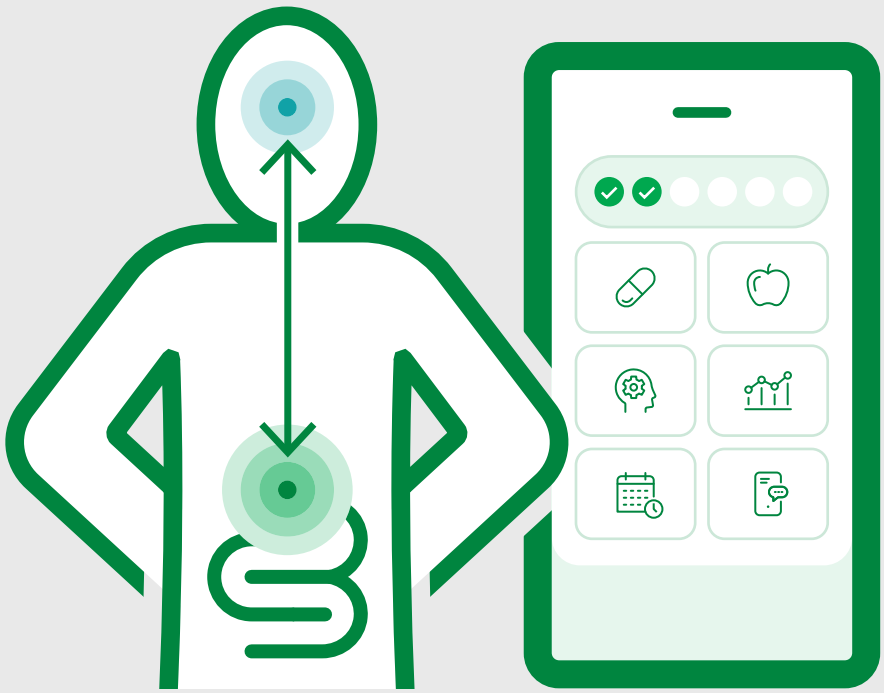
PETERSON HEALTH TECHNOLOGY INSTITUTE

Virtual Gastrointestinal Care Solutions

HEALTH TECHNOLOGY ASSESSMENT | MARCH 2026 | V1.0



PHTI.org

About This Report

The Peterson Health Technology Institute (PHTI) provides independent evaluations of innovative healthcare technologies to improve health and lower costs.

Through its rigorous, evidence-based research, PHTI analyzes the clinical benefits and economic impact of digital health solutions. These evaluations inform decisions for providers, patients, health plans, and investors, accelerating the adoption of high-value technology in healthcare.

PHTI focuses on health technologies designed to replace or augment traditional care delivery, including digital therapeutics, chronic care management apps, and remote patient monitoring technologies.

PHTI selects assessment topics based on the:

- Burden of disease to the healthcare system;
- Investment and innovation in the digital health technology;
- Body of evidence about the effectiveness of the technology; and
- Stakeholder interest (purchasers, providers, and patients).

PHTI assessments evaluate evidence of the clinical and economic impact of these technologies using the ICER-PHTI Assessment Framework for Digital Health Technologies, which was designed by a team of experts specifically for digital health products and solutions. This is a secondary research review that relies on published literature and information, as well as proprietary data submitted directly from companies. PHTI did not conduct original testing of the products. All companies included in this report were notified and given an opportunity to submit clinical, commercial, and economic data, which were included in the evaluation if eligible.

The economic models used in this report are intended to compare clinical outcomes and expected costs at the population level. Model results represent average findings and should not be presumed to represent cost or outcomes for any specific patient or payer.

The findings and recommendations contained within this report represent the opinions of PHTI based on the information considered in this assessment. The findings are current as of the date of publication. Readers should be aware that new evidence may emerge following the publication of this report that could influence the results. Gastrointestinal (GI) solutions are likely to evolve over time, which may impact their performance. PHTI may revisit its analyses in updates to this report in the future.

The Peterson Health Technology Institute

PHTI was founded in 2023 by the Peterson Center on Healthcare, a nonprofit organization dedicated to making higher-quality, more affordable healthcare a reality for all Americans. PHTI and the Center are wholly owned subsidiaries of, and are funded entirely by, the Peter G. Peterson Foundation. PHTI does not accept financial contributions.

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Letter From the Executive Director

Most people have experienced episodic GI trouble—enough to know how disruptive it can be. But for the one in five U.S. adults with conditions like irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD), the disruption is chronic and can affect every dimension of daily life. Yet patients frequently lack access to the coordinated, specialized care they need. The good news is that virtual GI solutions can meaningfully help by reducing symptoms and improving quality of life for patients.

Among PHTI's six assessments to date, the GI solutions stand out for delivering higher net savings—thousands of dollars per engaged member, compared to a few hundred for other digital health categories. That savings potential, combined with demonstrated health improvements, should give purchasers a compelling reason to act. Yet our savings estimates are a fraction of company claims, underscoring the need for more robust, sober economic evidence to inform purchasing decisions.

This report also highlights a tension in the digital health market: whether to choose targeted, disease-specific solutions or broader chronic condition platforms. The GI conditions in this report require distinct treatment approaches. Effective IBS care, including gut-brain behavioral therapy, nutritional counseling, and always-on support, can be delivered directly to patients through lower-cost, "wraparound solutions" that complement but may not directly integrate with care from a patient's doctor. For the large population of people with IBS, wraparound solutions deliver strong clinical benefit and the highest per-user savings.

IBD is a different clinical challenge. Effective treatment must be led by a gastroenterologist who can perform diagnostic procedures, prescribe and manage biologics, and prevent the flare-ups that drive disease progression. Wraparound solutions may help patients with IBD manage symptoms, but they do not address the underlying inflammation and tissue damage. "Clinician-led solutions" can close access gaps by delivering more intensive, specialized care virtually, but at a higher price point.

This creates a purchasing dilemma. Wraparound solutions are cost effective for the much larger IBS population but insufficient for patients with IBD. Clinician-led solutions can effectively serve both conditions, but they may be more than what many patients with IBS need. There is no one-size-fits-all answer; purchasers must weigh their contracting preferences, network access, and budget constraints carefully. Regardless of their choice, integrating a virtual GI solution is likely to deliver health benefits to patients and savings to payers.

Sincerely,

Caroline Pearson, Executive Director
Peterson Health Technology Institute

Report Contributors and Reviewers

PHTI partners with a diverse set of contributors, advisors, and stakeholders. Those who directly contributed to this report are listed below. See our website for a full list of partners and advisors, including our Advisory Board and Purchaser Advisory Council, who offer general guidance but do not participate in the assessment process.

Clinical Advisors

The following clinical advisors provided expertise about usual clinical care for GI, the role of digital solutions, and primary and secondary health outcomes. The clinical advisors have no conflicts of interest with respect to this assessment.

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Evaluation Partners

The following independent evaluation partners contributed to this report. The evaluation partners have no conflicts of interest with respect to this assessment.

- Analysis Group assessed the clinical and economic impact of these technologies, including a systematic literature review and budget impact assessment, using the ICER-PHTI Assessment Framework.
- Charm Economics developed insight into how different technologies work, what they cost to deliver, and their impact on patients and purchasers.
- The Institute for Clinical and Economic Review (ICER) codeveloped the ICER-PHTI Assessment Framework for Digital Health Technologies and reviewed the framework's implementation in this report.

Other Partners

Manatt Health provided consulting, research, and operational support throughout the development of the report.

Patient Perspectives

PHTI interviewed 10 patients with GI conditions (e.g., inflammatory bowel disease, irritable bowel syndrome) who had experience with virtual GI solutions. Patients were recruited for diversity across age, gender, race and ethnicity, income level, geography, and insurance type.

Company Submissions

PHTI directly engaged companies included in the report and accepted submissions of public and proprietary information to inform the assessment. PHTI did not conduct any primary analysis of company data. PHTI applied the same standards for minimum evidence requirements and risk of bias reviews to company-submitted information as to all other studies included in the report. Companies did not influence the assessment methods or findings.

Report contributors and reviewers provided important expertise and insight throughout the evaluation process. PHTI is solely responsible for the report and its findings.

Executive Summary

Gastrointestinal (GI) conditions impact one in five adults in the United States, causing symptoms that negatively affect patients' quality of life, productivity, and mental health. These disorders account for $112 billion in total healthcare spending per year—driven by diagnostic imaging, scoping, specialty medications, emergency department visits, and hospitalizations.[1] While there is a broad range of GI conditions, this report focuses on irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD) as representative conditions, because of their high prevalence and cost burden, respectively.

Because IBS and IBD affect multiple dimensions of health, clinical guidelines increasingly recommend multidisciplinary care that includes gastroenterologists, dietitians, and behavioral health specialists to deliver coordinated, nutritional, psychological, and medical interventions. However, for many patients with IBS and IBD, access to high-quality, effective GI care is limited. Gastroenterologists have the third longest wait times for specialists in the United States and nearly all multidisciplinary programs are located within academic medical centers.[2]

Virtual GI solutions aim to provide expanded access to multidisciplinary GI services, with the goals of both improving symptom control and quality of life and reducing the total cost of care. This evaluation reviews the clinical effectiveness and economic impact of five virtual solutions that provide GI care for a range of conditions, including IBS and IBD. These solutions are designed to replicate a multidisciplinary GI care experience for patients by providing a suite of support services, including nutrition counseling, behavioral health support, care navigation, and symptom tracking. The solutions can be divided into two distinct categories by whether they offer support services that complement the patient's existing clinical care team ("wraparound solutions") or they integrate gastroenterologist care directly within the solution ("clinician-led solutions").

1 **Wraparound Solutions** complement patients' existing GI treatment by offering them a virtual program that includes support services, as well as engagement with coaches, dietitians, and mental health providers. These solutions generally operate independently of patients' GI specialist, primary care provider, or other clinicians. Wraparound solutions are typically purchased by health plans and employers for a flat rate per engaged member, and patients enroll directly in these solutions.

2 **Clinician-Led Solutions** are designed to offer comprehensive GI care that includes gastroenterologists and other clinicians integrated with a suite of support services, to deliver a virtual multidisciplinary care model. The solutions rely on clinical teams to develop and modify treatment plans —including prescribing and adjusting medications—and directly oversee nutrition, behavioral health, and other support services. Most of these solutions are reimbursed as in-network providers. One solution sells directly to gastroenterologists and other providers who want to offer virtual support services to deliver multidisciplinary care for their patients.

CATEGORIES OF VIRTUAL GI SOLUTIONS*

Wraparound Solutions

Cylinder Health Digbi Health

Clinician-Led Solutions

Ayble Health Oshi Health Salvo Health

*Note: Some solutions are evolving their business models to offer products in multiple categories. These groups represent the primary configuration for each company and the product design most commonly reflected in their evidence, company materials, and discussed in company meetings.

PHTI Assessment Approach

This evaluation has two primary components: clinical effectiveness and economic impact. Findings are based on the evidence from a systematic literature review, company-submitted information, and company website review.

Clinical Effectiveness: This evaluation reviewed evidence assessing the clinical effectiveness of virtual solutions in improving symptoms and quality of life for patients with GI conditions. The systematic literature review identified 41 unique studies that met inclusion criteria. Most studies had relatively short follow-up periods of 1–6 months, though some included up to two years of follow-up. Studies used both validated and nonvalidated scales to capture changes in symptoms and quality of life, which limits the direct comparison of results across studies. This report also examines secondary outcomes, including behavioral health, patient condition knowledge and self-efficacy, safety, healthcare resource use (HCRU), and user experience.

Economic Impact: The budget impact model estimates annual healthcare savings from offering virtual GI solutions to patients with IBS and IBD over one year. The economic model estimates the number of adults with IBS or IBD who could be eligible for the virtual solutions, the gross reduction in expected healthcare spending resulting from changes in HCRU, and the net impact on healthcare spending once such savings are offset by the cost of virtual solutions. The model also estimates the impact of virtual GI solutions on a higher-cost subgroup of patients with moderate-to-severe IBD.

Stakeholder Engagement: During the assessment process, PHTI partnered with clinical advisors, experts in health technology assessment, and health economists. PHTI also conducted interviews with patients with GI conditions who had experience using virtual solutions. All companies included in the report had an opportunity to submit clinical, economic, and other commercial information to inform the assessment; all five of the companies engaged with PHTI during the assessment process, and all five submitted evidence.

Summary of Findings

Based on PHTI's review of clinical evidence, virtual GI solutions improve clinical and economic outcomes for patients with IBS and IBD. Solutions that include gut-brain behavioral health and nutrition counseling deliver clinically meaningful improvements in symptoms and quality of life for patients with IBS compared with usual care. Clinician-led solutions that integrate gastroenterologists with other virtual support services may be effective alternatives to in-person multidisciplinary care for patients with IBD. All of these solutions can reduce total healthcare spending for some patients by helping to avoid hospitalizations and other high-cost healthcare services. Clinician-led solutions that address both IBS and IBD deliver the greatest overall savings potential across a broader set of patients, while wraparound solutions that address IBS-only populations also offer substantial savings per user but benefit a smaller share of GI patients.

Wraparound Solutions deliver clinically meaningful improvements in symptoms and quality of life for patients with IBS. However, the limited available evidence examining wraparound solutions for patients with IBD shows no clinical benefit over usual care. For the one-third of patients with IBD who also suffer from IBS symptoms, wraparound solutions may offer benefits for their functional GI symptoms. More evidence is needed to understand whether wraparound solutions—absent a GI specialist to coordinate care—can provide clinical benefits for patients with more complex, structural GI conditions, like IBD. Wraparound solutions substantially decrease net healthcare spending for patients with IBS by $1,889 per year in the commercial market and result in greater per user savings than clinician-led solutions for IBS.

NET SAVINGS FOR VIRTUAL GI SOLUTIONS, BY CATEGORY, IN A COMMERCIAL PLAN

	Wraparound Solutions	Clinician-Led Solutions	
	IBS Only	IBS + Average IBD Combined	IBS + Moderate-to-Severe IBD Combined
Estimated Percent of Plan Members Using a Virtual Solution	0.68%	0.86%	0.77%
Average Annual Savings per User	$1,889	$1,539	$2,901
Total Annual Savings per 1M Members	$12.8M	$13.3M	$22.2M

Clinician-Led Solutions appear to deliver comparable clinical outcomes to in-person multidisciplinary care for patients with IBD, including improved quality of life, based on the limited evidence available. These solutions also offer support services, like gut-brain hypnotherapy and nutrition counseling, which achieve clinically meaningful improvements for patients with IBS that are on par with those achieved by wraparound solutions. Despite having a higher price, clinician-led solutions may also reduce utilization for patients with IBS and IBD, resulting in lower net healthcare spending. The potential for savings is greatest when these solutions are targeted to patients with moderate-to-severe IBD, as well as those with IBS—saving an estimated $2,901 per user on average.

PHTI RATINGS FOR VIRTUAL GASTROINTESTINAL CARE SOLUTIONS BY CATEGORY

● Positive ● Moderate ● Negative
● Higher Clinical Evidence Certainty ○ Lower Clinical Evidence Certainty

Category of Solution	Clinical Effectiveness[a]	Economic Impact	Summary Rating[b]
Wraparound Solutions Cylinder Health Digbi Health	● **Results:** Clinically meaningful improvements in symptoms and quality of life for patients with IBS compared with usual care No evidence of clinical benefit for patients with IBD only **Evidence Certainty:** Higher (for IBS)	● Decreases net spending for patients with IBS	● **Evidence supports broader adoption for patients with IBS; patients with IBD require clinician-led interventions**
Clinician-Led Solutions Ayble Health Oshi Health Salvo Health	○ **Results:** Improvements in symptoms and quality of life for patients with IBS and/or IBD compared with usual care **Evidence Certainty:** Lower	● Decreases net spending for patients with IBS and/or IBD, with the highest savings for patients with moderate-to-severe IBD	● **Evidence supports broader adoption for patients with IBS and/or IBD, particularly those with moderate-to-severe IBD**

Source: PHTI, Virtual Gastrointestinal Care Solutions, March 2026. See PHTI.org for complete report, methods, and recommendations.

Notes: [a] Not all solutions have clinical data that meet the inclusion standards for this report. [b] Summary rating reflects the combination of clinical and economic results. Some solutions are evolving their business models to offer products in multiple categories.

Next Steps

These positive clinical and economic findings warrant broader adoption of virtual GI solutions; however, further evidence is needed to build purchaser confidence, target their deployment across a broad and heterogeneous set of GI conditions, and hone their pricing and contracting models.

