Allurion

Allurion Assurance Plus

Allurion wants to support patients and give them confidence in their decision to participate in the Allurion Program and receive the Allurion Gastric Balloon. The known risks associated with the use of our products are described in our Instructions for Use. While there are known risks of all gastric balloons and every patient assumes the risk of use, Allurion will endeavor to provide support to patients that experience certain covered events, as described below.

This document describes the Allurion Assurance Plus patient support program for placements of the Allurion Gastric Balloon on or after February 19, 2024, as follows:

Covered Event	Assurance Plus Program
Spontaneous premature balloon deflation within the first 90 days	Allurion will provide a replacement balloon for the patient at no charge. The patient and/or clinic are responsible for any costs associated with any subsequent placement procedure. In addition, the patient will receive $1000 if the balloon is returned to Allurion for inspection and analysis. Please note that we must be provided proof/evidence that the balloon has passed within the covered period– i.e., a picture taken within the first 90 days following placement of the passed balloon or other imaging showing no balloon.
Hyperinflation requiring endoscopic removal	Allurion will provide a replacement balloon for the patient at no charge, and will reimburse reasonable out-of-pocket expenses incurred by the patient for balloon removal that are not covered by insurance, subject to a cap. Eligible reimbursable expenses consist of X-rays and endoscopic procedure fees directly related to the balloon removal procedure that are not covered by insurance.
Catheter break	Allurion will provide a replacement balloon for the patient at no charge, and will reimburse reasonable out-of-pocket expenses incurred by the patient for balloon removal that are not covered by insurance, subject to a cap. Please note that we must be provided proof/evidence that the catheter has broken, such as a photograph and confirmation by the attending health care provider. Eligible reimbursable expenses consist of X-rays and endoscopic procedure fees directly related to the balloon removal procedure that are not covered by insurance.

Small bowel obstruction requiring removal	Allurion will reimburse reasonable out-of-pocket expenses incurred by the patient for balloon removal that are not covered by insurance, subject to a cap. Eligible reimbursable expenses consist of surgical fees, operating room fees, anesthesia expenses, and hospital stay costs directly related to the balloon removal procedure that are not covered by insurance. In addition, the patient will receive $1000 if the balloon is returned to Allurion for inspection and analysis.

The Health Care Provider's Role and Responsibilities

Allurion relies on certified health care providers to determine the suitability of our products for their patients, explain risks, and obtain informed consent. Product usage is the sole responsibility of the health care provider; all usage of products must be in accordance with approved Instructions for Use provided by Allurion.

The certified health care provider's medical training, familiarity with the devices and procedures used, understanding of the indications and contraindications explained in our Instructions for Use, and knowledge of the patient and the patient's medical history and physical condition, place the health care provider in the best position to determine suitability and provide the patient with information about our products and the associated risks and benefits, as well as all follow-on care. Therefore, the health care provider, as learned intermediary, is responsible for providing the patient with appropriate risk information before the procedure, including (but not limited to) the risk of spontaneous premature balloon deflation, hyperinflation, and small bowel obstruction, and other possible adverse reactions and complications associated with gastric balloons, and resolving any adverse events a patient may experience following placement. The primary source of risk information for patients is through this learned intermediary, although Allurion also makes available to all health care providers and patients a copy of the Instructions for Use (IFU) describing the benefits and risks of the Allurion Gastric Balloon via our website. Copies can also be obtained by contacting Allurion directly. This Assurance Plus patient support program description is not intended to, and cannot, take the place of a full and candid discussion between the health care provider and patient, or the important safety information contained in the IFU. A digital copy of the IFU can be found at https://www.allurion.com/quality-and-risk.

By using the products, the certified health care provider agrees that:

- He/she/they is fully trained to use the products in accordance with the applicable IFU and can do so in compliance with Allurion's and the individual provider's professional standards of care and training; and

- He/she/they will provide all required care necessary following placement, both medically and consistent with the Allurion Program, including managing and resolving adverse events experienced by patients and any claims with respect thereto.

Patients should consult with their health care providers regarding any questions about Allurion's products and how they apply to the patient's specific medical and physical condition. If the patient does not want to assume the described risks, he/she/they should not use the products.

