

New weight-loss treatment is marked by heavy marketing and modest results

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First came the "edible billboard," which appeared last year during the holidays in New York's East Village loaded with cake treats. Then, in late January, came the national marketing campaign, with TV and digital

media promoting the idea that trying to lose weight doesn't mean a person can't enjoy eating.

Those advertising messages are pushing a product named Plenity as a potential liberation from dieters' woes. It's a \$98-a-month [weight loss treatment](#) that looks like a drug: Patients take three capsules twice a day. But it isn't a drug. And its success in racking up lost pounds, on average, is modest.

Plenity is FDA-approved as a device, one that contains sugar-sized grains of a plant-based, absorbent hydrogel. Each grain swells to 100 times its size, cumulatively filling about a quarter of a person's stomach. The three capsules containing them must be taken with two cups of water at least 20 minutes before eating. The gel is not absorbed and eventually exits the body in stool.

The treatment is also generally not covered by insurance.

"We thought we would price it low enough that most consumers can pay out-of-pocket," said Dr. Harry Leider, chief medical officer and executive vice president of Gelesis, the maker of Plenity.

Although far less costly than some other prescription weight loss treatments, it still "isn't affordable for someone in the low-income bracket," said Jena Shaw Tronieri, an assistant professor and director of clinical services at the University of Pennsylvania's Center for Weight and Eating Disorders.

Plenity is designed to help patients who want to eat less, and taking it is comparable to consuming a big salad before lunch and dinner, without the actual raw vegetables.

It joins a growing selection of prescription weight loss and obesity

treatments, from old-school oral medications that are often low-cost generics to far pricier brand-name injectable diabetes drugs newly repurposed as weight loss treatments. Results varied widely among trial participants; 59% of those who got Plenity lost at least 5% of their body weight, although the rest did not meet that threshold.

Plenity, whose [active ingredient](#) is a form of cellulose, embraces a strategy that has been used for decades by some people: to feel full before eating a main meal, thus reducing the calories they take in. Studies have shown that "if you fill up on broth-based soup or vegetables before a meal, you will feel fuller and eat less," said Tronieri. She noted that filling up with water doesn't produce the same satiating effect.

Still, some patients say that they "hate vegetables" and that "capsules are a lot easier," said Dr. Christina Nguyen, medical director of obesity medicine at Northeast Georgia Health System. She is not affiliated with Gelesis but has been prescribing Plenity since its soft launch in late 2020.

So far, Gelesis credits the marketing campaign with helping it pick up 40,000 new customers in the first three months of the year, adding \$7.5 million in revenue, although the company still lost money in the first quarter.

So where does this latest treatment fit as a potential weight loss tool for the more than 70% of American adults who are overweight or obese?

"I'm glad to see it on the market, but I tend to want more weight loss in patients than what I'm looking at with this device," said W. Timothy Garvey, professor at the University of Alabama at Birmingham and director of the university's Diabetes Research Center.

Gelesis reported that participants in its clinical trial who used Plenity lost

on average 6.4% of body weight—above the 5% that many physicians say is a good target threshold. For a 200-pound person, that would equal almost 13 pounds. Still, that's only a bit better than the 4.4% weight loss, on average, that people given a placebo in the six-month trial experienced. All 436 participants were put on diets that averaged 300 calories a day less than they needed to maintain their weight.

Nguyen said she tells her patients they must change their eating and exercise habits or Plenity won't work. "You have to be realistic and set expectations," she said. "What I've seen with Plenity is weight loss of about 5%."

She noted it has relatively few side effects—mainly gastrointestinal, such as bloating, nausea, constipation or flatulence—and the FDA has approved it for use in people with lower body mass index numbers than required for many other prescription products.

Plenity's average weight loss is comparable to or below that of some other oral medications and is far less than that of the much more expensive new additions to the market such as Novo Nordisk's Wegovy, a once-a-week injection that costs \$1,300 a month. Wegovy helped patients lose nearly 15% of their [body weight](#) over 17 months, on average, according to clinical trials. In April, Eli Lilly said an injectable drug it is testing helped patients achieve an average weight loss of 22.5%. More details were released June 4.

"We don't see Wegovy as a competitor," said Leider, of Gelesis.

Nor does Leider view the weight loss products available without a prescription as competitors.

Leider said Gelesis sought FDA prescription approval for the treatment, rather than over-the-counter status, because "there's a whole wall of

nutritional supplements and products" and "we felt it was absolutely important to do the study and prove it scientifically works." Down the road, "once we've built the brand," Gelesis could seek over-the-counter status, he added.

As with other treatments, weight loss with Plenity can vary widely, he noted. Study data shows 27% of those given the treatment were considered "super responders," losing an average of 14% of their weight. Patients with diabetes or prediabetes may respond better than those with normal blood sugar levels.

Still, it didn't work for 40% of participants in the trial.

"If you take it for two months and you're not losing weight, it may not be the therapy for you," Leider said.

Patients can request Plenity from their physicians. In a move aimed at setting it apart from other treatments, Gelesis offers potential patients another choice: skipping an in-office visit entirely by requesting the treatment online. It has partnered with Ro, a direct-to-patient platform, which provides its network of affiliated physicians for online health assessments and delivers the treatment to eligible customers. Ro is also a large purchaser of Plenity, placing a \$30 million prepaid order in late 2021.

Ro, originally named Roman, launched in 2017 and initially focused on men's health concerns, including erectile dysfunction and hair loss. It has since expanded to cover other conditions.

Online visits with physicians through Ro are free, including those for weight loss. Patients must answer questions about their health and experiences trying to lose weight. Pregnant patients, people younger than 22, and those allergic to Plenity's ingredients should not take it.

Information provided to Ro is not protected under the federal privacy law called the Health Insurance Portability and Accountability Act, or HIPAA, but CEO Zachariah Reitano said all data is stored in "HIPAA-compliant" ways.

Ro added Plenity to its offerings because of the clinical trial results and because it saw a business opportunity with weight loss. Help for "challenges with weight management" was one of the top items his customers requested, Reitano said.

Even though it's not covered by his insurance plan, patient Rene Morales said the \$98 a month he spends is worth it. "If I spend that [much] on coffee, I can spend it to benefit my health," said the 51-year-old, who is president of a skateboard company in Montclair, California, and was made available for an interview by Gelesis.

He started taking Plenity in late January after his doctor brought it up during his annual physical. Morales said he has lost 15 pounds from his original [weight](#) of nearly 280 pounds and wants to stay on the treatment until he has dropped 30.

Morales said the treatment is also helping him reshape his view of food and focus on smaller portions: "I've come to (the) realization that you don't have to pile your plate up to enjoy your food."

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