To fully realize the benefits of these solutions, PHTI recommends:

- **Strengthening evidence generation to clarify where virtual GI solutions deliver the greatest value,** including comparative studies that assess durability of impact, effectiveness across disease stages, and performance among diverse and underserved patient populations.
- **Generating evidence on the durability of outcomes and the role of patient adherence,** including longer-term follow-up to assess sustained clinical improvement and the relationship between engagement, treatment duration, and long-term economic impact.
- **Leveraging virtual GI solutions to expand access to specialty care,** particularly in regions with limited gastroenterology capacity, while pairing access expansion with targeted outreach and enrollment strategies to ensure that solutions reach the patients most likely to benefit.
- **Aligning payment models with sustained clinical and economic outcomes,** prioritizing validated clinical measures, durability of benefit, and reductions in avoidable utilization over short-term engagement or enrollment-based metrics.

These findings are based on the criteria set forth in the ICER-PHTI Assessment Framework and the currently available evidence. Please see the full PHTI report and appendices, and online data supplement for complete assessment, methods, and recommendations.

The Case for Innovation

Gastrointestinal (GI) conditions affect one in five adults in the United States, causing a range of symptoms that negatively impact patients' physical and mental health, quality of life, and productivity.[3] Nationally, these disorders carry a substantial economic burden—$112 billion in healthcare spending per year—driven by diagnostic imaging, endoscopies, specialty medications, emergency department (ED) visits, surgeries, and hospitalizations.[4]

Despite the high prevalence of GI conditions, access to effective GI care is limited because of specialist shortages, long wait times, and fragmented care delivery.[5, 6] Recommended care integrates primary or specialty providers with multidisciplinary services, like dietary counseling and behavioral health support. Proactive management can help ease symptoms and reduce disease flare-ups that otherwise would lead to escalations in care. Unfortunately, patient access to the right combination of specialists and multidisciplinary services remains largely concentrated in areas with academic medical centers.[7]

Irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD) are one of the most prevalent and costliest GI conditions, respectively. However, these luminal conditions have distinct clinical features and require different approaches to treatment. IBS is a disorder of the gut-brain interaction that causes chronic symptoms like abdominal pain, diarrhea, and constipation, which are primarily managed with dietary changes and behavioral health therapy.[8] IBD causes visible, structural changes in the GI tract. To manage IBD symptoms and slow disease progression, patients are often treated with biologic medications and may require surgery to address structural damage to the gut.[9] About one in three people with IBD also suffer from IBS symptoms.[10]

Early access to GI specialists is important to maintain disease control and prevent symptom recurrence. Patients suffering from IBS and IBD symptoms often face long diagnostic journeys involving lab work, endoscopic exams, and careful documentation of patient history to diagnose their condition, but subsequent treatment varies by condition. Unlike episodic GI conditions, IBS and IBD require chronic, longitudinal management with ongoing specialist oversight. For both conditions, treating comorbid nutrition and psychological complications can reduce health expenditures, emergency visits, and hospitalizations.[11, 12]

Virtual GI solutions aim to expand access to effective treatment and lower costs of care. Some solutions offer nutritional and behavioral health services that are designed to complement a patient's existing GI care plan without replacing physician oversight. Other solutions offer a virtual multidisciplinary team that includes a gastroenterologist, as well as nutritional and behavioral health services. By coordinating multiple components of GI condition management through virtual delivery, these solutions may reduce wait times for patients to access GI care and may help prevent symptom flare-ups, intercept disease progression, and avoid some high-cost care.

As a result, purchasers must evaluate solutions' ability to improve access and clinical outcomes while managing costs effectively across a heterogeneous GI population. The clinical interventions and potential to reduce healthcare spending differ markedly between IBS and IBD. Some virtual solutions are optimized to support patients with IBS at lower price points for purchasers, while other solutions emphasize clinician integration to maximize clinical and economic benefits for both IBS and IBD populations. In practice, most solutions are offered as bundled packages that serve mixed populations, limiting purchasers' ability to match solution selection to their population's clinical composition.

The report incorporates scientific evidence, company data, and budget modeling to answer three fundamental questions: **How well do these virtual solutions work? For whom? Are they worth it?**

COMPANIES WITH VIRTUAL GI SOLUTIONS REVIEWED IN THIS REPORT

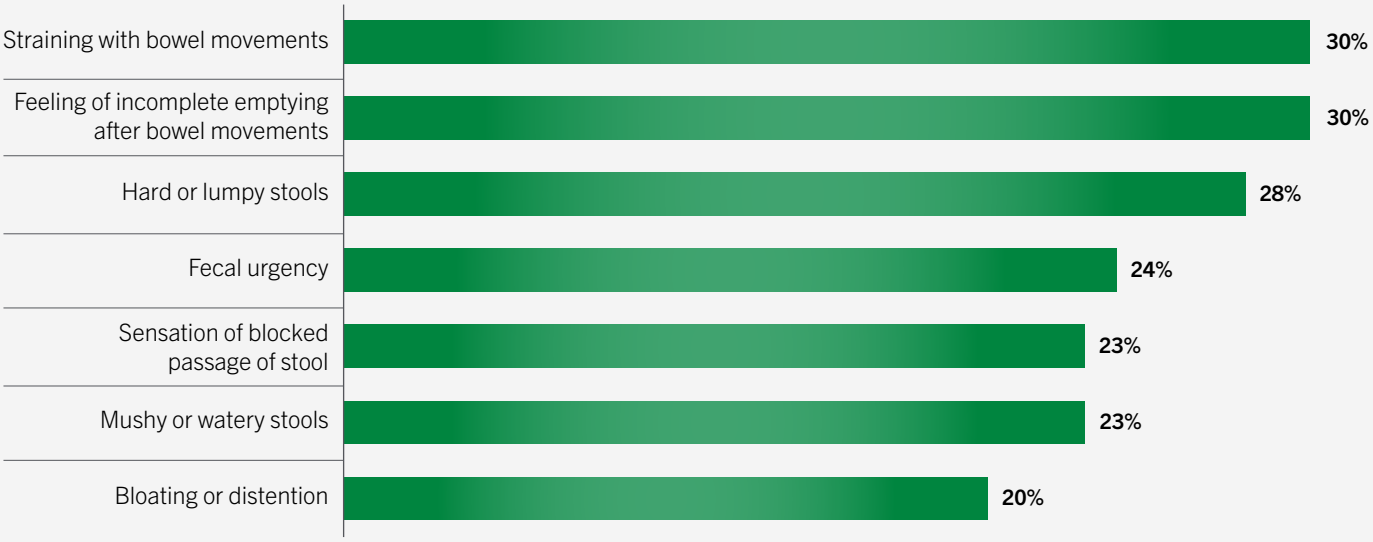
Ayble Health | **Cylinder Health** | **Digbi Health** | **Oshi Health** | **Salvo Health**

Condition Overview

Gastrointestinal (GI) conditions affect more than 60 million people in the United States, negatively impacting patients' physical and mental health and overall quality of life.[13–16] Diagnosis and treatment of GI conditions generate substantial healthcare spending, totaling $112 billion per year.[17] More than 60% of U.S. adults report experiencing at least one frequent GI symptom, such as straining with bowel movements, hard or lumpy stool, or fecal urgency (Exhibit 1).[18] Prevalence of these digestive conditions has increased over the past decade, with women, Black patients, and older adults experiencing a disproportionate disease burden overall.[19]

Exhibit 1

PREVALENCE OF GI SYMPTOMS IN U.S. ADULTS, 2017–2018



Source: Anne F. Peery, Caitlin C. Murphy, Chelsea Anderson, et al., "Burden and Cost of Gastrointestinal, Liver, and Pancreatic Diseases in the United States: Update 2024," *Gastroenterology* 168, no. 5 (2025): 1000–1024. https://doi.org/10.1053/j.gastro.2024.12.029

GI conditions are broadly divided into two categories: "functional" disorders (also known as disorders of the gut-brain interaction [DGBI]), in which the GI tract appears normal despite symptoms like pain, constipation, or frequent diarrhea; and "structural" disorders that result in physical changes, such as polyps or ulcers in the intestinal tract.[20, 21] Among functional disorders, IBS is one of the most prevalent GI conditions, accounting for more than 40% of diagnoses made by gastroenterologists.[22] While IBD —a structural disorder—is less common, it is the most expensive category of GI conditions, generating $13.9 billion in annual healthcare costs, just over 10% of all GI-related spending.[23]

Irritable bowel syndrome (IBS) is a functional condition characterized by recurring symptoms, like abdominal pain, diarrhea, and constipation, without visible damage in the digestive tract.[24] IBS is a disorder of the gut-brain interaction that may be acute or chronic and is frequently managed through lifestyle interventions.[25, 26] In the United States, approximately 16 million (6.1%) adults have a diagnosis of IBS, with the highest prevalence among women and individuals aged 35–49.[27] There are four subtypes of IBS based on symptomology: diarrhea and abdominal discomfort (IBS-D), constipation (IBS-C), alternating diarrhea and constipation (IBS-M), and varied symptoms (IBS-U). Each subtype requires a different, tailored treatment approach.[28]

Inflammatory bowel disease (IBD) is a group of structural conditions—primarily including ulcerative colitis and Crohn's disease—characterized by intestinal inflammation and blockages.[29] IBD causes persistent symptoms and requires medical treatment, including medication and surgery.[30] In the United States, 3.1 million adults (1.2%) have a diagnosis of IBD, with higher prevalence among people aged 45 and older.[31] IBD is a lifelong, chronic, and progressive condition with periods of remission and flare-ups.[32]

This report focuses on IBS and IBD, as they represent two distinct luminal GI conditions with high per-patient healthcare spending and require specialty management. Access to gastroenterology specialists remains limited in many geographic areas, creating treatment gaps that virtual platforms may be uniquely positioned to address. All virtual GI solutions evaluated in this report target patients with IBS, IBD, or both, and these populations represent the primary focus of existing research on virtual GI solutions.

Impact on Healthcare Spending

IBS and IBD result in substantial healthcare spending. In one study of commercially insured individuals, GI conditions accounted for 7% of employer-paid healthcare spending.[33] GI-related complaints also account for 10% of all ED visits and 8% of hospital admissions.[34–36] Early detection and proactive symptom management can help avoid hospitalizations and ED visits.[37]

Patients with **IBS** experience high healthcare utilization from more frequent office visits and other outpatient services, such as diagnostic tests and laboratory or radiology services.[38, 39] Patients with IBS typically have healthcare spending that is 3–3.5 times higher than their counterparts (Exhibit 2).[40, 41] Average annual spending for people with IBS is more than $16,500.[42, 43] People with IBS also have lower productivity, with approximately 90% of employees with IBS reporting missed work because of symptoms.[44]

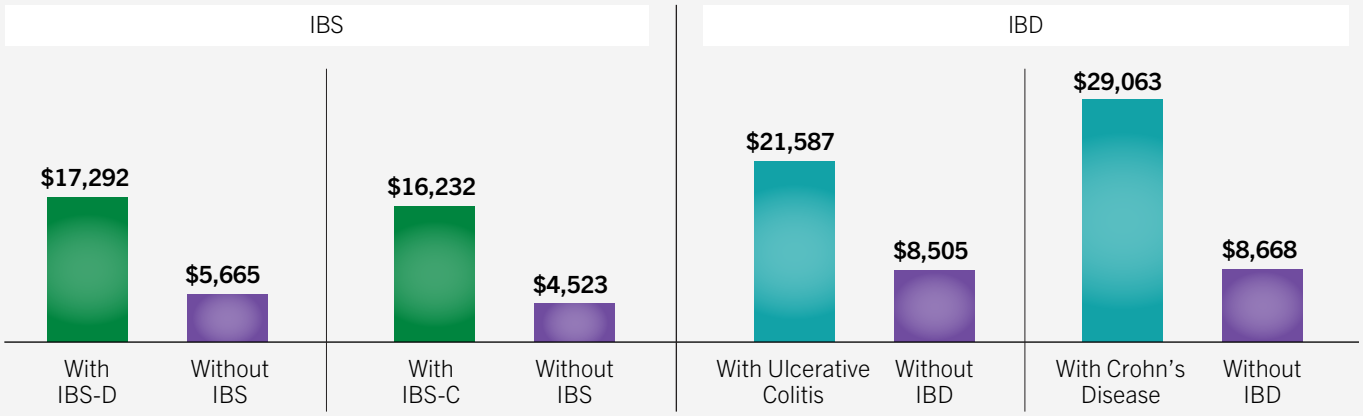
IBD is one of the most expensive GI conditions in the United States, with annual direct costs exceeding $13 billion.[45] People with IBD have an average annual spend of about $25,000, but spending varies widely across patients.[46, 47] Patients with moderate-to-severe IBD incur twice the average spending as average patients with IBD (Exhibit 2). A small subset of high-need patients drives more than 80% of spending—largely due to increased frequency of hospitalization.[48–50]

> **"The chronicity of IBS and IBD is what makes digital solutions helpful and impactful.**
>
> Other conditions you treat for a while, then they go away—IBS and IBD, patients may have symptoms for the rest of their lives.
>
> —Dr. Folasade P. May

Exhibit 2

ANNUAL ECONOMIC BURDEN OF IBS AND IBD

Average Annual Healthcare Spending



Notes: Costs have been adjusted to 2024 USD. Exhibit does not include all conditions that fall under IBS and IBD. Patients with IBS-D were matched to patients without claims for IBS, diarrhea, abdominal pain, or symptom-related prescriptions. Patients with IBS-C were matched to patients without claims for IBS, constipation, abdominal pain, or bloating or pharmacy claims for constipation-related prescriptions. Patients with ulcerative colitis and patients with Crohn's disease were matched to patients without claims for IBD.

Sources: Jessica L. Buono, Kush Mathur, Amelia J. Averitt, et al., "Economic Burden of Irritable Bowel Syndrome with Diarrhea: Retrospective Analysis of a U.S. Commercially Insured Population," *Journal of Managed Care & Specialty Pharmacy* 23, no. 4 (2017): 453–460. https://doi.org/10.18553/jmcp.2016.16138. Jalpa A. Doshi, Qian Cai, Jessica L. Buono, et al., "Economic Burden of Irritable Bowel Syndrome with Constipation: A Retrospective Analysis of Health Care Costs in a Commercially Insured Population," *Journal of Managed Care Pharmacy* 20, no. 4 (2014): 382–390. https://doi.org/10.18553/jmcp.2014.20.4.382. Dominic Pilon, Zhijie Ding, Erik Muser, et al., "Long-Term Direct and Indirect Costs of Ulcerative Colitis in a Privately-Insured United States Population," *Current Medical Research and Opinion* 36, no. 8 (2020): 1285–1294. https://doi.org/10.1080/03007995.2020.1771293. Ameur M. Manceur, Zhijie Ding, Erik Muser, et al., "Burden of Crohn's Disease in the United States: Long-Term Healthcare and Work-Loss Related Costs," *Journal of Medical Economics* 23, no. 10 (2020): 1092–1101. https://doi.org/10.1080/13696998.2020.1789649.

Standard of Care

Many patients with IBS and IBD symptoms experience long diagnostic journeys that may include months of symptom tracking and dietary changes, in addition to lab tests and scoping procedures. Once a patient receives a diagnosis, their symptoms may subside or they may flare, sometimes requiring acute intervention to manage pain and other symptoms. The section below describes the recommended or "standard of care" treatment for IBS and IBD. In practice, "usual care" is highly variable, with many patients struggling to access specialists and receiving suboptimal treatment—or no care at all.

Screening and Diagnosis

Patients with persistent IBS and IBD symptoms typically initiate care with primary care clinicians or urgent care providers, who often order basic laboratory tests—including blood or stool labs.[51–54] Because symptoms overlap across conditions, diagnosing GI conditions often requires extensive evaluation to confirm underlying pathology and exclude other plausible causes of patients' symptoms. No definitive diagnostic test exists for IBS, which is diagnosed via symptom patterns and the absence of objective inflammatory findings.[55] Patients suspected of having IBD are referred to gastroenterologists for endoscopies, colonoscopies, and radiologic imaging.[56, 57]

> **"About 10–15% of patients with IBS spend years cycling through providers**
>
> before finding the right specialist and care. They may spend five years seeing different doctors before they land on the right specialist."
>
> —Dr. Folasade P. May

Exhibit 3

OVERLAPPING AND DISTINCT FEATURES OF IBS AND IBD

	IBS	Both	IBD
Condition	Functional GI disorder with no structural abnormalities	• Manageable but not curable • Chronic disorder • Impairs quality of life	Structural GI disorder with inflammation
Symptoms	• Bloating • Gas • Pain related to bowel movements	• Abdominal pain • Chronic diarrhea • Constipation • Fatigue • Psychological comorbidities	• Anemia • Bloody stools • Weight loss • Bowel tissue damage
Diagnosis	• Often diagnosis of exclusion with noninvasive testing	• Long diagnostic journeys	• Requires objective biomarkers • Surveillance labs • Endoscopy with biopsy • Radiologic imaging
Treatment	• Nutritional diet changes including low FODMAP diet • Over-the-counter medications • Focused gut-directed psychotherapies	• Behavioral health support • Nutritional modifications • Long-term monitoring • Iterative treatments	• Anti-inflammatory therapies • Biologics • Immunomodulators • Surgery for complications

Note: Low FODMAP = elimination diet to identify food triggers (fermentable oligosaccharides, disaccharides, monosaccharides, and polyols) in those who have functional GI disorders.