Allurion does not guarantee any particular result. Allurion also does not guarantee against any known risks or side effects in connection with the use of its products and cannot treat patients' adverse events – only trained health care providers are able to provide medical care.

Application of the Assurance Plus Program

A. PROGRAM

1. **Timeline**: The Allurion Assurance Plus patient support program applies automatically to Allurion Balloons placed in all Allurion markets outside the United States of America on or after February 19, 2024, and supersedes any previous program or patient warranty. Events occurring with respect to balloons placed prior to February 19, 2024 shall be covered by Allurion's prior warranty program. Claims must be made as follows:

   (a) Claims for spontaneous premature balloon deflation within the first 90 days inside the body must be made within **120** days of initial balloon placement.

   (b) Claims for catheter break must be made within **30** days of initial balloon placement.

   (c) Claims for hyperinflation and small bowel obstruction must be made within **180** days of initial placement.

The applicable period will start the day after placement, with the date of placement considered Day Zero (0).

2. **Covered Events:** The Allurion Assurance Plus patient support program applies only to the following covered events (each a "Covered Event"):

   (a) Spontaneous premature balloon deflation within the first 90 days inside the body entitles the patient to one (1) no-charge device provided to the original placement clinic to replace the affected balloon, and $1,000 if the original balloon is returned to Allurion for inspection and analysis. Individual health care providers shall determine if any additional charges will be incurred by the patient for the placement procedure, but the patient will not be charged for the replacement balloon should the patient elect to undergo a subsequent placement procedure.

   (b) Hyperinflation with approximately half of the balloon filled with gas requiring endoscopic removal entitles the patient to one (1) no-charge device and reimbursement of reasonable out-of-pocket reimbursable expenses incurred by the patient directly related to the balloon removal procedure that are not covered by insurance, subject to a cap.

   (c) Catheter break entitles the patient to one (1) no-charge device and reimbursement of reasonable out-of-pocket reimbursable expenses incurred by

the patient directly related to the balloon removal procedure that are not covered by insurance, subject to a cap.

(d) Small bowel obstruction entitles the patient to reimbursement of reasonable out-of-pocket reimbursable expenses incurred by the patient directly related to the balloon removal surgery that are not covered by insurance, subject to a cap. In addition, the patient will receive $1000 if the balloon is returned to Allurion for inspection and analysis.

Eligible reimbursable expenses for hyperinflation and catheter break include X-rays and endoscopic procedure fees. Eligible reimbursable expenses for small bowel obstruction include surgical fees, operating room fees, anesthesia expenses and hospital stay costs.

All eligible reimbursable expenses must be documented to Allurion's reasonable satisfaction.

3. **Events Not Covered:** The Allurion Assurance Plus patient support program does not apply as follows:

(a) Allurion does not guarantee that any individual patient will lose weight, or how much weight any individual will lose, and this Assurance Plus program does not cover weight loss not meeting any stated clinical study average and/or patient expectations;

(b) Gastric balloons can cause varying degrees of discomfort and other symptoms of intolerance, which at times may result in premature endoscopic removal, but this Assurance Plus program does not cover endoscopic removal that is not accompanied by another covered event outlined in A.2 above;

(c) Off-label or contraindicated use;

(d) Non-compliance with Instructions for Use;

(e) Insufficient training or failure to comply with Allurion training, including with respect to product placement (including Allurion SOP 27 and any related or successor SOPs);

(f) Health care provider or patient-related negligence or misuse, or medical malpractice of any sort;

(g) Any modification or alteration of the products;

(h) Any determination as to suitability;

(i) Failure to obtain informed consent;

(j) Representations or warranties made by any party, including the patient's health care provider and any employee, agent or representative of Allurion, inconsistent with the applicable IFU, this Assurance Plus patient support program, or Allurion's product defect warranty; and

(k) Any other events, including adverse events, outside the Covered Events listed in section A.2 above.

4. **Release:** Patients must provide a signed, general release to Allurion to obtain a replacement device, payment for product return, and/or reimbursement of eligible reimbursable expenses (subject to a cap), as applicable.

B. PATIENT INFORMATION REGARDING THE ALLURION PRODUCTS AND INFORMED CONSENT

Before the procedure, the certified health care provider should explain the risks of the Allurion products and provide the patient with access to a copy of the device IFU provided by Allurion, describing the benefits and risks of a gastric balloon procedure. A digital copy of this IFU can be found at https://www.allurion.com/quality-and-risk.

