Medical Policy

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

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Policy Number: 471
BCBSA Reference Number: 7.01.19

Related Policies

- Sacral nerve neuromodulation/stimulation #153
- Biofeedback as a treatment of urinary incontinence #173
- Posterior Tibial Nerve Stimulation for Voiding Dysfunction #583

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Urinary Incontinence
The use of cross-linked collagen, carbon-coated spheres, calcium hydroxylapatite, or polydimethylsiloxane may be **MEDICALLY NECESSARY** to treat stress urinary incontinence in men and women who have failed appropriate conservative therapy.

The use of autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells), autologous fat, and autologous ear chondrocytes to treat stress urinary incontinence is **INVESTIGATIONAL**.

The use of any other periurethral bulking agent, including, but not limited to Teflon®, to treat stress urinary incontinence is **INVESTIGATIONAL**.

The use of periurethral bulking agents to treat urge urinary incontinence is **INVESTIGATIONAL**.

Fecal Incontinence
The use of perianal bulking agents to treat fecal incontinence is **INVESTIGATIONAL**.

Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Urinary Incontinence
BCBSMA covers collagen implants, and the procedure to inject it for the following indication(s) for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:
Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;

Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;

Male patients following trauma, including prostatectomy and/or radiation; and

Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H2O or less.

National Coverage Determination (NCD) for Incontinence Control Devices (230.10)

Fecal Incontinence
The use of perianal bulking agents to treat fecal incontinence is considered INVESTIGATIONAL.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
Prior authorization is NOT required.

Commercial Members: PPO, and Indemnity
Prior authorization is NOT required.

Medicare Members: HMO BlueSM
Prior authorization is NOT required.

Medicare Members: PPO BlueSM
Prior authorization is NOT required.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>51715</td>
<td>Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck</td>
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</tbody>
</table>

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>L8603</td>
<td>Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies</td>
</tr>
<tr>
<td>L8605</td>
<td>Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies</td>
</tr>
<tr>
<td>L8606</td>
<td>Injectable bulking agent synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies</td>
</tr>
<tr>
<td>C9735</td>
<td>Anoscopy; with directed submucosal injection(s), any substance</td>
</tr>
</tbody>
</table>
### ICD-9 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9-CM diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>599.82</td>
<td>Intrinsic (urethral) sphincter deficiency [ISD]</td>
</tr>
<tr>
<td>625.6</td>
<td>Stress incontinence, female</td>
</tr>
<tr>
<td>788.30</td>
<td>Urinary incontinence, unspecified</td>
</tr>
<tr>
<td>788.32</td>
<td>Stress incontinence, male</td>
</tr>
<tr>
<td>788.34</td>
<td>Incontinence without sensory awareness</td>
</tr>
<tr>
<td>788.35</td>
<td>Post-void dribbling</td>
</tr>
<tr>
<td>788.36</td>
<td>Nocturnal enuresis</td>
</tr>
<tr>
<td>788.37</td>
<td>Continuous leakage</td>
</tr>
<tr>
<td>788.38</td>
<td>Overflow incontinence</td>
</tr>
<tr>
<td>788.39</td>
<td>Other urinary incontinence</td>
</tr>
</tbody>
</table>

### ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N36.42</td>
<td>Intrinsic sphincter deficiency (ISD)</td>
</tr>
<tr>
<td>N36.43</td>
<td>Combined hypermobility of urethra and intrinsic sphincter deficiency</td>
</tr>
<tr>
<td>N39.3</td>
<td>Stress incontinence (female) (male)</td>
</tr>
<tr>
<td>N39.42</td>
<td>Incontinence without sensory awareness</td>
</tr>
<tr>
<td>N39.43</td>
<td>Post-void dribbling</td>
</tr>
<tr>
<td>N39.44</td>
<td>Nocturnal enuresis</td>
</tr>
<tr>
<td>N39.45</td>
<td>Continuous leakage</td>
</tr>
<tr>
<td>N39.490</td>
<td>Overflow incontinence</td>
</tr>
<tr>
<td>N39.498</td>
<td>Other specified urinary incontinence</td>
</tr>
<tr>
<td>R32</td>
<td>Unspecified urinary incontinence</td>
</tr>
</tbody>
</table>

### Description

Periurethral bulking agents are substances that are injected periurethrally to increase tissue bulk as a treatment of stress incontinence and perianally as a treatment of fecal incontinence. Patients receive one or several treatment sessions. A number of products have been developed and are commercially available; key factors in determining the optimal product are biocompatibility, durability, and absence of migration.

Improvement in stress incontinence with bulking agents is achieved by increasing the tissue bulk and thereby increasing resistance to the outflow of urine. The bulking agent is injected into the periurethral tissue as a liquid that then solidifies into a spongy material to bulk the urethral wall. Bulking agents may be injected over a course of several treatments until the desired effect is achieved.

Examples of periurethral bulking agents for treatment of urinary incontinence include Contigen from Allergan, Inc., Durasphere from Advanced UroScience and Uryx from CR Bard.

To date, only one bulking agent has been approved by the FDA for treating fecal incontinence which is marketed by Q-Med as Solesta.

All periurethral bulking agents for treatment of urinary and fecal incontinence are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except as noted in the policy statement.
Summary
There is sufficient evidence to conclude that cross-linked collagen improves the net health outcome (i.e. effective in some patients who failed conservative treatment with fewer adverse events than surgery). Moreover, there is evidence that carbon-coated spheres, calcium hydroxylapatite, and polydimethylsiloxane have efficacy for treating incontinence and have efficacy and safety similar to cross-linked collagen. Thus, these bulking agents may be considered medically necessary for patients with urinary incontinence who have failed conservative therapy.

There is insufficient published evidence on the efficacy of autologous cellular therapy, autologous fat, autologous ear chondrocytes, and other treatments such as Teflon. Therefore, use of these agents to treat urinary incontinence is considered investigational.

There is insufficient evidence that injectable bulking agents improve the net health outcome for patients with fecal incontinence. The available evidence from randomized controlled trials has not consistently found that perianal bulking agents improve health outcomes compared to a comparison intervention; 1 of 2 trials evaluating the FDA-approved product found benefit, but had limitations. Thus, injectable bulking agents are considered investigational for treating fecal incontinence.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>11/2013</td>
<td>Removed HCPCS codes L8604, Q3031 and diagnosis code 788.33 as they do not meet the intent of the policy.</td>
</tr>
</tbody>
</table>
| 9/2013 | BCBSA National medical policy review.  
New investigational indications described. Effective 9/1/2013. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
| 1/2010 | BCBSA National medical policy review.  
No changes to policy statements. |
No changes to policy statements. |
No changes to policy statements. |
| 5/2008 | BCBSA National medical policy review.  
No changes to policy statements. |
Changes to policy statements. |

Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines
References


