Bath and North East Somerset, Swindon and Wiltshire Together

Bath and North East Somerset, Swindon and Wiltshire Together recommendation: IQoro® neuromuscular training device

30th June 2022

The BSW Area Prescribing Committee (APC) ratified the East of England Priority Advisory Committee (EoEPAC) recommendations that IQoro® neuromuscular training device is not recommended for prescribing on FP10.

BSW APC have not received a formal application to include this device on BSW formulary and there is limited objective evidence available and a distinct lack of high quality large, randomised studies to support the use of IQoro® for any indication currently.

The effect of IQoro® compared with NHS standard care or spontaneous improvement is unclear.

The East of England
Priorities Advisory Committee
Hosted by PrescQIPP

GUIDANCE STATEMENT

IQoro® neuromuscular training device

PAC recommendations	
Indication	Commissioning recommendation
Stroke related dysphagia	Not recommended
Hiatus hernia	Not recommended
All other uses	Not recommended

Background

The IQoro® product is a neuromuscular training device, also known as an oral screen. When used along with an associated exercise regime, known as IQoro® training, it has been advocated to strengthen the muscles of the oropharynx, oesophagus and diaphragm. This could potentially reduce the symptoms of conditions such as hiatus hernia and dysphagia. IQoro® has been advocated for treatment of stroke related dysphagia, hiatus hernia as well as snoring, sleep apnoea and speech issues.[1-3]

It is a reusable, slightly curved plastic panel with a handle, available in two sizes (adult and child). It is held in the mouth between the teeth and behind the lips. 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 it is not clear whether treatment must be continued long term or repeated periodically to maintain effect.[1-3]

IQoro® was added to the Drug Tariff in May 2022 at a cost of £121 per device.[4] It can also be privately purchased via the company website for £145.[1] The NICE Medtech innovation briefings for IQoro®, published in 2019, stated that the cost was £116 per unit excluding VAT and that discounts are available for bulk purchases.[2,3]

Summary of evidence

There is limited evidence available to support the use of IQoro® currently. All studies to date include small numbers of participants and appear to have been co-authored by the patent holder, with inadequate or even no control or placebo group: there is a distinct lack of high quality, large, randomised studies.[2,3] The effect of IQoro® compared with NHS standard care or spontaneous improvement remains unclear.[2]

NICE have published two Medtech innovation briefings (MIB) which summarise the evidence and key considerations on the use of IQoro®: MIB175 (stroke-related dysphagia) and MIB176 (hiatus hernia).[2,3]

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]

"Swallowing therapy" led by a speech and language therapist is the usual treatment for dysphagia after a stroke, with an exercise regimen tailored according to the individual patient's requirements.[2] NICE CG162 regarding management of stroke rehabilitation, recommends three-times weekly swallowing therapy, which could include compensatory strategies, exercises, and postural advice. Swallowing therapy and associated exercises may not be appropriate for all medical conditions and patients. It is vital that the patient is assessed by a speech and language therapist for individualised advice as part of the initial post stroke rehabilitation, as per this NICE guidance. No specific devices, such as IQoro®, are currently specifically recommended in this guidance.[7]

The intended place in therapy of IQoro® or similar devices would be in addition to standard speech and language therapy for post stroke patients.[2] The IQoro® device was initially developed for the management of post-stroke dysphagia, to counter the known limitations of the then-gold-standard of care in Sweden: palatal plate training, whereby exercises were performed by manipulating specific areas of a plate worn in the mouth with the tongue and lips.[1] Where used, IQoro® training had practical and economic advantages over plate training as plates must be individually made with dental moulds; making them expensive, and the exercise regimens were long and complex.[1] In the NHS, palatal plates are not commonly used as part of standard care. 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.[2]

A NICE Medtech innovation briefing on the use of IQoro® for stroke-related dysphagia (MIB175) was published in March 2019 and included the details of four observational studies, including 113 adults in Sweden with stroke related dysphagia. The results suggested 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. However, all trials to date involve very small numbers of patients, recruited over a number of years, with inconsistent follow up. Power calculations were not reported and not possible due to the low number of patients in each trial. There was also significant individual variability within the study populations for time between stroke and start of training (between two days and ten years over all groups).[2] Most patients with dysphagia after a stroke recover spontaneously over time, though 11% to 50% still have dysphagia at six months, therefore spontaneous improvement may have been a confounding factor.[6]

There have been no comparative trials with current standard NHS therapy. More data is required to define the place in therapy and benefit, if any, of IQoro® in post stroke patients.[2]