Sources: Jennifer Webster and Art Kastl, "Understanding the Differences, Similarities of IBD and IBS," Children's Hospital of Philadelphia, February 15, 2021. https://www.chop.edu/news/understanding-differences-similarities-ibd-and-ibs. Brian E. Lacy, Mark Pimentel, Darren M. Brenner, et al., "ACG Clinical Guideline: Management of Irritable Bowel Syndrome," *American Journal of Gastroenterology* 116, no. 1 (2021): 17–44; https://doi.org/10.14309/ajg.0000000000001036. Lin Chang, Shahnaz Sultan, Anthony Lembo, et al., "AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome with Constipation," *Gastroenterology* 163, no. 1 (2022): 118–136. https://doi.org/10.1053/j.gastro.2022.04.016. David T. Rubin, Ashwin N. Ananthakrishnan, Corey A. Siegel, et al., "ACG Clinical Guideline Update: Ulcerative Colitis in Adults," *American Journal of Gastroenterology* 120, no. 6 (2025): 1187–1224. https://doi.org/10.14309/ajg.0000000000003463. Gary R. Lichtenstein, Edward V. Loftus, Anita Afzali, et al., "ACG Clinical Guideline: Management of Crohn's Disease in Adults," *American Journal of Gastroenterology 120*, no. 6 (2025): 1225–1264. https://doi.org/10.14309/ajg.0000000000003465.

Microbiome Testing

Interest in microbiome-based diagnostic testing has grown in recent years but evidence suggests the clinical usefulness of the tests is minimal.[58] Studies show inconsistent associations between microbial profiles and treatment outcomes, and validated microbiome biomarkers are not sufficiently supported by clinical evidence to guide routine GI clinical decision making.[59] In 2022, a leading research institution, the Weizmann Institute of Science, convened a panel of experts who urged caution, finding that clinical adoption of nonstandardized commercial microbiome tests should be minimized until stronger evidence emerges.[60]

> **"Although there is growing interest in microbiome testing,**
>
> I do not currently use commercially available tests to guide clinical care. At present, there is limited clinical evidence demonstrating that results from these tests can be applied in a clinically meaningful way to improve patient symptoms or outcomes."
>
> —Dr. Andrea Shin

Management and Treatment

While IBS and IBD can present with similar symptoms, treatment approaches differ considerably (Exhibit 3). For both IBS and IBD, the overarching goals of treatment are to achieve and maintain remission, sustain symptom improvement, and preserve long-term quality of life through sustained disease control.[61–64] Symptom improvement is correlated with lower absenteeism and reduced healthcare spending. For patients with IBD, clinicians also prioritize objective measures of structural improvements (e.g., resolution of inflammation or ulcers, observed via imaging), as symptom improvement does not reliably indicate resolution of inflammation, which can allow underlying disease activity to trigger future flare-ups.[65, 66]

IBS: IBS management focuses on symptom relief and quality of life improvement by using dietary changes, medications, and behavioral health interventions to regulate the gut-brain axis. According to the American College of Gastroenterology and the American Gastroenterological Association, first-line treatment typically involves dietary modifications, over-the-counter medications (e.g., Miralax), and soluble fiber supplements.[67, 68] Recommendations also include elimination diets to identify food triggers, with the low FODMAP (i.e., fermentable oligosaccharides, disaccharides, monosaccharides, and polyols) diet being one of the most common.[69] Second-line treatments include neuromodulators and medications tailored to specific IBS subtypes.[70, 71] Guidelines also recommend gut-directed psychotherapy such as cognitive behavioral therapy (CBT), mindfulness-based interventions, and hypnotherapy to address IBS symptoms. However, access to providers trained in GI psychology is extremely limited, with reported wait times up to one year.[72, 73] There is currently no cure for IBS, therefore treatment focuses on long-term symptom management and quality of life improvement.[74]

Gut-Brain Connection

The gut-brain axis is a bidirectional communication system linking the GI tract and the central nervous system.[75] Many studies have established a link between the brain's emotional and cognitive centers and intestinal function, demonstrating that signals from the gut influence mood, stress responses, and cognition, while brain signals can directly affect digestive processes and symptoms through stress-related and hormonal mechanisms.[76–79] In 2016, the diagnostic standards introduced the term disorders of gut-brain interaction to replace functional GI disorders, reflecting an updated understanding of the biological mechanisms linking the gut and brain.[80]

> **"Patients with psychiatric comorbidities**
>
> (especially anxiety and depression) have more pain, more emergency visits, and more likelihood of presentation without active inflammation."
>
> —Dr. Ashwin Ananthakrishnan

IBD: IBD encompasses both ulcerative colitis and Crohn's disease, each with distinct presentations and progressions. As a result, no single, best-practice treatment pathway exists for all patients with IBD and approximately 30% of people with IBD also experience IBS symptoms.[81] First-line therapy can include anti-inflammatory agents, biologic specialty drugs, or immunomodulators.[82–84] Some patients need surgery if medication therapy fails or complications arise: Approximately 7% of patients with ulcerative colitis and 18% of those with Crohn's disease require surgery within five years of diagnosis.[85] Without early management of IBD, patients can experience uncontrollable flare-ups and relapses that negatively affect quality of life and ultimately increase costs of care.[86]

Biologics

Biologic medications target inflammation in the digestive tract and are commonly prescribed as maintenance therapy to sustain remission and prevent disease progression in patients with IBD.[87] These medications can deliver substantial improvements in IBD symptoms; however, approximately 40% of patients do not respond to therapy and 23–46% of initial responders experience disease relapse.[88] When disease control is lost, patients may develop worsening symptoms or flare-ups that, if not promptly managed, can result in ED visits or hospitalizations. The combination of high biologic drug costs and acute care utilization during flare-ups are key drivers of the overall economic impact of IBD.[89]

Multidisciplinary Care vs. Usual Care

Because both IBS and IBD affect multiple dimensions of health—including digestion, psychology, and nutrition—clinical guidelines increasingly recommend multidisciplinary care for management of both conditions.[90, 91] Multidisciplinary care typically involves a care team that includes gastroenterologists, dietitians, and behavioral health specialists to deliver coordinated, evidence-based, nutritional, psychological, and medical interventions.[92–97] A multidisciplinary approach is designed to enable ongoing, adaptive management and early intervention during symptom flare-ups, particularly for patients with IBD.

In contrast, usual care is fragmented; it may include care from a gastroenterologist, and it may not integrate other providers like dietitians and behavioral health specialists. Evidence suggests that coordinated, in-person multidisciplinary care outperforms usual care. One study found that patients with IBD who received in-person multidisciplinary care had 47% fewer ED visits and 36% fewer hospitalizations than in the year before multidisciplinary treatment.[98] Another study showed that among patients with functional GI disorders like IBS, multidisciplinary care outperformed gastroenterologist-only care across symptom management, psychological well-being, quality of life, and cost.[99] Some of the solutions in this report seek to replicate a multidisciplinary care team with a virtual delivery model.

> **“Access to urgent evaluation is a major determinant [of emergency visits].**
>
> Patients needing urgent imaging, surgical input, or who have potential complications often must go through the ED.
>
> —Dr. Emily Lopes

Barriers to Care

For patients with IBS and IBD, clinician shortages for both the diagnostic process and ongoing monitoring are a significant challenge. Gastroenterologists are the specialty with the third longest wait time (48 days) in the United States, and two-thirds of counties have no practicing gastroenterologist.[100] Access to multidisciplinary GI care is even more limited, as nearly all multidisciplinary programs are located within academic medical centers, where integration across clinical care, treatment, and research is more feasible.[101]

Access barriers cause substantial impacts to both the patient and system at large. Delays in diagnosing, monitoring, and treating GI conditions can cause symptoms to worsen, often pushing patients to seek care in emergency settings.[102] Similarly, delays in treatment contribute to disease progression and symptom escalation. Patients with IBD who experienced delayed diagnosis have higher odds of severe, progressive complications. These patients also had substantially higher odds of requiring intestinal surgery—two-fold higher for Crohn’s disease and four-fold higher for ulcerative colitis.[103] As symptoms intensify, patients experience higher rates of ED visits, hospitalizations, and surgeries, increasing the total cost of care.[104–106] Among those with IBS, more than 75% report difficulty managing symptoms and only 30% can accurately predict whether they will experience symptoms on any given day.[107]

Virtual GI solutions are designed to help close this access gap by delivering or enabling clinicians to deliver guideline-recommended elements of a multidisciplinary care intervention virtually.

Virtual Solutions

This assessment includes five companies that provide virtual GI care, including a broad set of support services like behavioral health, nutrition counseling, care navigation, and symptom tracking. Most solutions are designed to treat a range of GI conditions, including, but not limited to, IBS and IBD. These solutions seek to replicate a multidisciplinary GI care experience for patients, either by offering comprehensive clinical models or delivering support services that augment patients' existing GI treatment.

These solutions are broadly designed to:

1. **Deliver better clinical outcomes,** by improving care coordination and integrating support services that improve patients' symptoms and quality of life;
2. **Lower healthcare spending**, by avoiding unnecessary ED visits and procedures; and
3. **Improve patient access,** by addressing traditional barriers to in-person GI care.

Solutions considered for this assessment were identified through a market scan, a search of published literature, and company-by-company research. The final list of included companies was informed by company meetings; detailed company research; and input from a broad set of stakeholders, including health plans, employers, clinicians, and virtual health experts.

All of the solutions included in this report:

- Are sold by companies that have clinical evidence of treating GI conditions or indicate they target people with GI conditions;
- Offer a combination of clinician-based GI care, behavioral health support, nutrition counseling, care navigation, and symptom tracking;
- Are sold in the United States;
- Are sold to employers, payers, or health systems/providers; and
- Are sold by companies that have raised at least $10M in funding via private investors (Exhibit 4).

Exhibit 4

COMPANY HISTORY AND FUNDING

Company	Year Founded	Ownership[a]	Total Private Investment
Ayble Health	2020	Private	$11.4M
Cylinder Health	2016	Private	$49.3M
Digbi Health	2018	Private	$20.4M
Oshi Health	2018	Private	$118.5M
Salvo Health	2021	Private	$28.9M

Note: [a] None of these companies were public, as of February 6, 2026.

Source: PitchBook Data, Inc.

The assessment includes comprehensive GI solutions that seek to provide multidisciplinary care. It does not evaluate stand-alone interventions that provide individual support services, such as gut-brain hypnotherapy (e.g., Nerva) or symptom monitoring (e.g., SonarMD). However, because these support services may be incorporated within multidisciplinary care models, the report includes a discussion of both Nerva and SonarMD, along with a summary of relevant clinical and/or economic evidence related to these interventions.

Solution Categories

All of the solutions included in this assessment are designed to improve patient access to components of multidisciplinary GI treatment, particularly "support services" such as nutrition counseling, behavioral health support, care navigation, and symptom tracking (Exhibit 5). They can be broadly grouped into two categories based on whether they offer support services that complement the patient's existing clinical care team ("wraparound solutions") or they integrate gastroenterologist care directly within the solution ("clinician-led solutions").

Support Services

Virtual GI solutions include a suite of support services to help patients manage their symptoms, prevent exacerbations, and limit acute care escalations.

Nutrition counseling helps patients identify dietary triggers for their GI symptoms and develop individualized nutrition plans. Some solutions include registered dietitians and nutritionists to provide ongoing guidance to help patients implement dietary changes.

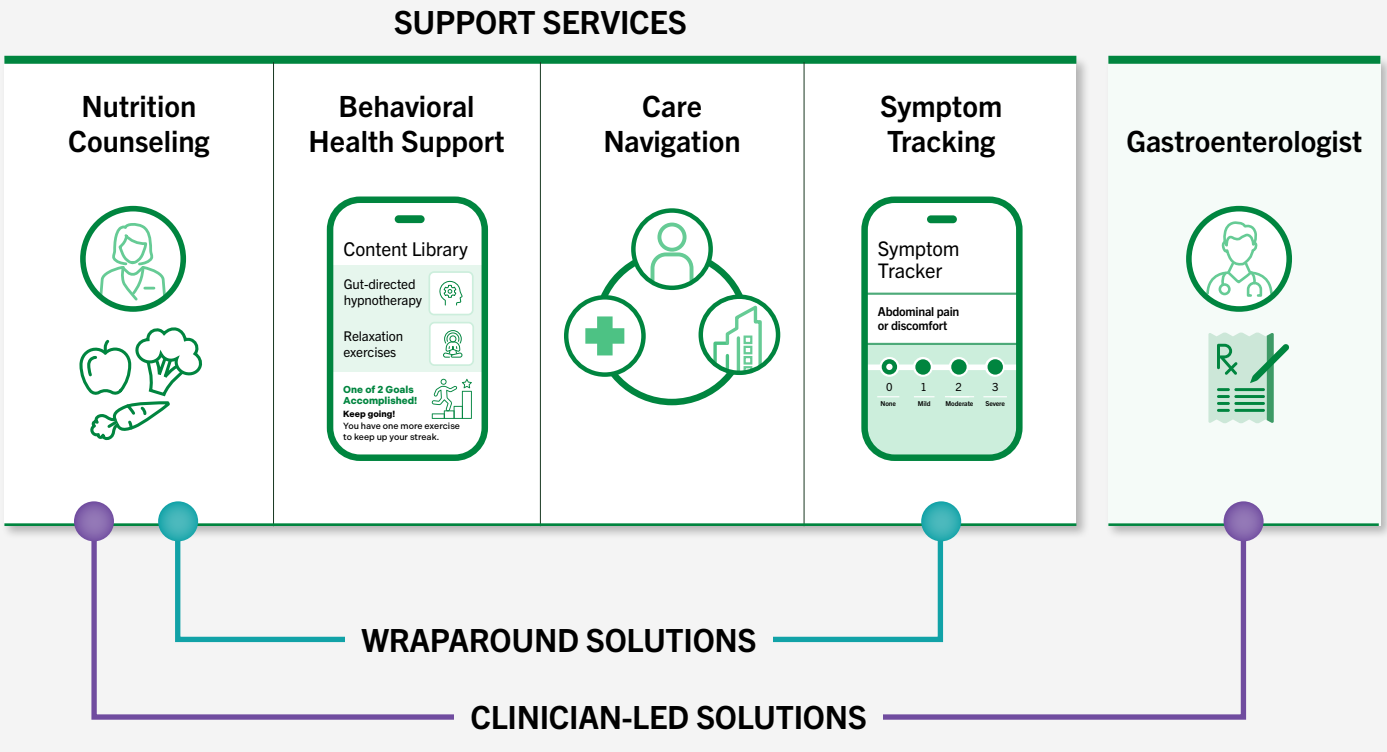
Behavioral health support addresses the gut-brain connection through interventions such as CBT and gut-directed hypnotherapy. These are delivered by licensed therapists, trained health coaches, or asynchronous self-guided modules. Self-guided modules provide on-demand interactive lessons, videos, and therapeutic exercises.

Care navigation includes services that help connect patients to the appropriate care team member. Care coordinators help recommend services and support tailored to patients' symptom severity and case complexity.

Symptom tracking collects patient data using automated prompts or virtual check-ins to inform dietary adjustments, medication titration, or escalation to a patient's gastroenterologist or emergency care.

Exhibit 5

CORE COMPONENTS OF VIRTUAL CARE FOR GI CONDITIONS



Wraparound Solutions (Cylinder, Digbi) complement patients' existing GI treatment by offering them a virtual program that includes support services, as well as engagement with coaches, dietitians, and mental health providers. These solutions generally operate independently of patients' GI specialist, primary care provider, or other clinicians. Wraparound solutions may employ physicians such as gastroenterologists as part of their solution, but providing one-on-one patient care is not their primary function. Wraparound solutions are typically purchased by health plans and employers for a flat rate per engaged member, and patients enroll directly in these solutions. Cylinder offers performance guarantees based on financial outcomes, member satisfaction, and clinical outcomes, while Digbi offers performance guarantees based on reduction in claims.

