

Service Definition Document

FOR

Oviva digital behaviour change for pre-diabetes/type 2 diabetes, obesity and weight management

BY

OVIVA UK LIMITED

G-Cloud 15

About the Service - The Oviva App

Oviva is a clinically led digitally enabled behaviour change company. We blend behaviour change therapy with our unique technology to support people to improve their health and better self-manage their conditions including weight management, obesity, pre-diabetes and type 2 diabetes. Combining the support of specialist healthcare professionals with technology to make healthcare accessible to all.

We deliver digital behaviour change programmes which offer the following:

Proven clinical benefits

Programme development is led by domain experts and uses the latest scientific evidence. We are the only provider with proven randomised control trial evidence of effectiveness.

Accessibility for everyone

We offer a range of pathways to support user access, including digitally via the Oviva app, remote and face-to-face support.

One-to-one and peer support led by expert healthcare professionals

Ensures care is personalised, engaging and tailored to individual needs and backgrounds.

Unique digital tools and user-friendly content to support behaviour change

NHS Digital approved app and online Learn portal support participants and patients to build sustainable self-management behaviours and drive long-term health improvements.

We have been delivering Behavioural interventions to support people to improve their health since 2015. Since then, we have supported over 285,000 NHS patients across Oviva programmes: <https://oviva.com/uk/en/>

We have created a series of expert-led evidence-based programmes to help people living with health conditions such as type 2 diabetes, pre-diabetes or obesity feel healthier and happier.

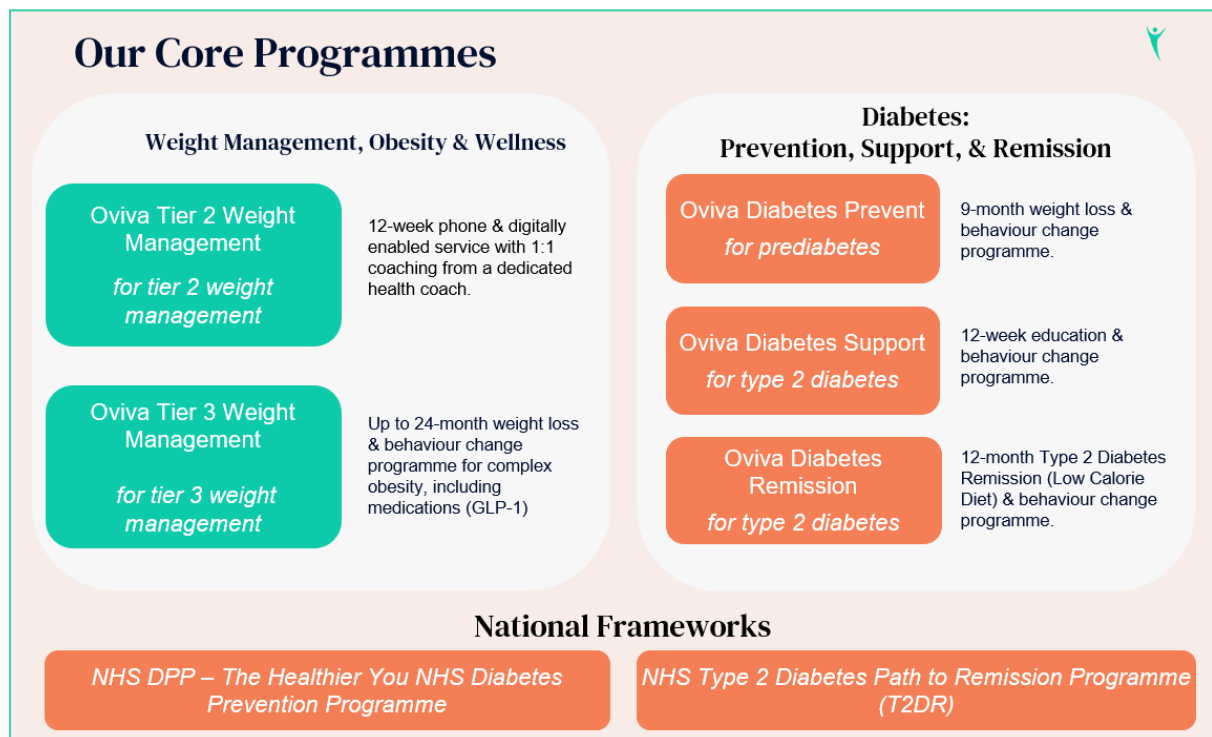
Oviva programmes comply with and align to:

