Table showing changes to addendum post committee meeting

Company clarification	EAG edit
EAG reports a concern for allocation concealment in the RCT. The allocation sequence was generated and implemented electronically. The healthcare professional enrolling the participant did not have access to the upcoming allocation prior to assignment. Treatment group allocation was revealed only after the patient had been formally included and all baseline data had been recorded. Therefore, allocation concealment was ensured, and there was no possibility for the enrolling healthcare professional to influence treatment assignment.	Removed statement from section 4.1: “The RCT appears to lack allocation concealment as the person enrolling participants accessed the allocation list directly and assigned participants based on the randomisation list. This means the person enrolling participants may have had foreknowledge of treatment allocation. Therefore, a potential for selection bias is noted.”
Although mortality was not a predefined primary or secondary efficacy endpoint, deaths were systematically captured as part of serious adverse event (SAE) monitoring procedures in accordance with the clinical monitoring plan. Throughout the study period, no deaths were reported in either treatment group.	The EAG have not provided an edit as the number of deaths (i.e. zero) was not explicitly reported. However, we have included this here to provide clarity that there were no deaths in the RCT.

GID-HTE10063 Digital technologies for asthma self-management – Addendum 1

External assessment report

Produced by: Newcastle University

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Number of attached appendices: 3

Purpose of the early value assessment report

The purpose of this external assessment report (EAR) by an external assessment group (EAG) for early value assessment is to review the evidence currently available for technologies within the decision problem and advise what further evidence should be collected to help inform future decisions on whether the technologies should be widely adopted in the NHS. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Committee when it is making decisions about the early value assessment.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

None

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Responsibility for report

The views expressed in this report are those of the authors and not those of NICE or the NIHR Evidence Synthesis Programme. Any errors are the responsibility of the authors.

Table 1. Summary of all confidential information and its source in report

Brief description	AIC/CIC	Page numbers	Source
Study information for JOE Digital Therapy	AiC	14-16	Company RFE
Quantitative results for JOE Digital therapy	AiC	17-20	Company RFE
Quantitative results for JOE Digital therapy	AiC	23-30, 33	Company RFE

Contents

1. Aim

The EAG previously completed a report for the early-use assessment for the use of apps in the self-management of asthma. This was discussed at MTAC in November 2025. Since the completion of the report a company with a product that is deemed to be in scope has been included, namely Ludocare's JOE Digital Therapy. This includes a personal robot and parent/guardian app for smart phone use. A targeted search was also conducted but identified no published literature, which is in line with the company's evidence submission that only identified two unpublished studies. The EAG has extracted data on these studies.

The aim of this addendum is therefore to present the data made available by Ludocare for the JOE Digital Therapy technology.

2. Technology

A summary of the newly included technology is available in Table 2. This has been derived from information found in the company supplied requests for information.

The JOE Digital Therapy (Ludocare) provides a companion robot (hardware) for children and a mobile phone application for parents/guardians (software).

The JOE Digital Therapy technology is classified as a Class I medical device. With CE marking according to Regulation (EU) 2017/745.

Ludocare's JOE is not currently available in the NHS but it is planned for release in Q3 2026.

The EAG reviewed the MHRA Field Safety Notices from Jan 2020 for Ludocare and JOE Digital Therapy and did not find any safety notices.

From information provided by companies and from company websites, the EAG notes that technologies included in this assessment:

- Require internet access.
- Require a device to display and or receive results.
- Are to aid the clinician in reporting, that is, they will not be used autonomously without human interpretation.

Additional detailed information relating to each device can be found in Appendix C.

Table 2: Description of technologies

Device (Company) [Previous Name]	Indications	Type of platform	Additional hardware	PAAP features	Types of Tracking
JOE Digital Therapy (LUDOCARE) Launched: Planned launch Q3 2026 Class I	Intended to support asthma self-management in children with persistent asthma aged 3 to 11 years by improving treatment adherence, supporting correct device use, and reinforcing education as defined by the healthcare professional. It is intended as an add-on to standard care and does not replace medical management or clinical decision-making nor parents' control.	Parent-facing mobile app (LUDOCARE mobile application), the JOE interactive robot and the LUDOCARE backend server.	Parent application requires an iOS (the current version and the two previous major versions) or Android (the four most recent major versions) smartphone or tablet. There is no web-based platform for routine use. The parent mobile application requires an active internet connection to operate. The robot can be used while connected via Wi-Fi and may continue to operate without an internet connection for up to 7 consecutive days.	The PAAP is defined by the healthcare professional and entered or validated within the platform to reflect the child's individual clinical plan. PAAP content can be input in the system through structured fields corresponding to the clinician-defined elements of the plan (for example daily treatment, symptom or peak expiratory flow (PEF) zones) and/or uploaded or referenced clinician-authored documents (such as a written PAAP), which are stored and made accessible within the parent application. The PAAP is fully customisable at the individual patient level and can be updated or changed at any time to reflect modifications made by the healthcare professional during routine reviews or following changes in the child's condition or treatment.	The app is designed to support parents in managing their child's asthma by enabling them to record inhaler technique, PEF, symptoms, and air quality, receive reminders via a calendar, generate monthly reports, store and retrieve the crisis protocol developed by the clinician to help manage emergency attacks.
Abbreviations: PAAP = personalised asthma action plan; PEF = peak expiratory flow					

3. Clinical evidence

3.1 Search strategies and study selection

A targeted search was completed using the same approach as defined in the full EAG report.

For screening, only 18 records were identified, which were double screened in Endnote by two reviewers (RPWK, JW).

3.2 Included and excluded studies

3.2.1 Results of the search

See Appendix A2 for the PRISMA diagram for clinical evidence. Only a single clinical trial record, which was linked to an unpublished RCT provided by the company was included.