Clinician-Led Solutions (Ayble, Oshi, Salvo) are designed to offer comprehensive GI care that includes gastroenterologists and other clinicians integrated with a suite of support services, to deliver a virtual multidisciplinary care model. The solutions rely on clinical teams to develop and modify treatment plans, including prescribing and adjusting medications, and directly oversee nutrition, behavioral health, and other support services. Ayble and Oshi are typically reimbursed by health plans as in-network providers that bill directly for visits and other services. Some clinician-led solutions also sell to employers that may waive employee cost sharing, which may increase patient participation and overall utilization. Oshi also receives payment for care coordination and support services through a bundled case rate. Ayble and Oshi both offer performance guarantees: Ayble's is based on clinical and financial outcomes, while Oshi's is based on total cost of care. Salvo is distinct in that it sells directly to gastroenterologists and other providers who want to offer virtual support services to deliver multidisciplinary care for their patients. Salvo is purchased by providers who then bill insurers using chronic care management, remote patient monitoring, or behavioral health integration codes.

Of note, virtual GI solutions are evolving their business models and product design. For instance, some clinician-led solutions are developing wraparound-only offerings that work with gastroenterologists external to the platform, and some wraparound solutions are incorporating clinician-led services into their platforms. The company categorizations shown in Exhibit 6 represent the historic, dominant approach for each company, many of which are actively spreading into other models.

Exhibit 6

CATEGORIES OF VIRTUAL GI SOLUTIONS*

Wraparound Solutions		Clinician-Led Solutions		
Cylinder Health	Digbi Health	Ayble Health	Oshi Health	Salvo Health

*Note: Some solutions are evolving their business models to offer products in multiple categories. These groups represent the primary configuration for each company and the product design most commonly reflected in their evidence, company materials, and discussed in company meetings.

Exhibit 7

CORE COMPONENTS OF VIRTUAL GI SOLUTIONS

● ● Standard Feature ○ ○ Optional Feature

	WRAPAROUND SOLUTIONS		CLINICIAN-LED SOLUTIONS		
CATEGORY Features	Cylinder Health[a]	Digbi Health	Ayble Health	Oshi Health	Salvo Health
TYPE OF PROFESSIONALS GUIDING TREATMENT Gastroenterologist serving as a patient's primary GI provider with the ability to oversee and prescribe medications	○		●	●	
Licensed mental health provider	●		●	●	●
Registered dietitian	●	●	●	●	●
Clinical pharmacist			●		
SERVICES OFFERED Nutrition counseling (e.g., personalized nutrition plans)	●	●	●	●	●
Behavioral health support (e.g., gut-directed hypnotherapy, CBT guidance)	●	●	●	●	●
Care navigation	●		●	●	●
Symptom tracking	●	●	●	●	●
INTEGRATION Provider responsible for care plan uses the digital solution as a tool to deliver and coordinate care. Platform is embedded in care workflow.	○		●	●	●
PATIENT MANAGEMENT Digital solution enables data sharing and communication with an external provider (e.g., patient's provider responsible for care plan). Primary clinical responsibility remains with external provider.	●	●	●	●	●

Notes: CBT = cognitive behavioral therapy. [a]Cylinder Health provides a gastroenterologist who can serve as the primary GI when clinically appropriate, oversee medication management, and the platform is integrated into the care workflow as of January 2026.

Source: Public information (e.g., websites, marketing materials, company-provided public information).

Company Overview

All of the companies included in this assessment engaged with PHTI during the evaluation process and all five submitted evidence for review. PHTI met with companies to understand their solutions and companies had an opportunity to submit commercial information and clinical evidence for review. See **Appendix B** for detailed company-specific information. Results for all included studies are captured in the detailed **online data supplement**.

Wraparound Solutions

Cylinder Health

Cylinder Health's core program offers a virtual platform that delivers support services such as nutrition counseling, behavioral health support, symptom tracking, and care navigation with engagement from registered dietitians, behavioral health teams, and health coaches (Exhibit 7). Cylinder has expanded its solution options to include configurations that offer virtual visits with clinicians, including gastroenterologists who can provide medication management. Cylinder facilitates referrals to external providers when patients require in-person testing and services. Cylinder sells to employers and health plans.

Digbi Health

In addition to delivering virtual support services, Digbi Health provides access to biological testing and follow-up care for digestive health conditions. Digbi's platform includes genetic testing, gut microbiome analysis, nutrition counseling supported by registered dietitians, behavioral health support, symptom tracking, and medication management (Exhibit 7). Patients access care teams including health coaches via online chat. Digbi sells to employers and health plans.

Clinician-Led Solutions

Ayble Health

Ayble Health provides virtual access to gastroenterologists who design and oversee care plans that include medication prescribing and support services such as nutrition counseling, behavioral health support, symptom tracking, and care navigation (Exhibit 7). Patients have access to a broad multidisciplinary care team of providers including clinical pharmacists, registered dietitians, behavioral health teams, and health coaches. Ayble sells to employers and health plans and can be offered as an in-network provider.

Oshi Health

Oshi Health is a virtual specialty clinic that provides multidisciplinary support services (see Exhibit 7) for a range of digestive conditions. Care plans are designed and overseen by gastroenterologists. Oshi's platform includes prescribing, medication management, nutrition counseling, behavioral health support, symptom tracking, care navigation, and access to Oshi Health clinicians through messaging or virtual visits. Oshi also connects with in-person GI care when needed for services such as infusions, imaging, and endoscopies. Oshi sells to employers and health plans and is offered as an in-network provider. In late 2025, Oshi announced that it plans to make their multidisciplinary services available to external providers and health systems as a wraparound solution.

Salvo Health

Salvo Health supplements in-person care for chronic digestive and metabolic GI conditions by offering virtual multidisciplinary care support services such as nutrition counseling, behavioral health support, care navigation, and symptom tracking (see Exhibit 7) to in-person GI practices. Patients access Salvo's virtual multidisciplinary care team, including registered dietitians, nurses, and behavioral health specialists, while remaining under their primary GI physician's supervision. Salvo sells to health systems and provider practices.

FDA Approval for Prescription Digital Therapeutics (PDTs) for GI Conditions

PDTs are software-based clinical interventions authorized by the U.S. Food and Drug Administration (FDA) that require a prescription from a licensed healthcare provider.[108] In 2021, Mahana IBS became the first FDA-approved PDT indicated for IBS, offering 10 sessions of app-based, gut-directed CBT over approximately three months.[109, 110] The Centers for Medicare & Medicaid Services (CMS) has not established Medicare coding and payment for GI-specific PDTs; although they solicited comments in the 2026 Medicare Physician Fee Schedule Proposed Rule, they did not finalize any changes that would expand reimbursement.[111]

Symptom Monitoring Solutions

SonarMD is a stand-alone symptom-monitoring solution designed for patients with IBD. The platform uses patient-reported health assessments and AI-enabled detection tools to alert gastroenterologists to potential disease flare-ups, to enable early intervention and prevent avoidable hospital admissions. SonarMD is sold to provider organizations, GI practices, and health plans.

Economic evidence for SonarMD suggests that symptom monitoring may support timely intervention and contribute to reductions in hospitalizations and ED visits for patients with IBD.[112–114] Additional research estimates that SonarMD resulted in gross savings of $44–543 per member per month over 12 months.[115–117]

Patient Perspectives

PHTI conducted interviews with 10 patients (five with IBS and five with IBD) who had experience using virtual solutions to manage their GI condition. Patients were recruited for diversity across age, gender, race, ethnicity, income level, geography, and insurance type.

Despite differing diagnoses, all patients reported severe quality of life impacts from IBS and IBD. Managing these conditions requires substantial time, energy, and resources. While each patient's care journey was unique, all shared the same primary goals: managing symptoms and regaining normalcy in their daily lives.

> **"We could all be diagnosed with Crohn's disease in this room,** but the way that Crohn's disease reacts to our body can be totally different…so the way that we achieve remission can be different and how our remission progresses is different."
>
> —Patient with IBD

> **"The pain is 24/7…** You can take an opioid or any of the major painkillers and they still won't touch abdominal pain. So, getting that under control would be number one."
>
> —Patient with IBS

Care Coordination and Access

Both patients with IBS and those with IBD expressed a desire for rapid access to gastroenterology expertise. Some patients experienced seamless coordination between virtual solutions and their gastroenterologist, while others had to manually share information between disconnected systems. Some used virtual platforms as their primary gastroenterology support, while others used them to supplement existing care between appointments.

> **"I was pleasantly surprised…** this is an amazing resource that feels on demand. I can make an appointment tomorrow to talk to someone to say I'm having these symptoms."
>
> —Patient with IBD

> **"You have those moments where you cannot get your gastroenterologist** or they take a long time to actually respond. The [virtual solution] is convenient. And they're there when you need them. They're flexible. Anytime you want to get in, you have a question, you can't get to a gastroenterologist, they're there. It gives you that sense of belonging and support."
>
> —Patient with IBD

Multidisciplinary Support for Whole-Person Care

Patients with IBS sought virtual interventions that addressed the gut-brain connection and helped them track diet, stress, sleep, and symptom severity to identify triggers. Patients with IBD appreciated when teams of gastroenterologists, nutritionists, and behavioral health professionals coordinated to create an integrated team approach.

> **"You can get in to talk to someone almost immediately.** They have therapists that will work with the gut-mind connection with you as well, which I thought was a really cool offering. And then also a nutritionist."
>
> —Patient with IBS

> **"The extra support. An extra person to talk to that has a different perspective.** But then most helpful [were] the resources. [The virtual solution provider] knew the gut-brain [provider] that I was talking to and could see what they recommended to me and what I was doing. The care coordination amongst the various different professionals [through the solution] was really helpful."
>
> —Patient with IBD

Clinical Effectiveness

This report evaluates the effectiveness of virtual solutions for IBS and IBD by examining improvements in patient symptoms and quality of life, as measured by general and condition-specific measures, as well as evidence related to HCRU, behavioral health, safety, patient self-efficacy, user experience, and health equity.

The systematic literature review identified a relatively small body of evidence, but one that did include several large comparative studies. While this evaluation focused primarily on IBS and IBD, clinical evidence for other GI conditions (e.g., disorders of the gut-brain interaction, fecal incontinence) were also captured in the systematic literature review. Outcomes for patients with IBS and IBD were assessed separately, and primary and secondary outcomes for other GI conditions are described on a study-by-study basis.

Systematic Literature Review

Using the ICER-PHTI Assessment Framework, independent reviewers conducted a systematic literature review of peer-reviewed and gray literature on virtual GI solutions on the basis of the predefined criteria in Exhibit 8 (Prospero Registry Link). The review included published evidence on clinical effectiveness from online databases (EMBASE, PUBMED, and ClinicalTrials.gov), conference proceedings, company-provided data, and company websites. See **Appendix A** for a detailed methodology.

The systematic literature review included more than 1,700 pieces of evidence. The five companies included in this assessment (Ayble Health, Cylinder Health, Digbi Health, Oshi Health, Salvo Health) submitted 53 pieces of clinical evidence for review. An additional six pieces of evidence from Nerva were included as noncompany evidence on the clinical effectiveness of digital gut-brain therapy for IBS. Three pieces of evidence from SonarMD were included as noncompany evidence on the impact of symptom monitoring on healthcare resource utilization for patients with IBD. Reviewers screened all evidence in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and identified 88 articles based on 41 unique studies for inclusion, including nine interventional and 32 observational studies; of the interventional studies, eight were randomized controlled trials (RCTs) (Exhibit 9). Most studies had relatively short follow-up periods of 1–6 months, though some claims-based studies included up to two years of follow-up.

Fifteen studies evaluated virtual GI solutions compared with a control arm and are referred to in this report as "comparative studies." Of those studies, 13 compared virtual solutions with traditional or in-person delivery of control interventions and two compared different digital solutions to one another. The remaining 26 studies were single arm (noncomparative). A substantial portion of the evidence (37% of all studies) was reported only in conference abstracts or posters, which include relevant outcome data but often lack sufficient methodological detail to assess study quality and risk of bias.

Exhibit 8

SUMMARY OF PICOS INCLUSION AND EXCLUSION CRITERIA

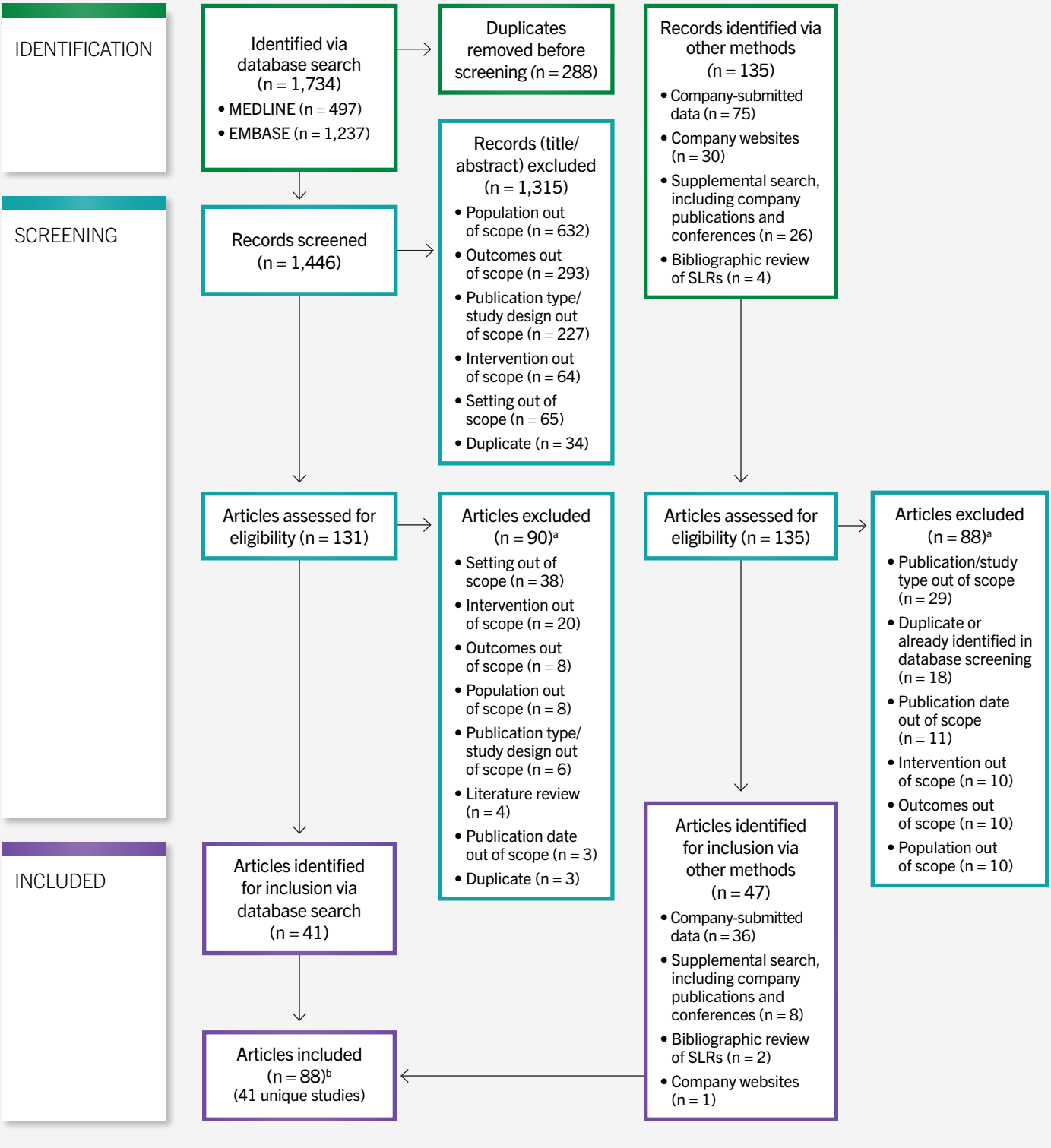
Criteria	Exclusion Criteria
POPULATION: • Adults managing/experiencing digestive disorders symptoms	• Individuals <18 years of age • Individuals who are pregnant • Individuals receiving urgent telehealth care • Individuals with GI conditions or symptoms secondary to another condition
INTERVENTION(S): • Virtual care team access, personalized symptom management or treatment, behavioral health service integration, medication management, or care navigation to virtual or in-person care	• Virtual care team access *only* solutions without wraparound solutions • Direct-to-consumer, self-pay models • Digital tools used for screening/diagnosis/gut microbiome testing without an actively managed care plan • Specialty telehealth-only
COMPARATOR(S): • Standard of care • No care for GI-related symptoms	N/A
OUTCOMES: See Exhibit 11	N/A
SETTING: • Virtual only or outpatient setting and virtual • United States	• Inpatient setting/ED setting only • In person only (no virtual component) • Outside of U.S.
STUDY DESIGN: • Randomized controlled trials and nonrandomized controlled trials • Observational studies • SLRs[a] • Budget impact models, cost-effectiveness models • Meta-analyses	• Editorials, letters, commentaries, study protocols, case reports, qualitative reports, animal and preclinical studies, and narrative reviews • ≤20 study participants
DATE OF PUBLICATION: 2015–2025, and Conferences: 2022–2025	N/A

Notes: N/A = not applicable. SLR = systematic literature review. ED = emergency department. See Appendix tables A-1 and A-2 for detailed list of search terms.

