



Mind her gut

Rethink IBS pain  
with digital gut-directed  
hypnotherapy (GDH)

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## PRESCRIBE THE FUTURE NOW

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Today, patients are searching for treatment that goes beyond the prescription of a drug. Introducing Regulora®, the first and only FDA-cleared GDH prescription digital therapeutic (PDT) indicated for the treatment of abdominal pain due to irritable bowel syndrome (IBS) in adults.<sup>1</sup>

**The American College of Gastroenterology includes clinically administered GDH in its guidelines as a recommended therapy for IBS.**<sup>2</sup> GDH helps to bridge the mind-gut connection and Regulora is an app that provides a convenient digital implementation of the gold-standard GDH protocol.<sup>1,3</sup>

Studied across all **3 IBS subtypes** (IBS-C, IBS-D, and IBS-M), Regulora is a safe and effective **non-pharmacological** option for your IBS patients.<sup>3</sup>



Put GDH in the palm of their hand

Regulora, the first and only PDT indicated for IBS abdominal pain, is ushering GDH into the future as a digital implementation of the standardized, fully scripted North Carolina treatment protocol—in a convenient mobile app.<sup>1,4</sup>

## CLINICALLY PROVEN RESULTS

**87.2%**

of participants in the clinical trial would recommend Regulora to someone else with IBS<sup>1</sup>

**No serious adverse events** have been associated with Regulora treatment<sup>1\*</sup>

\*Non-serious adverse events possibly related to treatment included headache, fatigue, abdominal pain, and constipation.<sup>1</sup>

## HOW IT WORKS



**7 individual 30-minute sessions** of therapist-recorded GDH<sup>1</sup>



**Symptom tracking via the validated IBS-Symptom Severity Scale**, with an end-of-treatment report that details symptom changes over time and patient adherence to therapy<sup>1</sup>



**Self-administered** every other week for 12 weeks<sup>1</sup>



**Optional practice sessions** to reinforce treatment<sup>1</sup>



## Rethink IBS pain

### Addressing brain-gut dysregulation with behavioral modalities

While there are many causes of IBS, most people suffering from the condition demonstrate brain-gut dysregulation.<sup>2</sup> Gut-directed hypnotherapy is a verbal intervention encouraging focused attention and deep relaxation during which the mind is more receptive to therapeutic suggestions.<sup>5</sup> These suggestions help address hypervigilance and attentional bias and allow the re-interpretation of visceral signals from the gut as routine and unimportant.<sup>6</sup>

The imagery, metaphors, and suggestions used in GDH are specifically tailored to address patients' GI symptoms, which can result in reduced pain sensitivity in the bowels, normalized motility, reduced stress reactivity in the body, and increased overall sense of well-being.<sup>5</sup>

The most studied behavioral therapies for IBS are GDH and cognitive behavioral therapy (CBT).<sup>5</sup> While CBT involves the effort to change thinking and behavior patterns, **GDH requires no conscious behavioral changes.**<sup>4,7</sup>

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## FOUR DECADES OF CLINICAL RESEARCH DEMONSTRATE THE EFFECTIVENESS OF GDH

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“Level 1 evidence (high-quality, randomized controlled trials [RCTs]) supports the use of brain-gut psychotherapies, particularly GI CBT and gut-directed hypnotherapy, with a **number-needed-to-treat between 3 and 4 and long-term maintenance of efficacy up to 2 years for GI CBT and 6 years for gut-directed hypnotherapy.**”<sup>6</sup>

Chey WD, et al.  
*Gastroenterology*, January 2021



Prescribe Regulora®  
from your EHR

## PRESCRIBING IS AS EASY AS 1-2-3

### Step 1

#### YOU

send prescription to  
our pharmacy partner,  
PhilRx, via:

- **eRx:** PhilRx (Columbus, OH)  
Can also be found by searching with the NABP/NCPDP #: 3685508
- **Phone:** 888.463.8263, Option 1
- **Fax:** 888.975.0603

**Be sure to include the patient's cell phone number with the prescription and let them know to expect a text from PhilRx.**

*Optional:* To minimize callbacks, include prior tried/failed treatments and ICD-10.

### Step 2

#### PHILRx

will process through  
insurance and send a text  
to your patient.

- After receiving the text, your patient will click on the link to enter payment information
- Regulora may be covered by your patient's health insurance and we're actively working to improve options. If your patient's health insurance doesn't cover Regulora, the cost will be no more than \$75.

### Step 3

#### YOUR PATIENT

receives a unique access  
code from PhilRx via  
text and email.

- Your patient can download Regulora from the App Store or Google Play, enter the access code, and follow the on-screen instructions

Scan to review the  
**Instructions for Use**



Scan to review the  
**Brief Summary**







# Mind his gut

If you need help with technical issues, please contact Technical Services at **888-463-8263** or **help@regulora.com**.

Learn more about the Regulora revolution at **ReguloraHCP.com**.



## IMPORTANT INFORMATION

Regulora® is a prescription-only digital therapeutic device intended to provide behavioral therapy through gut-directed hypnotherapy for adults 22 years of age and older who have been diagnosed with irritable bowel syndrome (IBS). Regulora is indicated as a 3-month treatment for patients with abdominal pain due to IBS and is intended to be used together with other IBS treatments.

US federal law restricts this mobile application device to sale by or on the order of a physician. Regulora is intended for patients who speak and read English. Regulora may not be appropriate for patients with mental or physical impairment that would prevent interacting with a mobile video application. Regulora may not be appropriate for patients with evidence of intestinal illness that better explains IBS symptoms such as celiac disease or inflammatory bowel disease. Regulora should not be used in lieu of your patient's current IBS medication or therapy. In a clinical trial of Regulora, side effects were low. About 1% of patients experienced abdominal pain, constipation, fatigue, or headache which was thought to be related to using Regulora.

**References:** **1.** Regulora® Instructions for Use for Patients and Physicians. metaMe Health, Inc.; April 2022. **2.** Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2021;116(1):17-44. **3.** Data on file. metaMe Health; 2022. **4.** Palsson OS. Standardized hypnosis treatment for irritable bowel syndrome: the North Carolina Protocol. *Int J Clin Exp Hypn*. 2006;54(1):51-64. **5.** The Rome Foundation. Brain-Gut Psychotherapy Referral Guide. Accessed July 29, 2022. [https://theromefoundation.org/wp-content/uploads/Rome-Foundation\\_GastroPsych-referral-project.pdf](https://theromefoundation.org/wp-content/uploads/Rome-Foundation_GastroPsych-referral-project.pdf) **6.** Chey WD, Keefer L, Whelan K, Gibson PR. Behavioral and Diet Therapies in Integrated Care for Patients With Irritable Bowel Syndrome. *Gastroenterology*. 2021;160(1):47-62. **7.** Palsson OS, Whitehead WE. Psychological treatments in functional gastrointestinal disorders: a primer for the gastroenterologist. *Clin Gastroenterol Hepatol*. 2013;11(3):208-216.