Anthem

Medical Policy

Subject: Artificial Anal Sphincter for the Treatment of Severe Fecal Incontinence
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Description/Scope

This document addresses the use of the artificial anal sphincter as a means of treating severe fecal incontinence.

Fecal incontinence is the involuntary leakage of stool from the rectum and anal canal. Fecal continence depends on a complex interplay of anal sphincter function, pelvic floor function, stool transit time, rectal capacity and sensation. The artificial anal sphincter has been investigated as a surgical treatment for severe fecal incontinence. Existing treatment options for fecal incontinence include medical therapy, biofeedback techniques and surgery in selected individuals.

Note: Please see the following related documents for additional information:

- SURG.00056 Transanal Radiofrequency Treatment of Fecal Incontinence
- CG-SURG-95 Sacral Nerve Stimulation and Percutaneous or Implantable Tibial Nerve Stimulation for Urinary and Fecal Incontinence; Urinary Retention

Position Statement

Investigational and Not Medically Necessary:

The artificial anal sphincter is considered **investigational and not medically necessary.**

Rationale

Most of the available studies on this procedure include uncontrolled studies that found that surgical implantation of an artificial anal sphincter resulted in a reduction of fecal incontinence in some individuals. Studies evaluating the long-term result of artificial bowel sphincter (ABS) implantation have also been published.

Wong and colleagues (2011) reported the results of a consecutive series of 52 participants who underwent implantation with the Acticon™ Neosphincter for severe fecal incontinence at a single institution from 1996 to 2010. All of the participants had failed to respond to prolonged medical treatment and pelvic floor retraining for at least 1 year. The participants had either a previous unsuccessful local sphincter repair or a preoperative physical examination had excluded the possibility of such a procedure due to extensive perineal scarring and inadequate soft tissue cover, such that the creation of a permanent end colostomy was the only surgical option. Indications for implantation were perineal colostomy, congenital malformation, pudendal neuropathy and sphincter destruction. Preoperative evaluations included anal endosonography, anorectal manometry, and electrophysiologic testing. Incontinence (Wexner) and Quality of Life scores were recorded before the procedure and at each follow-up appointment. Annual physiology assessments were also provided. The cumulative risks of device revision and explantation were evaluated using Kaplan-Meier survival curves.

The first 30 days postoperatively were uneventful for the majority of the participants, with no mortalities and a mean length of stay of 11.3 ± 3.2 days. A total of 14 of the participants (26.9%) experienced complications within 30 days of surgery. A total of 5 participants experienced emptying difficulties that responded to enemas or laxatives prior to discharge. A total of 5 participants were treated for a urinary tract infection and 1 participant had to have the pump repositioned on the third postoperative day. Of the study participants, 1 had a superficial dehiscence of the perineal wound, which successfully healed by secondary intention. In addition, 1 of the study participants developed deep vein thrombosis during the third postoperative week, and 1 other participant experienced an infection and vaginal erosion which required explantation of the device during the course of a reimplantation. Stoma closure for 3 of the participants with colostomy was performed after a mean of 8 weeks after implantation of the device.

The mean follow-up period for the participants was 64.3 ± 46.5 months (range 2-169). Of the 52 participants, 26 (50%) required revisions primarily due to device malfunctions from a leaking cuff, with 7 of the participants (13.5%) requiring two revisions. A total of 35 subjects (67.3%) still had an activated device in situ at the last review. In total of 2 participants had their device deactivated due to physical and psychological difficulties managing the device and 14 participants (26.9%) required definitive explantation with the majority (42.9%) due to infection. A total of 5 participants subsequently accepted an end colostomy and the remaining 9 participants were being managed conservatively. A total of 3 of the subjects had their devices temporarily removed and were subsequently successfully reimplanted with a new device. With regards to the 35 participants with an activated device in situ, the authors report a significant improvement in the FIQL scores from 1.41 (range 0-2.80) to 3.47 (range 1.94-4.10) at last follow-up. In the participants who had the devices either explanted or deactivated, there was no significant difference in FIQL scores at the end of follow-up compared with baseline scores.

The authors acknowledge that the primary concern with implantation of the artificial bowel sphincter remains the high revision and explantation rates and propose that the 50% revision rate is possibly attributed to the comparatively longer follow-up of the group and likely reflects the intrinsic wear-and-tear of the device components over time. The authors also state that the majority of the revisions required were due to leaks from the cuff (73.1%), which occurred from micro-perforations developing in the folds and creases of the cuff, and are likely the result of repeated cycles of inflation and deflation over years of usage. With regards to explantation, the authors state the majority of the explantations were carried out due to localized infections around the device components (42.9%) and the risk is higher during the early postoperative period accompanied by an earlier plateau compared to the risk of revisions. The authors reason that meticulous surgical technique and perioperative asepsis is of key importance to keep infection and subsequent explantation to a minimum. The authors conclude that the artificial bowel sphincter is not a perfect device, but for many of the individuals for whom a permanent colostomy remains the only other surgical option, the improvement in continence and quality of life with the artificial bowel sphincter somewhat diminishes the associated morbidity and financial costs.

