Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux (VUR)

Policy Number: 7.01.102  Last Review: 5/2017

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for periureteral bulking agents for VUR when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Periureteral bulking agents may be considered medically necessary as a treatment of vesicoureteral reflux grades II–IV when medical therapy has failed surgical intervention is otherwise indicated.

When Policy Topic is not covered
The use of bulking agents as a treatment of vesicoureteral reflux in other clinical situations is considered investigational.

Considerations
The use of bulking agents is contraindicated in patients with non-functioning kidney(s), hutch diverticuli, active voiding dysfunction, and ongoing urinary tract infection.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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| Individuals:  
  • With vesicoureteral reflux who have failed medical therapy and are eligible for surgery | Interventions of interest are:  
  • Endoscopic treatment with periureteral bulking agents | Comparators of interest are:  
  • Ureteral reimplantation surgery | Relevant outcomes include:  
  • Symptoms  
  • Morbid events  
  • Treatment-related morbidity |
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  • Ureteral reimplantation surgery  
  • Surveillance only | Relevant outcomes include:  
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Vesicoureteral reflux (VUR) is the retrograde flow of urine from the bladder upward toward the kidney and is most commonly seen in children. The primary management strategies have been use of prophylactic antibiotics to reduce urinary tract infections and, for higher grade disease, surgical correction of the underlying reflux. Injection of periureteral bulking agents is proposed as an alternative to surgical intervention.

The evidence for endoscopic treatment with periureteral bulking agents in individuals with VUR who have failed medical therapy and are eligible for surgery includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Overall, studies found similar rates of reflux resolution compared with ureteral reimplantation surgery and the body of evidence suggests that morbidity rates are similar or lower with bulking agents. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for endoscopic treatment with periureteral bulking agents in individuals with VUR who have not failed medical therapy and/or are not eligible for surgery consists of RCTs. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The RCTs, which had relatively small sample sizes in each group, compared periureteral bulking agents with antibiotic prophylaxis and/or surveillance only and had mixed findings. Additional, larger studies are needed before conclusions can be drawn about the efficacy of periureteral bulking agents as first-line treatment for patients with VUR. The evidence is insufficient to determine the effects of the technology on health outcomes.

Background
Treatment of vesicoureteral reflux (VUR) is based on the assumption that VUR predisposes patients to urinary tract infections (UTIs) and renal infection (pyelonephritis) by facilitating the transport of bacteria from the bladder to the upper urinary tract. Pyelonephritis causes renal scarring in as many as 40% of children, and extensive scarring may lead to renal insufficiency and hypertension. The period between first renal scarring from pyelonephritis and the development of hypertension or end-stage renal disease can be 30-40 years. (1)

In most cases, VUR is diagnosed during evaluation of UTIs. Approximately one-third of children with UTIs are found to have VUR. (2) The average age for the onset of UTI is 2 to 3 years, corresponding to the age when toilet training occurs. There also appears to be a genetic predisposition to VUR, and siblings may also be examined. The gold standard for diagnosis is voiding cystoureography, a procedure that involves catheterization of the bladder. The severity of reflux is described by a grade, typically with the International Reflux Study Group grading system, which grades severity from I (reflux partway up the ureter) to V (massive reflux of urine up the ureter with marked tortuosity and dilation of the ureter and calyces). Determination of VUR grade is not exact, however, due to factors such as bladder
pressure, which may vary at the time of measurement. In general, more severe reflux is associated with higher rates of renal injury, and less severe reflux (i.e., grade I and II) is associated with higher rates of spontaneous resolution and treatment success. (3, 4) Other factors found to be associated with the likelihood of spontaneous resolution of VUR and/or renal injury include age, sex, laterality, presence of renal scars, presence of voiding dysfunction, and history of UTI. (1)

Treatment strategies for VUR include bladder training, antibiotic prophylaxis, and surgical modification of the ureter to correct the underlying reflux. VUR is likely to resolve spontaneously over a period of 1–5 years; lower grades of reflux (i.e., grades I and II) are associated with a higher probability of spontaneous resolution. (3, 4) The decision to administer prophylactic antibiotic treatment includes the consideration of potential adverse effects of long-term antibiotic treatment, which can include allergic reactions and development of treatment-resistant bacteria resulting in breakthrough UTIs.