Since the publication of the NICE Medtech briefing, another trial has been published. The prospective controlled SOFIA trial, cluster randomised 116 older patients from 34 intermediate care centres, who were ≥65 years of age and had swallowing dysfunction. The patients were randomly assigned to oral neuromuscular training using the IQoro® device (n=49) or usual care (n=67) for five weeks. The primary endpoint was the change in swallowing rate (assessed with a timed water swallow test) from baseline to the end of treatment, and at six months. Secondary endpoints included changes in signs of aspiration during the water swallow test and swallowing related quality of life. At the end of treatment, the observed geometric mean of swallowing rate in the intervention group and control group were 6.22mL/s (standard deviation (SD) 2.16) and 3.64mL/s (SD 2.72) respectively. These were increases from the baseline rates of 3.18mL/s (SD 3.28) and 3.0mL/s (SD 3.20) respectively. Overall, 31% in the intervention group were reported to have gained normal swallowing rate (≥10mL/s) at end of treatment compared to 12% in the control group. At six months post treatment, the changes in swallowing rate were higher in the intervention group compared with the control group (geometric mean ratio 1.50, 95% CI 1.04-2.19; P=0.031). With respect to aspiration, the intervention group showed a reduction after five weeks

compared to the control group, however there was no significant between-group difference in signs of aspiration at six months post-treatment compared with baseline (odds ratio 0.63 CI 0.14-2.36; P=0.46). Two participants in the intervention group experienced temporary pain in the orofacial region during the treatment period which disappeared after treatment was stopped.[8]

East of England Speech and Language Therapists support a negative recommendation on the use of IQoro® for the treatment of stroke-related dysphagia, as there is a lack of objective evidence on clinical and cost effectiveness.

Hiatus hernia

IQoro®® is advocated for hiatus hernia on the product website.[1]

Hiatus hernia (or hiatal hernia) is when part of the stomach squeezes up into the chest through an opening ("hiatus") in the diaphragm. 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. Surgical correction via laparoscopic Nissen fundoplication (LNF) is one of the most common surgical techniques used to treat GORD and sliding hiatus hernias (80% of hiatus hernias are this type) as an alternative to long term medication. Para-oesophageal hiatus hernias, also called rolling hiatus hernias (about 5-15% of hiatus hernias are this type), occur where part of the stomach pushes up through the hole in the diaphragm next to the oesophagus. LNF surgery may be recommended to reduce the risk of the hernia becoming strangulated.[9]

IQoro®® is an innovative treatment as it is the only device available for treating hiatus hernia with oral neuromuscular training and an exercise regime. 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 Nissen fundoplication surgery in people with hiatus hernia.[3]

A NICE Medtech innovation briefing on the use of IQoro® for hiatus hernia (MIB176), published in March 2019, included details of three non-comparative, observational studies, involving 148 individual adults (21 patients were included in two of the studies) referred to a specialist speech and swallowing centre at a Swedish hospital. All patients had experienced symptoms of GORD or intermittent oesophageal dysphagia for more than one year. The total number of patients with a confirmed hiatus hernia in the three studies was 126. The results of the studies suggest that IQoro® may improve symptoms related to hiatus hernia when used for six to eight months in people with long-term hiatus hernia. Key uncertainties around the evidence are that it is limited in quantity and quality, with small numbers of patients and consequently no power calculations to assess adequate sample size, varied inclusion criteria and inconsistent or no long term follow up. Changes in symptoms were assessed by a variety of techniques, including oesophageal high-resolution manometry, swallowing capacity test (SCT) and lip force test (LFT), as well as self-assessment questionnaires. The effect of IQoro® may be overestimated because of a lack of a control group.[3]

Almost all the 148 adults studied had been on a proton pump inhibitor (PPI) for at least one year, without resolution of their symptoms, although it is not specified at what dose, or whether patients were compliant with treatment. Patients were advised to continue with their PPI medication. At end of training, the three studies quoted 93%, 58% and 61% of patients ceased all PPI medication respectively, with the remainder on a reduced dose and intake frequency.[3]

No further studies specific to hiatus hernia could be located. Further evidence is required to establish if IQoro® could be used before PPIs or as an alternative to minimise the risk of adverse effects of long-term PPI use, or if IQoro® will prevent or delay the need for LNF surgery to correct the hernia.[3]

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.[1] 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.

Costs and alternative treatments

IQoro® was added to the Drug Tariff in May 2022 at a cost of £121 per unit.[4] It can also be privately purchased via the company website for £145.[1] No additional consumables are required. IQoro® acquisition costs do not vary by size or indication. The NICE MedTech Briefings for IQoro®, published in 2019, stated that the cost was £116 per unit excluding VAT and that discounts are available for bulk purchases.[2,3]

IQoro® is the only device on the market using this specific methodology in relation to the recommended exercise programme which should be undertaken with the device. An alternative, visually similar device, Abilex®, was available but has been discontinued.[10,11] Its design followed the principles of the palatal plate, whereby exercises are performed with a tactile device (here, an air-filled bulb) manipulated with the tongue and lips. The "screen" is used to prevent the device being inserted too far into the mouth. There was limited evidence available in support of Abilex®.

