

## NORTH EAST LONDON INTEGRATED CARE BOARD (NEL ICB) POSITION STATEMENT FOR IQORO®

### Position Statement

- The formulary status for IQoro® in North East London ICB is 'NON-FORMULARY'.
- IQoro® is not recommended for prescribing in North East London for the treatment of hiatus hernia and reflux, stroke-related dysphagia and other indications.
- Stroke and gastroenterology specialists from acute trusts in North East London have been consulted and they do not recommend this treatment on the NHS.
- Additional clinical trials are required to assess the safety and efficacy of IQoro® and to define its potential place in therapy.

Title of Position Statement	<b>Position statement on the use of IQoro® for hiatus hernia and reflux, stroke-related dysphagia and other indications</b>
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## 1 BACKGROUND with SPECIFIC DETAILS

- IQoro® is a neuromuscular training device used for stimulating the nerves and strengthening the muscles in the face, mouth, throat, oesophagus, and diaphragm. The product is marketed for use in people with reflux, snoring and swallowing difficulties (dysphagia).
- IQoro® is included in the Drug Tariff (November 2023) at a cost of £121 per unit. It can also be privately purchased via the company website for £145.
- IQoro® is **non-formulary** and is **not recommended** for prescribing in North East London (NEL) for the treatment of hiatus hernia and reflux, stroke-related dysphagia and other indications.
- In March 2019, the National Institute for Health and Care Excellence (NICE) published two Medtech innovation briefings which summarise the evidence for using IQoro® in hiatus hernia [MIB176] and stroke-related dysphagia [MIB175]. The current evidence is based on a limited number of small observational studies which were authored by the owner of the IQoro® patent. Experts advising in the NICE Medtech innovation briefings in both indications agreed that further high-quality, randomised studies are necessary.

### Hiatus hernia (and reflux)

- Hiatus hernia itself rarely has any noticeable symptoms. However, it can cause gastro-oesophageal reflux disease (GORD) and require long term medications such as alginates and proton pump inhibitors (PPIs) to manage heartburn and indigestion associated with GORD. The intended place in therapy would be as an alternative to long-term proton pump inhibitor (PPI) treatment or laparoscopic fundoplication surgery in people with hiatus hernia.
- The main points from the evidence summarised in the NICE briefing [MIB176] are from three non-comparative, observational studies including 148 adults in Swedish ear, nose and throat clinics. They show that IQoro® may improve symptoms related to hiatus hernia when used for 6 to 8 months in people with long-term hiatus hernia.
- Key uncertainties around the evidence are that it is limited in quantity and quality. The effect of IQoro® may be overestimated because of a lack of a control group. A study comparing IQoro® with standard NHS care would help address this.

### Stroke-related dysphagia

- Swallowing therapy is the usual treatment for dysphagia (swallowing difficulties) after a stroke. The manufacturer for IQoro® claims swallowing exercises can be more accurately and effectively done using the device. The intended place in therapy would be for IQoro® to be used alongside standard speech and language therapy in people with stroke-related dysphagia.
- The main points from the evidence summarised in the NICE briefing [MIB175] are from four observational studies including 113 adults in Sweden with stroke-related dysphagia. They show that IQoro® may be at least as effective as swallowing exercises done with a prosthetic device (palatal plate). One study found improvement with IQoro® use regardless of whether the patients had early or late intervention.
- Key uncertainties around the evidence are the lack of high-quality, randomised studies and the unclear effect of IQoro® compared with NHS standard care or spontaneous improvement.

### Other indications

- There is very little supporting evidence available to date to support the use of IQoro® for other indications, including: non-stroke related dysphagia, sleep apnoea, snoring and several conditions associated with facial and oesophageal dysmotility including drooling, paralysis of the face, mouth and throat, improvement of indistinct speech and abnormal bite and jaw development.

## 2 SCOPE

- This position statement **applies** to requests for NHS prescribing of IQoro® in NEL primary care, community services and secondary care settings.
- This position statement **does not** apply to patients who purchase the IQoro® device over the counter/via the internet or those who are prescribed and obtain this privately.

## 3 ROLES AND RESPONSIBILITIES

- Specialists in NEL acute and community trusts should not prescribe or make recommendations for primary care to prescribe IQoro® for hiatus hernia, stroke-related dysphagia or any other indications.
- GPs and non-medical prescribers in primary care should not prescribe IQoro® on NHS prescriptions following request by patients or by specialists.
- Patients have the option to purchase IQoro® or obtain a private prescription for this (via a private specialist). Prescribers should inform patients of the limited high-quality evidence available to support the use of this device.

## 4 INTERNAL AND EXTERNAL REFERENCES

- NICE. IQoro® for hiatus hernia. Medtech innovation briefing MIB176. Published 06 March 2019. <https://www.nice.org.uk/advice/mib176>
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- Evidence search: [Primary Care] Use of IQoro neuromuscular training device for managing conditions advocated by the company. Sherin Francis. (30th October, 2023). Rainham, UK: NELFT Library and Knowledge Service.

- Evidence search: Use of the Iqoro device for dysphagia rehabilitation. Barbara Peirce. (23rd July, 2021). POOLE, UK: University Hospitals Dorset NHS Knowledge and Library Services.