NICE National Institute for Health and Care Excellence

Health Tech programme

HTE10063: Digital technologies to support self-management of asthma

Draft Guidance Collated Comments

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
Theme 1: Clinical evidence and additional new technologies					
1	Consultee 6 APTAR	13	3.6 Committee discussion Evidence base	*Qualitative data exploring patient perspectives, usability and acceptability was available for 4 technologies. There is limited evidence on user experience from the UK.* Aptar provided on DEC 2nd, 2025, a qualitative report entitled 20251114 qualitative interview GSTT with UK asthmatic feedbacks on the digital technology (RDMP). A final report will be provided in the following weeks from now as the trial is ending soon. The solution was perceived as helping patients in: 1. Recognising and rectifying suboptimal inhaler adherence:2. Being empowered to identify, avoid or mitigate environmental triggers:3. New or renewed enthusiasm and commitment to self-management:4. Enhanced surveillance and shared sense-making with health professionals.	Thank you for your comment. Section 3.6 in the guidance has been amended to state that *'Qualitative data exploring patient perspectives, usability and acceptability was available for **5** technologies. There is limited evidence on user experience from the UK'.*
New technologies					
2	Consultee 3 LUDOCARE		General	Technology: JOE Digital Therapy 1. Request for inclusion in scope LUDOCARE welcomes the opportunity to	Thank you for your comment. The technology falls within the scope of this evaluation.

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				comment during public consultation and respectfully requests that JOE Digital Therapy be considered for inclusion within the scope of this Early Value Assessment. Although JOE Digital Therapy was not included in the initial list of scoped technologies, we believe it represents a distinct and complementary approach that directly addresses priority needs identified during scoping and MTAC discussions, particularly for young children with asthma and their families. 2. Alignment with unmet need identified by the EAG The External Assessment Group (EAG) highlights persistent unmet needs in asthma self-management, including poor engagement with written Personalised Asthma Action Plans (PAAPs), incorrect inhaler technique, non-adherence to preventive treatment, and limited personalised support outside acute care. These challenges are particularly pronounced in children and families, where responsibility for daily management lies largely outside the clinical setting. JOE Digital Therapy has been specifically designed to address these needs through: • operationalisation of the clinician-defined PAAP in daily life,	The committee reviewed the available evidence and recommended the technology for use during the evidence generation period.

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				• structured support for inhaler technique, • behavioural reinforcement of adherence, • and age-appropriate education delivered in the home. This alignment reflects the type of plausible mechanism of benefit that the EVA pathway is intended to assess and support through structured evidence generation. 3. Differentiation: a solution specifically designed for children aged 3–11 years JOE Digital Therapy is exclusively dedicated to children aged 3–11 years, a population that remains largely underserved by existing digital self-management technologies and was explicitly highlighted during MTAC discussions as lacking appropriate solutions, particularly for younger children. The technology is differentiated by its combined and integrated design, comprising: a child-facing interactive companion with dedicated hardware, designed to actively engage young children in daily care,combined with a parent-facing app that operationalises the clinician-defined PAAP in everyday life. This dual approach allows asthma self-management support to be delivered in a way that is developmentally appropriate, engaging young children directly while supporting parents	

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				to implement the clinician-defined care plan at home. JOE Digital Therapy is conceived as a time-limited educational and behavioural intervention, designed to support children and families until key knowledge, skills, and competencies are acquired, enabling increasing autonomy in asthma management. The duration of use is individualised and typically spans several months, depending on the child's age, needs, and progression. This design directly responds to concerns raised during MTAC discussions regarding usability, engagement, and suitability of digital tools for children, as well as feedback from patient experts highlighting the importance of intuitive, child-friendly UX/UI. This differentiated approach directly addresses several gaps identified by the EAG, particularly around engagement, adherence, and usability in paediatric populations. 4. Relevance to pediatric asthma and equality considerations Pediatric asthma represents a significant public health burden, with known inequalities related to age, socioeconomic factors, and access to specialist support. Younger children are particularly dependent on caregivers to	

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				translate clinical advice into daily routines, and written or app-based tools alone may be insufficient to ensure engagement or correct technique. By combining a child-facing interactive device with a family-centred digital platform, JOE Digital Therapy supports: • children with age appropriate medical content to sustain health literacy, • families facing barriers to engagement or access, • and consistent implementation of clinician advice between reviews. Inclusion of JOE Digital Therapy would therefore strengthen the EVA's consideration of equity, accessibility, and age-appropriate design, in line with NICE's statutory duties. 5. Suitability for the Early Value Assessment pathway JOE Digital Therapy aligns well with the objectives of the EVA programme: • CE-marked medical device with an established quality and safety framework, • existing clinical evidence (randomised trial and real-world data) demonstrating feasibility, acceptability, and early signals of clinical benefits • and clearly defined evidence gaps suitable for an Evidence Generation Plan, including UK-specific effectiveness and implementation data.	

