Evidence for NHS adoption of IQoro neuromuscular training:
A comprehensive summary for managers considering inclusion in local formularies.

September 2022

IQoro is an effective treatment for several conditions, typically for acid reflux-based diseases, and for dysphagia. From May 2022 it is listed (alone) on the Drug Tariff schedule Part IXA in the category 'neuromuscular treatment devices'. Being innovative and newly-listed it is often unknown to local medicines management committees and other bodies seeking to render a decision on its possible inclusion on local formularies. Further, being a medical device and not a pharmaceutical, some facets of the NHS BSA Prescription Services' approval process may be unfamiliar to some reviewers.

This document, prepared by the manufacturer, seeks to present the relevant clinical outcome evidence and cost effectiveness data in a format that helps local management teams in their evaluation deliberations.

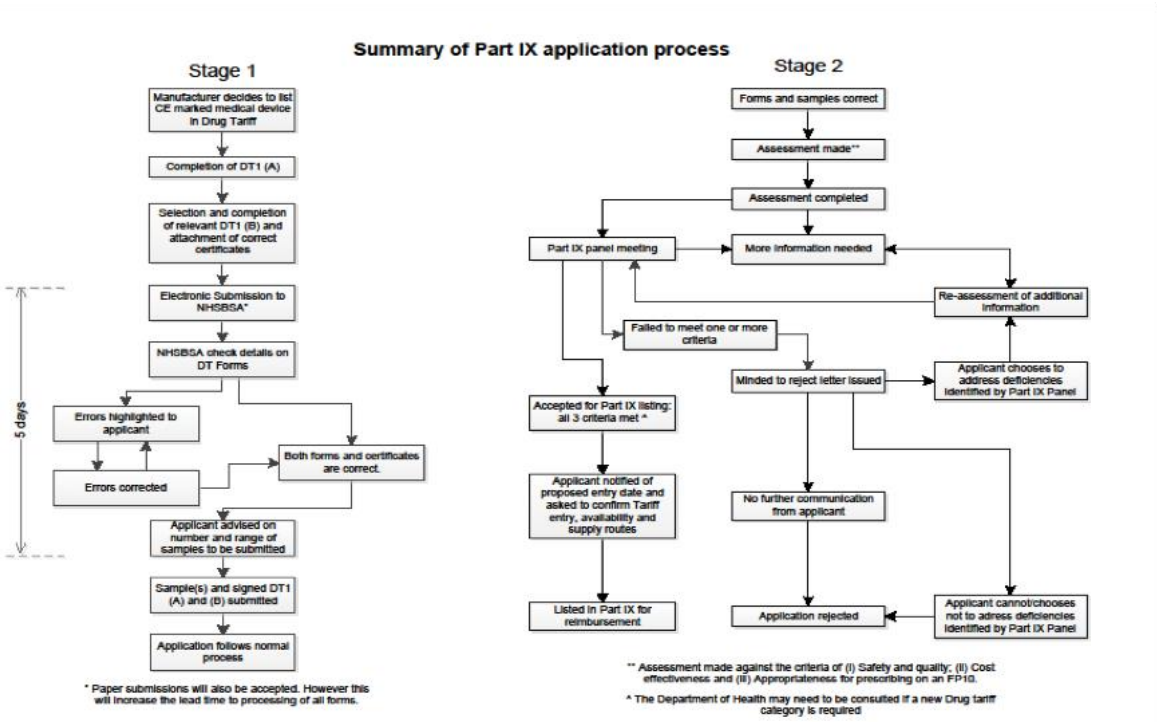
An important reason for producing this document is to ensure that all current and relevant data is referenced in one source document. It would be wrong, for example, to limit research to reading the relevant NICE MedTech Innovation Briefings (MIBs) relating to IQoro. These were written nearly four years ago and refer to a lack of Randomised Control Data studies, NHS service evaluations and experience, and more. These comments were correct at the time of writing but are not now. NICE report that MIBs are not updated, they present only a snapshot in time, and now provide a misleading picture as a sole source of research data.