- Government and the Office for Health Improvement and Disparities (OHID) guidance (including the EatWell guide)
- All relevant NICE guidelines including:
 - NG246 Overweight and obesity management
 - PH6: Behaviour change: general approaches
 - PH27 Weight-management before/during/after pregnancy
 - PH35 Type 2 diabetes prevention: population and community-level interventions
 - PH38 Type 2 Diabetes; prevention in people at high risk
 - PH49 Behaviour Change: Individual Approaches
 - NG28 Type 2 Diabetes in Adults: Management
 - TA664: Liraglutide for managing overweight and obesity
 - TA875: Semaglutide for managing overweight and obesity

- HTE14 (Health Technology Evaluation): Digital technologies for delivering specialist weight-management services to manage weight-management medicine: early value assessment

Oviva is:

- An approved provider on NHS England National Frameworks and holds an NHS Provider Licence
- QISMET certified
- CQC Registered
- GDPR compliant
- DTAC and Cyber Essentials Plus certified



Evidence-based behaviour change techniques (BCTs)

Oviva has been delivering behavioural interventions to support people to improve their health since 2015. Oviva clinical teams have designed our programmes to achieve sustained behaviour change across weight and wider health outcomes.

Our content and technology is developed utilising the latest BCT theories, designed to achieve sustained behaviour change across weight and wider health outcomes. COM-B (Mitchie et al 2011) underpins behavioural interventions as recommended by NICE/OHID.

Behaviour Intervention strategies to support high completion and outcome benefits include:

- Positive reinforcement techniques: frequent praise/encouragement
- Promoting self-monitoring of intake/weight/activity/mood/goal-progress
- Setting SMART goals (option to record them as 'To-Do's in Oviva app)
- Social/community support from family/friends/carers attending 1-to-1 sessions and peer support groups

- Prompts/nudges to learning modules focused on behaviour-change topics including psychology, revisiting goals, reminders to get active
- Individualisation through assessing/problem-solving motivation and any perceived engagement barriers at assessment/throughout programme
- Information on health consequences of being overweight, the impacts of obesity and Type 2 diabetes and the benefits of weight-loss
- Supporting modelling of desired behaviour changes including identification of self as a role model

Features

The Oviva app:

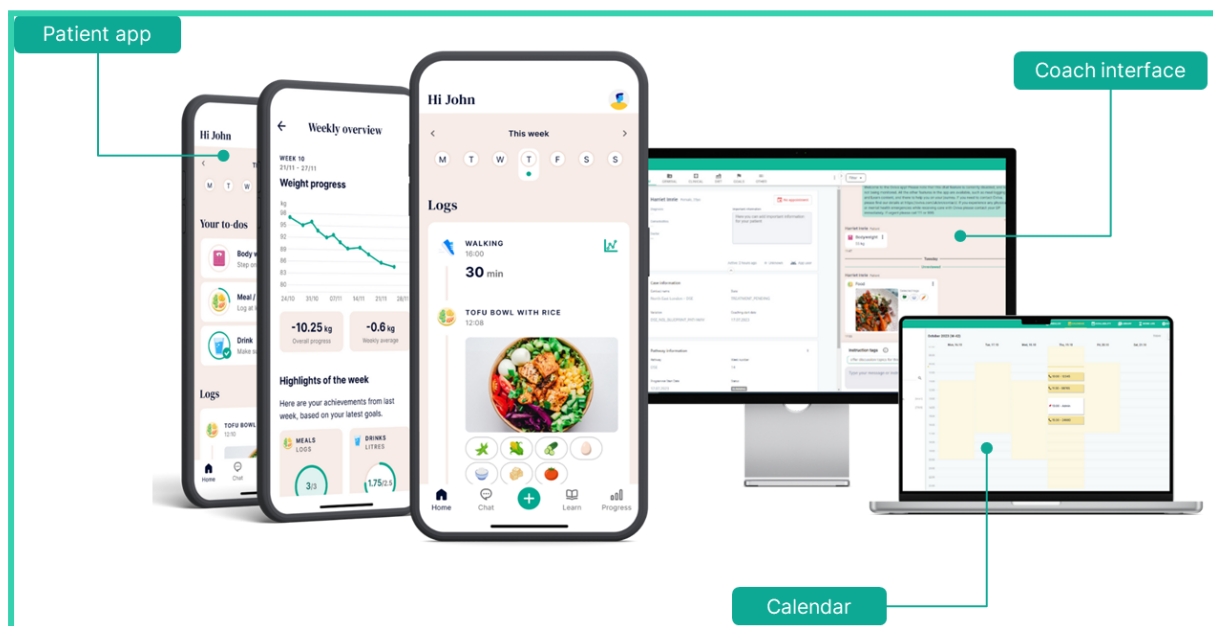
- Has passed the NHS Digital Technology Assessment Criteria
- Is certified as a CE Marked Class IIa medical device
- Is available in iOS and Android and can connect with Fitbit, Apple Health and Google Fit for activity tracking
- Is rated:
 - 4.6 based on 25,500+ reviews on Google Play
 - 4.6 based on 20,500+ reviews in the App Store
- Maximises accessibility by using minimal data

