

Curio Digital Therapeutics Inc.

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MamaLift Plus™

Rx Only

Clinician
Information

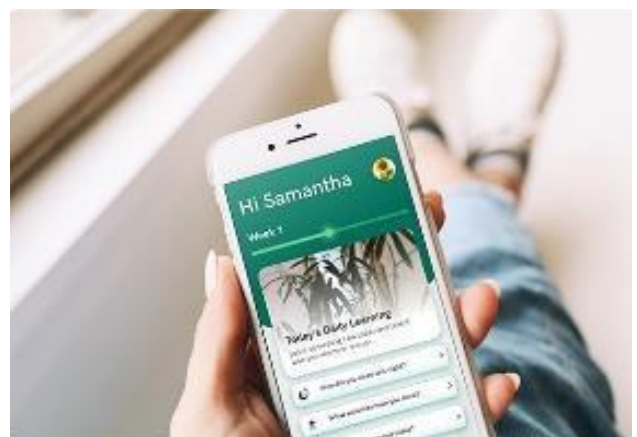


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Revision History

Version	Description of Change	Author	Date (mm-dd-yyyy)
1.0	Final Document	Sidhartha Shankar	11-15-2022

CLINICIAN INFORMATION

Instructions for Use

MamaLift Plus™ Prescription Digital Therapeutic for Perinatal Mood Disorders

Indications for Use

MamaLift Plus™ is a prescription-only digital therapeutic intended to provide neurobehavioral interventions to female patients 18 years of age and older, as an adjunct to standard of care. MamaLift Plus treats patients with perinatal mood disorders (with mild to moderate symptoms of anxiety and depression) by improving a patient's symptoms of depression and anxiety.

Who Should Not Use MamaLift Plus™ (Contraindications)

MamaLift Plus uses Cognitive Behavioral Therapy (CBT), Behavioral Activation Therapy (BAT), Interpersonal Therapy (IPT), and Dialectical Behavior Therapy (DBT) and is not intended to be used as a stand-alone treatment. MamaLift Plus may not be appropriate for everyone.

Patients with the following conditions or disorders should not use MamaLift Plus:

- Severe depression or anxiety
- Serious Mental Illness (SMI)
- Psychosis
- Suicidal thoughts
- Patients under 18 years of age

Warnings

MamaLift Plus is not for everyone. Please use your clinical judgment to determine whether MamaLift Plus is right for your patient.

- MamaLift Plus is not for emergency use. Please instruct patients to dial 911 or go to the nearest emergency room in the event of a medical emergency.
- Patients should be clearly instructed not to use MamaLift Plus to communicate severe, critical, or urgent information to their Health Care Provider.
- MamaLift Plus is not meant to be used as a treatment without supervision of a Health Care Provider.
- MamaLift Plus is not meant to be a substitution for any treatment medication. Patients should continue to take their medications as directed by their Health Care Provider.
- MamaLift Plus contains sensitive medical information. Please instruct patients to protect their information by password-protecting their smartphone and tablet, and ensuring no one else may access their device.
- The usage data collected in therapy lessons by MamaLift Plus are not intended to be used as a standalone assessment of treatment progress or for making determinations regarding a patient's depression or anxiety. Treatment decisions should be based on all medical history and data pertaining to a patient.
- Health Care Providers should use their best judgment when considering self-reported data about mood, sleep, and activities.
- Health Care Providers should engage in their normal care practices to monitor patients for medical problems and mental health disorders, including the risk of harming others and/or themselves.

Please instruct the patient to read and follow the instructions provided in each module, and to stay with the therapy until the end to achieve the best result with MamaLift Plus. Please instruct the patient that it is important to give honest and accurate answers when answering questions in the program.

Device Description

MamaLift Plus is a 8-week Prescription Digital Therapeutic (PDT) for perinatal mood disorders. MamaLift Plus can be used on a mobile device, such as a smartphone or tablet. MamaLift Plus is available by prescription only. A licensed Health Care Provider (HCP) must prescribe MamaLift Plus and use of MamaLift Plus should be undertaken only under the supervised care of a Health Care Provider.

