Medicines Optimisation Position Statement

Position statement	**IQoro® neuromuscular training device**
Position statement number	014
Agreed by NHS Frimley Medicines Optimisation Group	January 2023
Ratified by NHS Frimley Medicines Board	March 2023
Date of last review	n/a
Date of planned review	January 2025

Medicines Optimisation Position Summary

Indication	**Commissioning recommendation**
Dysphagia	Not recommended
Acid Reflux	Not recommended
All other uses	Not recommended

Background

The IQoro® product[1] is a neuromuscular training device. When used along with an exercise regime, it has been advocated to strengthen the muscles of the oropharynx, oesophagus and diaphragm. This could potentially reduce the symptoms of conditions such as snoring, acid reflux and dysphagia.

It is a reusable and available in two sizes (adult and child). It is held inside the lips and in front of the teeth. To exercise, the user presses their lips together and pulls forward strongly for 5-10 seconds, repeating the exercise three times with three seconds of rest between repetitions. Training should be done three times each day, preferably before meals. IQoro® is CE marked class 1 medical device with an in-use life of one year during active use, although length of required treatment is unclear.

It can be privately purchased via the company website for £145, with a money back offer if symptoms have not improved after six months. IQoro® was added to the Drug Tariff[2] in May 2022 at a cost of £121 per device.

Summary of evidence

There is currently limited evidence available to support the use of IQoro®. All studies to date include small numbers of participants and appear to have been co-authored by the patent holder, with inadequate or no control or placebo group: there is a lack of high quality, large, randomised studies. The effect of IQoro® compared with NHS standard care or spontaneous improvement remains unclear. There is limited evidence on the cost effectiveness of IQoro® compared with standard NHS care at this time.

NICE have published two Medtech innovation briefings which summarise the evidence and key considerations on the use of IQoro®: IQoro for stroke-related dysphagia, Medtech innovation briefing [MIB175] Published: 06 March 2019[3] and IQoro for hiatus hernia Medtech innovation briefing [MIB176] Published: 06 March 2019[4]

Stroke-related dysphagia

Swallowing problems (dysphagia) are very common after a stroke, with almost half of stroke patients experiencing dysphagia in the first few weeks post stroke.[5] Although many stroke patients recover swallowing spontaneously; 11–50% still have dysphagia at six months. Dysphagia leading to aspiration of ingested foods, liquids, or oral secretions, is thought to be the primary risk factor for pneumonia after stroke.[6]

Stroke rehabilitation in adults NICE CG162[7] recommends an assessment of swallowing in people after stroke in line with recommendations in the Stroke and transient ischaemic attack in over 16s: diagnosis and initial management NICE guideline128.[8] NICE suggests offering swallowing therapy at least 3 times a week to people with dysphagia after stroke who are able to participate, for as long as they continue to make functional gains. Swallowing therapy could include compensatory strategies, exercises and postural advice. No specific devices, such as IQoro®, are specifically recommended in this guidance.

The IQoro® device was initially developed for the management of post-stroke dysphagia in Sweden. IQoro® and other similar devices do not appear to have been directly compared to the usual level or mode of care used in the UK. [3]

There is a current lack of objective evidence on clinical and cost effectiveness. Trials to date involve small numbers of patients, recruited over a number of years, with inconsistent follow up. More data is required to define the place in therapy and benefit, if any, of IQoro® in post stroke patients.

Acid reflux / hiatal hernia

Medtech innovation briefing MIB176 summary states that IQoro® is a neuromuscular training device used for improving symptoms related to hiatus hernia by strengthening the oesophagus and diaphragm. It is initially used daily for 3 to 6 months, with follow up maintenance use dependent upon individual need.

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 MIB176 briefing are from 3 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. The resource impact would be greater than standard care, but costs may be offset by reducing long-term PPI maintenance. A study comparing IQoro® with standard NHS care is required to confirm the place in therapy of Iqoro® and its long term effectiveness.

Iqoro® for other indications

IQoro® has been advocated and investigated for effectiveness in several other conditions, 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. There is very little supporting evidence available to date to support use for these indications, and for some indications the evidence is limited to anecdotal reports only.

Comparative costs for stroke rehabilitation techniques

There is no published evidence on the cost effectiveness of IQoro® and the exact number of patients who would be eligible for IQoro® is difficult to estimate.

In the NHS, the standard treatment for dysphagia is swallowing therapy and diet modification, after specialised assessment by speech and language therapists. NHS swallowing therapy is likely to be delivered through a combination of group sessions, one to one assessment and monitoring and well as self care by the patient or their carers. Due to differences in local commissioning and service provision of stroke rehabilitations services, costs of swallowing therapy will vary according to locality.

Comparative costs for hiatus hernia

Patients with severe reflux disease, treated in primary care with a long-term course of full-dose PPI, would incur an approximate cost of between £18 and £60 per person per year, excluding any additional on-costs and the associated GP or hospital appointment time.[4]

Whilst IQoro® may have the potential to reduce the need for long term PPI treatment and/or surgical intervention, the level of data available to date is inconclusive. More data is required to confirm treatment benefit and place in therapy of IQoro® and similar devices.

References

Information in this policy document has been taken from and checked for accuracy with the PrescQIPP IQoro® neuromuscular training device guidance statement

[1] IQoro®. Product Information and Company Website. Accessed 11 August 2022. https://www.iqoro.com/

[2] Tariff.book (nhsbsa.nhs.uk) Accessed August 2022 IQoro®.

[3] NICE. IQoro® for stroke-related dysphagia, Medtech innovation briefing MIB175. Published 06 March 2019. https://www.nice.org.uk/advice/mib175

[4] NICE. IQoro® for hiatus hernia. Medtech innovation briefing MIB176. Published 06 March 2019. https://www.nice.org.uk/advice/mib176

[5] Stroke Association. Swallowing problems. Accessed August 2022. https://www.stroke.org.uk/effects-of-stroke/physical-effects-of-stroke/swallowing-problems

[6] Cohen DL, Roffe C, Beavan J et al. Post-stroke dysphagia: A review and design considerations for future trials. International Journal of Stroke 2016; 11: 399-411. https://doi.org/10.1177/1747493016639057

[7] NICE. Stroke rehabilitation in adults. Clinical guideline CG162. Published 12 June 2013. https://www.nice.org.uk/Guidance/CG162

[8] Stroke and transient ischaemic attack in over 16s: diagnosis and initial management NICE guideline [NG128] Published: 01 May 2019 Last updated: 13 April 2022 https://www.nice.org.uk/guidance/ng128