NICE advice

Lenus COPD Support Service for remotely managing chronic obstructive pulmonary disease

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Lenus COPD Support Service. It is a remote management service for people with high-risk chronic obstructive pulmonary disease (COPD).
- The **innovative aspects** are the combination of data from patient-reported outcomes, medical and wearable devices, and clinical records.
- The intended **place in therapy** would be in addition to standard care as part of the individualised care plan for people with high-risk COPD.
- The **main points from the evidence** summarised in this briefing are from 3 publications that reported findings from 2 observational studies, including a total of 278 adults. These suggested that people using Lenus COPD Support Service had improved patient-reported outcomes and reduced respiratory-related hospital admissions and occupied bed days.

- **Key uncertainties** around the evidence or technology are that the published evidence is limited to 1 non-peer-reviewed pre-print and abstracts that had limited details of methods and outcome data. Also, comparative analysis was limited to historical controls.
- **Experts advised** that Lenus COPD Support Service could lead to earlier intervention for exacerbations and fewer hospital admissions. But more evidence is needed on the clinical and cost effectiveness of Lenus COPD Support Service. Experts also noted barriers to uptake of digital technologies and potential drawbacks for users and the NHS.
- The **cost** of Lenus COPD Support Service is £10,000 (excluding VAT) for initial setup plus £30,000 yearly licence fee and £10 user fee per patient per month. There is a 20% discount on user fees for over 1,000 patients. Lenus COPD Support Service is an add-on to standard care.

The technology

Lenus COPD Support Service (Storm ID) is a remote management service for people with high-risk chronic obstructive pulmonary disease (COPD). COPD is a chronic inflammatory lung disease that causes difficulty breathing. The digital health technology allows people with high-risk COPD to share their health data with healthcare professionals. It integrates 3 components:

- A web app for people with COPD to record patient-reported outcomes. This allows 2-way messaging between healthcare professionals and patients, access to self-management plans, and links to information on pulmonary rehabilitation.
- Patient-acquired data from Fitbit and home non-invasive ventilation (NIV) devices.
- Cloud-based healthcare professional dashboard, including 2-way integration with electronic health record data.

Lenus COPD Support Service needs a smartphone, tablet, or computer with internet access for use. People with high-risk COPD complete regular patient-reported outcomes in the app including a symptom diary, COPD Assessment Test, Medical Research Council Dyspnoea Scale, healthcare episode questionnaire, and EQ-5D-5L. The app shows visualisations and trends in the data, which can be used to support self-management. Health data is also collected from connected Fitbit and home NIV devices.

All data is exported to the cloud-based healthcare professional dashboard and integrated with the person's clinical summary and electronic health record. Healthcare professionals are presented with visualisations of these data outputs. The company claims this data can be used to understand the likelihood of an exacerbation and to provide treatment when needed. Lenus COPD Support Service also allows asynchronous messaging between patients and healthcare professionals and sharing of care plans.

The service also generates longitudinal datasets that can be used to build artificial intelligence models to predict patient events.

Innovations

The company claims that Lenus COPD Support Service is the only technology for COPD on the market that combines data from patient-reported outcomes, medical and wearable devices, and clinical records. It claims that the device is more effective in reducing exacerbation events than other apps for COPD.

Current care pathway

People with COPD should be offered treatment and support to stop smoking, pneumococcal and influenza vaccinations, pulmonary rehabilitation if indicated, optimised treatment for comorbidities and a personalised self-management plan. Inhaled therapies may be prescribed if needed to relieve breathlessness and exercise limitation.

Self-management plans should include education and an individualised exacerbation action plan for people at risk of exacerbations. Treatments and plans should be revisited at every review. People with COPD should be on the primary care COPD register and should attend a follow-up review at least once a year and more often if needed. Follow up is typically done in primary care and includes a clinical assessment of smoking status and motivation to quit, symptom control, need for pulmonary rehabilitation, medication effects, inhaler technique, and need for referral to specialist services. The healthcare professional will also measure:

- forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC) with a spirometer
- body mass index (BMI)

- Medical Research Council dyspnoea score
- oxygen saturation of arterial blood in severe cases of COPD.