The following document provides a great deal of evidence – some previously published and some new – and provides links and references to the source data. Above all it seeks to explain the process and reasoning in the NHS Business Services Admin Prescription Service's decision to make IQoro available on prescription. In the absence of a directly comparable alternative treatment it is hoped that the logic that led to national listing will provide support for a similar decision at a local level.

The NHS Business Services Authority Prescription Services process

The full NHS BSA Prescription Services process is described here.

Represented in flowchart form it looks like this:



A device cannot achieve Drug Tariff Part IXA listing without satisfying the three criteria of:

> ***"Criteria for Inclusion of Products in Part IX***
>
> ***9. Applications must meet the following three criteria for inclusion in Part IX of the Drug Tariff:***
>
> - ***The products are safe and of good quality;***
> - ***They are appropriate for GP and, if relevant, prescribing by appropriate practitioners;***
> - ***They are cost effective.***"

Our company engaged with the NHS BSA Prescription Services from March 2019 to January 2022. Over these nearly three years there were repeated requests for more and better data, and calls for explanation on dozens of questions related to clinical use, outcomes, economics, and much more. By the end of 2021 the Prescription Services declared themselves satisfied on all points and the listing was approved by the Part IX Panel committee in February 2022.

The second two of the above criteria had to be proven to the Prescription Services' satisfaction both for the treating of dysphagia, and of acid-reflux based diseases.

The rest of this document addresses issues raised and successfully completed under each of the three inclusion criteria and also includes some data not available at the time of consideration for drug tariff listing.

Inclusion criterion 1

"The products are safe and of good quality"

The NHS Business Services Authority requirement:

"Manufacturers and suppliers have a responsibility to ensure the medical devices they supply comply with the relevant UK legislation, and to supply copies of the appropriate certificates as evidence."

Certification provided

The Prescription Services were satisfied on the above point having considered several factors. These included CE marking, materials, and construction and more. The company could show the appropriate Quality Management Systems and the appointment of a UKRP.

Inclusion criterion 2

"They are appropriate for GP and, if relevant, prescribing by appropriate practitioners;"

The NHS Business Services Authority requirement:

13. ***"Appliances may be supplied for community use by means other than on an FP10, and some appliances may be appropriate for use in the community but not appropriate for prescribing on an FP10 . . .***

14. ***Appliances considered appropriate for prescribing by GPs and other prescribers will usually be for self-administration by the patient, perhaps with the help of a carer. Some appliances may need to be administered by a doctor or other health professional. These products should not require enhanced training of the doctor or health professional specifically in their use. Some medical devices are only suitable to be used by a doctor or healthcare professional in a clinical setting.***

15. ***If a product can be prescribed by a GP or appropriate practitioner and can be used in the community, it would satisfy the above criteria. If however, a product was only suitable for use in a hospital setting it would not satisfy the criteria . . .***

16. ***Some medical devices may not be considered appropriate for prescribing. Prescribed items allowable on an FP10 should be for the treatment of a medical condition – which can include diagnosis and prevention. This does not include items that could be considered more appropriate for the social care of an individual . . .***

17. ***The above consideration is only likely to be necessary when similar products have not been previously listed in Part IX. If a similar product is already listed in Part IX, the criterion would generally be extended to a similar product. "***

Responses provided

Fulfilling this criterion was the reason for the bulk of the correspondence and evidence production since it encompassed: suitability for a GP prescription, questions on the scientific evidence, deployment in the NHS, patient compliance, and much more.

Evidence

An overview of the scientific evidence for IQoro effectiveness is shown here. This page references peer-reviewed and internationally published scientific studies, published book chapters, NHS service evaluation, the NICE Medtech Innovation Briefings, (MIBs) and more.

Inadequacy of the NICE MIBs

The Prescription Services raised concerns based on the content of the two published MIBs. These MIBs, referenced in the NICE pathways, were early recognition of the promise of IQoro in treating reflux-based diseases and dysphagia, but do not reflect the current evidence status. They were concluded in late 2018 and published to the NHS in March 2019. Progress has been made since then.

For example, NICE pointed out the lack of a Randomised Control Trial which has since been concluded and published. They also asked for a Service Evaluation of IQoro use in an NHS setting, which has since been completed by an Academic Health Science Network-funded study. Other reservations were also made.

The NICE MIBs are snapshots in time and not updated to reflect later evidence.

