FoodMed CERTIFIED

Ayble Health

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Certification for:
Tools to Manage Chronic Disease
Expires August 31, 2024

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Company Profile

Category:	**Tools – Chronic Disease Management**
Website:	www.ayblehealth.com
Public or Private:	Private
Year Established:	2020
CEO:	Sam Jactel, MBA
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Description Provided by the Company:

Ayble Health is an all-in-one digital solution for gut health, providing a comprehensive ecosystem of support through GI-specialized behavioral and dietary programs, all with the human touch of a licensed care team. Ayble empowers patients with chronic GI conditions to manage their care beyond the pill, improve symptoms and reduce costs.

Ayble combines the largest GI behavioral health database in the world with proprietary machine learning algorithms to build personalized, predictive care pathways for every patient.

Through a mobile app on the patient's smartphone, **Ayble's** precision nutrition program helps guide people to identify – and then remove – their personal trigger foods. Patients can use **Ayble's** last-mile nutrition tools to put

Company Profile

their diet to practice: discover compatible foods among 120,000+ grocery products, experiment with 2.3M+ recipes, purchase products through retail partners (Walmart, Kroger, Instacart) and scan barcodes in store.

Ayble's psychology program helps patients address the mind-gut connection through customized, curated exercises, education and interactive content built on gold standard GI-specialized clinical psychology protocols.

In addition to Ayble's data-driven tools, every user gets 1:1 access to board-certified health coaches who offer motivation, guidance, and education throughout the gut health journey. Finally, Ayble's integrated clinical referral tools
allow users connect with in-network physicians if needed to supplement their care.

Ayble's platform is built on 20 years of GI-specialized dietary and behavioral research, including primary publications in leading journals such as Gastroenterology, Inflammatory Bowel Diseases and Clinical & Translational Gastroenterology. Additional ongoing research is being conducted with partners at the Cleveland Clinic, Mayo Clinic, Northwestern University, Harvard, Massachusetts General Hospital and Brigham & Women's Hospital.

Ayble is accredited by the American Nutrition Association and partners with the Crohn's & Colitis Foundation and American Gastroenterology Association.

Overview of FoodMed Certification Review Components

Validation Institute's independent review of medical nutrition and food programs guides purchasers on selecting effective, well-designed programs. Programs that earn the Food Med Certified designation will meet the standards shown below.

- Program Foundation – The output, such as guidance to consumers or care plans for medical professionals, is based upon reliable and credible data. Selection of this data is overseen by appropriately licensed and experienced people. In addition, the data must come from recognized, accredited sources; users' data can be used to refine the output over time. The program has systems and procedures managed by competent personnel to ensure this data is accurate and up to date. If the data sources and systems are handled by a contractor, the program must show that the contracts provide for all of the requirements.

- Enrollment and Communications – Prospective users are given accurate and reasonable descriptions of the program and its results. The program will report the following:

  - Size of eligible population, if possible.
  - Definition of enrolled (such as minimum number of visits or interactions)
  - Enrollment attrition and cause, such as lack of engagement or loss of eligibility

Overview of FoodMed Certification Review Components

- Program Delivery –The program will demonstrate how it addresses users' barriers to optimal use. Barriers related to Social Determinants of Health and to cultural factors will be addressed. If the end user is a medical professional, then the program could integrate with existing record and workflow systems. If the end user is a consumer, the program needs to show how it accommodates different needs and preferences. The program also must show how it monitors program delivery success.

- Health Outcomes –If health outcomes are part of the program, the program will show how these are measured. Survey tools should generally be validated and be administered in the way they were validated. (Note: Food programs can separately have their health outcomes validated.) The program's website and enrollment materials will show health outcomes based upon a minimum of 12 months of participant data; shorter time periods are allowed for health conditions whose treatment regimens are shorter. Where the outcome is weight loss, 24 months of participant data and post-program data are preferred.

Ayble Health submitted its program which helps people who have irritable bowel syndrome, irritable bowel syndrome (Crohn's Disease, and Ulcerative Colitis) to manage and reduce their symptoms. (For a complete description of the program and its validated outcomes, see Validation Reports - Validation

Overview of FoodMed Certification Review Components

institute.) Ayble Health submitted descriptions of the four components and other documentation to support their application.

The submitted materials need to meet the requirements and standards and have an executive officer's attestation of their accuracy. All materials, except those containing proprietary information, are available upon request. Validation Institute reviewers, including staff and advisors, contributed to the evaluation.