MamaLift Plus delivers digital Cognitive Behavioral Therapy (CBT), Behavioral Activation Therapy (BAT), Interpersonal Therapy (IPT), and Dialectical Behavior Therapy (DBT) for Perinatal Mood Disorder therapeutic content. CBT, BAT, IPT, and DBT are neurobehavioral treatments which focus on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate during perinatal mood disorders.

CBT, BAT, IPT, and DBT for perinatal mood disorders are typically delivered by a specialty-trained clinician either 1:1 or in group format. Standard delivery of CBT, BAT, IPT, and DBT for perinatal mood disorder usually occurs in weekly sessions over 8–10 weeks. This can be conceptualized as eight sessions or Modules that deliver proven behavioral and cognitive treatment strategies. MamaLift Plus delivers treatment with the following 8 treatment Modules or Weeks:

1. **Week 1:** This Week sets the stage for the therapeutic experience by discussing the science and types of therapy behind the program as well as the difference between postpartum blues and depression. The patient understands the relationship between their thoughts and feelings and learns what to do when they find themselves overthinking. The trackers are introduced this week that weave BAT throughout the entire program.
2. **Week 2:** This Week is heavily focused on CBT. The patient learns about automatic thoughts, negative thoughts, and 10 negative thinking styles. The patient learns how to begin shifting their thinking to more healthy, adaptive thoughts by utilizing a Thought Record.
3. **Week 3:** This Week is focused on CBT and BAT. The patient identifies their unhelpful thinking styles, understands alternative constructive thinking methods, learns how to stop overthinking, and practices activities to shift and balance their thinking styles.
4. **Week 4:** This Week is focused on CBT. The patient continues to work on Thought Records, learn ways to manage feeling overwhelmed, learn sleep management tips that are critical during the postpartum period, and review time management techniques.
5. **Week 5:** This Week is heavily focused on IPT as well as DBT. Patients learn the science behind IPT and DBT and subsequently learn the DEARMAN technique and tap into their Wise Mind. They practice social support strategies and learn effective ways to manage interpersonal conflict.
6. **Week 6:** This Week the patient learns about postpartum anxiety and triggers for their anxiety and unproductive worry. They practice strategies such as worry postponement, scheduling worry appointments, senses grounding exercises, and progressive muscle relaxation to manage their anxiety and triggers.
7. **Week 7:** This Week the patient learns about getting back into a routine and coping with worries related to adjusting to the new role of motherhood. The patient learns about effective ways to return to work as well as techniques to improve their body image.

8. **Week 8:** This Week prepares patients for the future with various activities, such as writing in a gratitude journal and writing letters to their future selves. They also learn about the behavior chain and how to apply it. Patients also learn self-confidence tips, meditation, and mantras.

MamaLift Plus includes daily trackers for Sleep, Mood, and Activities in which patients record information about their sleep, mood, and activities. The Resources section provides selected resources and content from each Module for review. The My Learnings section in Resources is available after the Module is completed.

Patient Population

Your patient should only use MamaLift Plus if they:

- Are 18 years or older with perinatal mood disorders
- Are able to read and understand English
- Have regular access to a mobile device (such as smartphone or tablet)
- Are familiar with how to use mobile apps (applications)
- Are able to upload data periodically, i.e., have internet/wireless connection access
- Are under the supervision of a Health Care Provider

Clinical Study Results

Use of MamaLift Plus can result in significant improvements to symptoms of depression or anxiety for your patients, as measured by Edinburgh Postnatal Depression Score (EPDS). The long-term benefit of treatment with MamaLift Plus on recurrent depression has not been evaluated in studies lasting beyond eight weeks. The ability of MamaLift Plus to prevent potential depression relapse or recurrent depressive episodes after treatment discontinuation has not been studied.