Wexner and colleagues (2009) investigated the risk factors related to artificial bowel sphincter implantation. Data on all individuals who had an artificial bowel sphincter implanted for fecal incontinence at a single institution between January 1998 and May 2007 were collected retrospectively. During that period, a total of 51 artificial bowel sphincter implantations were performed in 47 individuals (43;

84.3% female) with a mean age of 48.8 ± 12.5 (range, 19-79) years and a mean incontinence score of 18 ± 1.4 (range, 0-20). Twenty-three (41.2%) of the artificial bowel sphincter implantations became infected, 18 (35.3%) of which developed early-stage infection, whereas 5 (5.9%) had late-stage infection. All 18 cases of early-stage infection had to be explanted. The authors found that the time to the first bowel movement is an independent risk factor for early-stage artificial bowel sphincter infections. Although there appeared to be no relation to late-stage infection, 9 of the 15 individuals (60%) who had the first bowel movement on or before Day 2 developed infection. Both the univariate and mutivariate analyses showed that the infection rate in this group was significantly higher than it was in those individuals whose first bowel movement occurred on or after Day 3. The univariate analysis also revealed that individuals with a stoma also had a tendency toward a higher infection rate than did those individuals without a stoma. The most common late-stage complication was device malfunction, followed by device erosion, persistent perianal pain, device migration, constipation and hematoma over the labia majora. Ultimately 13 of 33 participants (32%) required artificial bowel sphincter explantation with device malfunction being the most common reason for explanation (46.1%). Erosion through the rectal mucosa, anoderm or skin was the second most common reason for explantation (38.5%). Migration of the cuff to the subcutaneous space was another cause for explantation. Late-stage complications such as pain and constipation did not lead to explantation. The authors found that the rate of explantation increased with the time after artificial bowel sphincter implantation; the longer the artificial bowel sphincter was in use, the more complications occurred, and the more the artificial bowel sphincter was explanted. The 1-year cumulative risk of artificial bowel sphincter explantation was 9.7% and the 2-year cumulative risk of artificial bowel sphincter explanation was 13%. At 3 years, the risk of artificial bowel sphincter explantation increased to 43% and as high as 48% by the fourth year. At 5 years after implantation, the risk of artificial bowel sphincter explantation was 57%. The authors acknowledged that the number of participants in this study was relatively small and further device refinement may be necessary.

Implantation of an artificial anal sphincter has also been investigated as a treatment of obstructed defecation (OD). Gallas (2009) reported the results of a small case series study involving 44 subjects with fecal incontinence due to a variety of etiologies who underwent implantation of the Acticon Neosphincter. The duration of follow-up is unclear. During follow-up, 9 subjects (20.4%) had constipation with no obstructed defecation (OD) and 16 subjects (36.4%) had constipation with OD. The remaining 19 subjects (43.2%) were not constipated. A total of 18 of the 25 subjects (72%) with postoperative constipation were still incontinent at the end of follow-up, while this was only the case for 4 out of 19 subjects (21%) without postoperative constipation (p=0.003). Surgical revisions were significantly more frequent in subjects with OD (n=11) compared to those without OD (n=5) (p=0.04). The authors noted that constipation, with and without OD, is frequent after implantation and interferes with the functional outcome of the ABS.

In 2014, Hong and colleagues reported the results of a study which evaluated the outcome of various procedures for individuals with fecal incontinence who had failed sphincteroplasty. Individuals were assessed using the Fecal Incontinence Quality of Life (FIQoL) scale and the Cleveland Clinic Florida-Wexner Fecal Incontinence Score (CCFFIS). From January 2000 to June 2012, a total of 59 participants underwent either repeat sphincteroplasty (RS; n=33), artificial bowel sphincter implantation (ABS; n=11) or sacral nerve stimulation (SNS; n=15). The follow-up period ranged from 3-138 months with a median follow-up period of 31 months. Overall, individuals in the RS group had a significantly wider external sphincter defect and had undergone fewer previous sphincteroplasties. Infection was the most common complication amongst all participants; higher complication rates were found in the ABS group (73%) compared with RS (24%) and SNS (33%) (p=0.01). A total of 17 (29%) participants required re-operation for complications or failure, with a lower rate in the RS group (p=0.004). The researchers found no difference in the rates of device removal after ABS or SNS. At follow-up, 5 (45%) individuals in the ABS group and 10 (67%) individuals in the SNS group retained a functioning device (p=0.4). The mean postoperative CCFFIS decreased in all groups; from 17.5 to 11.5 in the RS group, from 18.7 to 8.6 in the ABS group, and from 17.6 to 9.1 in the SNS group (p≤0.02 for all). There were no differences observed in the improvement of CCFFIS or FIQoL scores among groups. The authors concluded that RS, ABS and SNS are associated with similar improvements in continence after failed sphincteroplasty and that due to increased complications and re-operation with ABS and SNS, RS may be a better initial option in managing these individuals.