[a] SLRs were included for manual reference checks for studies published between 2015–2025 and were not included in the qualitative evidence synthesis.

Exhibit 9

PRISMA DIAGRAM



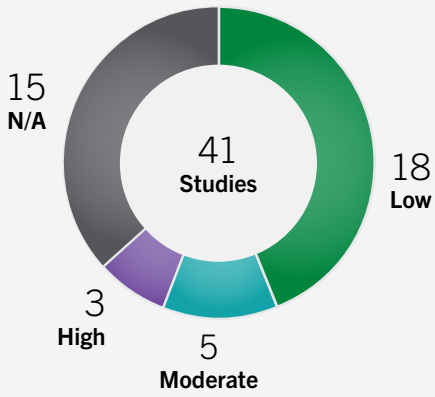
Notes: Systematic literature review (SLR) was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Articles include peer-reviewed publications, and conference abstracts and posters.

[a] For abstract/full-text publication pairs where the full-text was ultimately excluded, the corresponding abstract was assigned the same exclusion reason as was applied to the full-text.

[b] Among included records, there were seven conference abstract/poster pairs (14 articles total) representing an abstract submission and its corresponding poster presentation. There were also 14 abstract/full-text publication pairs (28 articles total), where the full-text publication superseded the conference abstract.

Exhibit 10

RISK OF BIAS RATINGS FOR CLINICAL STUDIES



Notes: N/A = not applicable; N/A means that studies could not be rated. Risk of bias is assessed for studies, not articles. For ease of interpretation across risk of bias ratings, "Low" refers to original ratings of "Low Risk of Bias" (RoB2) or "Good Study Quality" (NOS), "Moderate" refers to original ratings of "Some Risk of Bias" (RoB2) or "Fair Study Quality" (NOS), and "High" refers to original ratings of "High Risk of Bias" (RoB2) or "Poor Study Quality" (NOS). See Appendix C-1 and C-2 for more detail on risk of bias ratings.

Evidence Requirements and Risk of Bias

According to the ICER-PHTI Assessment Framework for Digital Health Technologies, the digital health interventions in this report qualify as Tier 3a. All solutions are intended to treat clinical GI conditions that could be diagnosed by a healthcare professional.

Independent reviewers conducted study quality risk of bias ratings on 26 studies with sufficient detail to rate (see Exhibit 10). Eight RCTs were rated with the Cochrane Collaboration Risk of Bias in Randomized Trials (RoB2), of which four were rated with a moderate risk of bias, three with high risk, and one with low risk. Fifteen of the 26 single-arm studies were rated with the Newcastle-Ottawa Scale (NOS); of those, all 15 were rated with low risk of bias. Five comparative studies and nine single-arm studies could not be rated for risk of bias because they lacked sufficient methodological detail (see **Appendix A** for complete methodology). Additional details on study design and control conditions can be found in the **online data supplement**.

Outcomes Assessed

This evaluation reviewed evidence across 11 outcome categories, with the primary clinical outcomes being symptom improvement and quality of life. Secondary outcomes included behavioral health, safety, patient self-efficacy, user experience, and health equity (Exhibit 11). Outcomes considered in this assessment were informed by the International Consortium for Health Outcomes Measurement (ICHOM) IBD outcome measures sets.[118]

Studies used both validated and nonvalidated scales to capture changes in symptoms and quality of life. Validated scales are specific per condition—the IBS-Symptom Severity Scale (IBS-SSS) for patients with IBS and the Inflammatory Bowel Disease Questionnaire (IBDQ) for patients with IBD—and are designed to measure distinct domains, such as abdominal pain and discomfort (see **Appendix A** for a detailed summary of validated scales). The IBS-SSS was the only disease-specific scale with a universally cited minimum clinically important difference (MCID) of 50 points on the 500-point scale.

Several studies used nonvalidated scales, particularly when study populations included patients with diverse functional and structural GI conditions. This approach enabled comparisons across different conditions within the same study but made cross-study comparisons of populations and outcomes difficult. This clinical assessment prioritizes studies that used validated measures of symptoms and quality of life to allow for direct comparisons of performance across the body of evidence. To facilitate comparison across studies, statistical significance was used to define meaningful change in patient status.

Exhibit 11

DETAILED SUMMARY OF CLINICAL, HCRU, COST, USER EXPERIENCE, PATIENT KNOWLEDGE, AND SELF-EFFICACY OUTCOMES

Primary Clinical Outcomes	Secondary Clinical Outcomes	User Experience and Health Equity Outcomes
SYMPTOMS Measured using validated and nonvalidated scales assessing domains such as: • Abdominal pain; • Bloating; • Bowel habits (frequency and quality); • Constipation; • Diarrhea; • Gassiness, etc.	MENTAL HEALTH Measured using validated and nonvalidated scales assessing domains such as: • Anxiety; • Depression; • General mental health symptoms	PROGRAM ENGAGEMENT • Participation in modules • Count of messages sent
QUALITY OF LIFE Measured using validated and nonvalidated scales assessing domains such as: • Emotional health / psychological well-being; • Food avoidance; • GI-related anxiety; • Social function; • Symptom control, etc.	SAFETY (ADVERSE EVENTS) PATIENT KNOWLEDGE AND SELF-EFFICACY **HCRU and Cost Outcomes** UTILIZATION • GI-related or non-GI related healthcare utilization WORKPLACE PRODUCTIVITY • Absenteeism and presenteeism (e.g., work time missed, sick days) • Change in WPAI scores	SATISFACTION/USABILITY • Satisfaction with care • Ease of use • Net promoter score (NPS) PROGRAM COMPLETION/ ADHERENCE HEALTH EQUITY • Access and accessibility • Distribution

Note: For a complete list of validated scales, see Appendix A.

Primary Clinical Outcomes

The following section reviews evidence about the impact of each category of virtual GI solutions on the primary clinical outcomes—symptoms and quality of life—for both IBS and IBD. Of the 15 comparative studies examining virtual GI solutions, six studies used validated scales to assess changes in symptoms and/or quality of life (see **Appendix D**). The remaining studies either lacked a comparative assessment of the primary outcomes or used nonvalidated outcome scales.

This report summarizes the impact of virtual solutions on primary outcomes of interest, organized by solution category. Control groups for comparative studies of virtual GI solutions fell into two categories:

- **Comparisons to usual care,** in which patients in the control group were not provided with anything above and beyond the usual care they receive during their care journey (e.g., visits with their regular GI provider, and any care they chose to access outside of the study); and
- **Comparisons to active control,** in which patients in the control group received the same or similar *content* as the digital intervention group, delivered through traditional methods (e.g., in-person, paper).

For each comparative study, this assessment presents details of both the intervention and control group designs.

Wraparound Solutions

Wraparound solutions deliver clinically meaningful improvements in symptoms and quality of life for patients with IBS but may not be sufficient to provide clinical benefit for patients with IBD.

Irritable Bowel Syndrome

The evidence reviewed suggests that virtual solutions that deliver behavioral health support and nutrition counseling are effective to improve symptoms and quality of life for patients with IBS. Three out of four comparative studies showed that users of these virtual solutions experienced statistically significant symptom improvements that were greater than those in patients receiving usual care or basic educational materials. Similarly, two out of three comparative studies showed superior improvements in quality of life for patients using the virtual solutions.

The literature review identified four comparative studies that evaluated the effect of virtual solutions on symptom improvement (measured using the IBS-SSS, IBS 100mm VAS, or GSRS-IBS) for patients with IBS (Exhibit 12). Three of those studies also assessed quality of life using the IBS-QoL.

Two comparative studies examined patients receiving virtual solutions involving either gut-brain therapies or nutrition counseling, with control groups receiving similar content through traditional delivery methods (e.g., paper-based or in-person). One study with a low risk of bias compared an app-delivered, gut-directed hypnotherapy program (Nerva) with patients receiving psychoeducational documents to read over six weeks. While both arms showed improvements on the IBS-SSS, the intervention arm was the only group to show symptom reductions that were statistically significant and met the MCID threshold (a 50-point change).[119] Quality of life also improved in both groups, with a between-group difference that was significantly greater in the intervention group. The second study, with a high risk of bias, compared an AI dietary mobile app to delivery of standard educational materials over a 30-day period. Patients in both arms experienced clinically meaningful symptom improvement, but there were not statistically significant differences between groups.[120]

Another two comparative studies suggest that virtual **wraparound solutions** are superior to receiving no support services for patients with IBS. These studies compared delivery of a virtual solution (consisting of nutrition and behavioral health therapies, telephone coaching, and/or an app-based CBT module) with a waitlist control, with follow-up at eight and 12 weeks, respectively.[121, 122] In both studies, patients who used the virtual solution experienced statistically significant reductions in symptoms relative to control. Both studies also reported improvements in quality of life from baseline for patients who received the virtual solution, though only one study[123] showed a quality of life improvement that was statistically significant, and significantly greater than in the control arm.

Findings from the single-arm studies largely affirm that **wraparound solutions** are effective in improving symptoms and quality of life for patients with IBS. Ten single-arm studies assessed virtual wraparound solutions, each of which included a combination of gut-brain behavioral health tools, nutrition counseling, and/or symptom tracking. Nine studies reported changes in symptoms and quality of life using validated, condition-specific scales over 6–24 weeks. Four studies measuring symptom improvement on the IBS-SSS showed statistically significant improvements, with all four meeting the MCID.[124–127] Five studies using the 100mm VAS to measure symptoms found improvements, four of which were statistically significant (one study did not report significance).[128–132] Lastly, the tenth study—which assessed virtual biological testing (Digbi) for patients with IBS (or, more broadly, patients with functional GI or disorders of the gut-brain interaction)—reported a statistically significant improvement in symptoms (measured via a study-specific scale).[133]

While the evidence is not specific enough to isolate the clinical benefits of any individual support services, taken together, these findings support the conclusion that virtual **wraparound solutions** that include gut-brain axis and nutrition interventions improve outcomes for patients with IBS.

Targeting the Gut-Brain Axis

Evidence from multiple studies demonstrated that virtual gut-directed hypnotherapy and CBT-based interventions can improve IBS symptoms by targeting gut-brain axis dysfunction. These interventions address miscommunication between the central nervous system and the GI system. One such program is Nerva, a platform offered by Mindset Health that includes a six-week, gut-directed hypnotherapy program, CBT-based educational content, symptom tracking tools, and breathing exercises.* Within the evidence reviewed, Nerva presented the strongest overall evidence for improving IBS symptoms. In a comparative study, Nerva patients experienced statistically significant improvements in symptoms and quality of life compared with the control group.[134, 135] Nerva also produced six single-arm studies, of which five demonstrated statistically significant symptom improvement among participants.[136–145] An economic study of Nerva that relied on self-reported cost estimates from users found that their IBS-related spending fell by almost half in the six months following program completion;[146] however, patient-reported spending can be unreliable and should be interpreted with caution. Nerva is currently sold primarily direct-to-consumer or through providers on a cash-pay basis.

* A portion of the clinical evidence for Nerva comes from Mahana Health, an FDA-cleared prescription digital therapeutic for IBS. Nerva acquired Mahana Health's assets in 2025.

Inflammatory Bowel Disease

In contrast to IBS, there is very little evidence about the impact of virtual **wraparound solutions** for patients with IBD, and the one available comparative study did not find that these solutions deliver clinically meaningful benefits compared with usual care (see Exhibit 12). Despite these findings, patients with IBD who also suffer from IBS symptoms may benefit from these solutions.

One study, which compared delivery of IBD-related educational content with generic health-related messages sent through an electronic health record (EHR) patient portal, found that patients with IBD who received the IBD-specific messages trended toward a greater increase in quality of life. However, this change was not statistically significant, nor significantly different from the control group.[147]

Exhibit 12

COMPARATIVE STUDY RESULTS FOR WRAPAROUND SOLUTIONS

Citation (Risk of Bias)	Type of Control	Follow-Up Timepoint	Sample Using Digital Solution	Primary Outcome(s)	Outcome Scale(s)	IMPROVEMENT FOR VIRTUAL SOLUTION: From Baseline	IMPROVEMENT FOR VIRTUAL SOLUTION: Compared to Control
IBS							
Anderson 2025 (L)	Educational Materials	8 Weeks	121	Symptoms	IBS-SSS 100mm VAS	**Yes**[1]	**Superior**
				Quality of Life	IBS-QoL	**Yes**	**Superior**
Hunt 2021 (M)	Usual Care	20 Weeks	62	Symptoms	GSRS-IBS	**Yes**	**Superior**
				Quality of Life	IBS-QoL	**Yes**	**Superior**
McDonald 2018 (H)	Usual Care	12 Weeks	22	Symptoms	IBS-SSS	**Yes**[2]	**Superior**
				Quality of Life	IBS-QoL	—	Equivalent
Rafferty 2021 (H)	Educational Materials	4 Weeks	14	Symptoms	IBS-SSS	—	Equivalent
IBD							
Reich 2019 (H)	Usual Care	6 Months	64	Quality of Life	SIBDQ	—	Equivalent

Notes: Virtual solutions were rated as "Superior" if they demonstrated statistically significant improvement from baseline that was *also* significantly greater than the change observed in the control group. Virtual solutions were rated as "Equivalent" if they demonstrated improvement from baseline but they were not statistically significantly greater than the change observed in the control group.

[1] Change was statistically significant and clinically meaningful, per MCID change ≥ 50 points. [2] Results were reported as the proportion of patients who achieved statistically significant improvement, and the proportion of patients who reported moderate to severe symptoms. Average change in IBS-SSS score was not reported.

A single-arm study of a chat-based, remote monitoring intervention (in which patients were classified by disease severity and received customized care reminders, and alerts were shared with the care team based on patient responses) reported no statistically significant quality of life improvements for patients with IBD.[148]

Clinician-Led Solutions

There is a limited body of evidence on clinician-led solutions. Based on the available literature, clinician-led solutions are as effective as wraparound solutions for improving IBS clinical outcomes and may be effective alternatives to in-person multidisciplinary care for patients with IBD.

Irritable Bowel Syndrome

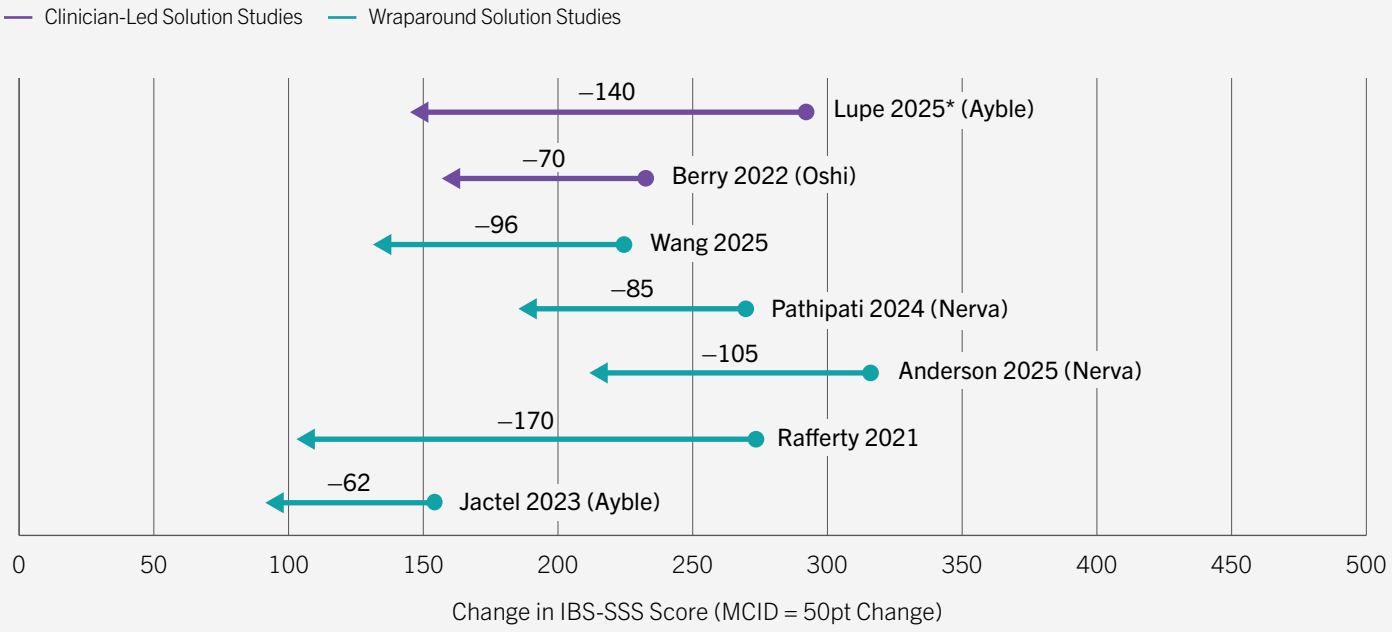
Based on the limited available evidence, **clinician-led solutions** also deliver clinically meaningful improvements in IBS symptoms, on par with the average improvements in **wraparound solutions.** However, there is no evidence that the integration of clinicians in these models results in superior outcomes for patients with IBS.

