

Service Definition

January 2026 v1.0

1. Service Overview

The CareLoop Service is a cloud-based remote monitoring and symptom management platform designed to support people living with psychosis and schizophrenia, and the NHS mental health teams who care for them. The service enables the early identification of potential relapse risk through ongoing, patient-reported symptom monitoring, supporting proactive intervention, continuity of care, and community-based management.

The CareLoop Service was developed through over a decade of research in collaboration with NHS clinicians and people with lived experience. CareLoop Health is a spin-out from the University of Manchester. The platform has been evaluated across multiple clinical studies and is recommended for use in the NHS by NICE through the Early Value Assessment (EVA) pathway. The CareLoop Service is registered as an MHRA Class I medical device.

The CareLoop Service is intended for use by NHS mental health providers, including community mental health teams (CMHTs), Early Intervention in Psychosis (EIP) services, and Rehabilitation and Recovery (R&R) services. The CareLoop Service may also be deployed in Primary Care through integrated neighbourhood teams. The service is used alongside usual care and is not intended to replace face-to-face clinical contact, clinical judgement, or crisis services.

2. Service Context

Relapse in psychosis and schizophrenia is a major driver of inpatient admissions and re-admissions, and places significant pressure on A&E, acute services, Community Mental Health Teams and Primary Care.

Prior to relapse, individuals experience a period of symptom escalation over

several days, during which timely intervention may prevent deterioration and relapse. Outside of scheduled clinical contact, it can be difficult for services to systematically identify when escalation is occurring.

The CareLoop Service addresses this challenge by providing a structured, digital approach to ongoing symptom monitoring and early identification of personalised warning signs. By capturing symptom data directly from patients between appointments, the CareLoop Service supports a more preventative, responsive model of care while maintaining alignment with existing clinical pathways.

3. What the Service Does

CareLoop Health provides and operates the CareLoop Service, which supports continuous symptom monitoring outside of routine clinical appointments. The CareLoop Service consists of three primary components:

- A **patient-facing mobile application (app)** that enables individuals to record symptoms and wellbeing data via a daily questionnaire. The app provides a structured library of Cognitive Behavioural Therapy for Psychosis (CBTp) informed self-management support, including coping strategies, guided exercises, mindfulness audio, recovery stories and space to journal and track mood.
- A **clinician-facing dashboard** that presents patient app reported data and longitudinal trends across 12 symptom areas to support decision-making and proactive early intervention. The platform analyses symptom data in real-time to identify personalised early warning signs that may indicate a person is becoming unwell. When individual symptom thresholds are reached, notifications are generated to prompt timely review by the care team.
- Trained **Digital Navigators** who provide non-clinical, practical support to help patients and care teams engage effectively with the platform. Digital Navigators support with app set-up, onboarding and technical troubleshooting, help individuals understand and engage with their own symptom data, and encourage sustained engagement with the app over time. Digital Navigators act as an enablement and engagement function and do not provide clinical care.

4. Core Functionality

4.1 Symptom monitoring and data capture

Individuals are able to record their symptoms and experiences through the mobile application. Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) data, based on standardised PANSS and CDSS questionnaires, is collected through the app. This data is viewable in the app for the individual and made available to their support team via the clinical dashboard.

4.2 Early warning sign identification

The CareLoop Service identifies patterns of symptom change over time that differ from that patient's personalised baseline. When predefined thresholds are reached, the system generates a non-urgent notification to prompt clinical review.

These notifications are intended to support awareness and prioritisation within routine caseload management and do not indicate an acute crisis or require immediate response.

4.3 Clinician dashboard

Clinicians access the CareLoop Service directly through the EPR, or alternately via a secure, web-based dashboard, providing:

- Visibility of current and historical symptom data
- Visualisation of trends over time across 12 separate symptom areas
- Notifications when early warning signs of symptom escalation are detected

4.4 Digital self-management support

The mobile application provides access to Cognitive Behavioural Therapy for Psychosis (CBTp) informed digital content, including coping strategies, guided activities, and journalling functionality. This content is intended to support self-management alongside clinical care.

5. Intended Users

The CareLoop Service is designed for use by the following user groups:

5.1 Patients

- Aged 16 years and over
- Primary diagnosis of psychosis, schizophrenia or schizoaffective disorder
- Able to provide informed consent

5.2 Clinical users

- Healthcare professionals responsible for the ongoing care and monitoring of patients
- Specialist mental health clinicians (Clinical Psychologists and Psychiatrists) reviewing patient-reported data to inform therapeutic work and prescribing decisions alongside usual practice
- Peer support workers and other key workers professionally engaged in ongoing support of patients

5.3 Administrative users

- Operational staff responsible for caseload oversight, task delegation, service configuration, and compliance reporting

6. How Users Access the Service

Patients access the CareLoop Service via a mobile app installed on a smartphone. Clinicians access the service through their normal EPR interface (where integration is available), or a secure, web-based dashboard using a standard internet browser.