People with very severe COPD may have reviews at least twice a year in primary care. For most people with stable severe COPD, regular hospital review is not needed but quick access to hospital assessment should be provided as needed. People with COPD who need interventions such as long-term NIV should attend regular review with a specialist. Hospital follow ups should also be available for people with frequent exacerbations, home ventilation, and lung volume reduction.

NICE's guideline on COPD does not recommend the routine use of telehealth monitoring of physiological status as part of the management of stable COPD.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on chronic obstructive pulmonary disease in over 16s: diagnosis and management
- NICE's medical technologies guidance on myCOPD for managing chronic obstructive pulmonary disease
- Health Improvement Scotland's Innovative Medical Technology Overview on NHSScotland COPD Support Service: remote and self-management of high-risk patients with COPD using a web app and machine learning predictive modelling.

Population, setting and intended user

Lenus COPD Support Service is intended for people with high-risk COPD, defined as Global Initiative for Chronic Obstructive Lung Disease (GOLD) group C or D. There are about 1.2 million people with diagnosed COPD in the UK. About 20% of people with COPD may have symptoms and exacerbations in line with GOLD 2017 group C or D (for example, Sansbury et al. 2021). People with high-risk COPD may be offered Lenus COPD Support Service in addition to standard care as part of their individualised care plan.

Costs

Technology costs

The technology costs (excluding VAT) are:

- initial setup, including information governance: £10,000
- a fixed licence fee to use the platform: £30,000 per year
- user fee: £10 per patient per month, with a 20% discount for over 1,000 patients.

Initial setup costs include integration costs for NHS settings with existing systems (including patient management systems and electronic medical records) that already have integrations with Lenus COPD Support Service. The company said integration costs would be agreed with NHS settings that have new systems which do not have existing integration within its catalogue. Costs do not include the Fitbit or NIV devices.

Costs of standard care

Lenus COPD Support Service would be offered in addition to standard care. The company claims it may result in earlier community intervention in cases of a likely exacerbation and may prevent unnecessary hospital admissions. These costs, based on the 2019/20 National Schedule of NHS costs, may include:

- community specialist asthma and respiratory nursing for adults: £48.03 for non-face-to-face care and £95.15 face-to-face care, per unit
- non-elective short stay for COPD or bronchitis with or without single or multiple interventions (DZ65A to DZ65K): average £488 to £4,319 per unit
- non-elective long stay for COPD or bronchitis with or without single or multiple interventions (DZ65A to DZ65K): average £704 to £5,578 per unit.

Resource consequences

Lenus COPD Support Service is currently used in the NHS. The company claims the technology provides multiple data sources, which help healthcare professionals determine when a person may be at risk of an exacerbation of their COPD. This may result in earlier

community intervention and prevent clinical deterioration and more costly hospital admissions. There is some evidence that Lenus COPD Support Service may result in fewer admissions, occupied bed days, and community reviews (Taylor et al. 2022, Taylor et al. 2021a).

Regulatory information

Lenus COPD Support Service is a CE-marked class I medical device under EU Medical Device Regulation (MDR) and UK Conformity Assessed (UKCA) marking. It passed the Digital Technology Assessment Criteria (DTAC) assessment.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Most people with chronic obstructive pulmonary disease (COPD) are over the age of 40, with chances of developing the disease increasing with age. There are about 10% more men with COPD than women. COPD may be associated with comorbidities, including cardiovascular disease, lung cancer, osteoporosis, depression and anxiety. Using Lenus COPD Support Service may positively affect some people in these groups.

COPD is also associated with socioeconomic status, with higher rates of COPD in communities with lower socioeconomic status. The evidence on Lenus COPD Support Service reported that 68% to 73% of people who took part in the studies lived in areas ranked in the lowest 2 quintiles on the Scottish Index of Multiple Deprivation. People need daily access to a smartphone, tablet, or computer with internet access to use the technology. Accessing these technologies may be more difficult for some people in communities with lower socioeconomic status.