The literature review did not identify any comparative studies for **clinician-led solutions** that focused on the primary outcomes for IBS. Five single-arm studies examined the effect of clinician-led, multidisciplinary care on patients with IBS. The intervention in each of these studies included a combination of behavioral health and nutrition interventions, combined with physician oversight. Of those, two studies found clinically meaningful symptom improvement (via IBS-SSS).[149, 150] Patients in the remaining three studies showed improvement in symptoms using other scales. Of these, one study reported statistically significant improvements, while the other two did not report on statistical significance.[151–153]

As seen in Exhibit 13, across studies in which symptom severity was measured using the IBS-SSS, patients using any virtual solution experienced clinically meaningful improvements that ranged from 62 to 170 points—averaging about double the threshold for clinically meaningful reduction in symptom scores. When these results are stratified by solution category, the evidence reviewed shows no difference in IBS symptom improvement between **clinician-led** versus **wraparound solutions.**

Exhibit 13

CHANGE IN IBS-SSS SCORE FOR PATIENTS WITH IBS USING VIRTUAL SOLUTIONS, CLINICIAN-LED VERSUS WRAPAROUND SOLUTIONS



Notes: Length of follow-up ranged from four to 24 weeks.

* Change in IBS-SSS score reflects the absolute change for the multidisciplinary treatment arm; however, the baseline score reflects the average for all study participants.

Exhibit 14

COMPARATIVE STUDY RESULTS FOR CLINICIAN-LED SOLUTIONS

Citation (Risk of Bias)	Type of Control	Follow-Up Timepoint	Sample Using Digital Solution	Primary Outcome(s)	Outcome Scale(s)	IMPROVEMENT FOR VIRTUAL SOLUTION: From Baseline	IMPROVEMENT FOR VIRTUAL SOLUTION: Compared to Control
IBD							
Cross 2019 (M)	In-Person Multidisciplinary Care	12 Months	36 (UC only) 79 (CD only)	Symptoms	SCCAI (UC only) HBI (CD only)	No (UC only) **Yes** (CD only)	Equivalent
			115	Quality of Life	IBD Q	**Yes**	Equivalent

Notes: Virtual solutions were rated as "Superior" if they demonstrated statistically significant improvement from baseline that was *also* significantly greater than the change observed in the control group. Virtual solutions were rated as "Equivalent" if they demonstrated improvement from baseline but they were not statistically significantly greater than the change observed in the control group.

Inflammatory Bowel Disease

The available evidence suggests that for most patients with IBD, virtual multidisciplinary care can be as effective as in-person multidisciplinary care.

As described above, in-person multidisciplinary care that includes medical, behavioral, and nutritional support coordinated by a gastroenterologist is shown to improve clinical outcomes for patients with IBD.[154, 155] One study of virtual solutions that provide this type of multidisciplinary, clinician-led care found they deliver similar improvements in quality of life for patients with IBD. Because many patients lack access to in-person multidisciplinary care, virtual solutions may improve access and clinical outcomes compared with usual care.

This multicenter comparative study with moderate risk of bias compared telemedicine multidisciplinary care (including chat functionality, educational content, symptom tracking, and care coordination) with in-person multidisciplinary care (see Exhibit 14).[156] After 12 months, both the intervention and control groups showed improved quality of life and there was no significant difference in the degree of improvement between virtual and in-person care. Patients with Crohn's disease also saw significant symptom improvement in both study arms, with no meaningful difference between groups. For patients with ulcerative colitis, both study arms experienced symptom improvement; however, this change was only significant for patients who received in-person multidisciplinary care.

In two single-arm studies of **clinician-led,** multidisciplinary care solutions, patients with IBD experienced improvement in quality of life; this change was statistically significant in one study, and the other did not report statistical significance.[157, 158] Another study of patients with general GI conditions (including IBD) found that participants using a clinician-led solution reported statistically significant symptom improvements, as measured by a self-reported, nonvalidated scale.[159]

Evidence Limitations

The clinical evidence reviewed uses a wide variety of scales to measure symptoms and quality of life, and only one of those scales has a universally cited MCID. The heterogeneity of scales and the lack of established MCIDs limit the ability to compare findings across studies. Many studies used nonvalidated scales and several companies have developed custom scales to use across multiple diagnoses. While this approach is pragmatic, given that many of these companies target patients with a range of GI conditions, it makes comparison of results across studies challenging.

While the virtual solutions within each category shared common content and features (e.g., gut-directed hypnotherapy, diet and nutrition interventions, symptom tracking), each solution also included other features that informed how information was delivered (e.g., chat access to a dietitian versus AI-enabled diet guidance). Studies included in the SLR had different combinations of virtual care and did not always align with the suite of features included in the solution categories included in this report, thereby limiting the ability to draw direct comparisons.

In addition, the definitions of "usual care" for control arms were poorly defined across studies. In most studies, it was not clear whether and what kinds of clinical care and support patients may have received outside of the study design. Given that the median time since diagnosis across studies was more than 10 years, it is reasonable to expect that patients who enrolled were actively receiving some kind of care or management for their condition. Without knowing the manner or quality of this care, it was challenging to fully interpret control conditions across studies.

Most studies lacked long-term, follow-up data and methodological detail. A substantial portion of the studies (15 of 41) were in abstract form only and not suitable for a risk of bias assessment. Most studies reported follow-up periods of only a few months, which limited insight into long-term intervention effects. This is particularly true given the chronic and relapsing nature of both IBS and IBD. Limited data on patient attrition is another limitation of the evidence base. Data on study participants lost to follow-up were often not reported adequately and many studies assessed outcomes only for participants who completed the intervention. Furthermore, the findings are most directly applicable to IBS and IBD and may not be generalizable to other GI conditions.

Secondary Clinical Outcomes

In addition to improving symptoms and quality of life, virtual GI solutions also aim to address comorbid behavioral health conditions among patients with IBS and IBD. Virtual solutions also report to improve disease knowledge and self-efficacy, elements that are associated with reductions in GI disease activity. The evidence for these secondary outcomes varies in quality and quantity, with a wide range of validated and nonvalidated instruments used to measure outcomes. All studies reporting on secondary outcomes are listed in the **online data supplement.**

Healthcare Utilization and Spending

A substantial portion of the published evidence evaluating virtual GI solutions focuses on changes in HCRU, as some features of these solutions are designed to influence how and when patients interact with the healthcare system. This reflects payer and health system interest in utilization patterns and associated costs in addition to clinical benefit.

Six studies (four comparative and two single-arm) reported on HCRU changes and primarily focused on ED visits and hospitalizations. One comparative study evaluated clinician-led telemedicine multidisciplinary care for IBD versus in-person multidisciplinary care over 12 months. The study found statistically significant reductions in inpatient hospitalizations for the intervention group but increases in ED visits, noninvasive diagnostic tests, and communication encounters.[160] Another comparative study assessing GI patients using a clinician-led solution compared with in-person care over a one-month period found no statistically significant reductions in ED visits, but did observe reductions in laboratory and radiology tests.[161] In contrast, a single-arm study of a clinician-led multidisciplinary care solution demonstrated statistically significant decreases in both inpatient hospitalizations and ED visits among patients with IBD over 12 months.[162]

Two comparative studies evaluating **wraparound solutions** —one among patients with IBS and one among patients with IBD—assessed HCRU changes over short follow-up periods of four weeks or less, and neither reported statistically significant changes in ED visits.[163, 164] A single-arm study assessing a wraparound solution for IBD that included gut-directed hypnotherapy reported statistically significant reductions in ED visits, although the sample size was relatively small.[165]

Overall, evidence suggests that virtual GI solutions have the potential to reduce hospitalizations, while findings related to ED utilization are mixed. Additional solution-specific HCRU and cost evidence is described in detail below.

Mental Health

There is a growing body of evidence on the bidirectional linkage between depression and anxiety and GI disease activity among patients with IBS and IBD.[166, 167] Successful clinical interventions for both conditions may also lead to improvements in mental health, including reduced symptoms of depression and anxiety.

Evidence reviewed on mental health outcomes in patients with IBD was limited, with mixed results across three single-arm studies and one comparative study. Three studies assessed virtual multidisciplinary care for patients with IBD and one assessed gut-directed hypnotherapy. The comparative study, with moderate risk of bias, found no statistically significant difference in the change in mental health outcomes between the virtual multidisciplinary care and control groups after one year, as measured by the Mental Health Index (MHI).[168] Of the single-arm studies, one that examined a multidisciplinary care model reported a small but statistically significant improvement in depression, as measured by the PHQ-9 after one year.[169] The other two single-arm studies, including the study assessing gut-directed hypnotherapy, reported that less than a third of participants had notable improvements in mental health.[170, 171]

Nine studies (three comparative and six single-arm) measured changes in mental health outcomes for patient with IBS or other functional GI conditions. Overall, participants using virtual solutions targeting the gut-brain axis showed improvements in mental health.[172–177] All three comparative studies reported statistically significant improvements in mental health outcomes on validated outcome scales (CES-D, DASS, PHQ) after 6–12 weeks.[178, 179] One of those studies, with moderate risk of bias, found that the intervention group had statistically significantly greater improvements than the control group.[180]

One single-arm study of patients with general GI conditions found most participants felt happier after using a virtual solution.[181]

Patient Knowledge and Self-Efficacy

Condition-specific knowledge and self-efficacy are important to patients' ability to manage their chronic disease, particularly for patients with IBD.[182] Two articles from one comparative study of patients with IBD found that condition-specific knowledge increased significantly more in the virtual solution arm than in controls receiving in-person multidisciplinary care; however, self-efficacy scores did not differ between groups and patient activation scores decreased in the intervention arm.[183, 184] A separate, single-arm study found that users of a virtual solution reported improved health literacy about their condition via self-assessment.[185]

Safety

Evidence reviewed suggests virtual GI solutions present minimal safety risks. Five studies reported on adverse events, with only two reporting any occurrences.[186–188] In both studies, the events were considered not related to the use of the virtual solution.[189, 190] Based on the available evidence, virtual solutions were generally well-tolerated and not associated with material safety concerns.

User Experience

To be clinically effective, virtual GI solutions must engage patients and deliver a strong user experience. Across studies in the literature review, virtual solution users consistently reported high satisfaction and usability scores. Evidence reviewed on engagement with virtual solutions was more variable, with engagement generally peaking at the start of use and declining over time—underscoring the challenge of sustained engagement over time.

Engagement

Engagement with virtual GI solutions varied substantially across studies. Metrics used to measure engagement ranged from adherence to full programs to completion of specific tasks. The heterogeneity in reported metrics limits direct comparisons but the evidence reviewed suggests patterns of initial engagement followed by decline, with notable drop-offs after the initial weeks.

Across studies, full program completion ranged from 19% to 74%. Several studies showed partial adherence, with users completing portions of programs but not maintaining full engagement. In many studies, less than half of participants maintained long-term engagement. Two studies found that less than one-third of users remained persistently engaged.[191, 192]

The evidence reviewed on sustained engagement is limited. The longest follow-up period in this body of evidence was two years, with most studies tracking engagement for substantially shorter periods. Given that GI conditions like IBS and IBD are chronic with symptoms that often fluctuate over time, the clinical value of these interventions depends on sustained improvement of symptoms and quality of life. The absence of long-term engagement and follow-up data in the evidence reviewed limits the ability to assess whether near-term improvements can be maintained over time, representing a large gap in the available literature.

Satisfaction and Usability

User satisfaction and usability metrics help determine whether virtual solutions meet user expectations and can easily be integrated into their lives. Most users reported high satisfaction with virtual solutions. Participants commonly cited ease of use and positive care experiences as key benefits. Despite challenges with sustained engagement and adherence, most users were satisfied with the experience and perceived the tools as helpful and easy to use.

Health Equity

Consistent with population-level prevalence estimates, the study populations in both IBS and IBD studies are primarily composed of female participants aged 35–50. While few studies stratified results by demographic groups, those that did suggest that virtual GI solutions are equally effective across sex, race/ethnicity, and age groups.

Sex and Gender: Six studies reported outcomes stratified by sex or gender. One single-arm study found that female participants showed greater improvement in symptoms than males.[193] Another study reported that women had slightly better responses on self-reported quality of life measures, particularly regarding their ability to manage their disease and to feel in control of their health after using the virtual solution.[194] The remaining four studies found no statistically significant differences in symptom improvement by sex or gender.[195–198]

Race and Ethnicity: Four studies examined outcomes stratified by race and ethnicity. One study found that African American and Native American participants demonstrated increased perceived control and symptom improvement after using the virtual solution, compared with participants of other racial and ethnic groups.[199] Three studies found no statistically significant differences in symptom or quality of life improvement by race or ethnicity.[200–202]

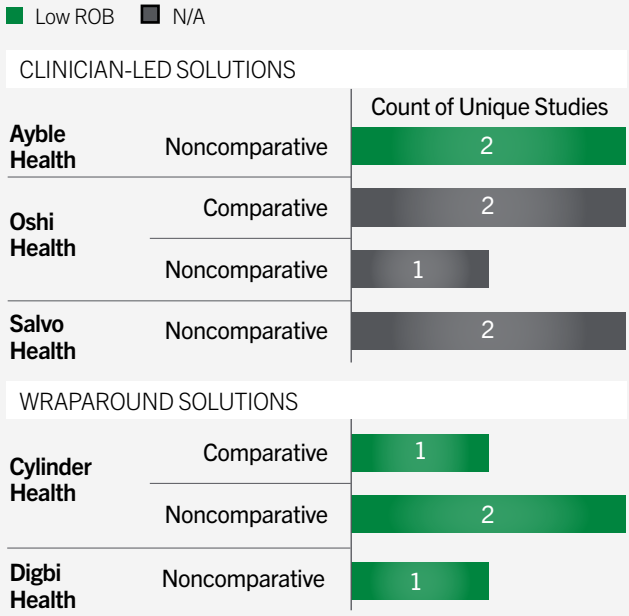
Age: Three studies reported outcomes stratified by age group. One study identified a statistically significant improvement in adherence among younger patients aged 18–40 who reported depressive symptoms.[203] Another study found a positive association between symptom response in patients older than 40.[204] The third study found no significant age-related differences.[205]

Solution-Specific Outcomes

All five companies included in this report produced peer-reviewed evidence on the clinical or economic effectiveness of their solutions that met inclusion criteria; however, a substantial portion of company clinical evidence came from abstracts and conference presentations, reflecting the relatively early stages of evidence generation for virtual GI solutions. As a result, many company studies—including comparative studies—could not be rated for risk of bias (Exhibit 15).

Exhibit 15

RISK OF BIAS RATINGS FOR CLINICAL STUDIES BY COMPANY



Notes: N/A = not applicable. N/A means that studies could not be rated. Risk of bias is assessed for studies, not articles. For ease of interpretation across risk of bias ratings, "Low" refers to original ratings of "Low Risk of Bias" (RoB2) or "Good Study Quality" (NOS), "Moderate" refers to original ratings of "Some Risk of Bias" (RoB2) or "Fair Study Quality" (NOS), and "High" refers to original ratings of "High Risk of Bias" (RoB2) or "Poor Study Quality" (NOS). See Appendix C-1 and C-2 for more detail on risk of bias ratings.

Health Equity Landscape

GI conditions constitute a wide variety of illnesses with complex treatment modalities. Studies report a complex interplay of demographic factors, such as socioeconomic status (SES), race, and gender; systemic factors, such as limited access to multidisciplinary care and shortages of GI specialists; and geographical factors, such as rural/urban location and travel distance.

IBS: Higher SES is associated with reduced risk of IBS incidence, with healthy lifestyle factors having a mediating effect. Interventions targeting both SES inequalities and lifestyle improvements may help reduce IBS burden.[206]

IBD: Black patients with IBD may have elevated rates of ED visits, hospitalizations, and steroid use relative to their white counterparts. Asian, Hispanic, and Black patients are less likely than white patients to receive advanced IBD therapies and more often face barriers to accessing specialist care.[207]

Healthcare utilization patterns in patients with IBS reveal both gender and racial disparities. Male patients and those of Asian or Hispanic ethnicity incur lower total and IBS-specific costs than female and white patients. Among racial groups, Black patients may experience higher IBS-specific total costs, prescription expenses, radiology/laboratory costs, and ED utilization than white patients, while Asian and Hispanic patients may have lower ED, hospitalization, and prescription costs.[208]

Despite differences in design and user interface, the consistency of the mechanisms of action and care models for these approaches means that findings for one company may apply to solutions with similar features or using a similar approach.