THD SphinKeeper™ prostheses (THD SpA, Correggio, Italy) consist of thin, solid cylinders that are surgically implanted in the intersphincteric space. In their native state, the cylinders measure 29 mm in length and 3 mm in diameter. Within 48 hours of contact with bodily fluids, the cylinders become softer and change size and shape (shorter than 23 mm in length and thicker than 7 mm in diameter). This device has only been evaluated in small, non-randomized studies and there is a lack of long-term outcome data on the use of this device as a treatment of fecal incontinence (LaTorre, 2019; Litta, 2020; Ratto, 2016). At the time of this review, the THD SphinKeeper device had not received clearance from the U. S. Food and Drug Administration (FDA). There is at least one active clinical trial that is being conducted to evaluate the safety and efficacy of this device (NCT03080753).

The clinical practice guideline for the treatment of fecal incontinence set forth by the Clinical Practice Guidelines Committee of the American Society of Colon and Rectal Surgeons indicates that the artificial anal sphincter has a role in the treatment of severe fecal incontinence, especially in those instances where all other treatments have failed. The guideline also points out that there is a high rate of complications including infections, device erosions, anorectal ulcerations, device malfunction, pain, and constipation (Paquette, 2015).

The American College of Gastroenterology (ACG) clinical practice guidelines on the Management of Benign Anorectal Disorders recommends that if available, the artificial anal sphincter may possibly allow some individuals with fecal incontinence to avoid colostomy. As evidence supporting this recommendation, the organization cites the systematic review by Mundy and colleagues (2004) which included a total of 14 studies evaluating the artificial anal sphincter. The ACG acknowledges that most of the studies were case series with little or no follow-up of participants in whom the device failed. The ACG also indicates that “complications were common, and the device was explanted in about one-third of patients. However, most patients with a functioning device reported clinically significant improvement in continence and quality of life” (Wald, 2014).

The available studies on this procedure include uncontrolled studies that found that surgical implantation of an artificial anal sphincter resulted in a reduction of fecal incontinence in some individuals. However, implantation of an artificial anal sphincter was also associated with a significant rate of serious complications including but not limited to infection, erosion of the device, injury during the surgical procedure, pain, constipation and incontinence. The diversity and seriousness of complications that occurred after artificial anal sphincter implantation and the high rate of explantation suggest that this device may not be as safe or effective a treatment of fecal incontinence as is a colostomy or other surgical options. In addition to the safety concerns, the value of the published studies is limited by their small sample size, lack of a control or comparison group, and limited periods of follow-up.

Background/Overview

Fecal incontinence is the inability to control the bowels, which results in leakage of stool or gas. Fecal incontinence may be caused by a variety of conditions that affect either the function or the anatomy of the anal sphincter. These conditions include but are not limited to congenital anorectal dysfunction, perineal injury during childbirth or surgery, nerve-related diseases/injury (e.g., stroke, multiple sclerosis or spinal cord injury), radiation therapy and age-related changes in muscle tone.

Management of fecal incontinence is provided in a tiered approach, beginning with lifestyle modification or pharmacologic therapy followed by selectively offering biofeedback therapy, pelvic floor muscle training and electrical stimulation. If conservative treatment

fails, surgery may be offered. Selection of which treatment modality to be employed depends on a number of aspects, such as severity of symptoms, availability of methods and the individual's adherence to treatment. Mild cases are frequently managed with anti-diarrheal medication or fiber products. Surgical intervention is usually reserved for severe cases of fecal incontinence. Surgical treatments include, but are not limited to sphincter repair, sacral nerve stimulation, graciloplasty, and implantation of an artificial anal sphincter. The most severe cases may require a permanent colostomy.

The artificial anal sphincter has been investigated as a surgical treatment for severe fecal incontinence. During the surgical procedure, a cuff is placed around the upper anal canal and tubing from the cuff is directed along the perineum and connected to a pump which is placed just below the skin in the scrotum or labia. Tubing is then used to connect the pump to a pressure regulating balloon that is implanted in the abdominal wall. The balloon contains approximately 40 ml of radio-opaque solution and the control pump controls the transfer of fluid from the balloon to the cuff. To use the sphincter, the person squeezes the pump which causes the fluid to be diverted from the anal cuff back to the balloon. This allows the anal sphincter to relax so that defecation can occur. Once defecation is complete, the fluid slowly returns to the cuff which results in the tightening of the anal sphincter and the achievement of continence.