Applicant's Program Goal

The Ayble Health program guides people who have irritable bowel syndrome (IBS), inflammatory bowel disease (IBD, including Crohn's disease and Ulcerative Colitis) in determining what foods are causing symptoms and building sustainable dietary habits to improve those symptoms. Using an extensive research database, the program analyzes the person's diet and their symptoms and guides them through a personalized elimination diet protocol according to best practice clinical guidelines. The program applies the research data, supported by a machine learning algorithm and clinical team to help users more quickly and accurately identify the foods that are most likely the cause of their symptoms. The goal is for patients to build the least restrictive diet possible that most improves their digestive symptoms, compared to traditional trial-and-error methods.

Program Foundation

The data underlying Ayble Health's program guidance is compiled from efficacy studies, clinical guidelines, meta-analyses of common diets recommended for digestive health patients, and survey studies on irritable bowel syndrome (IBS) inflammatory bowel disease (IBD, including Crohn's Disease and Ulcerative Colitis) patients' daily dietary practices. From these studies, a list of trigger foods was mapped to the clinical and demographic characteristics of patients in each study. Ayble's database grows with every user who completes the Ayble program - anonymized, aggregated data from patients adds to clinical literature to improve trigger food recommendation algorithms. New research from scientific literature is also added monthly.

The program foundation incorporates and applies data reported by users. Users. To establish a baseline and start the program, users report their symptoms and their regular diet for three weeks. Symptoms are self-reported using validated assessments: IBS patients use the IBS Symptom Severity Scale (IBS-SSS); Crohn's Disease patients complete the Mobile Health Index (mHI-CD); Ulcerative Colitis patients report symptoms using the Patient Simple Clinical Colitis Activity Index (P-SCCAI); patients with overlapping symptoms and diagnoses complete a combination of IBD and IBS questionnaires.

From the user's reported food and symptom baseline, the program then generates a list of foods shown in the literature (and prior Ayble users with similar characteristics) to be correlated with their symptoms. For the next two

Program Foundation

weeks, the user eliminates these likely trigger foods and continues reporting symptoms. The user continues to report foods and symptoms each day, week, or month. After the elimination phase, the user can then reintroduce certain foods, one at a time, every three days, to test if foods are truly triggers. By the end of the program, Ayble users will have determined a) whether a food is a trigger, b) if a food is a trigger, how severe symptoms are expected to be, and c) how much food a user can tolerate before symptoms appear.

A PhD level data scientist oversees refining and improving the data and analysis framework.

To help users identify and purchase foods at the grocery store compatible with their diet, the program filters a groceries database of more than 200,000 grocery products from 40,000 store locations and 100 retail chains. Users can scan bar codes from products and look up produce or other items. The program reports whether the food fits or does not fit the user's recommended diet built on the Ayble platform, but also additional dietary criteria such as allergies, religious beliefs, and general preferences (veganism, vegetarianism, organic, fair-trade, etc). The program's contract with the independent database provider has service and accuracy standards, ensuring that users have up to date guidance. The database grows by 8,000-10,000 new items each month and store and brand coverage is constantly expanding. The independent provider has appropriately credentialed staff and advisors and is considered a reliable source.

Target Audience and Communication

The Ayble Health program materials and website make reasonable promises, based upon the program's validated outcomes. Website visitors learn that 81% of users improved their symptoms, and 89% improved their quality of life as during their participation in the Ayble program. These outcomes came from a clinical study that ran for 9 weeks; this is an accepted period for treating and monitoring symptom improvement. These measures are both included in Ayble Health's outcomes validation which Validation Institute conducted. (Ayble's outcomes validation report is available at Validation Institute's website or by request.)

This program has specific target users: people diagnosed with irritable bowel syndrome (IBS), inflammatory bowel disease (IBD including Crohn's Disease and Ulcerative Colitis) who want to manage their symptoms by adjusting their diet. In addition, the program has specific measurable outcomes that mark a person's improvement. Thus, the target group and the program goals are simple and clear. There is little chance for non-target users to be enrolled or mis-informed about the goals.

Of the total number of people who download the app, 75% use it daily, another 10% use the program weekly and 15% use the program monthly. Virtually all those who download the program use it for 16 weeks, well beyond the nine weeks needed to achieve measurable improvement. This real-world level of retention is similar to retention achieved in Ayble's published clinical

Target Audience and Communication

studies. Users can learn what foods trigger their symptoms and make the suggested changes in a period of nine to sixteen weeks, but can work with Ayble's program, tools and coach indefinitely to build long-term sustainable dietary habits. Future analysis could address whether users continue to have symptom management success after they stop using the program.

Program Delivery

Users have access to the Ayble program on their smartphone. Thus, users can easily get guidance from the program in any setting at any time.