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				The technology is not yet available for routine NHS use but is planned for availability from Q3 2026, subject to completion of UK regulatory and assurance requirements and the outcome of this EVA. 6. Conclusion Including JOE Digital Therapy would enhance the scope and relevance of this EVA by: • ensuring representation of young children aged 3–11 years, • capturing a distinct, child-centred and educational intervention model, • and supporting NICE's aim to identify technologies with credible early value and a clear pathway for evidence development. LUDOCARE would welcome further engagement with NICE and the External Assessment Group to support inclusion and evidence generation within this evaluation.	
3	Consultee 4 MIR - Medical International Research S.p.A.		General 2.1 Recommendations -can be used during the evidence generation period	Executive Summary We respectfully submit this response to the NICE Early Value Assessment consultation on digital technologies to support self-management of asthma (GID-HTE10063). As a leading manufacturer of respiratory diagnostic devices with significant presence in the UK market, we wish to highlight the relevance of MIR devices already deployed in the United Kingdom for respiratory homecare.	Thank you for your comments Following review by the NICE technical team and the lead clinical expert, it was determined that the technologies do not meet the key inclusion criteria set out in the final scope for digital technologies to support self-management of asthma.

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				MIR devices are already integrated with several platforms recommended in this assessment, and our Smart One device has previously received a positive NICE Medtech Innovation Briefing (MIB96, 2017). We believe our technologies can contribute significantly to asthma self-management programmes in the NHS. 1. Previous NICE Recognition of MIR Smart One MIR Smart One has been evaluated by NICE in 2017 through a Medtech Innovation Briefing: NICE Medtech Innovation Briefing MIB96 (February 2017) "Smart One for measuring lung function" www.nice.org.uk/guidance/mib96 1.1 Key Findings from MIB96 The NICE briefing recognised several important aspects of MIR Smart One technology: Innovative Features: The device transmits measurements wirelessly to a smartphone or tablet via Bluetooth, recording results in a diary app which can be shared electronically with healthcare professionals. Turbine Technology: NICE noted that the turbine in Smart One used to measure FEV1 and PEF is the same as that in all MIR spirometers (including Spirotel and Spirobank). Studies showed good reproducibility between MIR devices and reference spirometers.	

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				Traffic Light System: The app compares measurements with baseline PEF and FEV1 values and displays a traffic light health indicator (green, yellow or red) to signify if measurements are above or below baseline. Self-Management Support: The MIB noted that Smart One could enable people who need spirometry to record their values in their own homes, allowing measurements when most needed (such as during an exacerbation). The app allows users to create and email PDF reports to healthcare professionals. Patient Organisation Support: Both Asthma + Lung UK and the Cystic Fibrosis Trust provided positive comments, noting potential benefits for reducing unnecessary appointments, enabling earlier intervention, and supporting self-management. 2. Integration with NICE-Recommended Platforms A critical point we wish to highlight is that MIR devices (Smart One and Spirobank Smart) are already integrated with several of the digital platforms mentioned and recommended in this assessment: - Platform: AsthmaTuner Integration Status: Currently integrated - Platform: Luscii Integration Status: Currently integrated - Platform: RDMP (Respiratory Disease Management Platform)	

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				Integration Status: Currently integrated - Platform: Other platforms in scope Integration Status: Potential future collaboration We do not understand how MIR devices may not have been considered as a method for acquiring measurements and patient management in asthmatic patients, given that they are already being used in the UK in this context and in patients with Cystic Fibrosis for several years. 3. Established UK Market Presence MIR has a significant established presence in the UK respiratory homecare market: Approximately 12,000 units installed (Smart One and Spirobank Smart combined, via Intermedical (UK) Ltd) These devices are actively used for asthma monitoring and in Cystic Fibrosis patient management, demonstrating proven acceptance and utility in the UK healthcare context. As noted in MIB96, the Cystic Fibrosis Trust highlighted that Smart One could help reduce the number of trips needed to specialist centres and enable remote monitoring while avoiding exposure to additional bacteria. 4. MIR Devices for Asthma Self-Management 4.1 MIR Smart One – Digital Peak Flow Meter and Spirometer	

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				Smart One is a portable spirometer that connects to a Bluetooth-enabled smartphone or tablet to monitor Peak Expiratory Flow (PEF) and Forced Expiratory Volume in 1 second (FEV1). The device includes the handheld Smart One unit, a turbine sensor, and a reusable plastic mouthpiece. The free Smart One app (available for iOS and Android) includes an electronic diary for recording results and on-screen messages to help improve test performance. 4.2 MIR Spirobank Smart – Home Spirometer Spirobank Smart is a home-use spirometer that combines simplicity with clinical-grade precision, enabling comprehensive lung function assessment. It uses the same proven turbine technology as Smart One and is designed for simple and user-friendly operation through a free app for Apple and Android smartphones. Spirobank Smart offers additional features including Live Video Exam for remote clinician support. 5. Features Supporting Asthma Self-Management 5.1 Traffic Light Alert System Both Smart One and Spirobank Smart include a traffic light indication system (as recognised in MIB96) with clinician-programmable thresholds, enabling patients to receive immediate	