NICE MIBs don't show cost effectiveness

The Prescription Services stated,

"Neither MIB provided any assurance on the cost effectiveness of the IQoro in an NHS primary care setting"

This is a misunderstanding of the role of a MIB, when you look at the declared aim of a MIB it specifically excludes any attempt to comment on cost-effectiveness. This is not a valid criticism of the strength of the MIB judgement on IQoro, it merely shows that this aspect lies outside of their remit.

Is spontaneous recovery a factor in the studies?

Studies used short term and long-term patient groups. Patients up to 10 years after stroke had the same statistically significantly results as those in short term groups only a few weeks after stroke. Spontaneous recovery is therefore unlikely (but not impossible). After further discussion and presentation, the Prescription Services accepted this.

Should the studies have used larger patient groups?

The Prescription Services were concerned that the studies referenced by NICE were far, far smaller than they were used to seeing; of course, much of the data that analysts are used to seeing is related to pharmaceuticals, not devices.

We could reassure them that all study sizes were the subject of Power Calculations conducted by statisticians at Uppsala University as part of each study design. In other

words, it was decided in advance what sample size would be necessary in order that statistically significant results could be obtained. All studies all had very high *p*-numbers for their results. This is true for all studies whether their subject groups were dysphagia or Hiatal-hernia related.

These are not drug studies requiring to test thousands of cases for possible side-effects, risks in combination with other medication, long-term effects, etc. Nor are placebo controls possible. And non-intervention control groups are not necessary where huge cohorts of patients on long-term medication, or with chronic dysphagia have shown no improvement. In the studies the patients do show statistically significant improvement.

Are there other outcome data besides these groups?

Customer Survey

Another source of data on customer outcomes is the Customer Survey that we conduct in June each year. It is administered and analysed by us, the manufacturer, but to a high standard of impartiality. All IQoro users for whom we have an email address, and that have purchased or received their device within the preceding 12 months are mailed and all responses are captured. In total over the last two years we have more than 7 000 responses which we have analysed. Prescription Services considered the data from the 2021 survey, the following short summary also includes the 2022 responses.

More detail and the source data are, of course, available on request.

Question 6

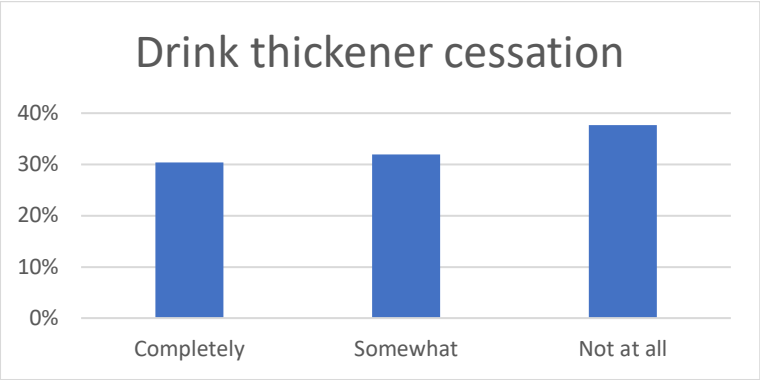
Which of the following is true? I have stopped using drink thickeners since I have trained with IQoro

Completely	21
Somewhat	22
Not at all	26
Never used	589
Total	658

It is helpful to take out the cohort that 'never used', giving us:

Completely	21
Somewhat	22
Not at all	26
Total	69

Graphically:



Hence 30% stopped completely and a further 32% reduced use of thickeners.

Question 7

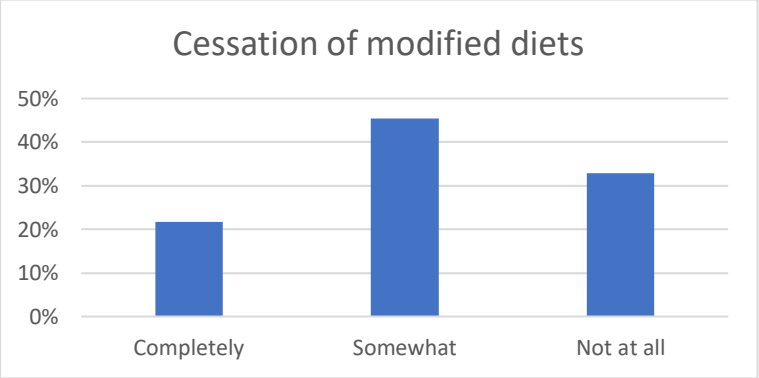
Which of the following is true? I have stopped needing to have modified-consistency foods since I have trained with IQoro