Similar exercises can also be done without any devices. The patent holders and manufacturers of IQoro® claim that their device helps make exercises faster (taking 30 seconds, three times daily), rather than 10-30 minutes, and simpler.[1]

Comparative costs for stroke rehabilitation techniques

In the NHS, the standard treatment for dysphagia is swallowing therapy and diet modification, after specialised assessment by speech and language therapists.[2]

NICE Clinical Guideline (CG162) on stroke rehabilitation in adults recommends swallowing therapy at least three times a week.[7] The IQoro® device may be used in a hospital, community, or home setting. In most cases, the exercise is done by the patient after initial training by a healthcare professional. A carer can help if the patient lacks upper limb mobility or dexterity. The carer does not need to be a healthcare professional. A band 6 speech and language therapist providing three 30-minute session per week (£43 per working hour) would cost approximately £65 per week.[2]

Initial assessment and treatment recommendations are likely to be delivered as part of a locally commissioned stroke rehabilitation service, or by community-based adult speech and language team. Both stroke rehabilitation services and adult community speech services are unbundled from the National Tariff and require local commissioning and agreement in relation to service provision and funding.[12] Therefore costs of swallowing therapy will vary according to locality. In addition, 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.

The exact number of patients who would be eligible for IQoro® is difficult to estimate. Two commentators on the NICE MIB provided estimates for how many people might be eligible for IQoro® per year. One suggested 30% of stroke patients in stroke units, reducing to about 5% to 10% of discharges. Another estimated 50 to 100 people per year might be eligible for speech and language therapy from a population of 180,000 and a hospital with 450 beds.[2]

In addition, 20% of stroke patients may need enteral tube feeding during the initial acute phase post stroke. Of these, 8% will need long-term enteral tube feeding for more than six months. The cost of enteral tube feeding in the home setting is about £95 per week, and it is feasible to consider

that IQoro® costs may be offset by a reduction in the need for tube feeding. In one study quoted in MIB175, all PEG-fed patients (n=5) were able to have their PEGs removed.[2] However, the small number of patients involved does not provide enough data to confirm benefit, and the impact of IQoro® on feeding tube placement and long-term enteral tube feeding needs remains inconclusive.

There is no published evidence on the cost effectiveness of IQoro®. It is possible that if swallowing improvements are greater with IQoro®, this could result in potential cost savings because of shorter lengths of stay in hospital and fewer medical complications and interventions (such as enteral feeding or antibiotic use). IQoro® could also potentially be used to help reduce time needed for speech and language therapy in the community. Two commentators on the NICE MIB felt that IQoro® was potentially cost effective, for example the device is low cost compared with some other high-tech electronic swallow treatment devices, however one did not envisage cost savings but two felt that initial costs for IQoro® may be more than standard care.[2]

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.[3]

Activity costs for general abdominal procedures range between £778 if completed as a day case to £6106 per episode if admission is required and also vary depending on the level of complexity.[11] Gastroesophageal reflux disease (GORD) is common, occurring in 10 to 20% of adults.[13] The precise incidence of hiatus hernia is not known, as most studies have looked only at individuals who presented with symptoms of dyspepsia. [14] Although it is estimated that a third of people over 50 have a hiatus hernia.[9] Over half of people with reflux oesophagitis diagnosed either endoscopically or radiologically are found to have a hiatus hernia.[14-16] However, only 5-15% of people with a hiatus hernia have a para-oesophageal hernia which may require surgical intervention.[9]

Whilst IQoro® and similar devices 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.

Comments sought from: East of England clinicians via PAC members.

Document history

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Document history	
Consultation process	East of England clinicians PAC members
QA process	Katie Smith, Director of Clinical Quality, PrescQIPP. 3rd May 2022

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Appendix 1: Assessment against Ethical and Commissioning Principles

Treatment assessed

IQoro®® neuromuscular training device.

East of England Priorities Advisory Committee recommendation

Commissioning not recommended for:

- Stroke-related dysphagia
- Hiatus hernia
- All other indications

Clinical effectiveness

There is limited objective evidence available and a distinct lack of high quality large, randomised studies. to support the use of IQoro® for any indication currently. The effect of IQoro® compared with NHS standard care or spontaneous improvement is unclear.

Cost effectiveness

There is limited evidence on the cost effectiveness of IQoro® compared with standard NHS care at this time.

Equity

No issues identified.

Needs of the community

The needs of the community are considered to be low as well established alternative treatments exist.

Need for healthcare (incorporates patient choice and exceptional need).

Well established alternative treatments exist.

Policy drivers

None.

Disinvestment

None.