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				feedback on their lung function status: GREEN FEV1 or PEF > 80% Under control YELLOW FEV1 or PEF 50–80% Caution needed RED FEV1 or PEF < 50% Medical assistance Threshold values are programmable by the clinician, providing a simple but effective feedback mechanism for patient self-management aligned with Asthma Action Plan requirements. 5.2 Symptom Questionnaires Spirobank Smart supports clinician-programmable symptom questionnaires that can be enabled based on individual patient needs. These collect information on: breathlessness, chest tightness, cough, sputum production, sleep disturbances, and wheezing. Each symptom is rated on an intensity scale (None/Moderate/Severe), enabling comprehensive remote symptom monitoring integrated with objective lung function measurements.	

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				5.3 Electronic Diary and PDF Reports As noted in MIB96, the Smart One app includes an electronic diary for recording results. Users can create and attach a PDF file to a standard email and send to their healthcare professional, selecting the time interval (from 1 day to 1 year) to be exported. This feature supports asthma reviews and enables healthcare professionals to have access to objective data about the patient's asthma control over time. 5.4 Live Video Exam – Remote Clinician Support Beyond self-monitoring, Spirobank Smart enables home monitoring with remote clinician support through Live Video Exam functionality. This allows healthcare professionals to supervise spirometry tests in real time via video call and transmit professional-format reports to healthcare facilities. This feature is particularly valuable for patients requiring additional support or those in remote areas with limited access to respiratory services. 6. Clinical Evidence 6.1 Evidence Cited in MIB96 The NICE MIB96 briefing summarised evidence from 3 studies (n = 496 people in total) involving MIR devices (Spirotel and Spirobank) which use the same turbine as Smart One. The studies showed good reproducibility between Spirotel and a pneumotachograph and laboratory spirometer, and that Spirobank had comparable	

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				precision to other office portable spirometers. 6.2 Bambin Gesù Hospital Paediatric Study A study conducted at Ospedale Bambin Gesù (Rome, Italy) evaluated Spirobank Smart for telemonitoring in 20 paediatric asthma patients. Key findings included: - Ease of Use: general consensus on device ease of use and reliable data transmission from patients' homes. - Clinical Benefits: reduction in school absences for children and lost working days for parents. - Early Detection: favourable impact on objectifying early signs of clinical deterioration and facilitating remote interaction. - Patient Satisfaction: all patients expressed favourable judgement on ease of use and improved understanding of their condition. - Remote Connectivity: successful data transmission verified from intercontinental distances (including Brazil). 7. Technical Standards Compliance According to ATS/ERS guidelines, only digital peak flow meters (as opposed to mechanical ones) can fully comply with ATS 2019 standards. MIR devices meet and exceed these requirements: - Standard/Feature: ATS 2019 Standards MIR Compliance: Fully compliant - Standard/Feature: ATS 2021 Standards MIR Compliance: Fully compliant - Standard/Feature: Sampling Rate	

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				MIR Compliance: 10 milliseconds (high precision) - Standard/Feature: GLI Reference Values MIR Compliance: GLI 2012/2022 multi-ethnic - Standard/Feature: Turbine Technology MIR Compliance: same proven turbine across all MIR devices 8. Conclusion and Request We respectfully request that the committee consider the inclusion of MIR devices (Smart One and Spirobank Smart) within the scope of this assessment, given: 1. Previous positive NICE evaluation (MIB96, 2017) 2. Existing integration with NICE-recommended platforms 3. Substantial UK installed base (~12,000 units) 4. Free smartphone apps with electronic diary and PDF reporting 5. Clinical evidence in paediatric asthma telemonitoring 6. Full compliance with ATS 2019/2021 standards 7. Support from patient organisations documented in MIB96 MIR welcomes the opportunity to provide additional information or participate in further discussions with the committee regarding the role of our technologies in supporting asthma self-management in the NHS.	

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4	Consultee 5 Intermedical (UK) Ltd		General 2 Recommendations	Executive Summary Intermedical (UK) Ltd respectfully submits comments to the NICE Early Value Assessment consultation on digital technologies to support self-management of asthma (GID-HTE10063). As the exclusive UK distributor supporting deployment, training and service for MIR connected respiratory devices, we wish to highlight the relevance of MIR devices already deployed in the United Kingdom for respiratory homecare and remote monitoring pathways. MIR devices are already integrated with several platforms referenced within this assessment, and the Smart One device has previously received a positive NICE Medtech Innovation Briefing (MIB96, 2017). We believe these technologies can support asthma self-management programmes by enabling the acquisition and sharing of objective measurements (PEF and/or FEV1) alongside symptom monitoring, aligned to clinician-led action plans. We also wish to highlight the established UK footprint: approximately 12,000 connected devices (Smart One and Spirobank Smart combined) have been placed in the UK via Intermedical (UK) Ltd. These devices are actively used for asthma monitoring and cystic fibrosis patient management, and are deployed within wider respiratory homecare services. Depending on local pathway design and	Thank you for your comments. Please see response to comment 3.

