

What is the Patient Access Support Program?

The Patient Access Support Program (PASP) is designed to help patients navigate the challenges they may encounter when seeking insurance coverage for endobariatric procedures using Boston Scientific devices including Endoscopic Sleeve Gastroplasty (ESG), Transoral Outlet Reduction Endoscopy (TORe), and the Intragastric Balloon. The PASP team assists with patient access activities including benefit verification, prior authorization, and the appeals process.

Who is a good candidate to pursue coverage?

Adults aged 22 and older who are interested in pursuing insurance coverage and meet the indication for use requirements. Patients should check with their insurance company to identify policy requirements for their individual plan.

What procedures are supported in the Patient Access Support Program?

Endoscopic Sleeve Gastroplasty (ESG), Transoral Outlet Reduction Endoscopy (TORe), and the Intragastric Balloon.

Will insurance cover the procedure?

There is no guarantee of insurance coverage. However, PASP is available to help patients seek insurance coverage for endobariatric procedures using Boston Scientific devices.

How will the patient receive updates during the prior authorization and appeals process?

Patients should receive regular communication updates from their insurance company by mail. Patients can also reach out to their healthcare provider for additional information.

What if the prior authorization is denied?

The PASP team is available to assist with the appeals process.

If a prior authorization approval is received, what will the financial obligation be?

As part of the benefit verification, PASP confirms estimated out of pocket costs which are shared with the patient's healthcare provider. Actual out of pocket costs should be further discussed with the provider for most accurate estimates.

To request an update on the prior authorization and/or appeal status, patients may contact their insurer or healthcare provider.

Indications for Use

The Apollo Endosurgery OverStitch NXT Endoscopic Suturing System (ESS) is intended:

- for endoscopic placement of suture(s) and approximation of soft tissue.
- to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastroplasty in adult patients with obesity with BMI between 30-50 kg/m² who have not been able to lose weight, or maintain weight loss, through more conservative measures.
- to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss in adult patients with obesity with BMI between 30-50 kg/m² by enabling transoral outlet reduction as a revision to a previous bariatric procedure.

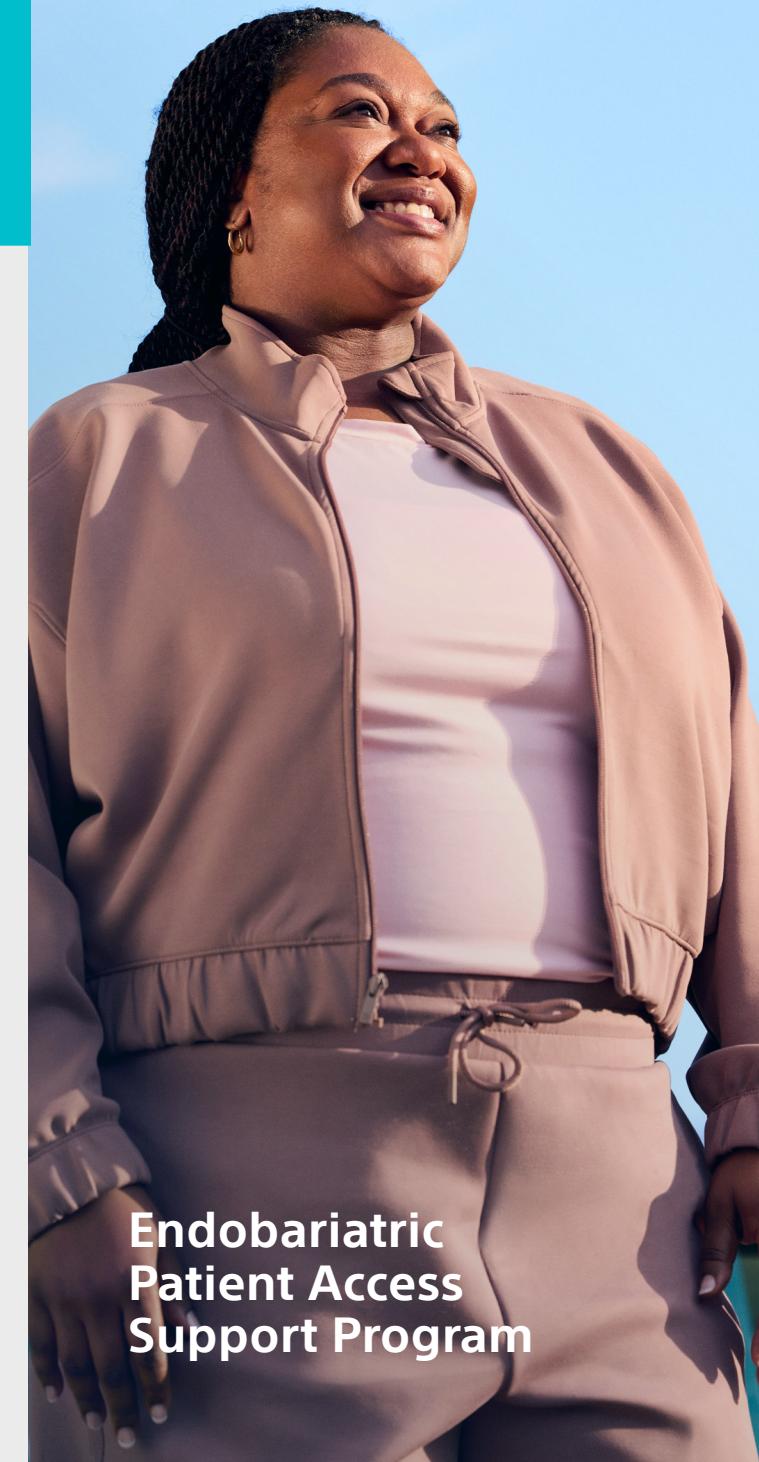
The ORBERA Intragastric Balloon System is indicated for use as an adjunct to weight reduction for adults with obesity with Body Mass Index (BMI) of ≥ 30 and ≤ 40 kg/m² and is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of significant long-term weight loss and maintenance of that weight loss. ORBERA is indicated for adult patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs. The maximum placement period for ORBERA is 6 months.

The deflation catheter is intended for use in bariatric and gastric surgical procedures to drain fluid from an Orbera intragastric gastric balloon, so that the empty balloon can be endoscopically removed through the esophagus with a grasper. Note: The wire grasper is a Class 1 instrument and does not have an indications for use statement.

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**Endobariatric
Patient Access
Support Program**

Reimbursement: The Prior Authorization and Appeals Process

Step 1

Request for Prior Authorization

PASP will submit the prior authorization request on the patient's behalf, along with a letter of medical necessity and clinical documentation.

Allow up to 30 days once all paperwork is submitted.

- ✓ *If the plan approves, no further action is required and the patient may schedule their procedure.*

Step 2

The Initial Appeal(s)

If the insurer does not approve the prior authorization request, PASP will submit an appeal supported by clinical records demonstrating the patient's medical necessity for the requested procedure.

Allow an additional 30-45 days once all paperwork is submitted.

- ✓ *If the plan approves, no further action is required and the patient may schedule their procedure.*

* In some cases there may be a need for a Level II appeal which could take an additional 30-45 days

Step 3

The External Appeal

If the insurer does not approve the initial appeal(s), the patient has the right to request an external review with an Independent Review Organization. PASP will assist with this process.

Allow an additional 30-45 days once all paperwork is submitted..

- ✓ *The decision of the Independent Review Organization is binding.*