Participants and patients can:

- Book and view upcoming appointments
- Message their coach or Oviva Connect community
- Access Oviva Learn on the go
- Personalise the app through adding a profile picture and personal goal/motto
- Create daily and weekly goals from a standard set or create bespoke ones with personalised reminders to suit their schedules which they can track progress against
- Additional tracking functionality based on their needs such as mindfulness, meal types, healthiness and hunger levels before eating
- View in-app diet suggestions which track the types of foods logged and gives recommendations regarding which food groups to eat more or less of
- Weekly report in the app which shows progress on goals, through the programme and weight loss.

Participants and patients can also track:

- | | |
|------------------------------------|-------------------|
| ● food and drinks | ● bowel movements |
| ● blood glucose and blood pressure | ● mood |
| ● waist circumference | ● symptoms |
| ● weight | ● activity |



Clinical trials demonstrate that self-monitoring helps participants and patients to better understand their health improvements as they progress through the programme and therefore increases retention.

Our app is developed using evidence-based behaviour change models and techniques offering a range of functions and support participants & patients on their journey, including:

- **Build health habits:** Learn and practice new ways to achieve your SMART goals
- **Food analysis:** Instant intelligent feedback on nutrition and goal setting to support continued behaviour change post-programme and post-human coach support
- **Direct feedback:** Chat with coach or peer support group for motivation
- **Self-tracking:** For self-regulation, motivation and driving long term behaviour change
- **Improved knowledge and confidence:** Learn about health management with multimodal content

Service Benefits

Oviva programmes offer the following core benefits:

- Clinically effective at lower cost offering greater value for commissioners
- Personalising care, removing barriers to access and engagement, reducing health inequalities
- Driving innovation and harnessing technology to empower participants and patients and deliver improved outcomes
- We partner with the NHS and Local Authorities, sharing the same values

Benefits for Users

Delivering an improvement in quality of life through promoting sustainable, long-term health changes.

Supporting self-management of prediabetes, type 2 diabetes, and obesity, not only are participants and patients supported to lose weight and improve their blood glucose, but they can also reduce the risk of diabetes complications, which can, in turn, lead to an improvement in the quality of life.

Through the programmes, participants and patients can reduce the number of diabetes and blood pressure medications they need to take and one in four people can achieve remission of their diabetes.

Evidence of successful outcomes:

Diabetes Support

In our 12-week programme, patients are supported to better manage their type 2 diabetes, improving their blood glucose levels, lose weight (if they need to) and to build new habits to help them lead a healthier, happier lifestyle:

- Patients on average lose 3.9kg
- People on average reduce their HbA1c by 8.1mmol/mol
- 1 in 4 achieve a HbA1c of <48mmol/mol

Tier 2 Weight Management

Our Tier 2 Weight Management helps participants to manage their weight, adopt new habits and become more confident in managing their health. In our 12-week programme, our coaches will work with participants to make manageable changes to their diet and lifestyle to maximise their health now and in the future.