The health care provider must also obtain a signed informed consent form. **Failure to obtain informed consent voids entitlement to the benefits available under this Assurance Plus program.**

C. FILING A CLAIM

If a Covered Event occurs, the health care provider should contact Product Safety to obtain instructions via email at complaints@Allurion.com.

In no event shall the health care provider instruct a patient to contact Allurion directly. It is the sole responsibility of the health care provider to handle a patient's claim of a Covered Event.

Required documentation for each Covered Event includes **a signed, general release from the patient** and documentation provided by the health care provider and reasonably satisfactory to Allurion evidencing the Covered Event, which includes:

Spontaneous premature balloon deflation within the first 90 days:

1. Endoscopic, X-ray or Ultrasound confirmation showing absence of balloon in the stomach, or passage of the balloon observed by patient and documented with an image, taken within the covered period;
2. Completed complaint report form (SOP13-F1 Product Feedback Report); and
3. If possible, return of the passed balloon for inspection and analysis.

Hyperinflation requiring endoscopic removal:

1. Endoscopic, X-ray, Ultrasound or CT confirmation showing hyperinflation of balloon in the stomach with approximately half of the balloon filled with gas;
2. Completed complaint report form (SOP13-F1 Product Feedback Report); and
3. Receipts for patient's reasonable out-of-pocket reimbursable expenses not covered by insurance.

Catheter break:

1. Evidence of broken catheter, such as a photograph and confirmation by the attending health care provider;
2. Completed complaint report form (SOP13-F1 Product Feedback Report);
3. Receipts for patient's reasonable out-of-pocket reimbursable expenses not covered by insurance; and
4. If possible, return of all pieces of the broken catheter for inspection and analysis.

Small bowel obstruction:

1. X-ray or CT confirmation of the small bowel obstruction;
2. Completed complaint report form (SOP13-F1 Product Feedback Report);
3. Receipts for patient's reasonable out-of-pocket reimbursable expenses not covered by insurance; and
4. If possible, return of the balloon for inspection and analysis.

Allurion will provide packaging materials and cover delivery costs for the return of a balloon and/or catheter, as applicable.

Allurion reserves the right to request additional information to confirm the authenticity of a claim.

The provision of false information is grounds for denial of a claim.

Paperwork can be emailed to Complaints@Allurion.com.

Upon receipt of the required documentation and claim form, and of the properly signed release, the replacement device and/or payment will be issued to the appropriate party or parties in accordance with the terms and conditions set forth in this document. Payment will be made to the party or parties indicated by the patient on the release form.

LIMITATIONS; DISCLAIMERS

THIS ASSURANCE PLUS PATIENT SUPPORT PROGRAM IS LIMITED AND SUBJECT TO THE TERMS AND CONDITIONS SET FORTH HEREIN. ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXCLUDED. THE REPLACEMENT OF QUALIFIED ALLURION BALLOONS AND PAYMENT OF APPROVED UNINSURED REASONABLE OUT-OF-POCKET EXPENSES (SUBJECT TO A CAP) AS SET FORTH HEREIN ARE, TO THE MAXIMUM EXTENT ALLOWED UNDER APPLICABLE LAW, THE PATIENT'S SOLE AND EXCLUSIVE REMEDY. ALLURION SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR SPECIAL LOSSES, DAMAGES, LIABILITIES OR EXPENSES ARISING DIRECTLY OR INDIRECTLY FROM THE USE OF OUR PRODUCTS. ALLURION NEITHER ASSUMES, NOR AUTHORISES ANY OTHER PERSON OR ENTITY TO ASSUME FOR ALLURION, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH OUR PRODUCTS. THIS SECTION, TOGETHER WITH OUR ASSURANCE PLUS PATIENT SUPPORT PROGRAM, ALLOCATES THE RISKS BETWEEN ALLURION AND THE PATIENT. THIS ALLOCATION IS REFLECTED IN THE PRICING OF THE PRODUCTS AND IS AN ESSENTIAL ELEMENT OF THE BASIS OF THE BARGAIN. SOME LOCALITIES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO A GIVEN PATIENT.