Completely	35
Somewhat	73
Not at all	53
Never used	494
Total	655

Once again it is helpful to take out the cohort that 'never used', giving us:

Completely	35
Somewhat	73
Not at all	53
Total	161

Graphically:



Hence 22% stopped completely and a further 45% reduced use of modified foods.

Question 8

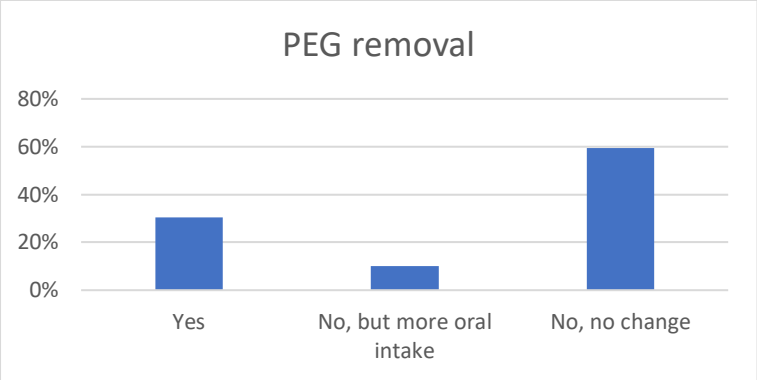
Which of the following is true? I have had my PEG removed since I have trained with IQoro

Yes	18
No, but more oral intake	6
No, no change	35
Never had one fitted	575
Total	634

Removing those that never had a PEG fitted we have:

Yes	18
No, but more oral intake	6
No, no change	35
Total	59

Graphically:



Hence 31% had PEGs removed, and a further 10% are perhaps on their way to doing so.

Question 13

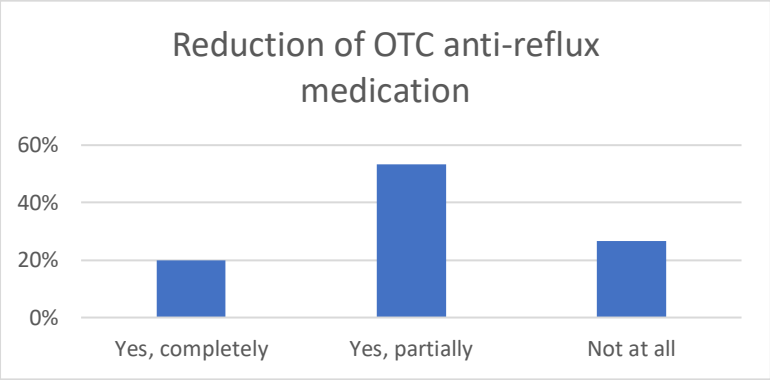
Which of the following is true? I have had reduced my intake of Over-The-Counter (store bought) medication

Yes, completely	843
Yes, partially	2263
Not at all	1132
I never used OTC medication	1551
Total	5789

Removing the 'never used'

Yes, completely	843
Yes, partially	2263
Not at all	1132
Total	4238

Graphically:



Hence 20% stopped completely and a further 53% reduced OTC medication. Only 27% had not, or had not yet, reduced.

Question 14

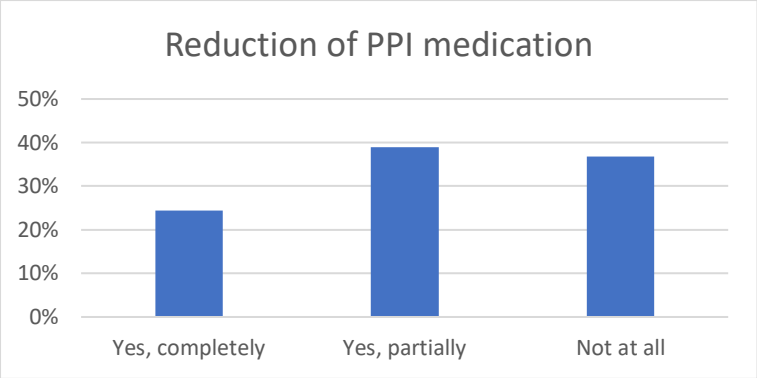
Which of the following is true? I have reduced my intake of prescription medication (perhaps a PPI drug like omeprazole, lansoprazole, etc.)