3.2.2 Characteristics of included studies

Table 3: Description of studies describing use of JOE Digital Therapy

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
JOE Digital Therapy (LUDOCARE) [NCT04942639]	Asthma JoeCare study (unpublished) RCT France	213 Patients aged 4 to 11 years old and their parents/guardians Setting: primary and secondary care (public or private hospital and/or in private practice) (full match to scope)	Intervention: JOE Digital Therapy + standard care (n = 105); JOE companion robot for patients and Ludocare application for parents/guardians. The JOE companion robot allows for reminders to take medication, explanation of correct inhaler technique, including multimedia content. (full match to scope) Comparator: standard care alone (n = 108); including training for patients and parents on proper use of the basic treatments, including dosages and administration.	Number of patients who had at least one severe exacerbation Time to first severe exacerbation Number of systemic corticosteroid doses taken during 12 months of follow-up. Number of hospitalizations/emergency room admissions Number of patients who had at least one hospitalization/emergency room admission Time to first hospitalization/emergency room admission, Number of patients who had at least one additional consultation Additional consultation,	Population: Included children with GINA grade 2, 3, 4, or 5. Intervention: No comments, fits the decision problem. Comparator: No comments, fits the decision problem. Outcomes: No comments, fits the decision problem. Setting: included private practice which may not be generalisable to NHS England care.

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
			(full match to scope)	Change in asthma control, Number of patients with controlled asthma, Patients' quality of life, Quality of life of parents or guardians, Patient school absenteeism, Absenteeism from work among parents or guardians, Changes in asthma maintenance treatments. Tolerance of the educational support provided by JOE Digital Therapy to help Patients take their medication. Effect of educational support for patients taking treatment, provided by JOE Digital Therapy, on the direct costs of patient care.	

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
				Exploratory analyses in the JOE Digital Therapy + standard care group Patients who wish or do not wish to continue with JOE Digital Therapy beyond the end of the follow-up period. Search for a link between response to treatment and use of JOE Digital Therapy	
	REJOICE (unpublished) Retrospective cohort France	[redacted]	[redacted]	[redacted]	[redacted]
Abbreviations: EAG = External Assessment Group; GINA = Global Initiative for Asthma; N/A = not applicable					

4. Clinical evidence review

4.1 Quality appraisal of studies

Formal critical appraisal was not undertaken. However, here we present considerations for risk of bias and other potential issues associated with the current evidence base, noting that results are only available from one unpublished study conducted in a non-NHS setting.

The majority of the baseline factors in the RCT were similar between the two groups, however the results noted there was a difference in baseline exacerbations[redacted].

The retrospective analysis conducted did not include analyses that were adjusted for confounding. This will incur a risk of bias for not considering potential confounders in the analysis.

The generalisability of both the RCT and retrospective cohort are limited due to the differences in healthcare settings. Whilst France does have a universal healthcare system, the set-up is not the same as the NHS in England. Additionally, both studies included private hospitals/practices. The results may therefore not be reflective of English NHS practice.

4.2 Results from the evidence base

4.2.1 Intermediate outcomes

Inhaler technique

Quantitative evidence

No included studies provided quantitative data assessing inhaler technique for the JOE Digital Therapy.

Qualitative evidence

No included studies provided qualitative data assessing inhaler technique for the JOE Digital Therapy.

Medication use

Quantitative evidence

One study assessing the JOE Digital Therapy provided evidence for medication use, evidence was derived from a multicentre RCT.[1]

Changes in medication use were reported as percentage of change based on a 3-category Likert scale (reduction, stability or increase). Between baseline to four months, four to eight months, and eight to 12 months (see Table 4). Data suggest both groups varied in terms of reduction, stability and increases in medication use. [redacted][1]

Table 4: Quantitative outcome data for medication use

Technology	Author (year) Study design (country)	Population	Intervention/ Comparator	Outcome measurement	Follow-up	Intervention results	Control results	Differences between groups
JOE Digital Therapy	Asthma JoeCare study (unpublished) RCT (France)	213 Patients aged 4 to 11 years old and their parents/guardians	Intervention: JOE Digital Therapy + standard care (n = 105) Comparator: Standard care (n = 108)	Reduction of medication use (%)	[redacted]	[redacted]	[redacted]	[redacted]
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
				Stable medication use (%)	[redacted]	[redacted]	[redacted]	[redacted]
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
				Increase of medication use (%)	[redacted]	[redacted]	[redacted]	[redacted]
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	

Abbreviations: RCT = Randomised Controlled Trial; n = number of patients

Source: Asthma Joe Care Study Clinical study report (unpublished)[1]

Qualitative evidence

No included studies provided qualitative data assessing inhaler technique for the JOE Digital Therapy.

Adherence/attrition rates

Quantitative evidence

Two unpublished studies assessing JOE Digital Therapy reported on adherence/attrition.[1, 2] One of which was an RCT[1] and the other a retrospective cohort.[2]

Both studies reported the number of therapeutic interactions, with a [redacted][1] and [redacted][2] The RCT also reported the [redacted] with the JOE Digital Therapy device/application.[1] The retrospective cohort stated that to be complaint with the JOE digital therapy at least 45 interactions were required. Of the [redacted] were considered compliant.[2]

The retrospective cohort study reported discontinuations for a subgroup of patients completing a non-mandatory question [redacted]. The became most commonly reported reason was [redacted][2] Finally, this study also reported the duration of use from those completing the non-mandatory questionnaire: [redacted][2]

Qualitative evidence

No included studies provided qualitative data assessing adherence/attrition for the JOE Digital Therapy.

Number of referrals to specialists

Quantitative evidence

No included studies provided quantitative data assessing the number of referrals to specialists for the JOE Digital Therapy.

Qualitative evidence

No included studies provided qualitative data assessing the number of referrals to specialists for the JOE Digital Therapy.

4.2.2 Clinical outcomes

Changes in symptoms/symptomatic improvement

No included studies provided quantitative or qualitative data assessing changes in symptoms/symptomatic improvement for the JOE Digital Therapy.

Lung function

No included studies provided quantitative or qualitative data assessing lung function for the JOE Digital Therapy.