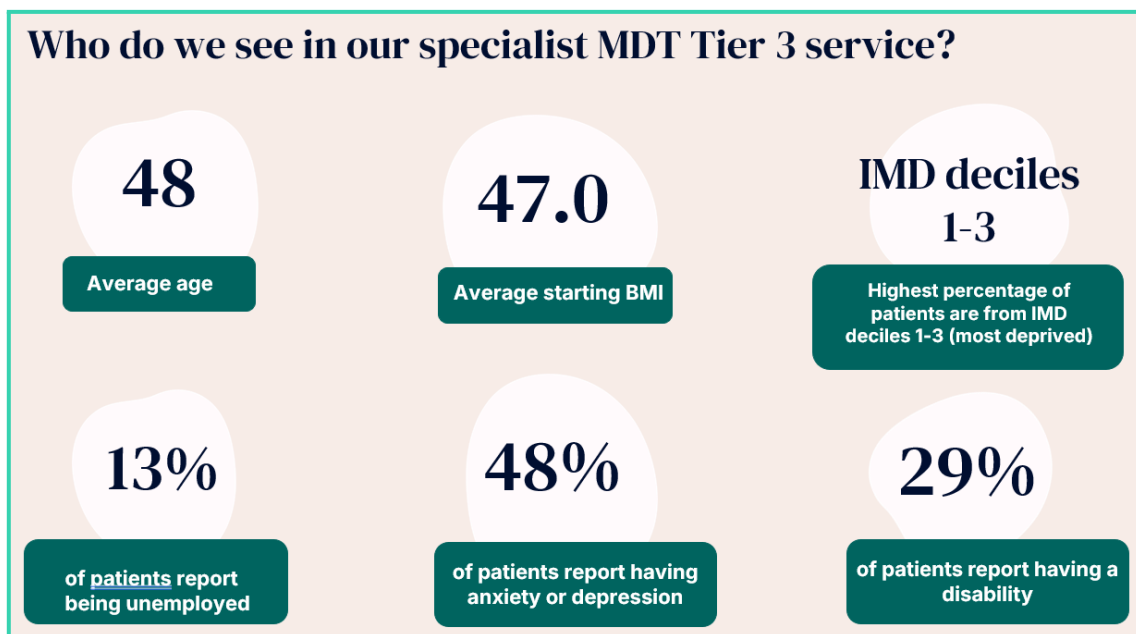
Through our approaches, we drive weight loss at a population level building on our clinical expertise. Based on OHID data (December 2022) we deliver 1.54x more cost effectiveness across our T2WM programmes, with Oviva participants achieving an average weight loss for completers of 4.25kg (3.4%):

- **% referrals enrolled on programme:** Oviva outcomes of 65% compared to 58% for OHID Benchmark data
- **% participants completing the programme:** Oviva achieve 56% compared to 38% for OHID Benchmark data
- **% of participants (those who attend at least one session) losing weight at the end of the active intervention:** 73% of Oviva participants achieve weight loss compared to 43% for OHID Benchmark data
- **% of participants (those who attend at least one session) losing >5% body weight at the end of the active intervention:** 21% of Oviva participants compared to 17% for OHID benchmark data

Tier 3 Weight Management

Through our Tier 3 Weight Management programme, patients are supported by their own team of healthcare experts to better manage their health, lose weight, become more active and to build new habits to help you lead a healthier, happier lifestyle.

Our Tier 3 Weight Management programme is available for up to 24 months for those patients who access GLP-1RA medications. Oviva evaluates patients' clinical suitability for pharmacotherapy weight loss and discusses its benefits and drawbacks to ensure patient commitment and optimised outcomes.