Results from the MamaLift Plus Pivotal Studies showed that between 50% to 66% of patients with at least mild depression (baseline EPDS score ≥ 10) experienced a clinically significant improvement in depressive symptoms as measured by EPDS. Studies also showed that between 56% and 73% of patients of patients with at least moderate depression (baseline EPDS score ≥ 13) experienced a clinically significant improvement in depressive symptoms, as measured by EPDS.

Therapeutic benefit from the use of MamaLift Plus is only possible for your patients if they follow the instructions and practice the exercises and strategies provided in the program. Treatment results may vary for your patients.

How to Use MamaLift Plus Clinician Dashboard

Go to <https://mamaliftplushcp.com/getstarted> to access the MamaLift Plus Clinician Dashboard and establish a secure login username and password. Use that username and password to access the MamaLift Plus Clinician Dashboard.

To prescribe MamaLift Plus to a patient:

- Choose “Patient List” from the left side of the screen,
- Choose “Add Patient”.
- Enter patient details, including first and last name, email address, mobile phone number, and preferred gender pronoun.
- Click “Save”.

To view details for patients who have been prescribed MamaLift Plus:

- Choose Dashboard from the left side of the screen.
- Search by patient name.
- “Last Seen” includes the latest date the patient has accessed the MamaLift Plus app.
- “Reports” includes data on app usage, trackers, assessments, and time spent using the app.
- All available usage and program data is available by clicking the “Data” icon under “Reports.”

Security

Please remind patients that it is their responsibility to secure their mobile device (smartphone or tablet). If the patient uses an iPhone or iPad, they should use a 6-digit passcode known only to them. If available, Touch ID or Face ID should be used. If the patient uses an Android phone or tablet, they should use a password or 6-digit passcode and enable fingerprint-unlock if available.

It is the patient’s responsibility to update their phone or tablet operating system when recommended by the platform vendor (Apple or Google). Important security updates are included in operating system upgrades. The vendor will do this by notifying the patient on their device that an update is available for download and install.

Additional Support

For additional support the patient can contact their Health Care Provider, or email MamaLift Plus support at contact@curiodigitaltx.com.

Patient Usage

Patients should be clearly instructed to complete a dose of all 8 treatment Modules. Patients who have completed all 8 Modules have shown the best outcomes.

Each module should be completed on a frequency of one module every 7 days.

Patients should complete their Sleep, Mood, and Activity trackers daily.

Patient access to MamaLift Plus will automatically discontinue after 10 weeks. The prescription will end automatically based on the start date. Additional use of the therapy may benefit the patient.

Downloading MamaLift Plus

Your patients will be able to download MamaLift Plus to access the product. Below are instructions needed to obtain access to MamaLift Plus:

To download MamaLift Plus on the **iPhone or iPad**:

- Tap the App Store icon on the home screen.
- Tap the search icon and type "MamaLift Plus."
- Tap the "GET" button. The patient may need to enter their Apple ID and password or use Touch ID or Face ID to approve the download.
- When MamaLift Plus is downloading, the MamaLift Plus icon will be visible on the home screen. Download progress is indicated within the icon.
- Tap the MamaLift Plus icon to open the app when download completes.

To download MamaLift Plus on an **Android phone or tablet**:

- Tap on the Play Store app on the Android phone.
- Tap on the search bar and type "MamaLift Plus".
- Tap "Install"
- When MamaLift Plus is downloaded, wither tap "Open" in the Play Store

- Or, go to the home screen and tap the MamaLift Plus icon.

Compatible Devices

MamaLift Plus is compatible with mobile devices (including smartphone and tablet) running:

- IOS version 9.0 or higher
- Android version 5.0 or higher

Please ensure your patient's mobile device is running an Operating System (OS) version matching those above. If not, then please instruct the patient to take the time to update their software version before downloading and using MamaLift Plus.

The MamaLift Plus Clinician Dashboard is optimized for desktop computer access and is supported on the following web browsers:

- Google Chrome
- Firefox
- Microsoft Internet Explorer
- Microsoft Edge
- Safari

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