Wraparound Solutions

Cylinder Health: Eleven articles covering three unique studies (one comparative and two single-arm) from Cylinder, all with low risk of bias, met inclusion criteria. In all three studies, Cylinder used a custom scale to assess changes in symptom severity. The comparative study assessed absenteeism and symptom improvements among a cohort of adult employees offered a digital digestive care program as part of their health benefits, and found improvements in symptoms that were not reported to be statistically significant.[209] However, a stratified analysis showed that employees aged 50 years or older who participated in the program had significantly fewer sick days compared to nonparticipants. The two single-arm studies followed Cylinder participants for three months. Both studies measured outcomes on the Cylinder scale and reported statistically significant improvements in symptom severity, demonstrating a 4.7-point (61%) decrease in symptom severity from baseline.[210–218]

One study assessed cost and HCRU outcomes for a retrospective claims-based cohort study of employees, comparing Cylinder participants versus nonparticipants using a difference-in-difference analysis. The study evaluated total healthcare spending of employees in a large public school system, comparing participants with any GI diagnosis to propensity-matched controls in the 12 months before and after Cylinder's program launch. For participants enrolled in Cylinder, the study reported $169 per member per month in gross savings, costs of $29 per member per month, and net savings of $140 per member per month. Savings were driven by reductions in inpatient admissions and emergency care spending that offset increases in outpatient and prescription drug spending.[219]

Digbi Health: Two articles from one single-arm study with a low risk of bias from Digbi met inclusion criteria. This study—a retrospective analysis of participants who achieved 5% or more body weight loss when enrolled in the Digbi program—found that 89% of participants with functional GI disorders experienced symptom improvements measured by a custom scale in which patients self-reported symptom severity.[220, 221]

A separate economics-focused study presented cost savings, but not HCRU outcomes, using claims data that compared medical spending between participants enrolled in Dibgi and nonenrolled matched controls.[222] For participants enrolled in Digbi, the study reported gross savings of $770 per member per month in medical spending among a small subgroup of 18 patients with digestive disorders. Reductions in medical nutrition therapy spending accounted for $283 per member per month in gross savings. Because the program was designed to treat individuals with multiple co-occurring conditions, observed savings in the digestive subgroup likely reflect combined improvements across multiple conditions rather than costs attributable solely to direct dietary impacts on GI health. The study notes that these results should not be interpreted to suggest that nutrition-based interventions can reverse the economic burden of digestive conditions.

Clinician-Led Solutions

Ayble Health: Six articles from two single-arm studies from Ayble, both with low risk of bias, met inclusion criteria. One study found that patients with IBS who engaged with one or more of Ayble's care pathways—multidisciplinary care, nutrition programs, or gut-brain interventions—experienced a statistically significant and clinically meaningful 140-point decrease in IBS-SSS scores, on average.[223–225] When stratified by care pathway(s) selected, those who selected two or more care pathways experienced significantly greater symptom improvement than those who selected only one. A second study found that patients with IBS and patients with comorbid IBS/IBD using Ayble experienced statistically significant improvements in symptoms as measured via condition-appropriate scales (IBS-SSS for patients with IBS; P-SCCAI or mHI-CD for patients with dual IBS/ulcerative colitis or dual IBS/Crohn's disease).[226–228] No studies reported on the impact of Ayble on costs or HCRU.

One single-arm study of clinician-led, multidisciplinary care (that included virtual components) for patients with IBD reported statistically significant improvements in disease activity and quality of life, as well as reductions in inpatient hospitalizations and emergency department visits over a 12-month period.[229] Ayble Health has exclusively licensed the clinical protocols evaluated in this study.

Oshi Health: Fifteen articles covering three unique studies (two comparative and one single-arm) from Oshi met inclusion criteria. All Oshi studies were published as abstracts or posters; as a result, none were assessed for risk of bias.

The two comparative studies examined HCRU (via claims) for Oshi users and a matched control group, and symptom severity (IBS-SSS) and quality of life (self-report) for the Oshi user group only.[230–242] Among patients with general GI conditions, Oshi participants experienced significant reductions, including 68% fewer ED visits and 52% fewer inpatient admissions over nine months. Oshi participants also had lower annual all-cause costs—resulting in an overall difference-in-difference gross savings of $6,081, or $507 per member per month.[243] The study also reported statistically significant improvements in symptom severity and symptom control (measured using a nonvalidated custom scale) among Oshi users. Cost savings were even greater for patients with IBD, with Oshi users seeing annual all-cause gross savings of $16,751, or $1,396 per member per month. This was driven by utilization reductions including 76% fewer ED visits and 48% fewer inpatient admissions over nine months.[244, 245]

A separate study evaluated changes in costs, utilization, and symptoms among Oshi users with IBS, functional GI disorders, or related signs and symptoms. Three difference-in-difference analyses using varying index dates showed six-month, all-cause, gross savings ranging from $3,483 to $10,292, or $581 to $1,715 per member per month.[246] While reductions in HCRU varied by index date, statistically significant decreases in endoscopies, imaging, and GI-related services were consistently observed. In contrast, reductions in GI-related inpatient admissions and other cost categories were mixed. The study also reported clinically meaningful improvements in symptom severity among Oshi users, with an average 70-point decrease on the IBS-SSS after two or more months—a clinically meaningful change, per the MCID. Additionally, 92% of Oshi users reported overall symptom improvement.

The single-arm study of patients diagnosed with disorders of the gut-brain interaction (including IBS) found that 81.2% of Oshi users reported symptom improvement after an average of 4–5 weeks.[247, 248]

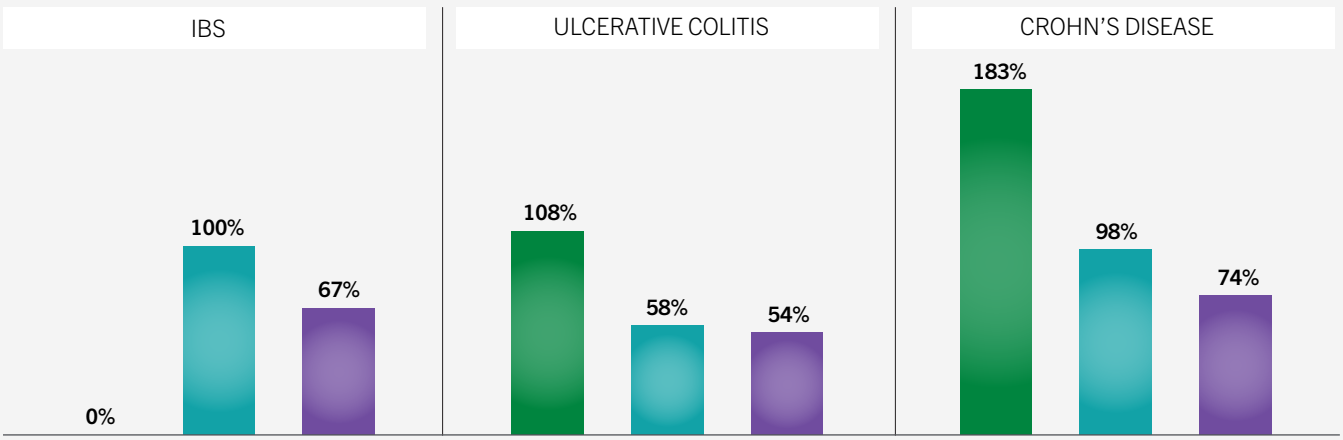
Salvo Health: Six articles from two single-arm studies from Salvo met inclusion criteria and assessed patients with IBS. Both studies were reported as conference posters and abstracts and could not be rated for risk of bias. One study found that 57% of patients experienced improvements on a composite symptom and quality of life score after 30 days.[249, 250] The study also reported statistically significant improvements for the overall population at both 30 and 60 days. The second study measured the proportion of patients who reported reduced avoidance of responsibilities, reduced GI-related anxiety, and improved symptom control, ranked on a scale from 1 to 5. The study reported that less than half of participants showed improvements across these measures; statistical significance was not reported.[251-254] No studies assessed Salvo's impact on cost or HCRU.

Economic Impact

GI conditions, such as IBS and IBD, are associated with high HCRU driven by frequent outpatient visits, emergency care, diagnostic testing, medication management, and, in the case of IBD, hospitalizations and surgery (Exhibit 16). Virtual GI solutions have the potential to impact GI-related healthcare spending by supporting symptom management and improvements in quality of life, helping to avoid flare-ups, and shifting care away from high-cost, high-acuity settings.

Exhibit 16

INCREASED HEALTHCARE UTILIZATION FOR PATIENTS WITH GI CONDITIONS COMPARED WITH CONTROLS



Notes: Values represent percentage increase in annual healthcare utilization compared with patients without GI conditions. Patients with IBS show similar annual inpatient admissions compared with controls. ED = emergency department.

Sources: Ameur M. Manceur, Zhijie Ding, Erik Muser, et al., "Burden of Crohn's Disease in the United States: Long-Term Healthcare and Work-Loss Related Costs," *Journal of Medical Economics* 23, no. 10 (2020): 1092–1101. https://doi.org/10.1080/13696998.2020.1789649. Dominic Pilon, Zhijie Ding, Erik Muser, et al., "Long-Term Direct and Indirect Costs of Ulcerative Colitis in a Privately-Insured United States Population," *Current Medical Research and Opinion* 36, no. 8 (2020): 1285–1294. https://doi.org/10.1080/03007995.2020.1771293. Andrea Shin and Huiping Xu, "Healthcare Costs of Irritable Bowel Syndrome and Irritable Bowel Syndrome Subtypes in the United States," *American Journal of Gastroenterology* 119, no. 8 (2024):1571–1579. https://doi.org/10.14309/ajg.0000000000002753.

The available body of clinical literature finds that **clinician-led** and **wraparound solutions** achieve superior (vs. usual care) symptom control and quality of life improvements for patients with IBS, while more limited evidence suggests that **clinician-led solutions** are effective for patients with IBD. In contrast, the economic evidence consistently shows substantial reductions in HCRU and associated costs for both patient populations. Improvements in disease symptoms and quality of life alone do not fully account for the observed reductions in health spending; rather, reductions in HCRU represent a distinct value driver when evaluating virtual GI solutions.[255, 256]

Therefore, this budget impact model focuses on estimating the effect of virtual GI solutions on HCRU patterns and total healthcare spending. Potential savings from virtual GI solutions may vary on the basis of differences in the patient population—particularly when solutions are deployed among patients with greater baseline severity, higher risk, or more complex needs. While the model captures reductions in inpatient, outpatient, and ED costs, differences in case mix and intensity or frequency of services within those settings can drive larger observed reductions.

Budget Impact Model Methodology

The budget impact model seeks to estimate the expected one-year change in total healthcare spending that results from offering virtual solutions for treating patients with IBS and IBD. The model estimates the number of people who would shift to using the virtual solution, the gross reduction in expected healthcare spending resulting from changes in HCRU for patients enrolled in these programs, and the net impact on healthcare spending once such changes account for spending on the virtual solution.

Due to variation in available evidence, the model applies different assumptions across solution types. Because of the lack of evidence on **wraparound solutions** for IBD, the model estimates the impact of these solutions on patients with IBS only. There is sufficient clinical evidence to demonstrate the effectiveness of **clinician-led solutions** for both IBS and IBD and, therefore, the model estimates the economic impact of these solutions in a combined population of patients with IBS and patients with IBD. These distinctions ensure that each solution type is modeled according to its current evidence base and intended use.

There are three primary components of the budget impact:

1. **Eligible population:** The total number of patients currently treated for IBS and IBD who may engage with a virtual solution, if broadly implemented;
2. **Costs from changes in healthcare utilization:** The changes in healthcare spending that result from differences in HCRU; and
3. **Technology price:** The price paid to a virtual solution company under a contractual agreement.

These components come together to estimate the net impact on healthcare spending per user of a virtual solution for IBS and IBD and the overall per member per month impact of that spending across all enrollees in a hypothetical one-million-member plan.

Eligible Population

The model estimates the number of U.S. adults with IBS or IBD who receive treatment across commercial insurance, Medicare, and Medicaid. Published IBS and IBD prevalence rates by age categories were mapped to each market's age distribution using U.S. Census population estimates.[257–259] Prevalence for IBS is higher than for IBD, with IBS affecting an estimated 6.1% of adults in commercial insurance and IBD affecting 1.2% of enrollees (Exhibit 17).[260–262] Approximately 32.5% of patients with IBD also have symptoms of IBS.[263] Patients that enroll in a virtual solution are assumed to have previously sought treatment for a GI-related symptom. The model estimates the proportion of treated patients is 56.3% for patients with IBS and 92.6% for patients with IBD.[264, 265] See **Appendix A** for prevalence estimates by market.

Taken together, up to 2.7% of all commercial enrollees, 1.7% of Medicare beneficiaries, and 2.1% of Medicaid beneficiaries are eligible to receive virtual solutions for IBS. Among patients with IBD, up to 0.9% of all commercial enrollees, 1.5% of Medicare beneficiaries, and 0.5% of Medicaid beneficiaries are eligible to receive virtual solutions. In a combined population of patients with IBS and IBD, patients with IBD and concurrent IBS symptoms are removed from the patient population of IBS to prevent double counting. In total, the model estimates there are 3.4%, 2.9%, and 2.5% of commercial, Medicare, and Medicaid eligible enrollees with IBS and IBD. When estimating the budget impact of these solutions, the model assumes a 25% participation rate—consistent with prior PHTI reports—in virtual solutions among all eligible individuals.

Exhibit 17

ESTIMATING THE ELIGIBLE POPULATION FOR VIRTUAL GI SOLUTIONS FOR IBS AND IBD

		Commercial	Medicare	Medicaid
PROPORTION OF ENROLLEES WHO ARE ADULTS		79.5%	99.9%	52.5%
PREVALENCE OF CONDITION	IBS	6.1%	3.1%	7.0%
	IBD	1.2%	1.6%	1.0%
PROPORTION RECEIVING TREATMENT	IBS	56.3%	56.3%	56.3%
	IBD	92.6%	92.6%	92.6%
ELIGIBLE POPULATION FOR VIRTUAL SOLUTION	IBS	2.7%	1.7%	2.1%
	IBD	0.9%	1.5%	0.5%
PROPORTION OF ELIGIBLE POPULATION THAT USE A VIRTUAL SOLUTION	IBS	0.68%	0.43%	0.52%
	IBD	0.86%	0.73%	0.62%

Usual Care Costs

The budget impact model relies on published literature to estimate annual, all-cause, total healthcare spending for patients with IBS and IBD. See detailed methodology in **Appendix A.**

For IBS, the model uses two retrospective commercial claims analyses that report annual, all-cause healthcare costs for individuals with IBS-D and IBS-C.[266, 267] These studies define all-cause costs to include inpatient, ED, outpatient, and pharmacy spending across all care settings. The model assumes that patients with IBS have an average of $11,686 more in annual, all-cause healthcare spending than those without IBS.

For IBD, the model draws on two retrospective commercial claims analyses reporting annual, all-cause, healthcare costs for individuals with Crohn's disease and ulcerative colitis.[268, 269] As with IBS, all-cause costs encompass inpatient, ED, outpatient, and pharmacy services. The model assumes that patients with IBD spend an extra $16,490 per year than controls. Healthcare spending for patients with IBD varies widely. Patients with moderate-to-severe disease, including 58% of those with Crohn's and 40% of those with ulcerative colitis, incur double the average annual healthcare costs—$53,303 for moderate-to-severe Crohn's and $56,488 for moderate-to-severe ulcerative colitis.[270, 271] Patients with higher disease severity experience more frequent hospitalizations and ED use, which drives the higher spending.[272, 273]

Health economics research produced by some of the virtual solution vendors report high average annual healthcare spending for their IBD enrollees, suggesting that they are disproportionately enrolling more complex patients. For instance, Oshi Health's study reports annual, all-cause spending for their enrollees of $50,000, compared with approximately $25,000 for the average patient with IBD.[274] Virtual solutions may have more potential to produce savings for patients who have higher annual healthcare costs and utilization of acute care services. Therefore, the model also estimates the impact of virtual GI solutions on this higher-cost, moderate-to-severe IBD subgroup.