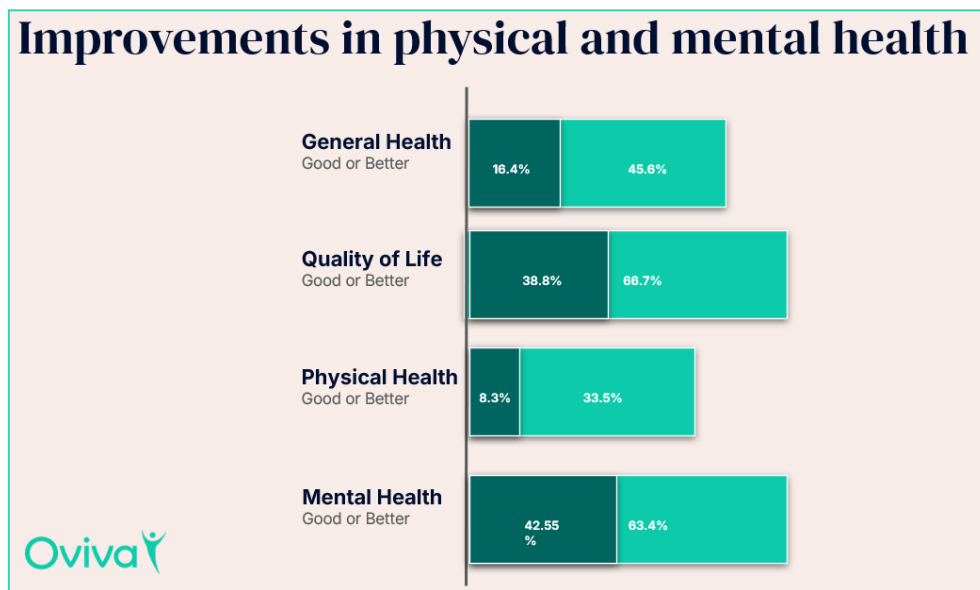


Patients achieve on average a staggering 19.8kg weight loss, equivalent to 15.8% of their starting weight.

The Oviva team also monitors patient outcomes and discontinues medication to prevent wastage if it does not produce the expected results or causes side effects.

Patients are supported by a weight management specialist dietitian to implement a personalised nutritional approach from the outset of the programme. This will help to optimise weight loss outcomes on GLP-1 medications, as well as put strategies in place to minimise weight regain at the end of the treatment.

Psychological support is also available to those who need it to facilitate meaningful behaviour changes, delivering improvements in not only their physical wellbeing but also positive changes within their mental wellbeing.



Our app is endorsed by NICE (October 2023) to deliver digital/remote specialist weight management services with GLP-1 RA prescribing.

Diabetes Prevent

As part of the NHS Diabetes Prevention Programme Oviva offers a digital remote programme, offering personalised support and advice to the patients we support. In this 9-month programme, patients are supported to feel more confident managing their health, improve their blood glucose levels, lose weight (if they need to) and to build new habits to help patients lead a healthier, happier lifestyle.

Diabetes Remission

Oviva has partnered with the NHS to deliver a programme for people who are overweight and living with type 2 diabetes. Formerly called the NHS Low Calorie Diet, this 12-month programme supports patients to lose weight using a low calorie diet, improving their blood glucose levels, reducing their medications, and aiming to put their type 2 diabetes into remission.

Data Backup, Restore, and Disaster Recovery

We comply with applicable data protection regulations.

We protect personal data appropriately with firewalls and other technical means, aligning with industry standards and applicable law. Only employees and agents of Oviva UK, which are obligated to maintain confidentiality, can access applicable data and only as reasonably necessary to perform their role. Other third parties do not have access to patient data without explicit consent.

We use Google Cloud Platform, Google Cloud EMEA Ltd, to host the data. We have concluded a data processing agreement with Google Cloud EMEA Ltd to provide secure cloud storage. This means that all data is securely stored in the cloud and can be accessed anytime, anywhere providing reassurance that data is safe and protected from any potential loss or damage. Oviva's data processing contract with Google includes standard contractual clauses whereby Google must comply with current and future EU and UK data protection requirements.

Oviva offers regular data backups to ensure that your data is always up to date and secure. Backups of our application data and the database are done once every night.

We are equipped with back-up processes and procedures to counteract incidents and restore services quickly and effectively.