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				commissioning, this may include remote monitoring support within respiratory services where objective lung function measurement is used as part of care planning. Previous NICE Recognition of MIR Smart One Smart One has previously been evaluated by NICE through a Medtech Innovation Briefing: NICE Medtech Innovation Briefing MIB96 (February 2017) “Smart One for measuring lung function” www.nice.org.uk/guidance/mib96 1.1 Key points noted in MIB96 (summary) The MIB96 briefing recognised several characteristics of Smart One relevant to self-management pathways: Wireless connectivity: measurements transmitted via Bluetooth to a smartphone or tablet and recorded within an app-based diary, with the ability to share electronically with healthcare professionals. Turbine technology: NICE noted the turbine used to measure FEV1 and PEF is the same as that used across MIR spirometers (including Spirotel and Spirobank). Evidence summarised in MIB96 reported good reproducibility between MIR devices and reference spirometers.	

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				Traffic light feedback: the app compares measurements with baseline PEF and FEV1 values and displays a green/yellow/red indicator to show when results are above or below baseline. Support for home measurement when most needed: the MIB noted potential value where people can take measurements at home during periods such as exacerbations, and share data with clinicians for review. Reporting: the app allows users to create and send PDF reports to healthcare professionals. Patient organisation input: Asthma + Lung UK and the Cystic Fibrosis Trust provided positive comments in MIB96, including potential for avoiding unnecessary appointments, supporting earlier intervention and enabling self-management. Integration with Platforms Referenced in the Assessment Intermedical (UK) Ltd wishes to highlight that MIR devices (Smart One and Spirobank Smart) are already integrated with multiple platform environments referenced in the respiratory remote monitoring ecosystem: Platform – Integration status AsthmaTuner – Currently integrated	

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				Luscii – Currently integrated RDMP (Respiratory Disease Management Platform) – Currently integrated Other platforms in scope – Potential for future collaboration From a UK implementation perspective, we consider it important that the EVA conclusions recognise that the acquisition of reliable home measurements is a practical enabler of effective self-management programmes, and that device interoperability with commissioned platforms is often decisive for adoption at scale. Established UK Market Presence (deployment context) Intermedical (UK) Ltd has supported a substantial UK installed base of connected respiratory home monitoring devices: Approximately 12,000 units installed (Smart One and Spirobank Smart combined, via Intermedical (UK) Ltd) These are in excess to the integrated devices to the platforms and apps already evaluated by NICE in this document, so we belive that the MIR Smart range (Smart One and Spirobank Smart) is potencially the most used respiratory self test device in the UK, particularly since NUVO Air has ceased UK activities and the majority of their accounts are converting to MIR remote monitoring systems.	

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				These devices are actively used for asthma monitoring and cystic fibrosis patient management in the UK. As referenced within MIB96, the Cystic Fibrosis Trust highlighted potential value in reducing the number of trips needed to specialist centres and enabling remote monitoring while avoiding exposure to additional bacteria. The same model of home monitoring and remote review is also relevant to broader respiratory homecare services, including COPD pathway models where local services commission home measurement to support clinical oversight. MIR Devices Supporting Asthma Self-Management 4.1 Smart One – digital peak flow meter and spirometry device Smart One is a portable device connecting to a Bluetooth-enabled smartphone or tablet to monitor Peak Expiratory Flow (PEF) and Forced Expiratory Volume in 1 second (FEV1). The device includes the handheld Smart One unit, turbine sensor and a reusable plastic mouthpiece. The free Smart One app (iOS and Android) includes an electronic diary for recording results and on-screen messages designed to help improve test performance. 4.2 Spirobank Smart – home spirometer	

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				Spirobank Smart is a home-use spirometer designed for simple operation through a free app for Apple and Android smartphones. It uses the same turbine technology approach as Smart One and includes additional functionality, including Live Video Exam for remote clinician support. Features Supporting Asthma Self-Management 5.1 Traffic light alert system Smart One and Spirobank Smart support a traffic light indication approach (recognised in MIB96) with clinician-programmable thresholds, providing immediate feedback aligned with Asthma Action Plan requirements: GREEN: FEV1 or PEF > 80% – Under control YELLOW: FEV1 or PEF 50–80% – Caution needed RED: FEV1 or PEF < 50% – Medical assistance / follow agreed plan Threshold values are programmable by the clinician. 5.2 Symptom questionnaires (Spirobank Smart) Spirobank Smart supports clinician-programmable symptom questionnaires that can be enabled based on individual patient needs. Symptoms captured can include breathlessness, chest tightness, cough, sputum	