Asthma control

Quantitative evidence

One RCT assessing JOE Digital Therapy reported data on asthma control.[1]

In the Asthma Joe Care RCT the Childhood Asthma Control Test (C-ACT) was used to assess asthma control in patients with GINA grades 2, 3, 4, or 5 asthma receiving JOE Digital Therapy in addition to standard treatment compared to a control group receiving standard treatment only.[1]

The C-ACT is a 7-item questionnaire for children with asthma aged 4 to 11 years. Out of the 7-items, 4 are filled out by the child and 3 items by the parent and provide a composite score of up to 27. A cut-off score of under 19 is indicative of uncontrolled asthma and minimal clinically important difference of 2 is considered for this tool.[3] [redacted].[1]

[redacted][1]

Table 5: Overview of quantitative evidence for asthma control

Technology	Author (year) Study design (country)	Population	Intervention Comparator	Outcome measure	Follow up	Intervention results	Control results	Follow up Analysis results
JOE Digital Therapy	Asthma JoeCare study (unpublished) RCT (France)	213 Patients aged 4 to 11 years old and their parents/guardians	Intervention: JOE Digital Therapy + standard care [redacted] Comparator: Standard care [redacted]	Total C-ACT score	[redacted]	[redacted]	[redacted]	[redacted]
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
			Intervention: JOE Digital Therapy + standard care [redacted] Comparator: Standard care [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	

Technology	Author (year) Study design (country)	Population	Intervention Comparator	Outcome measure	Follow up	Intervention results	Control results	Follow up Analysis results
Abbreviations: C-ACT = Children's Asthma Control Test; CI = confidence intervention; RCT = randomised controlled trial; SD = Standard deviation Source: Asthma JoeCare Study Clinical study report (unpublished)[1]								

Symptom-free days

No included studies provided quantitative or qualitative data assessing symptom-free days for the JOE Digital Therapy.

Exacerbations or attacks

Quantitative evidence

One RCT assessing JOE Digital Therapy reported data on exacerbations.[1]

In the Asthma JoeCare RCT, the primary endpoint evaluated the number of severe exacerbations inpatients with GINA grades 2, 3, 4, or 5 asthma receiving JOE Digital Therapy in addition to background treatment compared to a control group receiving standard treatment.[1] [redacted] (see Table 6). [redacted]

[redacted][1]

[redacted][1] [redacted][1] [redacted][1]

[redacted][1] [redacted][1] [redacted][1]

Table 6. Overview of quantitative evidence for exacerbations in the Asthma JoeCare study

Technology	Author (year) Study design (country)	Population	Intervention Comparator	Outcome measure	Follow up	Intervention results	Control results	Follow up Analysis results
JOE Digital Therapy	Asthma JoeCare study (unpublished) RCT (France)	213 Patients aged 4 to 11 years old and their parents/guardians	Intervention: JOE Digital Therapy + standard care (n = 105) [redacted] Comparator: Standard care (n = 108) [redacted]	Number of severe exacerbations in the past 12 months	[redacted]	[redacted]	[redacted]	[redacted]
			Intervention: JOE Digital Therapy + standard care	Number of patients who had at least one severe exacerbation	[redacted]	[redacted]	[redacted]	[redacted]

Technology	Author (year) Study design (country)	Population	Intervention Comparator	Outcome measure	Follow up	Intervention results	Control results	Follow up Analysis results
			[redacted] Comparator: Standard care [redacted]		[redacted]	[redacted]	[redacted]	
			Intervention: JOE Digital Therapy + standard care [redacted] Comparator: Standard care [redacted]	Time to first severe exacerbation from inclusion (days)	[redacted]	[redacted]	[redacted]	[redacted]
			Intervention: JOE Digital	Number of hospitalization	[redacted]	[redacted]	[redacted]	[redacted]

Technology	Author (year) Study design (country)	Population	Intervention Comparator	Outcome measure	Follow up	Intervention results	Control results	Follow up Analysis results
			Therapy + standard care [redacted] Comparator: Standard care [redacted]	s/emergency room admission	[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
			Intervention: JOE Digital Therapy + standard care [redacted] Comparator: Standard care [redacted]	Number of patients who had at least one hospitalization /emergency room admission	[redacted]	[redacted]	[redacted]	[redacted]
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	

Technology	Author (year) Study design (country)	Population	Intervention Comparator	Outcome measure	Follow up	Intervention results	Control results	Follow up Analysis results
			Intervention: JOE Digital Therapy + standard care [redacted] Comparator: Standard care [redacted]	Time to first hospitalization /emergency room admission (days)	[redacted]	[redacted]	[redacted]	[redacted]
			Intervention: JOE Digital Therapy + standard care [redacted] Comparator: Standard care	Number of additional unplanned consultation	[redacted] [redacted] [redacted] [redacted]	[redacted] [redacted] [redacted] [redacted]	[redacted] [redacted] [redacted] [redacted]	[redacted]

Technology	Author (year) Study design (country)	Population	Intervention Comparator	Outcome measure	Follow up	Intervention results	Control results	Follow up Analysis results
			[redacted]					
			Intervention: JOE Digital Therapy + standard care [redacted]	Number of patients who had at least one additional unplanned consultation	[redacted]	[redacted]	[redacted]	[redacted]
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	
					[redacted]	[redacted]	[redacted]	

Abbreviations: CI = confidence interval; HR = hazard ratio; RCT = randomised controlled trial; RR = risk ratio; SD = Standard deviation

Source: Asthma JoeCare Study Clinical study report (unpublished)[1]

Qualitative evidence

No included studies provided qualitative data assessing exacerbations or attacks for the JOE Digital Therapy.

Mortality

No included studies provided quantitative or qualitative data assessing mortality for the JOE Digital Therapy.

4.2.3 Patient-reported outcomes

Time off work or school

Quantitative evidence

One study assessing JOE Digital Therapy reported data on the number of days missed from school or work by patients and their parents or guardians respectively.[1]

[redacted][1] [redacted][1] [redacted][1]

[redacted][1] [redacted]section 4.2.2[redacted]

Qualitative evidence

No included studies provided qualitative data assessing time off work or school for the JOE Digital Therapy.

