Clinical Policy Title: Transanal radiofrequency for fecal incontinence

Clinical Policy Number: CCP.1404

Effective Date: February 1, 2019
Initial Review Date: November 6, 2018
Most Recent Review Date: January 8, 2019
Next Review Date: January 2020

Related policies:
- CCP.1168 Injectable bulking agents for fecal incontinence
- CCP.1223 Cecostomy for fecal incontinence
- CCP.1228 Pelvic floor stimulation for incontinence
- CCP.1246 Peristeen® anal irrigation system

About this policy: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of transanal radiofrequency (also called anal sphincter remodeling) to be investigational and, therefore, not medically necessary.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of transanal radiofrequency treatment are not medically necessary.
Alternative covered services:

- Conservative treatment (e.g., lifestyle and dietary modifications, patient education, pelvic floor exercises, rectal irrigation, biofeedback, and pharmaceuticals) per standards of care (Paquette, 2015; Wald, 2014).
- Peristeen® anal irrigation system.
- Surgical treatment per standards of care (Paquette, 2015; Wald, 2014).

**Background**

Fecal incontinence is a clinical diagnosis primarily based on history and examination (National Institute of Diabetes and Digestive and Kidney Diseases, 2018). The strongest risk factors are diarrhea, strong urge, and chronic illnesses (e.g., irritable bowel syndrome, diabetes, and neurological impairment of the pelvic floor). Bowel disturbances such as constipation may occur with or without fecal impaction or overflow diarrhea and without evidence of a structural or biochemical explanation (Bharucha, 2015).

Initial treatment typically begins with conservative approaches (e.g., patient education, pelvic floor exercises, biofeedback, and pharmaceuticals), which can improve symptoms by about 60 percent and achieve continence in an estimated 20 percent of patients (Whitehead, 2016). For fecal incontinence refractory to conservative treatment or for colonic pseudo-obstruction, more invasive options such as electrical stimulation implants, injectable bulking agents, and surgery may be indicated.

**Transanal radiofrequency/anal sphincter remodeling:**

Transanal radiofrequency (also called anal sphincter remodeling) delivers thermo-controlled radiofrequency energy to the internal anal sphincter muscle, with the intent of improving muscle structure and sphincter function. The U.S. Food and Drug Administration (2002) issued 501(k) premarket approval in 2002 to the SECCA® system (Curon Medical, Freemont, California) for treating patients with incontinence to solid or liquid stool at least once per week and who have failed conservative therapy.

SECCA represents a nonsurgical option for treating fecal incontinence caused by anal sphincter muscle weakness. The procedure can be performed in an outpatient setting in approximately 60 minutes.

**Searches**

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.
We conducted searches on September 17, 2018. Search terms were “fecal incontinence/therapy” (MeSH), “catheter ablation, radiofrequency” (MeSH), and the free-text terms “SECCA” and “transanal radiofrequency.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews**.

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

For this policy, we included an Agency for Healthcare Research and Quality comparative effectiveness review of fecal incontinence treatments (Forte, 2016); results from a randomized sham-controlled trial (Visscher, 2017) and a small, prospective, single-center, observational study (Frascio, 2017); and two clinical practice guidelines (Paquette, 2015; Wald, 2014). Forte (2016) found insufficient evidence of effectiveness of transanal radiofrequency for fecal incontinence, as no controlled studies had been published at the time the review was undertaken, whereas results from randomized controlled trials supported the effectiveness of other established procedures for fecal incontinence, although the quality of that evidence was quite variable.

The results from Visscher (2017) and Frascio (2017) offer inadequate evidence to inform clinicians of the effectiveness of the SECCA procedure relative to other noninvasive or invasive options. The clinical significance of reported symptom improvement in the absence of any objective improvement in anorectal function (e.g., manometry or endoanal ultrasonography) is unclear, and patient-related factors associated with treatment success need to be determined from prospective study.

The American Society of Colon and Rectal Surgeons offered a weak recommendation for the procedure to treat fecal incontinence after conservative options have failed, based on limited evidence (Paquette, 2015). The American College of Gastroenterologists found insufficient evidence to recommend transanal radiofrequency ablation treatment; results were conflicting and studies reported no change in anorectal manometric measurement and persistent significant fecal incontinence after the procedure (Wald, 2014).

**Policy updates:**

None.
### Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Frascio (2017)</strong></td>
<td><strong>Key points:</strong></td>
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| Radiofrequency procedure (SECCA®) for fecal incontinence: One-year experience | - Prospective, single-center, observational study of 21 patients who underwent the procedure, 19 of whom completed one-year follow-up (Cleveland Clinic Florida Fecal Incontinence score, Fecal Incontinence Quality of Life Scale, anorectal manometry, and endoanal ultrasound).
- The mean Fecal Incontinence Score significantly improved at three months’ follow-up from 14.5 prior to treatment to 11.9 after treatment and 12 at six months after treatment. A slight worsening was observed at one year (12.9) with no impact on global satisfaction.
- During the same period, only 1/4 of subsets of the Fecal Incontinence Quality of Life score improved.
- Manometry and endoanal ultrasound showed no significant changes post procedure. |
| **Visscher (2017)**               | **Key points:**                     |
| Temperature-controlled delivery of radiofrequency energy in fecal incontinence | - Randomized sham-controlled clinical trial of 40 patients with severe symptoms was carried out from 2008 to 2015 in an outpatient clinic. The Vaizey incontinence score (range 0 – 24) and the fecal incontinence quality-of-life score (range 1 – 4) were measured at baseline and at six months; anorectal function was evaluated at baseline and at three months.
- At baseline, Vaizey incontinence score was 16.8 (standard deviation [SD] 2.9).
- At six months, Vaizey incontinence score improved in both groups, but by 2.5 more points in the index group compared with the sham group (13.2 [SD 3.1] versus 15.6 [SD 3.3], respectively, \(P = .02\)).
- The fecal incontinence quality-of-life score at six months was not statistically different between groups.
- Anorectal function did not show any alteration.
- Although statistically significant, the clinical impact for most of the patients was negligible. |
| **Forte (2016) for the Agency for Healthcare Research and Quality** | **Key points:**                     |
| Treatments for fecal incontinence | - Comparative effectiveness review included 63 unique randomized controlled trials, and an additional 53 surgical case series were examined for adverse effects. No randomized controlled trials or nonrandomized controlled studies of the SECCA procedure were found.
- Overall quality: low due to short follow-up, incomplete reporting of baseline information (etiology, duration, and severity), and variable outcome measures.
- Comparing the effectiveness of surgical and nonsurgical treatments is difficult because nonsurgical approaches generally precede surgery.
- Limited evidence supports any fecal incontinence treatments beyond three to six months. Long-term follow-up is needed.
- Most current interventions showed modest improvements in outcomes that met minimal important differences in the short term, where they were known. |
Noninvasive nonsurgical treatments had few minor adverse effects, but more invasive surgical procedures had substantial complications.

References

Professional society guidelines/other:


Peer-reviewed references:


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<table>
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<table>
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