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				production, sleep disturbances and wheezing. Each symptom is rated on an intensity scale (None / Moderate / Severe), enabling remote symptom monitoring alongside objective lung function measurements. 5.3 Electronic diary and PDF reports As noted in MIB96, the Smart One app includes an electronic diary for recording results. Users can create a PDF report and send it by standard email to a healthcare professional, selecting the export interval from 1 day to 1 year. This supports asthma reviews by providing objective data on trends in control over time. 5.4 Live Video Exam – remote clinician support (Spirobank Smart) Spirobank Smart includes Live Video Exam functionality allowing healthcare professionals to supervise spirometry tests in real time via video call and transmit professional-format reports to healthcare facilities. This may be particularly helpful for patients needing additional support or those with limited access to respiratory services. Clinical Evidence 6.1 Evidence cited in MIB96 MIB96 summarised evidence from three studies (total n=496 people) involving MIR devices (Spirotel and Spirobank) which use the same	

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				turbine as Smart One. The studies reported good reproducibility between Spirotel and reference devices and that Spirobank had comparable precision to other office portable spirometers. 6.2 Bambino Gesù Hospital paediatric study A study at Ospedale Pediatrico Bambino Gesù (Rome, Italy) evaluated Spirobank Smart for telemonitoring in 20 paediatric asthma patients. Reported findings included: Ease of use and reliable data transmission from patients' homes Reported family and education impacts including fewer school absences for children and fewer lost working days for parents Technology integration supporting earlier recognition of clinical deterioration and remote interaction between parents and healthcare staff Positive patient feedback on understanding of condition and app alerts Successful data transmission over long distances, including a patient using the system while on holiday in Brazil Technical Standards Compliance	

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				The consultation document notes that, according to ATS/ERS guidance, digital peak flow meters (as opposed to mechanical ones) can support full compliance with ATS 2019 standards. MIR devices are described as meeting these requirements: ATS 2019 standards: fully compliant ATS 2021 standards: fully compliant Sampling rate: 10 milliseconds (high precision) GLI reference values: GLI 2012/2022 multi-ethnic Turbine technology: consistent turbine methodology across MIR device families Conclusion and Request Intermedical (UK) Ltd respectfully requests that the committee considers the inclusion of MIR connected devices (Smart One and Spirobank Smart) as measurement acquisition options within self-management programmes, given: Prior positive NICE evaluation for Smart One (MIB96, 2017), recognising connectivity, reporting and potential pathway benefits Existing integration with multiple platforms referenced in the respiratory remote monitoring	

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				ecosystem (AsthmaTuner, Luscii, RDMP) Substantial UK installed base (approximately 12,000 units supplied via Intermedical (UK) Ltd), actively used for asthma monitoring and cystic fibrosis patient management, and deployed within wider respiratory homecare contexts (including COPD pathway models where commissioned locally). These are in excess to the integrated devices to the platforms and apps already evaluated by NICE in this document, so we belive that the MIR Smart range (Smart One and Spirobank Smart) is potencially the most used respiratory self test device in the UK, particularly since NUVO Air has ceased UK activities and the majority of their accounts are converting to MIR remote monitoring systems. Free smartphone apps (iOS and Android) including electronic diary and PDF reporting (1 day to 1 year export range) Paediatric telemonitoring evidence (Bambino Gesù study) reporting usability, potential family/school benefits, early deterioration recognition and long-distance connectivity Stated compliance with ATS 2019/2021 standards and use of established turbine technology across device families	

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				Patient organisation support recorded in MIB96 (Asthma + Lung UK, Cystic Fibrosis Trust) Intermedical (UK) Ltd welcomes the opportunity to provide further information or participate in additional discussions with the committee regarding how connected measurement devices can support asthma self-management pathways in the NHS.	
Theme 2: Evidence generation and evidence generation plan					
5	Consultee 2 Asthma and Lung UK	6	Recommendations -can be used during evidence generation period What evidence generation is needed	resource use, including staff time The impact on staff must also be measured and understood in terms of cognitive load, potential workflow disruption, and training burden - and how adequate training can be provided in a time-poor environment.	Thank you for your comment. Section 3.14 of the guidance document has been updated to note potential burden on NHS staff time due to training needs and set-up. Section 2.1 of the evidence generation plan includes NHS staff time under healthcare resource use as an essential evidence requirement. The plan also suggests a qualitative study to collect user and clinician experience of the technology. Burden on clinical staff due to training requirement is noted as a barrier in the plan (covered in section 6).
6	Consultee 6 APTAR	6-7	2.3 What evidence generation is needed	We agree with the committee's identification of the key evidence gaps. Evidence generation during the EGP will focus on clinically appropriate populations and outcomes for our technology and that can be assessed using	Thank you for your comment.