The evidence on Lenus COPD Support Service showed that some people were unable to take part in studies using the device because they did not have access to these technologies. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies or do not have access to smart devices. People with a visual or cognitive impairment, problems with manual dexterity, a learning disability, or who are unable to read or understand health-related information (including people who

cannot read English) may need additional support to use the technology. The company said Lenus COPD Support Service was audited under the Web Content Accessibility Guidelines (WCAG 2.1) and received an AA assessment for accessibility for people with low digital literacy and disabilities. Age, sex, and disability are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 3 publications, including 278 adults. The publications reported results from the RECEIVER and DYNAMIC-SCOT studies. It is assumed that publications on the same studies included the same people.

All studies were observational cohort studies that were reported in 1 non-peer-reviewed pre-print and 2 abstracts. There are other abstracts not described here reporting interim results from the RECEIVER study (Taylor et al. 2021a, Taylor et al. 2020). The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

Lenus COPD Support Service is a tier C digital health technology for active monitoring and self-management based on NICE's evidence standards framework for digital health technologies. The published evidence is limited to 1 non-peer-reviewed pre-print and 4 abstracts. The RECEIVER study meets the minimum evidence standard for this type of digital health technology. But it was affected by the COVID-19 pandemic and was paused in March 2020. This study was later scaled-up to include people who had previous contact with secondary care chronic obstructive pulmonary disease (COPD) services (DYNAMIC-SCOT).

The evidence reported that people using Lenus COPD Support Service had improved patient-reported outcomes and reduced respiratory-related hospital admissions and occupied bed days. The studies show significantly lower take-up and use of the service compared with the number of people initially offered it. Some of this is attributed to lack of access to the required technologies. The evidence would be strengthened by peer-reviewed prospective studies comparing Lenus COPD Support Service with standard care.

Taylor et al. (2022)

Study size, design and location

Observational cohort studies in 225 adults with COPD in the UK who had daily access to a smartphone, tablet, or computer with internet. This non-peer-reviewed pre-print reports minimum 1-year results of the RECEIVER (n=83) and DYNAMIC-SCOT (implementation cycle 1, n=142) studies.

People enrolled in the DYNAMIC-SCOT trial had lower rates of smoking, home oxygen or non-invasive ventilation (NIV) therapy needs, pulmonary rehabilitation, and osteoporosis than people in the RECEIVER trial. But they had higher rates of bronchiectasis and ischaemic heart disease.

Intervention

Lenus COPD Support Service.

Comparator

A matched control cohort was used for analysis. Each person in the RECEIVER trial was matched with 5 people from the NHS Greater Glasgow and Clyde Safe Haven dataset.

Key outcomes

People in the RECEIVER and DYNAMIC-SCOT studies did an average of 3.5 and 3 daily patient reported outcome sets per week, respectively.

The intervention groups had significantly lower risk of respiratory-related hospital admission or death than the matched control cohort. The hazard ratio for admission or death was 0.47 (95% confidence interval [CI] 0.34 to 0.63, p<0.001) in the RECEIVER

cohort and 0.39 (95% CI 0.26 to 0.59, p<0.001) in people in the DYNAMIC-SCOT group who had an admission in the year before enrolment. Results also reported lower 12-month all-cause mortality in the RECEIVER cohort (17%) and the DYNAMIC-SCOT group with admission in the year before enrolment (9%) than the control group (33%).

Median time to respiratory-related hospital admission or death was 338 days (interquartile range [IQR] 73.5 to 596) in the RECEIVER cohort, 400 days (IQR 161 to 450) in people in the DYNAMIC-SCOT group who had an admission in the year before enrolment, and 43 days (IQR 4 to 284) in the control cohort.

Occupied bed days were also reduced after enrolment to Lenus COPD Support Service in the RECEIVER study (median 9 compared with 0, effect size 0.53) and DYNAMIC-SCOT group with an admission in the previous year (median 8 compared with 0, effect size 0.44) compared with the matched control (median 9 compared with 3, effect size 0.26).