The premarket approval from the U. S. Food and Drug Administration indicates that the Acticon Neosphincter system is indicated to treat severe fecal incontinence in males and females 18 years and older who have failed, or are not candidates for less invasive forms of restorative therapy. In 2011, a class 2 recall was issued for the Acticon Neosphincter control pumps due to concerns that the pumps may not function properly. However, this recall was terminated on July 6, 2012.

A search of the U.S. Food and Drug Administration databases did not indicate that the SphinKeeper implantable artificial anal sphincter has been cleared for use in the United States.

Definitions

Fecal incontinence: The inability to control the bowels, which results in leakage of stool or gas.

Gluteoplasty: A surgical procedure which transposes one or both gluteus muscle(s) from the buttock and uses them to encircle the anal canal. This procedure may be done in combination with an electrical stimulator (stimulated gluteoplasty).

Graciloplasty: A surgical procedure which transposes the gracilis muscle from the leg and wraps it around the anus to form a new sphincter. An implanted electrical stimulator is used to keep the muscle contracted and thus the anus closed. This procedure is also known as dynamic graciloplasty.

Levatorplasty: A surgical procedure which tightens the external anal sphincter and the pelvic floor muscles by bringing together the muscles of the pelvic floor above the anal canal.

Obstructed defecation: A broad term used to describe the condition of an individual experiencing defecatory dysfunction and constipation. Symptoms include constipation, the inability to initiate rectal emptying, incomplete evacuation, pelvic pressure, or excessive straining at stool. Possible causes of OD include pelvic dyssynergy, rectal intussusception, enterocele, rectocele, pelvic organ prolapse and overt rectal prolapse.

Sacral nerve stimulation: A surgical procedure which involves stimulating the sacral nerves, usually sacral nerves 3 or 4.

Sphincter repair: The external anal sphincter is repaired or simply tightened to try and improve control. This procedure is also known as sphincteroplasty or direct sphincter repair.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT	
46999	Unlisted procedure, anus [when specified as anal sphincteroplasty for incontinence with implantation of an artificial sphincter]
ICD-10 Procedure	
0DHQ0LZ-0DHQ4LZ	Insertion of artificial sphincter into anus [by approach; includes codes 0DHQ0LZ, 0DHQ3LZ, 0DHQ4LZ]
0DPQ0LZ-0DPQ8LZ	Removal of artificial sphincter from anus [by approach; includes codes 0DPQ0LZ, 0DPQ3LZ, 0DPQ4LZ, 0DPQ7LZ, 0DPQ8LZ]
0DWQ0LZ-0DWQ8LZ	Revision of artificial sphincter in anus [by approach; includes codes 0DWQ0LZ, 0DWQ3LZ, 0DWQ4LZ, 0DWQ7LZ, 0DWQ8LZ]
ICD-10 Diagnosis	
	All diagnoses

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Government Agency, Medical Society, and Other Authoritative Publications:

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References and History sections.
Reviewed	11/10/2022	MPTAC review. Updated References and History sections.
Reviewed	11/11/2021	MPTAC review. Updated Rationale, Background/Overview, References, Index and History sections.
Reviewed	11/05/2020	MPTAC review. Updated References and History sections.
Reviewed	11/07/2019	MPTAC review. Updated References section.
Reviewed	01/24/2019	MPTAC review. Updated References section.
	12/27/2018	Updated Coding section with 01/01/2019 CPT changes; removed 46762 deleted 12/31/2018.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, Background/Overview, and References sections.
Reviewed	02/02/2017	MPTAC review. Updated Review Date, References and History sections.
Reviewed	02/04/2016	MPTAC review. Updated Review Date, Rationale, References and History sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Review Date, Rationale, References and History sections.
Reviewed	02/13/2014	MPTAC review. Updated Review Date, Rationale, References and History sections.
Reviewed	02/14/2013	MPTAC review. Updated Review Date, Rationale, Background/Overview, Definitions, History and References sections.

Reviewed	11/08/2012	MPTAC review. Updated Review Date, History and References sections.
Reviewed	11/17/2011	MPTAC review. Updated Review Date, History and References sections.
Reviewed	11/18/2010	MPTAC review. Updated Review Date, History and References sections.
Reviewed	11/19/2009	MPTAC review. Updated Review Date, History and References.
Reviewed	11/20/2008	MPTAC review. Updated Review Date, History and References.
New	11/29/2007	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.