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				relevant performance metrics within the 3-year timeframe.	
7	Consultee 6 APTAR	15	3.10 Committee discussion Clinical evidence gaps	*Evidence was lacking for some subgroups including children under 5 (supported by parents and carers), people with severe asthma and people who are newly diagnosed.* While subgroup evidence is important, feasibility constraints should be recognised. Evidence generation strategies may need to prioritised depending on the intended population and care setting of each product.	Thank you for your comment which the committee has considered.
8	Consultee 2 Asthma and Lung UK	6	Evidence generation plan 3 Approach to evidence generation 3.3 evidence collection plan Prospective real-world comparative cohort study	*Ideally, the study should be done across multiple centres to reflect the diversity of the NHS service provision.* This is an essential element of any study.	Thank you for your comments. The evidence generation plan recommends that a prospective comparative cohort study is done in multiple NHS centres to reflect diversity of NHS service provision and better understand the generalisability of the findings to NHS practice.
9	Consultee 6 APTAR	6	2.3 What evidence generation is needed	*Such as exacerbations* The potential impact of digital solutions on exacerbations may require a specific population selection, a long follow up duration and a large sample size that may lead to build a study design which cannot be fully realistic. This will be assessed with close attention with biostatisticians in the EG plan. Definition of	Thank you for your comments. A definition of exacerbation has been added to Section 3.4 in the evidence generation plan.

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				exacerbation would have to be agreed upon and harmonized and based on Nice ones...(Nice, BTS/SIGN, ERS/ATS).	
10	Consultee 1 Association of Respiratory Nurses (ARNS)	7	Evidence generation plan 3.4 data to be collected	Clinical outcomes- Define 'exacerbations' (reported by patient or reviewed by healthcare professional and prescribed medication); this is also dependant on healthcare professional coding during documentation (eg: LRTI, asthma exacerbation, cough).	Thank you for your comments. Please see response to comment 9.
11	Consultee 6 APTAR	14	Draft guidance3.7 Committee discussion Impact on asthma and patient outcomes	The focus on asthma control and quality of life is appropriate. For digital self-management tools, intermediate outcomes (such as adherence, action-plan use and symptom awareness) may be a support as early indicators before strongest outcomes such as reduction of hospitalisations can be robustly demonstrated.	Thank you for your comments. The evidence generation plan also includes collecting data on adherence to medication (see section 3.4).
12	Consultee 1 Association of Respiratory Nurses (ARNS)	7	Evidence generation plan 3.4 data to be collected	Consideration of peak flow readings and comparison to patient's normal (calculation of % of patient's best or normal peak flow reading) as part of monitoring	Thank you for your comments. The evidence generation plan includes lung function measurements (ideally spirometry) should be collected under clinical outcomes. Peak flow monitoring may be captured when relevant and feasible. Where feasible and relevant to the technology and population, lung function data may support interpretation of changes over time.
13	Consultee 1 Association of Respiratory Nurses (ARNS)	8	Evidence generation plan	Impact on condition management - Include peak flow monitoring, especially if asthma symptoms increase. Peak flow monitoring is still recommended in NICE CKS for assessment of	Thank you for your comments. Please see response to comment 12.

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			3.4 data to be collected	acute asthma exacerbation severity. This could be a useful tool if the digital technology can integrate with GP clinical systems e.g. SystmOne and EMIS.	
14	Consultee 1 Association of Respiratory Nurses (ARNS)	8	Evidence generation plan 3.4 data to be collected	Healthcare resource use - applicable to all listed - can these be specific to Asthma interventions? e.g. Number of GP visits due to asthma	Thank you for your comments. The evidence generation plan (Section 3.4) has been amended to explicitly state that these should be asthma specific.
15	Consultee 2 Asthma and Lung UK	16-17	3.13 Committee discussion Barriers to implementation and uptake	The draft guidance phrases section 3.13 with the assumption that systems are ready to implement digital technologies, and that this readiness is universal. Asthma + Lung UK's assessment of the implementation of the BTS, NICE, SIGN NG245 asthma guideline highlights that, even when changes to guidance are expected and even underway with early-adopters, there are significant barriers to implementation at all levels. Barriers of a similar scale should be expected with the implementation and uptake of digital technology for the self-management of asthma, and full assessment must be made of these barriers. The draft guidance also makes no mention of competing priorities and demands on finite resources within health systems and how these may impact implementation and uptake.	Thank you for your comments. The evidence generation plan (Section 3.3) recommends evidence generation across NHS sites to reflect diverse care pathways. The plan also notes the importance of multi-centre evidence generation to reflect diversity of NHS service provision along with qualitative work to better understand barriers and facilitators in real world use.
16	Consultee 1 Association of Respiratory Nurses (ARNS)	8	Evidence generation plan	Barriers and facilitators - Although this is mentioned, healthcare professional feedback is also vital as they will be the main advocates for	Thank you for your comments.