Quality of life

Quantitative evidence

One study assessing JOE Digital Therapy reported data on the quality of life of both patients with asthma and their parents or guardians.[1]

In the phase 3 randomised, parallel study conducted in France, the mini-Paediatric Asthma Quality of Life Questionnaire (mPAQLQ), was used to assess the impact of JOE Digital Therapy in addition to standard treatment, on the quality of life of patients aged 4 to 11 years with GINA grades 2, 3, 4, or 5 asthma, compared to parents or guardian of patients in the control group

receiving standard treatment only.[1] The mPAQLQ, while shorter and less precise than the full length PAQLQ, is a validated tool that can be completed more quickly, and therefore ideal for long-term monitoring in large clinical trials.[4, 5] The mPAQLQ contains 13 items, each relating to the three domains: symptoms (6 items), activity (3 items), or emotional function (4 items). Response to each item is given on 7-point scale where 1 represents severe impairment and 7 represents no impairment, with a minimal clinically important difference of 0.5 being considered for a domain or total score.

[redacted][1][redacted][1]

In the same study the Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) was used to assess the impact of JOE Digital Therapy in addition to standard treatment on the quality of life of parents or guardians compared to those of patients in the control group receiving standard treatment only.[1] The validated PACQLQ is comprised of 13 items comprising the following two domains activity limitations (4 items) and emotional function (9 items).[6] As for mPAQLQ, response to each item is given on 7-point scale (1 = severe impairment; 7 = no impairment), with a minimal clinically important difference of 0.5 being considered for a domain or total score.[redacted][1]

As outlined in section 4.2.2,[redacted][1]

Qualitative evidence

No included studies provided qualitative data assessing quality of life for the JOE Digital Therapy.

Ease of use and acceptability

Quantitative evidence

One study assessing JOE Digital Therapy reported data on the ease of use and acceptability.[1]

[redacted][1]

Qualitative evidence

No included studies provided qualitative data assessing ease of use and acceptability for JOE Digital Therapy.

Patient perception of technology

No studies presented quantitative or qualitative data relevant to this outcome.

4.3 Adverse events and clinical risk

Evidence for the JOE Digital Therapy was available from two studies.[2] [redacted].[2] [redacted].[2]

[redacted].

4.4 Clinical evidence summary and interpretation

Two studies were included in the review of evidence for JOE Digital Therapy (Ludocare), both of which were unpublished.

[redacted]

[redacted]

[redacted]

[redacted]

5. Economic evidence

5.1 Existing economic evidence

5.1.1 Economic literature searches

No targeted searches were conducted for the inclusion of the Ludocare technology JOE digital Therapy, and no economic evidence was found in the clinical search.

The company stated in their RFE that there was, at the time of submission, no published economic evaluation which could be directly used within the scope

of the current early use assessment. Additionally, the company stated that economic evaluations conducted in other jurisdiction or healthcare settings were not provided as they are not directly applicable to an NHS setting.

5.2 Conceptual model

The cost of the JOE Digital Therapy technology (without VAT) was included in the conceptual model described in the original EAG report. The time horizon and costs, including when they were applied, were varied to explore how the technology would be used, as described by the company, but no other clinical parameters were changed.

5.2.1 Resource use and cost parameters

The EAG have added the technology cost breakdown for JOE Digital Therapy in Table 7. Unlike the other technologies, JOE Digital Therapy includes an end of use cost. As this parameter was not included in the original model, the cost was incorporated as an upfront cost within the model. The company stated that most patients are only treated with the technology for 6 months, and for a maximum of 12 months. However, the clinical data suggests that patients can often use the technology for nine or more months.[2] To explore the full range of possible costs, costs were applied in two ways: firstly, as a monthly recurring cost with total annual costs of 3 months', 6 months' and 12 months' worth of costs. This was to ensure the technology was modelled equivalently to the others in the original EAG report. Secondly, as a single upfront cost of 3 months', 6 months' and 12 months' worth of costs followed by £7.46 per year for practice nurse review. For the JOE Digital Care technology, both modelled scenarios potentially overestimate total per patient costs. In the first scenario this is because technology costs continue to be incurred per cycle for all users who have not yet dropped out (that is, the only mechanism by which costs stop being incurred is by dropping out). In the second scenario the overestimation may occur because those dropping out will incur costs associated with management in the 'NoApp' arm on top of the upfront costs already applied. The second scenario may be a more accurate reflection of the intended use of the technology, and allows the clinical benefit to continue without incurring more than 3 months', 6 months', or 12 months' worth of total

costs. The dropout rate was maintained at 50% per year for both scenarios, and time horizons of 1 year, 5 years, and 10 years were considered.

Table 7: Economic modelling: monitoring costs (per patient); all costs excluding VAT

Price category	Standard care	BreatheSmart/Respi.me (Respiratory Disease Management Platform (RDMP) Aptar Digital Health)	Asthmahub (The Institute of Clinical Science and Technology - ICST)	Luscii (Luscii healthtech B.V)	AsthmaTuner (MediTuner)	myAsthma (my mHealth)	NuvoAir Home (NuvoAir Medical)	Smart Asthma (Smart Respiratory Products Ltd)	Digital Health Passport (Tiny Medical Apps)	JOE Digital Therapy (Ludocare)
Hardware	-	£112	No RFE	NR	[redacted]	NR	£360	£66.65	NR	£56.67
Platform/license	-	-	£29	-	-	£35*	-	-	£77	N/A (included in price)
Integration	-	-	No RFE	£8.50	-	NR	N/A (online portal)	N/A	NR	N/A
Training (for staff)	-	-	No RFE	NR	[redacted]	NR	N/A (included in price)	N/A	NR	N/A
Practice nurse time to train patient on using technology (5 minutes)	-	£4.42	£4.42	£4.42	£4.42	£4.42	N/A	£4.42	£4.42	N/A (included in price)
Upfront costs, per patient (one-off)	**£0**	**£116.42**	**£33.42**	**£12.92**	[redacted]	**£39.42**	**£360**	**£71.07**	**£81.42**	**£56.67**
Software	-	-	£0.00 (Assumed free app to patient)	-	[redacted]	**£30**	NR	NR	£0.00 (Assumed free app to patient)	-
Maintenance	-	-	No RFE	-	N/A (support included in pricing)	NR	N/A	NR	NR	-
Cost of technology, applied per patient per year (fixed annual cost)	**£0**	**£0**	**£0**	**£0**	[redacted]	**£30**	**£0**	**£0**	**£0**	**£0**
Cost of technology	-	£180	-	£180	-	-	-	-	-	£1,240
Standard care monitoring (primary care)	£29.85	-	-	-	-	-	-	-	-	-
Practice nurse time to review results of app	-	£7.46	£7.46	£7.46	£7.46	£7.46	£7.46	£7.46	£7.46	£7.46

Costs per patient, per year (no fixed timeframe; can be applied monthly)	**£29.85**	**£187.46**†	**£7.46**†	**£187.46**†	**£7.46**†	**£7.46**†	**£7.46**†	**£7.46**†	**£7.46**†	**£1247.46**
End of service and device return fee	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£45** (applied with the £56.67 upfront cost in economic model)

5.3 Results from the economic modelling

5.3.1 Asthma (children)

The JOE Digital Therapy app is intended to support asthma self-management in children (3 to 11 years old) with persistent asthma therefore the only analysis conducted is for this age group.