Yes, completely	946
Yes, partially	1510
Not at all	1426
I never used PPI medication	1935
Total	5817

Remove the 'never used'

Yes, completely	946
Yes, partially	1510
Not at all	1426
Total	3882

Graphically:



Hence 24% stopped completely and a further 39% reduced PPI medication, only 37% had not, or had not yet. Most clinicians agree that all PPI reduction is good, and this analysis shows 63% of people reduced or stopped.

In this analysis, and in all the previous questions above, it is important to remember that some patients had only trained with an IQoro for a month and could not expect to have seen a dramatic improvement. The above analyses thus probably underestimate the efficacy of IQoro training.

Why no control groups in the studies?

Prescription Services quoted NICE's MIB comment*:*

"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."

We answered this in two ways. The SOFIA study was a Randomised Control Trial and published after the MIBs, it included a control group of equal size to the intervention group. Secondly, the Service Evaluation in the Royal Devon and Exeter NHS FT compared IQoro with standard NHS care.

Scientific studies

Prescription Services found our library of scientific studies difficult to reference and this overview was produced to satisfy them.

Care pathways considerations

The Prescription Services were concerned that, although IQoro was mentioned by name in the relevant NICE healthcare pathways for treatment of GERD in adults, and in children and

young people, it was classed as a self-management device, rather than a mainstream treatment. They accepted that this was because it was the only treatment in the pathway that was not NHS funded and thus required patient self-funding. They accepted that without prescription status it could not sit it in the mainstream healthcare pathway.

IQoro is also listed in the dysphagia after stroke pathway.

Is IQoro suitable for a GP to prescribe in primary care?

Prescription can and should be made by a GP with a patient that presents with the condition and symptoms of GERD (acid reflux). Endoscopies are still needed as 'same day referral' in 'Red Flag' cases. Otherwise IQoro can be a routine alternative to patients who are unwilling, unable or unsuccessful to continue long-term PPI medication. There are no unwanted side-effects, few contraindications exist, and thus criteria for prescribing are thus relatively simple.

Do SLTs want IQoro on prescription?

Prescription Services were very keen to know if Speech and Language Therapists were supportive of IQoro having prescription status. The company sent a simple questionnaire to SLTs known to have used IQoro with their patients and 26 replied. One answered 'Unsure', one replied 'Possibly' and 24 replied 'Yes'. This and other data reassured the Prescription Services that SLTs were in favour of prescription status and that they would refer patients to GPs as necessary for prescription if allowed.

A Head of Service, Adult Speech and Language Therapy was asked if availability on prescription by FP10 would solve problems of accessibility to any patients in primary care. She said,

> *"I completely agree. Although we could possibly tap into some charity funding initially, on a longer-term basis, having the device available on prescription would improve access and availability and hopefully ensure that more patients are effectively treated."*

SLTs adoption of IQoro in the NHS

Every month the company trains dozens of SLTs and others who are adopting IQoro in their patient treatment regimes. They are supplied with demo devices and feasibility kits and attend remote training sessions. They ask, and have answered, both basic and complex questions on patient treatment with IQoro.

In some geographies: Somerset, Devon, Salisbury, Preston and others for example, whole SLT teams have been trained. In these areas clinicians are treating with IQoro, recommending GPs to prescribe, and some actively lobbying for local formulary inclusion. Patients' conditions include legacy of stroke, acquired brain injury, progressive conditions, dysphagia of various aetiology, and issues caused by acid reflux.

In Northern Ireland, a programme of training SLTs with IQoro is underway as part of the Public Health Agency's Swallow Aware initiative.

Will prescribing IQoro make extra work for a GP or other healthcare professional?