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			3.4 data to be collected	patients to improve uptake on digital technologies.	
17	Consultee 2 Asthma and Lung UK	3	Evidence generation plan 2 Evidence gaps 2.2 Evidence that further supports committee decision making Generalisability to NHS practice	In addition to ensuring the an evidence base outlining how this technology could be applied to use within the NHS as a whole, there must be a comprehensive assessment of the barriers to implementation that exist across health systems of varying sizes. Geographic disparities are well evidenced across NHS provision and care quality varies from ICB to ICB; any assessment of how technology can support asthma self management must include this discussion.	Thank you for your comments. The evidence generation plan (Section 3.3) recommends evidence generation across NHS sites to reflect routine pathways of care. The plan also notes the importance of multi-centre evidence generation to reflect diversity of NHS service provision along with qualitative work to better understand barriers and facilitators in real world use.
18	Consultee 6 APTAR	18	3.16 Committee discussion Uptake and attrition rates	*The committee noted that initial uptake and dropout (attrition) rates appear to be important drivers in the model for some technologies and there is currently no data available.* Additional data on adherence to the RDMP will be provided through the GSTT trial which is ongoing and by mid 2026.	Thank you for your comments.
19	Consultee 2 Asthma and Lung UK	2	Evidence generation plan 2 Evidence gaps 2.1 Essential evidence for future committee decision making	*This limits the understanding of how people engage with the technologies, specifically across people with different levels of asthma control.* Similarly, this lack of evidence means there is inadequate assessment of how this technology would impact health inequalities; whether it would reduce unequal outcomes or exacerbate	Thank you for your comments. The evidence generation plan includes demographic and baseline characteristics (including age, sex, asthma level of control, ethnicity and postcode deprivation index) along with engagement metrics. These data will allow assessment of uptake and attrition

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			Uptake and attrition rates	them for certain groups. This evidence base is essential.	across population groups and asthma control levels. Information is also detailed in the guidance under Section 3.17 ‘equality considerations’.
20	Consultee 1 Association of Respiratory Nurses (ARNS)	7	Evidence generation plan 3.4 data to be collected	Uptake and attrition rates - Long term benefits are vital as people naturally get "app fatigue" over time. How often are the apps updated/refreshed, and does this increase use of the digital technology?	Thank you for your comments. The evidence generation plan includes long term follow up of engagement and attrition, including percentage of active users at different time points and reasons for discontinuation. These outcomes will help assess sustained use and reasons for attrition during the evidence generation period to address key uncertainties and inform future economic modelling (see Section 3.4, uptake and attrition rates on page 8).
21	Consultee 1 Association of Respiratory Nurses (ARNS)	7	Evidence generation plan 3.4 data to be collected	Uptake and attrition rates - Define "active" user	Thank you for your comments. A definition for an ‘active user’ has been added and can be defined as ‘those who sustain engagement at each defined time point.’

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22	Consultee 2 Asthma and Lung UK	18	3.16 Committee discussion Uptake and attrition rates	The acknowledged lack of data highlighted by section 3.16 also highlights that there is no requirement for the technologies discussed in the draft guidance to demonstrate a grounding in established behavior change theory. The benefit of this would be that assessment of uptake and attrition would have been made, and would be supported by evidence-based recommendations on how to ensure uptake was widespread and attrition reduced.	Thank you for your comment. The evidence generation plan does not request evidence grounded in behaviour change theory. The committee agreed this type of evidence would be welcomed but decided it should not be incorporated into the plan because of the burden it may place on companies in order to conduct this robustly.
23	Consultee 2 Asthma and Lung UK	2	Evidence generation plan 2 Evidence gaps 2.1 Essential evidence for future committee decision making Uptake and attrition rates	The acknowledged lack of data highlights that there is no requirement for the technologies discussed in the draft guidance to demonstrate a grounding in established behavior change theory. The benefit of this would be that assessment of uptake and attrition would have been made, and would be supported by evidence-based recommendations on how to ensure uptake was widespread and attrition reduced.	Thank you for your comments. Please see response to comment 22.
Theme 3: Current practice					
24	Consultee 2 Asthma and Lung UK	5	Recommendations -can be used during evidence generation period What this means in practice Potential benefits of use in the NHS during the	Effectively Asthma + Lung UK's 2025 Life with a Lung Condition survey found that only 57% of people with asthma in the UK have a PAAP, and that only 32% of people with asthma in the UK receive all three elements of basic asthma care. Digital technology may offer benefits to patients, but this benefit must build on a foundation of	Thank you for your comment. Section 3.3 and 3.4 discusses issues with unmet need and limited access to self-management support.

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			evidence generation period	universally excellent access to basic asthma care.	
25	Consultee 2 Asthma and Lung UK	6	Recommendations -can be used during evidence generation period What this means in practice Managing the risk of use in the NHS during the evidence generation period	*Patient outcomes: The digital technologies are not intended to replace clinical review. So the risk from using them is low because people will still have regular reviews with healthcare professionals.* We know that access to annual asthma reviews is not universal, and that only 32% of people with asthma in the UK receive all aspects of basic asthma care. The concern with digital technology supplanting clinical reviews must be expanded to include concern with current poor levels of care, and include strategies to mitigate this.	Thank you for your comments. Please see response to comment 24.
26	Consultee 2 Asthma and Lung UK	12	3.2 Committee discussion Current practice	*Some people may also find it difficult to remember the steps in their PAAP or may apply them incorrectly because they do not fully understand their PAAP.* This highlights the importance of providing all three aspects of basic asthma care, especially annual asthma reviews to ensure that clinicians are able to address these issues in person.	Thank you for your comment. See response to comment 24.
27	Consultee 1 Association of Respiratory Nurses (ARNS)	11	3.1 Current practice	*"guidance on increasing inhaled corticosteroid dose if asthma control worsens and guidance on what to do if symptoms do not improve".* Not all patients will be on a MART/AIR regime. Still need the option of increasing short-acting bronchodilator.	Thank you for your comment. Section 3.1 in the guidance summarises the required components of a PAAP as detailed in the asthma guideline NG245. For clarity and better alignment with the guideline, this section has been amended to