As with the original report, the EAG considered the value proposition of maintaining higher levels of symptom control as the most plausible.

When considering time horizons of 1 year, 5 years and 10 years, and varying total costs applied, and when drop-out rates are applied, JOE Digital Therapy would not be considered cost-effective at a £20,000 willingness to pay threshold, in any scenario (see Table 8).

Table 8: Economic sensitivity analysis (children)

Scenario	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Comparator – base case (time horizon, 5 years)	432.40	3.872	NA	NA	NA	NA
Intervention + costs of SmartAsthma technology (time horizon, 5 years) with 50% drop out at 1 year	456.20	3.874	23.85	0.002268	10,516	21.50
Intervention + costs (12 months, applied upfront) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	1,409.00	3.874	976.80	0.002268	430,644	-931.40
Intervention + costs (12 months, applied annually) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	2,110.00	3.874	1678.00	0.002268	739,601	-1632.00
Intervention + costs (6 months, applied upfront) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	944.20	3.874	511.80	0.002268	225,638	-466.40
Intervention + costs (6 months, applied annually) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	1,295.00	3.874	862.20	0.002268	380,117	-816.80
Intervention + costs (3 months, applied upfront) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	711.70	3.874	279.30	0.002268	123,135	-233.90
Intervention + costs (3 months, applied annually) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	886.80	3.874	454.50	0.002268	200,375	-409.10
Comparator – base case (time horizon, 1 year)	92.57	0.8261	NA	NA	NA	NA
Intervention + costs of SmartAsthma technology (time horizon, 1 year) with 50% drop out at 1 year	132.90	0.8264	40.31	0.0003714	108,527	-32.90
Intervention + costs (12 months, applied upfront) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	1,086.00	0.8264	993.30	0.0003714	2,674,268	-985.80
Intervention + costs (12 months, applied annually) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	875.50	0.8264	782.90	0.0003714	2,107,948	-775.50
Intervention + costs (6 months, applied upfront) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	620.80	0.8264	528.30	0.0003714	1,422,291	-520.80
Intervention + costs (6 months, applied annually) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	515.70	0.8264	423.10	0.0003714	1,139,131	-415.70
Intervention + costs (3 months, applied upfront) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	388.30	0.8264	295.80	0.0003714	796,303	-288.30
Intervention + costs (3 months, applied annually) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	335.70	0.8264	243.20	0.0003714	654,723	-235.70
Comparator – base case (time horizon, 10 years)	796.00	7.141	NA	NA	NA	NA
Intervention + costs of SmartAsthma technology (time horizon, 10 years) with 50% drop out at 1 year	817.80	7.143	21.74	0.002759	7,877	33.50
Intervention + costs (12 months, applied upfront) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	1,771.00	7.143	974.70	0.002759	353,235	-919.50
Intervention + costs (12 months, applied annually) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	2,589.00	7.143	1,793.00	0.002759	649,671	-1,737.00
Intervention + costs (6 months, applied upfront) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	1,306.00	7.143	509.70	0.002759	184,714	-454.50
Intervention + costs (6 months, applied annually) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	1,715.00	7.143	918.70	0.002759	332,932	-863.50
Intervention + costs (3 months, applied upfront) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	1,073.00	7.143	277.20	0.002759	100,454	-222.00
Intervention + costs (3 months, applied annually) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	1,278.00	7.143	481.70	0.002759	174,562	-426.50

Abbreviations: FP, false positives; ICER, incremental cost-effectiveness ratio; NA, not applicable; NMB, net monetary benefit; QALY, quality-adjusted life year; * dominance should be interpreted cautiously due to the conceptual nature of the model and the small incremental gains estimated.

5.4 Summary and interpretation of the economic evidence

The EAG considered the JOE Digital Therapy technology within the context of the economic model developed previously. There are therefore limitations around modelling costs of the technology, which the company described as typically being used for only 6 months. This has been explored by varying the costs applied, including when they are applied, to cover a range of scenarios reflecting how the technology might be used in practice. However, with all ICERs much greater than a £20,000 willingness to pay threshold, it is unlikely that the technology would be cost-effective, without large changes in other key parameters driving the model. Further evidence demonstrating the clinical effect of the technology over a longer time period is needed.

6. Evidence gap analysis

6.1 Ongoing studies

No ongoing studies were identified by the EAG. Additionally, the company did not supply evidence of any ongoing studies through the RFE.

6.2 Evidence gap analysis

In line with the original EAG report, we have updated following the same assumptions (see Table 9).