An annual penetration test is carried out, and we have other extremely vigorous testing procedures to ensure that systems are protected and fail safe:

- If a system failure has been established relating to any of Oviva's systems, the IT department must be immediately informed.
- Oviva's Business Continuity Team must also be informed with immediate effect.
- Those employees affected by a system must be contacted and updated appropriately.
- Regular updates must be communicated to ensure that employees are fully aware of time scales for systems to be back up and running so that they can keep relevant stakeholders up to date
- IT will activate back-up procedures to ensure that business can ensue as normal at the earliest possible point.

These approaches are supported by our robust Business Continuity Policy and Disaster Recovery plans/policies. It is the policy of Oviva to:

- Maintain a strategy for reacting to and recovering from situations which may be classed as adverse in line with an agreed level of risk
- Ensure that appropriate action is taken to prevent the occurrence of an incident by adopting the necessary risk controls
- Maintain a set of activities which ensures we can react appropriately, and recover from adverse situations in line with pre agreed business continuity objectives
- maintain the awareness of employees and what is expected of them during a business continuity threatening situation
- In line with the risks faced, maintain a level of resilience
- Ensure that response plans and the overall business continuity strategy is at all times kept in line with changing business needs
- At all times remain aligned with good practice in business continuity management

To ensure all personal data is protected against accidental destruction or loss, all server configuration and software is externally archived in order to rebuild Oviva's systems and services in a matter of hours. All software deployments are archived and can be used to roll back to a known working state. Up to date detailed instructions are kept for setting up the entire environment.

Onboarding and Offboarding support

Access to Oviva programmes

Initial contact with participants and patients begins once we have received their referral from the referring GP or Healthcare Professional. Participants and patients receive a Welcome Email and or Text with onboarding steps within 1 working day. This provides an understanding of how to book their first session plus log-in details to the Oviva App (NHS Digital DTAC certified).

If participants/patients do not have a mobile number/email address/do not complete any onboarding step, our multilingual and region-specific Patient Support Coordinators contact them via the most appropriate manner including phone, email or text.

Oviva's in-house technology platform, the Oviva Coaching Suite has been designed to manage all course booking capabilities, show real-time coach availability, and record participant and patient preferences, e.g. location, times and languages. This means Oviva's Patient Support Coordinator team has real-time data to support participants and patients to access the right programme for their needs, as well as identify where demand requires updates to programme availability.

Offboarding

Depending upon the chosen service we can provide Discharge Summaries for the participants and patients we support. The level of detail required within the summary can be agreed with the commissioning body, but our existing approach will provide details of the participant/patient's care, including progress and outcomes achieved whilst on the relevant Oviva programme.

Participants and patients are supported by signposting to other local services to continue their journey once the Oviva programme has been completed.

Service Levels and Support

Our communications to participants and patients include information on how to access our Patient Support Coordinator Help Desk: either via Oviva website or phone

Our Patient Support team is available 8am - 8pm Monday to Thursday; 8am - 5.30pm Friday, and Weekends (Saturday/Sunday).

The Help Desk is available throughout the programme from onboarding until discharge.

Technical Requirements

Our app operates on both Android and iOS mobile devices, and the programme Learn content can be accessed on any internet enabled devices eg. laptop or tablet.

The Learn content contains content in different formats such as audio with transcripts, video with transcripts, and written format where webpages are Screen Reader compatible.

Virtual groups are carried out via a secure platform compliant with NHS Information Governance standards, which we have tested to ensure maximum accessibility for target users.

Each group is provided with a link to dial into the session using any internet enabled device or participants and patients may also join by telephone.

On-going Maintenance

We encourage lifelong behaviour change post programme completion through:

- Giving participants and patients a set of skills throughout the programme which helps them continue to put behaviour change into practice after completion. This is done through evidence-based behaviour-change strategies including the COM-B model and 3rd wave cognitive behavioural therapies (CBTs) focusing on long-term healthy-habit formation. Our in-house training programme is led by our Clinical Lead Psychologist and Oviva Dietitians/Health Coaches are trained in these theories/constructs/interventions, with the skills to utilise them in practice.
- In the final weeks of a programme, participants and patients are supported to develop a post-programme action plan; there is also a 'Long-term goal-setting' themed week
- Content is updated bi-annually
- Participants and patients have on-going access to the app and learn content to support them on their journey and maintaining their healthy living

Technical Support

The Oviva technology team provides all support in-house. We have clear Service Level Agreements with our technology team on turnaround time to support.