To give accurate guidance, the program requires the user to enter certain data during their participation. In the first three weeks, the user enters all food consumed and symptoms experienced; this data allows the program to link foods to the symptoms reported. After the initial phase, users need only report consumption of the foods that are triggering digestive symptoms. Users can also choose whether to report their consumption daily, weekly, or less often. This greatly reduces the burden on the user and increases the likelihood that a person will continue it.

The user can make sure the program's recommendations fit their diet preferences by entering these into the program. The program has more than 60 diet preferences available. For example, a vegan would receive recommendations that have no animal products The program filters out foods containing nuts for an individual with that allergy, suggest organic or free-range products for a user interested in those criteria, or recommends low-sodium foods for people looking to reduce their salt intake. This feature ensures that the output is practical and valuable to the person.

Ayble has two service packages. The higher cost package includes unlimited access to a health coach and offers priority customer support. Pricing scales

Program Delivery

with the service level and number of months in subscription. The service can be offered through an employer or a health plan with customized contracting terms.

The low rate of people dropping out (95% completion of the pilot program, according to published results) is evidence that the program delivery is accessible and valuable to users. Having employers offer the program as a benefit could make it available to users who could not afford the price.

Health Outcomes

The Ayble Health program has specific, measurable outcomes that are tracked by validated assessments. Irritable Bowel Syndrome patients use the IBS Symptom Severity Scale (IBS-SSS); Crohn's Disease patients complete the Mobile Health Index (mHI-CD); and Ulcerative Colitis patients respond to the Patient Simple Clinical Colitis Activity Index (P-SCCAI). These assessments are widely used in clinical settings and in research to measure symptoms for this population. The IBS-SSS, for example, has been used in clinical practice to evaluate the severity of symptoms for IBS patients since the late 1990's. Users respond to these questionnaires periodically. Thus, the program can measure score improvement over time.

The measured outcome is relevant and valuable to the user, who has a goal of reducing their symptoms.

Ayble Health program users' improvement in symptoms has been reviewed by Validation Institute. The validation report is available on Validation Institute's website and by request.

Summary of Results

Ayble Health's program for IBS and IBD (including Crohn's Disease and Ulcerative Colitis) patients uses credible, reliable, and up to date data to support the nutrition guidance it provides. The guidance is also informed by the users' data about their success in reducing symptoms and the program seeks user input to customize a user's path through each step. By gathering data from users (which is then anonymized and aggregated), Ayble's program continually improves the accuracy and value of the guidance the program provides. The data infrastructure has appropriate systems and staff to ensure that the algorithm correctly applies to new data (generalizes) and is not distorted by inaccurate or unnecessary data (overfitting).

The program does not make unrealistic promises to users. Communication is clear and simple about who the program benefits and how results are measured.

It uses valid tools to measure users' symptoms and improvement over time. The program is accessible to individual users who can pay the monthly fees; it is accessible to a broader range of people when it is offered as an employer benefit or health plan member benefit. The program itself is easily available to users on their smart phone, and the data input burden is kept to a manageable level.

Limitations

Analyzing how closely the Ayble Health program's recommendations (output) align with the data underlying it (foundation) is beyond the scope of this review.

Certificate of Achievement

Ayble Health Program
Certified Program

Ayble Health
52 Appleton St. Boston, MA, 02116
Company

Certificate Level: Outcomes

Ayble Health submitted its program which helps people who have irritable bowel syndrome, Crohn's Disease, and Ulcerative Colitis to manage and reduce their symptoms.

September 2023
Award Date

Linda Riddell
Chief Data Scientist
Validation Institute

Benny DiCecca
Chief Executive Officer
Validation Institute

About Validation Institute

FoodMed Certified, a Validation Institute (VI) program, vets and verifies the effectiveness of nutritional programs and tools that enable individuals and employers to manage their health and healthcare solutions. By leveraging VI's validation process for its Food as Medicine program, FoodMed Certified brings transparency to the market by delivering unbiased insights into effective nutritional programs. Validation Institute is a membership organization comprising healthcare vendors, benefits advisors, and managers that offers unbiased, data-driven insights on healthcare solutions and services to drive transparency and cost-savings.

This approach highlights the significance of utilizing data-driven solutions to bring about positive change and encourage healthy habits.

Validation Institute is a professional community that advocates for organizations and approaches that deliver better health value - stronger health outcomes at lower cost. We connect, train, and certify health care purchasers, and we validate and connect providers delivering superior results. Founded in 2014, the mission of the organization has consistently been to help provide transparency to buyers of health care.