The Prescription Service was concerned that prescribing IQoro to a patient would require time to explain, introduce and possible even train the patient.

Since the listing by Prescription Services the company has continued to develop customer support material, the carton now includes a QR link to a training support app. The app provides them with 'How to train' instruction videos, the ability to set training reminders, record their training regime, their symptoms and their improvement.

In the case of patients presenting with reflux-based conditions the GP will prescribe as appropriate and can simply point the patient to the app and to support documents like this. The IQoro carton includes an Instructions For Use (IFU) manual – which was critiqued and improved by Prescription Services - contains all the necessary information to get started including a training diary and more.

The company also provides a customer support helpdesk to help patients with training and progress queries.

IQoro users state that they find it easy to get started without assistance. The Prescription Services looked at the results of a 2021 customer survey of individuals who have self-purchased in which 4,076 IQoro users responded to the assertion,

- It was easy to start training.
    - *(70.57% 'strongly agree, 25.99% 'somewhat': total 96.56%)*

- The training instructions were simple.
    - *(73% 'strongly agree, 25% 'somewhat': total 98%)*

There is no need for a GP to be present when a patient starts her or his IQoro training.

In the case of dysphagia, the Prescription Service also asked;

"If a patient is given an FP10 prescription in primary care by their GP, will they then need to have another appointment with the SLT to be taught how to use the IQoro?"

In all cases an SLT will already be involved in the assessment, monitoring and review of the patient and IQoro training will be merely another component in their therapy.

The Prescription Service also asked,

"How many follow up appointments will be needed to assess the technique and progress?"

A Head of Service, Adult Speech and Language Therapy answered,

> *"The number of appointments required is difficult to estimate as will depend on individual prognosis and progress made as well as compliance with the exercise*

program. However, it shouldn't involve more appointments than if the IQoro was not being used (as alternative therapies would be required)"

Will prescribing IQoro place an ongoing time burden on a GP?

After the prescribing phase, what are the ongoing resource implications for a GP with a patient training with an IQoro?

In the case of reflux-based conditions, the experience of the more than 60,000 IQoro users treating this condition is that none of them has turned to a GP for help or support with training. Patients have turned to their GP for advice on reducing their prescribed reflux control medication as their symptoms have improved.

The company provides a free-of-charge help desk facility which provides a support centre for all manner of questions related to IQoro usage.

In the case of dysphagia, the SLT may request the GP to review and reduce other prescriptions like drink thickeners, anti-sialorrhea medication, PPI's (voice patients), etc. Additionally, they may suggest referral to gastroenterology consultant for removal of a PEG feed.

What if the patient can't use the device?

The Prescription Services asked,

"***What happens if the patient returns to the SLT and can't use the device? It can't be returned because it belongs to the patient, and the money is wasted****."*

Where an SLT is involved she or he will have had opportunities to access to training and feasibility kits to maximise the certainty that IQoro is an appropriate treatment. In the case of GPs prescribing, the usual questions regarding the patient's suitability, and motivation to train according to the prescribed regime must be considered.

What is the compliance rate, and what is the evidence to support this?

The Prescription Services were concerned about the above. We were able to show them 2,892 user responses to the following question that checks compliance to the prescribed regime from a survey carried out by the company in mid-2021.

- How often do you train with IQoro?
    - *(52.04% trained 3 times per day, 7 days per week as prescribed'. 27.38% trained 2-3 times per day at least 5 days per week. Total 79.42%)*

Of the rest, some will have dropped back to occasional 'maintenance training' at a lower frequency as their symptoms have receded, or even stopped completely.

A possible criticism is that a patient that has self-funded is more likely to be compliant than one who has a device issued at little or no cost. GPs need to ensure that patient motivation exists.

A major reason for continued good compliance after the first period is, of course, if the patient starts to notice symptom improvement. All experience is that this improves motivation to continue training according to the instructions.

- How much time did it take before you first noticed positive changes that you attribute to your IQoro training?
    - *(40.75% within 2 months, a further 24.73% before 5 months. Total 65.48%)*

Prescription Services took into account that this group included some who had not trained for more than one month and were thus probably not yet seeing improvements.