The Oviva Coaching Suite is developed, designed and managed in house by the Oviva technology team. The Oviva Coaching Suite is a web-based platform and we operate 2-week sprint cycles for updates, meaning all users are running the latest version.

Data Privacy and Access to Data

Data processing by Oviva UK is subject to English law and as applicable, European law i.e. GDPR. Pursuant to applicable data protection regulations (UK GDPR, UK DPA 2018, etc.), we work to ensure Oviva users have appropriate protection of their privacy and personal data.

Under data protection legislation, data subjects have the following rights with regards to their personal information:

- the right to be informed about the collection and the use of their personal data – the right to access personal data and supplementary information
- the right to have inaccurate personal data rectified, or completed if it is incomplete – the right to erasure (to be forgotten) in certain circumstances
- the right to restrict processing in certain circumstances
- the right to data portability, which allows the data subject to obtain and reuse their personal data for their own purposes across different services
- the right to object to processing in certain circumstances
- rights in relation to automated decision making and profiling
- the right to withdraw consent at any time (where relevant)
- the right to complain to the Information Commissioner

Participants and patients can make a Subject Access Request (SAR) to change or delete the personal data entrusted to us at any time by mail to Oviva UK Limited, Runway East, 20 St Thomas Street, London, SE1 9RS, United Kingdom or by e-mail to privacy@oviva.com.

After receiving a request for information, Oviva sends a print-out of the data collection to the address given in the request. The request must be answered by Oviva within 30 days after receipt.

We provide service users with Oviva's Data Privacy Policy at first contact and obtain consent. Oviva's standard data privacy is available anytime on our website: <https://oviva.com/uk/en/standard-data-privacy>.

Personal data is retained only for as long as necessary, per contract and in accordance with data protection regulations. Most data is deleted automatically after a set period of time (time periods vary based on type of data i.e. certain data has to be kept for 8 years per NHS contracts/retention standards). Other data is deleted or anonymised automatically after a set period of time.

We keep some (limited) data until the service user deletes their account, such as information about how often they use our services. Finally, some data we retain for longer periods of time when necessary for legitimate business or legal purposes, such as security, fraud and abuse prevention, or financial record keeping.

Data Security

Data is securely held in compliance with Caldicott Principles, duty of confidentiality, Data Protection Act, UK General Data Protection Regulation (GDPR), Freedom of Information Act, and NHS Record Management requirements.

Certifications and registrations include:

- NHS Digital Technology Assessment Criteria
- NHS Digital Data Security Protection Toolkit: standards exceeded
- NHS Digital DCB0129 Clinical Risk Management: ongoing-compliance
- Cyber Essentials and Cyber Essentials Plus
- ICO Registered Data Controller

We maintain robust procedures for preventing security breaches, as set out in our Risk Management Policy and Information Governance Manual. Staff undertake training and must pass an Information Governance assessment at induction and annually thereafter. We supplement this with quarterly audits.

All Oviva staff have training and assessed competencies in managing confidential and sensitive patient confidential data. Training is mandatory, completed at induction and refreshed annually. Training includes:

- IG Training Module
- Data Privacy Policy
- Level 1 Data Security Awareness
- Introduction to Cyber Security

What our participants and patients think of our support



"I feel more confident and that my face looks fresher and younger. I have reduced my diabetes medication!"
(Mr D ,43)



"My health has dramatically improved and I have lost 20kg in 6 months!"
(Steve,68)



"I have become so much healthier with the help of my Oviva coach and the app."
(Fran,58)

Since beginning Oviva's Tier 3 support, Catherine has lost **14.9kg**.

The programme provided her with the opportunity to speak openly with an Oviva psychologist about her own experiences with disordered eating, describing the support as life-changing.

Today, she feels stronger, more positive, and determined to continue her progress, saying she wishes she had started sooner but is now excited for what's ahead.