have further strokes compared with people without loss-of-function CYP2C19 alleles. Clinical experts agreed that it would be beneficial to treat people with loss-of-function CYP2C19 alleles with alternative antiplatelet treatment, but the evidence was less clear on the size of this benefit.

The economic evidence shows that CYP2C19 genotype testing is cost effective compared with not testing, regardless of which alternative antiplatelet therapy people have. So CYP2C19 genotype testing is recommended.

Preventative value

- Reduces the risk of recurrent strokes by guiding antiplatelet therapy.

Social value

- Reduces patient dependencies by improving functional ability by reducing the risk of recurrent strokes.

Service value

- Frees up pressured resources (laboratory time, clinical hours and beds).

Experiential value

- Improves patient experience by reducing inconvenience or invasiveness due to sample type

Efficiency value

- Reduces the need for follow-up care by informing correct treatment which reduces the risk of recurrent strokes

Supply details

Complete requirements in form on https://www.supplychain.nhs.uk/dps

Route - Direct Supplier - GeneDrive Diagnostics Ltd Brand - Genedrive

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Genedrive CYP2C19 ID Kit Box	Box	10
Genedrive CYP2C19 Control Kit Box	Box	10
Genedrive System , GS-003 (1 device) including 1 x Multilanguage User Manual, 1 x Product Notification Sheet, 1 x Certificate of Conformity, 1 x UK Power Supply Cable, 1 x EU Power Supply Cable and 1 x Ethernet cable	each	1
Bluetooth label printer with charging cradle and 1 roll of labels	each	1
Replacement Labels for GS-PTR-01	Box	2 x rolls (200 per roll)

Supporting evidence / notes

https://www.nice.org.uk/guidance/htg724/resources/cyp2c19-genotype-testing-to-guide-clopidogrel-use-after-ischaemic-stroke-or-transient-ischaemic-attack-pdf-1809600642386629
NICE Health Tech guidance 724.

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