The service is accessed over the public internet using secure authentication. It does not require a direct connection to NHS private networks and can be accessed from NHS sites or other appropriate locations.

7. Service Delivery Model

The CareLoop Service is delivered as a centrally hosted Software as a Service (SaaS) solution. The service is cloud-hosted and managed by CareLoop Health, with no requirement for local installation or on-premise infrastructure.

Where already integrated into the local EPR system (such as RiO) access to the CareLoop clinical dashboard is available as an optional add on through the EPR contract. Where CareLoop Health is not already integrated into the local EPR system, users access a web-based dashboard following local IT set-up. Alternatively, where required, bespoke integration with local EPR systems is available.

The mobile app for patients is available for download via standard app stores on iOS (Apple App Store) and Android (Google Play Store).

Updates, maintenance, and improvements to the CareLoop Service are delivered centrally, ensuring all users benefit from enhancements without additional local configuration.

8. Onboarding, Training and Adoption

The CareLoop Service is designed to integrate with established NHS mental health clinical pathways and existing ways of working. The service is supported by a structured onboarding, training and on-going support model that focuses on enabling confident and sustainable use of the platform.

8.1 Onboarding and initial setup

Onboarding approaches may vary depending on local service models and workforce arrangements. CareLoop Health works with services to align onboarding with existing care pathways and operational processes.

8.2 Training for clinical teams

CareLoop Health provides structured training for clinical teams to support safe

and effective use of the platform. Training may be delivered through online sessions, workshops, and practical demonstrations, depending on local preference, and is CPD accredited. Ongoing learning resources and refresher support are available to support continued confidence and capability over time.

8.3 The role of Digital Navigators

Digital Navigators provide non-clinical, practical support to help services embed the platform into routine care, reducing the operational burden on NHS teams.

Digital Navigator support includes:

- Supporting patients with app setup and technical troubleshooting
- Helping patients understand and engage with their own data
- Supporting clinical teams to use patient-reported data during appointments
- Encouraging sustained engagement and adherence with the platform

Digital Navigators act as an enablement and engagement function and do not provide clinical care.

8.4 Ongoing support

The CareLoop Service supports services to monitor engagement and adoption over time. Ongoing support may include refresher training, access to updated resources, and guidance on optimising use of the platform as service needs evolve.

9. Security, Data Protection and Clinical Safety

The CareLoop Service is developed, deployed, and maintained in accordance with NHS clinical safety requirements, including full compliance with DCB0129. A formal Clinical Safety Case is in place, supported by a hazard log and ongoing clinical risk management processes. Clinical safety documentation is actively maintained, regularly reviewed, and updated throughout the service lifecycle, and is available to commissioning organisations on request. A designated Clinical Safety Officer oversees the CareLoop Health clinical safety processes.

CareLoop Health is registered with the MHRA as a Class I medical device and is ISO 13485 certified.

CareLoop Health is registered with the Information Commissioner's Office (ICO) and operates under a formal data protection framework with a nominated Data Protection Officer. The service is compliant with the NHS Data Security and Protection Toolkit (DSPT) and is subject to regular information security and risk assessments across the platform and internal systems.

10. Service Management and Technical Support

CareLoop Health provides ongoing service management and technical support to customers to address issues, service queries, and incidents.

Service performance and availability are monitored to support reliable operations as part of our Service Level Agreement (SLA).

11. Reporting and Account Management

CareLoop Health provide service-level reporting to support governance, oversight, and continuous service improvement. Reporting is designed to help services understand adoption, engagement, and operational use of the platform over time.

In line with UK GDPR and agreed data protection terms, CareLoop Health can provide reports covering areas such as:

- Patient enrolment and activation
- Ongoing engagement with the platform
- Questionnaire completion and usage patterns
- High-level symptom trends over time
- Volumes and frequency of early warning sign alerts

Where permitted, CareLoop Health can also provide aggregated and anonymised summaries for stakeholder and service-level reporting. These insights may be used to support implementation monitoring, quality improvement activity, and service evaluation, as well as to inform ongoing

product development.

Reporting outputs and frequency can be aligned with local governance and oversight requirements.

CareLoop Health provides a named account manager to act as a primary point of contact for the customer, supporting ongoing communication, coordination, and service review throughout the duration of the contract.

12. CareLoop Service Constraints and Assumptions

- The CareLoop Service requires reliable internet connectivity and compatible mobile devices (Android or iOS) for patients to access the mobile application
- Is intended to be used alongside existing clinical care and is not a crisis response service
- Does not replace clinical judgement or responsibility for care decisions