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					include a statement "for adults who are using an inhaled corticosteroid (ICS) in a single inhaler".
Theme 4: Information about the technologies					
28	Consultee 1 Association of Respiratory Nurses (ARNS)	8	2.1 information about the technologies	There is a greater value in technologies which integrated within GP clinical systems (e.g. EMIS/SystmOne) so that PAAPs/medications/peak flow readings are the most up to date information for both the patient, and the healthcare professional.	Thank you for your comment which the committee has considered.
29	Consultee 2 Asthma and Lung UK		2.2 Information about the technologies	Features While support such as videos can be a useful resource, it cannot replace in-person, clinician-guided inhaler technique reviews.	Thank you for your comment. Please see response to comment 24.
30	Consultee 6 APTAR	15	3.11 Committee discussion Value of connected devices	*questioned the additional value of having connected devices.* Aptar supports the RDMP with or without added spirometry at the prescriber's discretion.	Thank you for your comment. Section 3.11 in the guidance includes information about the added value of connected devices. It already states *"company representatives confirmed the apps can also be used independently without connected devices"*.
31	Consultee 6 APTAR	16	3.12 Committee discussion value of connected device	*The committee recalled that there was no clinical evidence to suggest that the addition of a connected device improves outcomes more than a standalone app (see section 3.12)* RDMP can be used with or without connected devices, however we believe that the inhalation	Thank you for your comment. Please see response to comment 30.

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				tracker can bring value regarding the inhalation technique close follow up.	
Theme 5: Cost-effectiveness					
32	Consultee 2 Asthma and Lung UK	10	2.3 Information about the technologies Table 1 (far right column)	Estimated technology cost per patient per year, £ The long-term sustainability of digital technologies with annual costs is weakly addressed. If the technologies prove efficacious, these costs can be mitigated by reduced care costs, but the draft guidance doesn't present the necessary evidence base to assess this. The draft guidance also doesn't include assessment of minimum engagement thresholds of benefit thresholds to highlight at what point the technology becomes a cost effective intervention. Similarly, the draft guidance doesn't model economies of scale at either a national or system-level scale, nor include comment as to how the cost effectiveness of these technologies may differ depending on the population size being served.	Thank you for your comment. The EAG highlighted that this is an early economic model, which is not fully parameterised for each individual technology. Due to this, the points raised in this comment cannot be fully assessed. Remaining questions about the longer-term sustainability, effectiveness, and therefore cost-effectiveness of each of the technologies recommended for use with evidence generation should be addressed by the companies through their engagement with the evidence generation plan in order to collect data to allow a more complete economic evaluation considering these points. The economic model does however include some reduced care costs, which are presented in appendix C2. Specifically, the EAG assumed 5 minutes practice nurse time for training patient (£4.42), and a 75% reduction in standard care costs (£7.46; which is the equivalent of 8.5 minutes of

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					a practice nurse who would review results). However, the data are currently lacking to explore this more thoroughly.
33	Consultee 2 Asthma and Lung UK	17	3.14 Committee discussion Economic model	The draft guidance doesn't include assessment of minimum engagement thresholds of benefit thresholds to highlight at what point the technology becomes a cost effective intervention. Similarly, the draft guidance doesn't model economies of scale at either a national or system-level scale, nor include comment as to how the cost effectiveness of these technologies may differ depending on the population size being served.	Thank you for your comment. Please see response to comment 32.
Theme 6: Recommendations- comments in support, minor amendments					
34	Consultee 6 APTAR	7	2.3 Can be used during the evidence generation period What this means in practice	We support NICE's early-use of digital technologies approach, which appropriately balances early NHS access for patients while structured evidence will be built to address current uncertainties.	Thank you for your comment.
35	Consultee 2 Asthma and Lung UK	5	Recommendations -can be used during evidence generation period What this means in practice Potential benefits of use in the NHS during the	*'technologies support people'* This wording should be amended to say that technologies 'may' support people in following their PAAPs.	Thank you for your comment. This wording has been amended.

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			evidence generation period		
Theme 7: Equality considerations					
36	Consultee 6 APTAR	18	3.17 Committee discussion Equality considerations	We support the committee's emphasis on equality and inclusion. We agree that evidence generation should actively include diverse populations and assess barriers related to digital literacy, access to devices and language, to ensure equitable implementation in the NHS.	Thank you for your comment.