Table 9: Evidence gap analysis

Outcomes	Asthmahub	Asthmahub for Parents	AsthmaTuner	Digital Health Passport	Luscii	myAsthma	NuvoAir	Smart Asthma	BreatheSmart and Respi.me (RDMP)	JOE Digital Therapy	All technologies or pathway-related
Inhaler technique	RED	RED	RED	RED	RED	RED	RED	RED	RED	RED	RED
Medication use	AMBER	RED	AMBER	RED	RED	AMBER	RED	RED	AMBER	AMBER	RED
Adherence/attrition rates	RED	RED	RED	RED	RED	RED	RED	RED	AMBER	AMBER	RED
Number of referrals to specialists	RED	RED	RED	RED	RED	AMBER	RED	RED	RED	RED	RED
Changes in symptom/symptomatic improvement	RED	RED	RED	RED	RED	RED	RED	RED	AMBER	RED	RED
Lung function	RED	RED	RED	RED	AMBER	RED	RED	RED	AMBER	RED	RED
Asthma control	AMBER	AMBER	AMBER	AMBER	AMBER	AMBER	RED	REDRED	AMBER	AMBER	AMBER
Symptom-free days	RED	RED	RED	RED	RED	RED	RED	RED	RED	RED	RED
Exacerbations or attacks	RED	RED	RED	AMBER	RED	AMBER	RED	REDRED	AMBER	AMBER	RED
Mortality	RED	RED	RED	RED	RED	RED	RED	RED	AMBER	RED	RED
Time off work or school	RED	RED	RED	AMBER	RED	AMBER	RED	RED	AMBER	AMBER	RED
Quality of life	AMBER	RED	RED	AMBER	RED	AMBER	AMBER	AMBER	AMBER	AMBER	RED
Ease of use and acceptability	RED	RED	RED	AMBER	RED	AMBER	AMBER	AMBER	AMBER	AMBER	RED
Patient perception of technology	RED	RED	RED	AMBER	RED	AMBER	AMBER	RED	AMBER	RED	RED

Outcomes	Asthmahub	Asthmahub for Parents	AsthmaTuner	Digital Health Passport	Luscii	myAsthma	NuvoAir	Smart Asthma	BreatheSmart and Respi.me (RDMP)	JOE Digital Therapy	All technologies or pathway-related
Adverse events and clinical risk	**RED**	**RED**	**RED**	**RED**	**RED**	**RED**	**AMBER**	**RED**	**AMBER**	**AMBER**	**RED**
Key: **AMBER**, some evidence available; **GREEN**, evidence available; **RED**, no evidence available											

7. References

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6.Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in the parents of children with asthma. *Qual Life Res* 1996;**5**:27-34. https://doi.org/10.1007/bf00435966

8. Appendices

Appendix A – Literature searching

Appendix A1: Search strategies

Clinical effectiveness searches

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions 1946 to January 27, 2026

#	Searches	Results
1	robot.ti,ab,kw.	40116
2	asthma.ti,ab,kw.	188091
3	1 and 2	12
4	ludocare.ti,ab,kw.	0
5	child*.ti,ab,kw.	1869060
6	3 and 5	3

7	JOE.ti,ab,kw.	744
8	3 and 7	0

Embase 1996 to 2026 Week 04

#	Searches	Results
1	robot.ti,ab,kw.	52849
2	asthma.ti,ab,kw.	247755
3	1 and 2	36
4	ludocare.ti,ab,kw.	0
5	child*.ti,ab,kw.	2040639
6	3 and 5	4
7	JOE.ti,ab,kw.	833
8	3 and 7	0

Cochrane DSR and CENTRAL

All Text: ludocare (Word variations have been searched)

CINAHL(Via EbscoHost)

All Fields: Ludocare

TX (Ludocare)

INAHTA

Ludocare

Clinicaltrials.gov

Other Terms: Ludocare

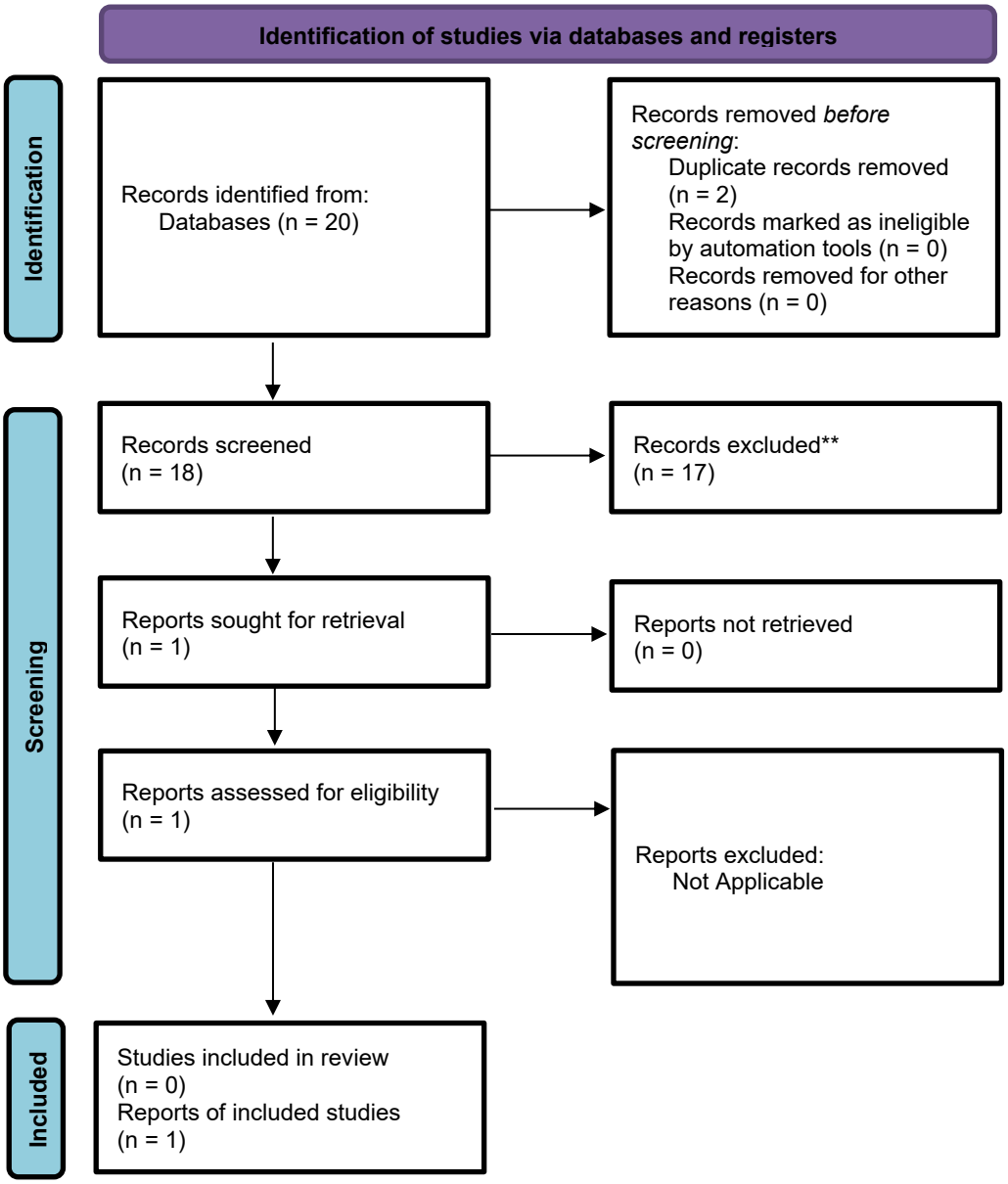
World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP)