Why not more widely used in secondary care?

The Prescription Services expressed,

". . . our need to understand why these products are not being initiated and used more widely in secondary care by clinicians"

We explained that IQoro was being used to a limited extent in hospital settings but that the primary obstacle to its wider use in secondary care is the lack of a Drug Tariff listing. SLTs can often be based within Secondary Services but with referrals for patients sitting within Primary Care. Prescription status enables treatment of these patients irrespective of who employs the SLT.

Despite this, some 30 NHS trusts (*then*) had managed to find budget to buy and deploy IQoro in a limited way – maybe 900 devices in all (*again, at that time*). Individuals self-purchasing IQoro at the recommendation of their NHS professional account for 2.56% of our sales to private customers.

Deployment in NHS against existing standards

A constant theme, in the NICE MIBs, and from the Prescription Services, was one of needing proof of successful IQoro deployment in an NHS setting. A comparison of IQoro treatment against existing care methods for chronically ill patients was needed.

A Service Evaluation conducted by the Royal Devon and Exeter NHS Trust and funded and supported by the South West Academic Health Science Network specifically evaluated the suitability of IQoro for treating patients in NHS acute, in-patient rehab, and community settings. The outcomes were compared with traditional treatments. Most patients suffered with chronic dysphagia: other therapies having been tried and not effective.

Prescription Services considered the full report. The authors of the report have given us permission to share this data with selected bodies such as yours who are considering IQoro efficacy evidence. Please contact us for a copy. PLEASE NOTE that the authors are still hoping for publication in an international journal and thus request that you use this data only internally or otherwise with care and do not share it on public forums.

A copy of the abstract of this study can be found on our website here. Key outcomes were:

Diet modification

On the subject of thickeners and modified diets the service evaluation says,

> "***The IDDSI levels gave detail on the amount of change, participants typically moved from a minced and moist diet (IDDSI level 5) and level 2 thickened drinks to normal diet (IDDSI level 7) and drinks (IDDSI level 0).***"

If your colleagues want to know more about the IDDSI levels then this is useful.

PEG feeding

The issue of PEG feeding was summarised in the service evaluation report as,

> '***There were also four participants who showed an even greater change, as they moved from enteral feeding for all intake to fully oral intake for both diet and fluids. All four ended the training having normal diets and either normal fluids or level 1 thickened fluids'***.

One of the peer-reviewed and internationally-published scientific studies included 5 patients with PEG feeds at the start of the study. See abstract here, click on #11. At end-of-training all 5 PEGs had been removed.

More data on PEG removal or avoidance is shown in this report. The table of contents is clickable to take you to the desired sections.

Inclusion criteria 3

They are cost effective.

The NHS Business Services Authority requirement:

"Cost Effectiveness

18. Issues of cost effectiveness centre around whether it would be sensible for the NHS to pay for the device to be used. The two main considerations are:

i. Whether the product should be reimbursed at all i.e.
It may be more cost effective to lend it to a patient, or to treat a patient in a clinic with the appliance.

ii. Cost. There are two aspects:
The cost of using the product in a given treatment regime compared with the cost of the most effective alternative treatment regime (or no treatment regime if there is none currently available).

The price of the product compared with the price of similar products. . .

The following paragraphs discuss these points in detail.

Whether the NHS should reimburse at all

19. This issue may arise if similar products have not been listed before. Not all appliances registered as a medical device would be considered suitable for reimbursement by the NHS if, for example, the product is for a purpose which does not form part of NHS services or if provision of the product via prescribing would be unaffordable.

Cost compared with alternative treatments
20. ***This issue may also arise if similar products have not been listed before. NHS Prescription Services' consideration will centre on the question of whether other products/treatment regimens are available which deal with the condition in question at less cost and/or more effectively, which translates to a similar or reduced total cost.***

Cost compared with similar products
21. This question may arise if similar products have previously been listed. . ."

As stated earlier, the company was required to provide properly referenced and reasoned cost effectiveness data for both the condition treatment areas: dysphagia, and reflux-based diseases. The documents summarising this data are available here:

The costs / benefits of IQoro treatment of dysphagia here.

The costs / benefits of IQoro treatment of GERD and reflux-based conditions, here.