Changes in Healthcare Utilization

The model estimates the impact of virtual solutions on healthcare spending by applying changes in healthcare utilization derived from independent published literature (prioritized where available) or from company-provided data. Major drivers of utilization changes include outpatient visits, ED visits, and hospitalizations. The model assumes no changes in pharmacy spending attributable to the digital intervention, as medication use—including biologics—is typically driven by disease severity rather than care-delivery modality and there is no evidence to suggest that digital tools reduce medication use. Further details on study selection and model inputs can be found in **Appendix A.**

IBS: To estimate change in healthcare spending for **wraparound solutions,** the model relies on a retrospective matched-cohort analysis of commercially insured users of Cylinder's digital digestive care management program.[275] Participants had a mix of GI conditions (2% IBD, 10% IBS, 0.5% GI cancers, 78% any GI diagnosis). The intervention arm had 23% lower spending in the 12 months of the intervention than the control arm.

To estimate the impact of **clinician-led solutions** on IBS-related healthcare savings, the model relies on an observational, matched-cohort analysis comparing patients with IBS, functional GI disorders, or signs and symptoms of either condition who used Oshi's virtual integrated care program over nine months.[276] When comparing spending in the 12 months after patients saw a new GI provider, users of the virtual solution reduced their spending by 21% more than the control group.

IBD: Estimates for the impact of **clinician-led solutions** on healthcare spending are based on a peer-reviewed RCT that compared utilization between patients receiving a virtual multidisciplinary care program and in-person multidisciplinary care over 12 months.[277] When applied to the model, changes in HCRU for hospitalizations, emergency care, and outpatient visits resulted in a 17% gross reduction in spending for users of the virtual solution compared with usual care.

Technology Price

To estimate the net spending impact of virtual solutions for IBS and IBD, the model offsets the price of the virtual solution provided to the entire member plan from the estimated healthcare spending driven by changes in HCRU.

Clinician-led solutions are estimated at a price of $1,025 in all markets, based on vendor-supplied pricing information. **Wraparound solution** price is estimated at $825 per engaged member per year based on information from published economic studies and vendor-supplied pricing, with no variation across plan type.[278]

Change in Overall Spending

For **wraparound solutions** (Exhibit 18), based on estimates of reductions in cost as described above and 25% participation in a million-member plan of just patients with IBS:

- For a commercial plan, the one-year net healthcare savings would be $12.8 million—or an average of $1,889 per user per year and $1.07 per month across all members.
- For Medicare, the one-year net healthcare savings would be $2.7 million—or an average of $629 per user per year and $0.23 per month across all members.
- For Medicaid, the one-year net healthcare savings would be $1.6 million—or an average of $303 per user per year and $0.13 per month across all members.

Exhibit 18

ESTIMATED CHANGE IN ANNUAL HEALTHCARE SPENDING [AVERAGE IBS AND IBD ENROLLEES], BY SOLUTION CATEGORY

Average Complexity Patients	Commercial	Medicare	Medicaid
WRAPAROUND SOLUTIONS			
AVERAGE IBS POPULATION			
Δ Total Cost	–$12.8M	–$2.7M	–$1.6M
Δ PMPM	–$1.07	–$0.23	–$0.13
Δ PUPY	–$1,889	–$629	–$303
CLINICIAN-LED SOLUTIONS			
AVERAGE IBS POPULATION			
Δ Total Cost	–$9.9M	–$1.3M	–$0.01M
Δ PMPM	–$0.82	–$0.11	$0.0
Δ PUPY	–$1,454	–$303	–$5
AVERAGE IBD POPULATION			
Δ Total Cost	–$4.0M	–$2.2M	–$0.30M
Δ PMPM	–$0.33	–$0.18	–$0.02
Δ PUPY	–$1,781	–$581	–$239
COMBINED — IBS + IBD AVERAGE			
Δ Total Cost	–$13.3M	–$3.3M	–$0.32M
Δ PMPM	–$1.10	–$0.27	–$0.03
Δ PUPY	–$1,539	–$446	–$53

Notes: Negative numbers represent healthcare savings and positive numbers represent healthcare spending. PMPM = per member per month. PUPY = per user per year.

For **clinician-led solutions** (Exhibit 18), based on estimates of reductions in cost as described above and 25% participation in a million-member plan of both patients with IBS (74%) and patients with IBD (26%):

- For a commercial plan the one-year net healthcare savings would be $13.3 million—or an average of $1,539 per user per year and $1.10 per month across all members.
- For Medicare, the one-year net healthcare savings would be $3.3 million—or an average of $446 per user per year and $0.27 per month across all members.
- For Medicaid, the one-year net healthcare savings would be $0.32 million—or an average of $53 per user per year and $0.03 per month across all members.

Both **clinician-led** and **wraparound solutions** would result in substantial savings to purchasers. While the savings for IBS per user are higher for wraparound solutions than for clinician-led solutions, the combined savings for clinician-led solutions due to both IBS and IBD users result in higher total savings across the entire plan, with even greater savings potential if deployed in patients with moderate-to-severe IBD (Exhibit 19).

Exhibit 19

ESTIMATED CHANGE IN ANNUAL HEALTHCARE SPENDING [MODERATE TO SEVERE IBD ENROLLEES], BY SOLUTION CATEGORY

Moderate-to-Severe IBD Patients	Commercial	Medicare	Medicaid
CLINICIAN-LED SOLUTIONS			
AVERAGE IBS POPULATION			
Δ Total Cost	–$9.9M	–$1.3M	–$0.01M
Δ PMPM	–$0.82	–$0.11	$0.0
Δ PUPY	–$1,454	–$303	–$5
MODERATE-TO-SEVERE IBD POPULATION			
Δ Total Cost	–$12.6M	–$11.1M	–$2.7M
Δ PMPM	–$1.05	–$0.93	–$0.23
Δ PUPY	–$11,836	–$6,152	–$4,593
COMBINED — IBS + IBD MODERATE-TO-SEVERE			
Δ Total Cost	–$22.2M	–$12.3M	–$2.8M
Δ PMPM	–$1.85	–$1.02	–$0.23
Δ PUPY	–$2,901	–$2,141	–$490

Notes: Negative numbers represent healthcare savings and positive numbers represent healthcare spending. PMPM = per member per month. PUPY = per user per year.

Exhibit 20

NET SAVINGS FOR VIRTUAL GI SOLUTIONS, BY CATEGORY, IN A COMMERCIAL PLAN

	Wraparound Solutions	Clinician-Led Solutions	
	IBS Only	IBS + Average IBD Combined	IBS + Moderate-to-Severe IBD Combined
Estimated Percent of Plan Members Using a Virtual Solution	0.68%	0.86%	0.77%
Average Annual Savings per User	$1,889	$1,539	$2,901
Total Annual Savings per 1M Members	$12.8M	$13.3M	$22.2M

Patient Out-of-Pocket Costs

Patient out-of-pocket spending for such GI conditions as IBS and IBD varies by disease severity, treatment intensity, and insurance benefit design. Due to the permanent policy extension allowing high-deductible health plans to cover telehealth, many employers may offer telehealth and remote care services, including virtual GI solutions, at low or no cost-share depending on plan design. As such, users of virtual GI solutions may have lower out-of-pocket costs than patients receiving in-person GI care.[279] For individuals with IBS, out-of-pocket costs are largely driven by symptom management, including nonprescription medications and alternative therapies that are often not covered by insurance. Annual out-of-pocket spending for IBS averages approximately $406 per patient.[280] In contrast, patients with IBD face substantially higher out-of-pocket costs due to cost sharing for specialist visits, hospital-based care, and high-cost pharmacotherapies, such as biologics. Average annual out-of-pocket spending for IBD is estimated at $2,213 per patient.[281] Virtual solutions that reduce reliance on frequent outpatient utilization for IBS or mitigate high-cost utilization and treatment-related cost sharing for IBD may play an important role in improving affordability, access to care, and overall patient experience.

Summary Ratings

PHTI assigns summary ratings based on its review of the clinical evidence and estimated economic impact from the budget model.

Based on PHTI's review of clinical evidence, virtual GI solutions improve clinical and economic outcomes for patients with IBS and IBD. Solutions that include gut-brain behavioral health and nutrition counseling deliver clinically meaningful improvements in symptoms and quality of life for patients with IBS. Clinician-led solutions that integrate gastroenterologists with other virtual support services may be effective alternatives to in-person multidisciplinary care for patients with IBD. All of these solutions can reduce total healthcare spending for some patients by helping to avoid hospitalizations and other high-cost healthcare services.

Wraparound Solutions: Based on PHTI's review of the evidence, wraparound solutions deliver clinically meaningful improvements in symptoms and quality of life for patients with IBS compared with usual care. However, the limited evidence on the effectiveness of wraparound solutions for patients with IBD shows no clinical benefit over usual care. For the one-third of patients with IBD who also suffer from IBS symptoms, wraparound solutions may offer benefits for their functional GI symptoms. More evidence is needed to understand whether wraparound solutions—absent a GI specialist to coordinate care—can provide clinical benefits for patients with more complex, structural GI conditions, like IBD.

Based on the ICER Evidence Rating Matrix, virtual wraparound solutions receive a C+, with moderate certainty of a comparable or small net health benefit and high certainty of at least a comparable net health benefit, for patients with IBS.

The budget model estimates that at a lower solution price, wraparound solutions can also substantially reduce net healthcare spending across all payers for patients with IBS. These solutions may also improve health equity by making gut-brain behavioral health and nutrition counseling available to patients who lack access to specialists.

Clinician-Led Solutions: Based on PHTI's review of the available evidence, clinician-led virtual solutions deliver comparable clinical outcomes to in-person multidisciplinary care for patients with IBD. These solutions also offer support services, like gut-brain hypnotherapy and nutrition counseling, which achieve clinically meaningful improvements for patients with IBS that are on par with the improvements achieved by wraparound solutions.

Based on the ICER Evidence Rating Matrix, clinician-led solutions receive a C+, with moderate certainty of at least a comparable net health benefit. However, there were few high-quality, comparative clinical studies on clinician-led solutions. Additional evidence is needed to confirm these findings.

Beyond the clinical benefits, clinician-led solutions may result in reduced healthcare utilization—especially in high-cost categories—and subsequent economic savings. The budget model estimates that these solutions substantially reduce net healthcare spending across all payers for both patients with IBS and IBD. These solutions may be particularly financially beneficial if they are targeted to patients with moderate-to-severe IBD who have greater opportunities for saving potential.

Exhibit 21

PHTI RATINGS FOR VIRTUAL GASTROINTESTINAL CARE SOLUTIONS BY CATEGORY

● Positive ● Moderate ● Negative
● Higher Clinical Evidence Certainty ○ Lower Clinical Evidence Certainty

Category of Solution	Clinical Effectiveness[a]	Economic Impact	Summary Rating[b]
Wraparound Solutions Cylinder Health Digbi Health	● **Results:** Clinically meaningful improvements in symptoms and quality of life for patients with IBS compared with usual care No evidence of clinical benefit for patients with IBD only **Evidence Certainty:** Higher (for IBS)	● Decreases net spending for patients with IBS	● **Evidence supports broader adoption for patients with IBS; patients with IBD require clinician-led interventions**
Clinician-Led Solutions Ayble Health Oshi Health Salvo Health	○ **Results:** Improvements in symptoms and quality of life for patients with IBS and/or IBD compared with usual care **Evidence Certainty:** Lower	● Decreases net spending for patients with IBS and/or IBD, with the highest savings for patients with moderate-to-severe IBD	● **Evidence supports broader adoption for patients with IBS and/or IBD, particularly those with moderate-to-severe IBD**

Source: PHTI, Virtual Gastrointestinal Care Solutions, March 2026. See PHTI.org for complete report, methods, and recommendations.

Notes: [a] Not all solutions have clinical data that meet the inclusion standards for this report. [b] Summary rating reflects the combination of clinical and economic results. Some solutions are evolving their business models to offer products in multiple categories.

Next Steps

Virtual GI solutions offer clinical benefits for patients and can reduce healthcare spending for payers. Given the limited number of gastroenterologists, these virtual solutions hold the potential to increase access to GI care for many patients. Coupled with a strong economic value, there is an opportunity for these solutions to both help increase access **and** lower costs. However, realizing the full potential of these solutions will require additional efforts on the part of both innovators and purchasers.

The evidence base for these solutions is still nascent and the companies' business models are evolving rapidly. Innovators need to generate additional evidence on the populations that can benefit the most from treatment, the optimal timing and duration of treatment, and the best and most effective way to deploy these solutions across a large population. Purchasers should focus on how best to integrate these solutions into their current benefit plans in a way that drives efficient scale, clinical outcomes, and economic savings.

Expand Evidence Generation

Wraparound Solutions for Patients with IBD

Today, there is limited evidence on the impact of wraparound solutions on symptoms and quality of life for patients with IBD. Innovators should conduct well-designed studies to evaluate whether and under what circumstances wraparound services improve clinical outcomes. Additional research should identify which components or combinations of components drive clinical value for patients with IBD.

Validated Scales

Many solutions in this assessment use custom-designed, nonvalidated scales to measure clinical outcomes, like symptom severity. The wide variety of scales used in the literature limits the ability to verify company research findings and compare results across studies. Further, many of these scales lack a defined MCID, making it impossible to determine whether improvements in outcomes are clinically meaningful for patients.

Access for Underserved Populations

One promise of virtual solutions is the expansion of access to treatment and other specialty services, as in-person multidisciplinary care for GI conditions is severely limited by geography and provider availability. However, current evidence does not adequately address how virtual solutions perform across diverse patient populations, including traditionally underserved groups. Innovators should conduct additional research that 1) evaluates solution performance across patients with varying demographics, disease severity, and care settings; and 2) identifies patient acquisition strategies that effectively reach populations with limited access to GI care.

Durability

Clinical studies with short follow-up periods and high rates of participants lost to follow-up offer limited evidence about how durable these outcomes are and how well patients adhere to the program over time. Understanding durability of effects is critical to assess how well these solutions work and their potential long-term economic impact. Innovators should 1) conduct longer-term studies that extend beyond initial treatment periods, 2) examine optimal treatment duration and engagement levels needed to maintain clinical benefit, and 3) evaluate the relationship between patient adherence and long-term clinical and economic outcomes.

Disease Stage

Additional research is needed to better identify where virtual GI solutions deliver the greatest value across the different disease stages. Clinical and economic outcomes may differ for newly diagnosed patients and those in a maintenance phase, yet current research largely focuses on established patients. Additionally, receiving a correct and definitive diagnosis is a significant challenge for many patients with GI conditions. Virtual solutions should explore the role that they may be able to play in accelerating acute diagnosis.

Align Payment with Clinical Benefits

Purchasers play a critical role in determining whether these models deliver sustained clinical and economic value at scale. To maximize impact, purchasers should align payment structures with demonstrated clinical benefit, durability of outcomes, and reductions in avoidable utilization.

Prioritize Clinically Meaningful and Validated Outcome Measures

Performance-based contracts that tie payment to incremental improvements in clinical outcomes or reductions in utilization may better reflect the value delivered by virtual GI solutions. Contracting should focus on clinically validated measurement and sustained reductions in hospitalizations or emergency department visits, rather than on proxy measures like enrollment or app usage. Purchasers should ensure that outcome definitions, matched controls, data sources, and measurement methodologies support meaningful patient clinical goals. Tiered performance thresholds that account for variation in disease severity and baseline risk can further support fair and effective payment alignment.

Integrate Virtual Solutions Thoughtfully into Benefit Design

Purchasers should consider how and which virtual GI solution would work best for them within their benefits package. Particularly in areas where in-person GI care is limited, virtual solutions may serve as an important access point for specialty support and ongoing disease management. For patients with IBS, purchasers may also consider direct-to-consumer, self-guided solutions that have demonstrated effectiveness using components of multidisciplinary care; these offerings can provide members with additional support options outside traditional benefit structures. Purchasers should assess strategies to promote awareness and appropriate enrollment among eligible members, including targeted outreach, education, and alignment with existing care navigation resources.

Evaluate Performance Across Disease Stages and Patient Populations

Purchasers should evaluate vendor performance across clinically relevant subgroups, including disease stage, symptom severity, and patient complexity. Understanding how solutions perform for newly diagnosed patients, those in maintenance phases, and those with more severe disease will help purchasers determine where these models deliver the greatest value.

Require Condition- and Stage-Specific Reporting

To support informed purchasing decisions, purchasers should require condition-specific and disease stage–specific performance data. This includes reporting outcomes separately for IBS and IBD populations, as well as stratifying results by treatment phase, when possible.

List of Appendices

Appendix A
Methodology Overview

Appendix B
SLR Studies, Company-Specific Clinical Citations, and HCRU Data

Appendix C
Risk of Bias Ratings for SLR Studies

Appendix D
Key Comparator Studies on IBS and IBD

To access all appendices, please visit https://phti.org/assessment/virtual-solutions-gi-conditions/#appendices.

Online Data Supplement

Access the online data supplement at: https://phti.org/assessment/virtual-solutions-gi-conditions/#data-supplement.

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