Ludocare

INAHTA

Ludocare

Appendix A2: PRISMA diagram: clinical



Appendix B – Economic modelling

Appendix B5: Results from sensitivity analysis

Asthma (children)

Scenario	Controlled App	Partially Controlled App	Uncontrolled App	Exacerbation App	NoDisease Treated App	Controlled (NoApp)	Partially Controlled (NoApp)	Uncontrolled (NoApp)	Exacerbation (NoApp)	NoDisease Treated (NoApp)	No Disease	Deaths	Total costs, £	Total QALYs	Incremental costs, £	Incremental QALYs	ICER	Incremental NMB (£)
Comparator – base case (time horizon, 5 years)	0	0	0	0	0	27942	30386	31174	447	9997	0	54.25	432.4	3.872	NA	NA	NA	NA
Intervention + costs of SmartAsthma technology (time horizon, 5 years) with 50% drop out at 1 year	2139	1715	1926	30.09	583.3	26334	28219	29167	416.8	9413	0	54.25	456.2	3.874	23.85	0.002268	10516	21.5
Intervention + costs (12 months, applied upfront) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	2139	1715	1926	30.09	583.3	26334	28219	29167	416.8	9413	0	54.25	1409	3.874	976.8	0.002268	430644	-931.4
Intervention + costs (12 months, applied annually) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	2139	1715	1926	30.09	583.3	26334	28219	29167	416.8	9413	0	54.25	2110	3.874	1678	0.002268	739601	-1632
Intervention + costs (6 months, applied upfront) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	2139	1715	1926	30.09	583.3	26334	28219	29167	416.8	9413	0	54.25	944.2	3.874	511.8	0.002268	225638	-466.4
Intervention + costs (6 months, applied annually) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	2139	1715	1926	30.09	583.3	26334	28219	29167	416.8	9413	0	54.25	1295	3.874	862.2	0.002268	380117	-816.8
Intervention + costs (3 months, applied upfront) of JOE Digital Therapy (time horizon, 5	2139	1715	1926	30.09	583.3	26334	28219	29167	416.8	9413	0	54.25	711.7	3.874	279.3	0.002268	123135	-233.9

Scenario	Controlled App	Partially Controlled App	Uncontrolled App	Exacerbation App	NoDisease Treated App	Controlled (NoApp)	Partially Controlled (NoApp)	Uncontrolled (NoApp)	Exacerbation (NoApp)	NoDisease Treated (NoApp)	No Disease	Deaths	Total costs, £	Total QALYs	Incremental costs, £	Incremental QALYs	ICER	Incremental NMB (£)
years) with 50% drop out at 1 year																		
Intervention + costs (3 months, applied annually) of JOE Digital Therapy (time horizon, 5 years) with 50% drop out at 1 year	2139	1715	1926	30.09	583.3	26334	28219	29167	416.8	9413	0	54.25	886.8	3.874	454.5	0.002268	200375	-409.1
Comparator – base case (time horizon, 1 year)	0	0	0	0	0	24157	30908	34477	448.1	9999	0	11.53	92.57	0.8261	NA	NA	NA	NA
Intervention + costs of SmartAsthma technology (time horizon, 1 year) with 50% drop out at 1 year	12318	13171	15616	214.6	4500	13206	16428	18801	233.3	5499	0	11.53	132.9	0.8264	40.31	0.0003714	108527	-32.9
Intervention + costs (12 months, applied upfront) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	12318	13171	15616	214.6	4500	13206	16428	18801	233.3	5499	0	11.53	1086	0.8264	993.3	0.0003714	2674268	-985.8
Intervention + costs (12 months, applied annually) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	12318	13171	15616	214.6	4500	13206	16428	18801	233.3	5499	0	11.53	875.5	0.8264	782.9	0.0003714	2107948	-775.5
Intervention + costs (6 months, applied upfront) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	12318	13171	15616	214.6	4500	13206	16428	18801	233.3	5499	0	11.53	620.8	0.8264	528.3	0.0003714	1422291	-520.8
Intervention + costs (6 months, applied annually) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	12318	13171	15616	214.6	4500	13206	16428	18801	233.3	5499	0	11.53	515.7	0.8264	423.1	0.0003714	1139131	-415.7
Intervention + costs (3 months, applied upfront) of JOE Digital Therapy	12318	13171	15616	214.6	4500	13206	16428	18801	233.3	5499	0	11.53	388.3	0.8264	295.8	0.0003714	796303	-288.3

