

# CLINICIAN INFORMATION

## Brief Summary Instructions

### MAHANA™ IBS Prescription Digital Therapeutic Mobile Application

#### Important Safety Information:

**Warnings/precautions:** Mahana™ IBS is intended for patients whose primary language is English and who have access to an Apple iOS or Android mobile device (phone/tablet) and internet connectivity. Mahana IBS is intended for patients who are familiar with the use of mobile applications.

The ability to use Mahana IBS may be limited for patients who are visually impaired.

Mahana IBS is not intended to be used as a standalone therapy for Irritable Bowel Syndrome (IBS). Mahana IBS does not replace care by the provider and is not a substitute for other IBS treatments the patient may be using. Patients should continue to take their medications as directed by their provider.

Patients should be clearly instructed that Mahana IBS cannot be used to communicate with their healthcare provider about emergency medical issues. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

Users should seek medical care if they have feelings or thoughts of harming themselves or others while using Mahana IBS.

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#### What is Mahana IBS?

Mahana IBS is a Prescription Digital Therapeutic (PDT) mobile application designed to deliver Cognitive Behavioral Therapy (CBT) to patients with Irritable Bowel Syndrome (IBS). PDTs are a new class of treatment using software to treat medical diseases.

The Mahana IBS CBT program has been tailored for patients with IBS. The rationale for applying CBT to treat IBS is grounded in the biopsychosocial model. This model states that one's biology, thoughts, emotions, and behaviors influence IBS symptom expression in a bidirectional way.<sup>1</sup> The biological substrate of these interactions that affect IBS outcomes is the 'brain-gut axis'. The brain-gut axis underlies the pathways (e.g., psychological, behavioral functioning, and physiological interactions) that contribute to IBS symptom manifestation.<sup>2</sup> CBT allows patients to influence brain-gut communication in order to reduce the severity of IBS.

Mahana IBS is available by prescription only and is intended to provide 3 months (90 days) of cognitive behavioral therapy for adult patients, aged 22 years and older, with IBS. Mahana IBS is intended to provide CBT, as an adjunct to other IBS treatments. Mahana IBS is intended to be used together with the patient's other IBS treatments. The Mahana IBS application uses the patient's mobile phone or tablet to deliver therapy on demand as a complement to the provider's care.

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<sup>1</sup> Moss-Morris, R., *et al.* (2010). A randomized controlled trial of a cognitive behavioural therapy-based self-management intervention for irritable bowel syndrome in primary care. *Psychological medicine*, 40(1), 85-94.

<sup>2</sup> van Tilburg, M. A., *et al.* (2013). Which psychological factors exacerbate irritable bowel syndrome? Development of a comprehensive model. *Journal of psychosomatic research*, 74(6), 486-492.

## How to Start Using Mahana IBS:

The following steps will help guide the patient's use of Mahana IBS:

- You will E-prescribe Mahana IBS by sending a prescription to a Mahana-specified pharmacy.
- The Mahana-specified pharmacy will send a confidential text to the patient, determine the copay, assist with prior authorizations . .
- Once the prescription is approved and paid for, Mahana will unlock the complete program for your patient in the Mahana IBS app.
- Once the patient gains access to the Mahana IBS treatment, they can begin completing sessions, answering questions, and reporting on their symptom severity.
- Mahana IBS incorporates review screens such that, as the patient progresses through the modules, they may review data that was entered earlier in the program.
- After 90 days from the start of therapy, the application will no longer allow progression or unlock new content. However, the patient may access existing content previously unlocked.

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## Mahana IBS is optimized for mobile phone/tablet) access and is supported on the following mobile operating systems:

- iOS
- Android

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## General Information About the Safe and Effective Use of Mahana IBS:

Mahana IBS is not intended to replace other IBS

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<sup>33</sup> Francis, C. Y., et al. (1997). The irritable bowel severity scoring system: a simple method of monitoring irritable bowel syndrome and its progress. *Alimentary pharmacology & therapeutics*, 11(2), 395-402.

treatments. Clinicians should engage in their normal care practices to monitor patients for medical problems.

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## Indications for Use Statement:

Mahana IBS is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy for adults aged 22 years of age and older who have been diagnosed with Irritable Bowel Syndrome (IBS). Mahana IBS is indicated as a 3 month treatment for patients with IBS. Mahana IBS treats IBS by reducing the severity of symptoms and is intended to be used together with other IBS treatments.

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## Summary of Clinical Testing:

Mahana IBS has been studied in a randomized, controlled trial in 558 patients with IBS. Patients with mild to severe IBS (IBS-Symptom Severity Scale [IBS-SSS]  $\geq 75$ ) were randomly assigned to one of three treatment groups: Treatment-as-Usual (TAU), Therapist-delivered Cognitive Behavioral Therapy (TCBT) via telephone, or Web-based CBT (Mahana IBS). At Month 3, group mean changes in IBS-SSS scores were reduced in the Mahana IBS group vs. TAU, and met the minimum clinically-important difference (MCID) of 50 points as defined for the IBS-SSS by Francis *et al.*<sup>33</sup> The frequency of related, treatment-emergent adverse events (TRAEs) revealed no notable differences between treatment groups. The full clinical study summary is also available in publication.<sup>44</sup>

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## Additional Support Available:

<sup>44</sup> Everitt, H., et al. (2019). Therapist telephone-delivered CBT and web-based CBT compared with treatment as usual in refractory irritable bowel syndrome: the ACTIB three-arm

For additional technical support with any aspect of the Mahana IBS application, you can contact Mahana via email at [support@mahanatx.com](mailto:support@mahanatx.com) or by phone at 1-844-MAHANA-01-844-624-2620

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Latest revision: 07/19/2021

03-0007-002 B