Strengths and limitations

This paper reports 1-year data from the RECEIVER and DYNAMIC-SCOT studies. It used a matched control cohort from an NHS database. People needed daily access to a smartphone, tablet, or computer with internet to take part. The RECEIVER trial screened 283 people, with 83 having the intervention. The authors noted that 41 people were unable to take part in the study because they did not have access to the necessary technology. This may limit generalisability of findings to people with lower digital literacy and reduced access to technology.

People in the RECEIVER cohort used Lenus COPD Support Service more than the DYNAMIC-SCOT group. Authors suggested there may be different motivations that could affect use and noted the need for healthcare professional contact and supporting resources. They concluded that more analysis is needed on patient-perceived benefits, motivations, and barriers for use. The company was involved in the research.

Taylor et al. (2021b)

Study size, design and location

Observational cohort study of remote recruitment to a digital self-management service in 195 adults with high-risk COPD identified from secondary care datasets in the UK.

Intervention

Lenus COPD Support Service. In response to the COVID-19 pandemic, people were sent a text message inviting them to the digital service and registration was done online.

Key outcomes

A total of 195 people applied to the digital service. Of these, 112 people completed the service setup, which included a virtual review with a healthcare professional, self-management planning, and COPD multidisciplinary team input as needed. Authors stated that app usage was positive. Qualitative data showed that more information about the service was needed at invitation.

Strengths and limitations

This study reports remote enrolment to Lenus COPD Support Service in response to the COVID-19 pandemic. A total of 1,576 text message invites were sent between May and July 2020 to people who had any previous contact with secondary care COPD services. Of these, 7.1% completed setup to the service. The study was reported in abstract only and lacked details of study methods and findings. It stated that there was positive patient experience, but data on this was not provided. The company was involved in the research.

Taylor et al. (2021c)

Study size, design and location

Observational cohort study in 32 adults with high-risk COPD who used Fitbit continuously in the UK. This abstract reports 6-month interim results of the RECEIVER trial.

Intervention

Lenus COPD Support Service with Fitbit Charge 3 device. Daily patient reported outcomes and exacerbation events were recorded along with daily step counts and daily average heart rate.

Key outcomes

There was a mean 58 days of data available (range 8 to 147). Authors reported that there

were trends in daily step count and heart rate around exacerbation events. There was an increase in daily step counts and a decrease in heart rate after exacerbation events and after people started home NIV. Authors concluded that Fitbit data could be used to track and predict COPD events.

Strengths and limitations

This was an interim analysis reported in abstract. There were limited details of study methods and findings, with trends in data reported graphically. Although the study aimed to capture daily outcomes, data was recorded less often (mean 58 days). This suggests that people used the devices less than advised. The company was involved in the research.

Sustainability

The company claims the technology uses less energy and has a lower environmental impact than standard care. There is no published evidence to support these claims.

Recent and ongoing studies

RECEIVER: Digital service model for chronic obstructive pulmonary disease (COPD). This is a prospective observational cohort study evaluating a continuous and preventative digital health service model for COPD. ClinicalTrials.gov identifier: NCT04240353. Status: active, not recruiting. Indication: COPD. Device: Lenus COPD Support Service. Last updated: February 2021. Country: UK.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Five experts provided comments on Lenus COPD Support Service. Two experts were familiar with the technology while 2 experts were familiar with similar devices. None of the experts had used Lenus COPD Support Service before.

Level of innovation

Two experts thought that Lenus COPD Support Service is novel, but 3 mentioned similar remote technologies. One expert believed that Lenus COPD Support Service differs from these in its integration of patient-reported outcomes, Fitbit and non-invasive ventilation (NIV) data, and clinical data.

Potential patient impact

Potential patient benefits of Lenus COPD Support Service include early intervention for exacerbations, fewer hospital admissions, and increased reassurance of patients through the monitoring of their chronic obstructive pulmonary disease (COPD). One expert believed the technology could promote more activity and healthy behaviours in people who are motivated and have digital access. People who may particularly benefit from using the technology include those with high healthcare use because of frequent exacerbations or severe COPD, little or no social support, anxiety, agoraphobia, or who are good with technology and like to monitor symptoms.