Scenario	Controlled App	Partially Controlled App	Uncontrolled App	Exacerbation App	NoDisease Treated App	Controlled (NoApp)	Partially Controlled (NoApp)	Uncontrolled (NoApp)	Exacerbation (NoApp)	NoDisease Treated (NoApp)	No Disease	Deaths	Total costs, £	Total QALYs	Incremental costs, £	Incremental QALYs	ICER	Incremental NMB (£)
(time horizon, 1 year) with 50% drop out at 1 year																		
Intervention + costs (3 months, applied annually) of JOE Digital Therapy (time horizon, 1 year) with 50% drop out at 1 year	12318	13171	15616	214.6	4500	13206	16428	18801	233.3	5499	0	11.53	335.7	0.8264	243.2	0.0003714	654723	-235.7
Comparator – base case (time horizon, 10 years)	0	0	0	0	0	28660	31059	29701	446.3	9992	0	142.2	796	7.141	NA	NA	NA	NA
Intervention + costs of SmartAsthma technology (time horizon, 10 years) with 50% drop out at 1 year	190.7	151.4	156.6	2.594	45.36	28532	30877	29513	443.7	9946	0	142.2	817.8	7.143	21.74	0.002759	7877	33.5
Intervention + costs (12 months, applied upfront) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	190.7	151.4	156.6	2.594	45.36	28532	30877	29513	443.7	9946	0	142.2	1771	7.143	974.7	0.002759	353235	-919.5
Intervention + costs (12 months, applied annually) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	190.7	151.4	156.6	2.594	45.36	28532	30877	29513	443.7	9946	0	142.2	2589	7.143	1793	0.002759	649671	-1737
Intervention + costs (6 months, applied upfront) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	190.7	151.4	156.6	2.594	45.36	28532	30877	29513	443.7	9946	0	142.2	1306	7.143	509.7	0.002759	184714	-454.5
Intervention + costs (6 months, applied annually) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	190.7	151.4	156.6	2.594	45.36	28532	30877	29513	443.7	9946	0	142.2	1715	7.143	918.7	0.002759	332932	-863.5
Intervention + costs (3 months, applied upfront) of JOE	190.7	151.4	156.6	2.594	45.36	28532	30877	29513	443.7	9946	0	142.2	1073	7.143	277.2	0.002759	100454	-222

Scenario	Controlled App	Partially Controlled App	Uncontrolled App	Exacerbation App	NoDisease Treated App	Controlled (NoApp)	Partially Controlled (NoApp)	Uncontrolled (NoApp)	Exacerbation (NoApp)	NoDisease Treated (NoApp)	No Disease	Deaths	Total costs, £	Total QALYs	Incremental costs, £	Incremental QALYs	ICER	Incremental NMB (£)
Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year																		
Intervention + costs (3 months, applied annually) of JOE Digital Therapy (time horizon, 10 years) with 50% drop out at 1 year	190.7	151.4	156.6	2.594	45.36	28532	30877	29513	443.7	9946	0	142.2	1278	7.143	481.7	0.002759	174562	-426.5

[Key: bold=base case] Abbreviations: exac, exacerbation; FP, False Positive; ICER, Incremental Cost-Effectiveness Ratio; NA, Not Applicable; NMB, Net Monetary Benefit; pcontrol, partially controlled; QALY, Quality Adjusted Life Year; RR, Relative Reduction; SoC, Standard of Care; uncontrol, uncontrolled; VP, Value Proposition

Appendix C – Additional detail on technologies

Appendix C1: Additional technical information

Device (Company) [Previous Name]	Contraindications	Planned changes or updates	Training Requirements	Installation methods	Patient Data	How this technology fits into the clinical care pathway	Provides education	Communication features	Outputs (for patients)	Outputs (for HCPS)	Safety features	Additional features (as claimed by company)
JOE Digital Therapy (Ludocare)	NR	Ludocare implements periodic updates	HCPs would require minimal training as the home based intervention does not require HCPs to operate or technically manage the technology. Brief written materials and short online resources are all that is needed. Patients and families are supported through in app guidance and step by step instructions, set up materials, and age appropriate content for home use.	App installed on patient device. Companion robot. No NHS infrastructure, hardware installation, or mandatory system integration is required.	Data is stored online cloud servers (OVHcloud, France) that are GDPR compliant.	Intended for home use between routine clinical contacts. Prescribed by the HCPs alongside standard services. Supports families in applying the PAAP. It is designed to be a time limited educational medical device, allowing for patients and families to gain correct treatment behaviours and skills.	Provides educational materials for understanding asthma in age appropriate way, correct inhaler technique and use of accessories (such as spacers), importance of daily adherence, recognition of common triggers and avoidance strategies, and reinforcement of key messages from the clinical PAAP. For children this is provided via short, interactive videos. For parents, the mobile application provides structured educational information.	Does not provide direct clinical communication or messaging between patients/families and HCPs. Does not provide real-time or asynchronous clinical messaging from HCPs. Allows families to communicate directly with Ludocare.	NR	Generates structured data that can support clinical review in a monthly report, including medication adherence information, patient reported symptoms and clinical signs, peak expiratory flow values (if used), and notes/observations from family.	Platform allows families to store and access PAAP, including written emergency instructions. If PAAP includes symptom-based or PEF-based zones, these are defined and validated by the clinician and displayed to help families identify when to follow emergency instructions. Safety-related events are logged and can be reviewed as part of routine follow-up, but do not trigger automatic clinical alert or treatment changes.	The parent app provides outdoor air quality and pollen information, based on location. A notification system to remind families of scheduled treatments, appointments, and key self-management activities. A centralized calendar, for organizing medical and pharmacy appointments and to track important events related to asthma care. Note-taking functionality.

Abbreviations: ACQ, Asthma Control Questionnaire, ACT; Asthma Control Test, AIR/MART; Anti-inflammatory Reliever/Maintenance and Reliever Therapy, API; Application Programming Interface, COPD; Chronic Obstructive Pulmonary Disease, FEV1; Forced Expiratory Volume in one second, FVC; Forced Vital Capacity, GINA; Global Initiative for Asthma, HCP; Healthcare Professional, NR; Not reported, PAAP; Personalised asthma action plans, PEF; Peak Expiratory Flow, PROM; Patient Reported Outcome Measures, RCP; Royal College of Physicians, SABA; short-acting beta-2 agonist

Appendix C2: Additional cost breakdown

Device (Company) [Previous Name]	Cost	What is included	Integration	Training Cost
Standard care	Recurring: £29.85 per patient per year	Monitoring costs associated without FeNO (NG245); assuming 1 practice nurse appointment for 80% of patients, 2 appointments for 15%, and an outpatient visit for 5%		
JOE Digital Therapy (Ludocare)	Upfront: £68 Recurring: £124 per patient per month End of use: £54	Upfront cost covers installation and onboarding of service (including training). Monthly cost allows access to JOE companion robot and parent mobile application (including hosting of data, customer support, and software updates). End of use cost covers support of service closure and archiving, return of device, the reconditioning of the device, and deletion of patient data from device/associated systems.	-	Included in cost