One expert claimed that there were no clear clinical benefits of Lenus COPD Support Service based on the current evidence. They added that people with severe COPD would already be familiar with self-management strategies. Two experts advised that some people who use Lenus COPD Support Service may increase contact with their healthcare professional. But 3 experts cautioned that people may rely on the technology and delay seeking help when needed.

Potential system impact

Lenus COPD Support Service could have system benefits if it prevents or reduces hospital admissions and improves outcomes. One expert noted that evidence of this is needed by prospectively comparing the device with standard care. All experts believed Lenus COPD Support Service would initially cost more than standard care. Additional resource needs may include more nurse time to monitor data and answer patient questions, time for getting patients started using the technology, and additional resources to give timely interventions to avoid more emergency calls. The experts advised that the technology would also need integration with existing IT services, training of staff and patients, and compliance with governance standards. One expert noted that it was unclear if all the components of the technology are needed to achieve the claimed benefits. They

questioned whether individual aspects of the technology, such as an activity monitor, could be used individually to produce the same benefits with lower costs.

General comments

Lenus COPD Support Service is currently being used in the NHS in Scotland and will soon be piloted in England. Two experts commented that it is not currently widely used. One added that most people would probably want to see a healthcare professional if they had concerns with their COPD.

One expert advised that telemedicine and similar remote platforms have had difficulty with uptake in the NHS because of costs and lack of evidence. Remote monitoring is a growing area with more expansion likely as part of the NHS's 2022/23 priorities and operational planning guidance. But the experts noted that some people may not have access to technology or reliable internet needed to use Lenus COPD Support Service. People also need a certain level of digital literacy to be able to use the technology. One expert noted that evidence is needed on the use of Lenus COPD Support Service by people with COPD who have little technological experience. All experts commented that more evidence is needed on the clinical and cost effectiveness of Lenus COPD Support Service. One expert also stated that more evidence is needed to identify which patient groups may benefit the most from using the technology.

Patient organisation comments

A representative from Asthma UK and the British Lung Foundation gave the following comments.

About 50% of people with chronic obstructive pulmonary disease (COPD) die within 4 years of their first emergency admission. Preventing emergency admissions would therefore be a huge benefit. Lenus COPD Support Service may offer greater access to care. This is currently a significant problem for people with COPD. The organisation's annual COPD survey found that 75% of respondents were not having appropriate care as outlined in NICE's guideline. Consistent monitoring with Lenus COPD Support Service may also benefit people with high levels of social isolation who may feel left behind. But if not implemented correctly, the technology could result in people feeling disconnected without regular contact with a healthcare professional.

Lenus COPD Support Service may be most useful to people with high digital literacy who want their care to be easier and more accessible. It may help healthcare services reach people who are less engaged in their care or who have less access to care in their location. The service should aim to reach people with inequalities in accessing care first. Some people with lower digital literacy may have difficulty using the technology. Some people may also have different expectations of care and may be resistant to digital alternatives. It is important that the technology is not seen as a compromise to standard care.

Healthcare professionals need to be able to assess and make decisions using the data in Lenus COPD Support Service without increasing their workload. Also, Lenus COPD Support Service does not address the burden of undiagnosed COPD. The technology would also benefit from considering the impact of COPD on people's daily living in addition to their healthcare needs.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Martin Allen, consultant physician, University Hospitals of North Midlands and NHS England. Made recommendations in Getting It Right First Time (GIRFT) report.
- Dr Andrew Fogarty, reader in clinical epidemiology, University of Nottingham. Did not declare any interests.
- Dr Samuel Kemp, consultant physician, Nottingham University Hospitals NHS Trust. Negotiations ongoing to participate in clinical trial or pilot project funded by NHSX.
- Dr Ari Manuel, respiratory consultant, Liverpool NHS Trust. Did not declare any interests.
- Dr John Seymour, consultant respiratory physician and deputy medical director, Frimley Health NHS Foundation Trust. Did not declare any interests.

A representative from Asthma UK and the British Lung Foundation also contributed to this briefing.

Development of this briefing

This briefing was developed by NICE. NICE's interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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