Open surgical treatment is typically reserved for patients with high-grade reflux (grades III and IV) or as salvage therapy for those who are noncompliant with antibiotic therapy or have breakthrough UTIs while receiving prophylactic therapy. Surgical management involves lengthening the intramural ureter by modification of the ureterovesical attachment with reimplantation of the ureter. Success rates for open surgery are reported to be greater than 95% and nearly 100% for patients with lower grades of reflux. In recent years, there have been advances in surgical technique, including use of a lower abdominal transverse incision that leaves a smaller scar. Combined with a reduction in the use of ureteral stents and prolonged catheterization; the changes have led to shorter hospital stays and reduced surgery-related morbidity. Moreover, surgeries can now be done on an outpatient basis. Surgery, however, still involves risks associated with anesthesia and potential complications, such as ureteral obstruction, infection, and bleeding. (1) Some centers have reported using laparoscopic antireflux surgery, but this is technically difficult and has not become widespread. Robotic-assisted laparoscopic methods are being developed to overcome some of the technical difficulties. (5)

Treatment of VUR remains controversial. There is a lack of good evidence that VUR actually increases the risk of pyelonephritis and renal scarring, and the long period of time before renal scarring, hypertension, and end-stage renal disease makes these serious conditions difficult to study. Moreover, VUR has a relatively high rate of spontaneous resolution, more than 60% over 5 years, so many children may not benefit from treatment. (6) An important challenge is to identify the subset of children most likely to benefit from VUR treatment. At present, in the absence of definitive answers on the utility of treating VUR or the best treatment option, antibiotic prophylaxis to prevent recurrent UTIs and surgery to treat the underlying reflux remain accepted management strategies.

The use of bulking agents in the treatment of VUR has been reported for more than 20 years and has been suggested as an alternative to either antibiotic or surgical therapy. Bulking agents can be injected into tissue around the ureteral orifices to minimize reflux. The STING procedure (subureteral transurethral...
injection) involves the endoscopic injection of a bulking agent into the submucosal bladder wall just below the ureteral opening. In the more recently used modified STING procedure, the needle is placed in the ureteral tunnel, and the bulking agent is injected into the submucosal intraureteral space. When successfully injected, the compound tracks along the length of the detrusor tunnel and establishes a coapted ureteral tunnel. This endoscopic procedure can be performed in an outpatient setting.

A variety of bulking agents have been tested for biocompatibility and absence of migration. Some of the compounds used in clinical studies are collagen (Contigen, Zyderm, Zyplast), polytetrafluoroethylene paste (Teflon), polydimethylsiloxane (Macroplastique®), calcium hydroxyapatite (Coaptite®), and dextranomer/hyaluronic acid copolymer (Deflux® or Dx/HA), and polyacrylamide hydrogel (Bulkamid®).

**Regulatory Status**

In 2001, Deflux® received premarket application (PMA) approval from the U.S. Food and Drug Administration (FDA) for the “treatment of children with vesicoureteral reflux (VUR) grades II-IV.” Contraindications include patients with nonfunctioning kidney(s), duplicated ureters, active voiding dysfunction, and ongoing urinary tract infection. Duplicated ureters were initially considered a contraindication to Deflux treatment, but this was changed to a precaution in 2007.

Note: Polytetrafluoroethylene may migrate, causing serious adverse events; this agent is not FDA approved. Coaptite®, Macroplastique®, and Tegress® are categorized by the FDA as “Agent, Bulking, Injectable for Gastro-Urology Use.” Tegress was voluntarily withdrawn from the market by CR Bard as of January 31, 2007.

**Rationale**

Treatment of vesicoureteral reflux (VUR) with periurethral bulking agents is proposed as: (1) an alternative to other types of surgery for patients with high-grade VUR (predominantly grades IIII and IV) who have failed or are noncompliant with prophylactic antibiotics; and (2) an alternative to prophylactic antibiotics for patients with low-grade or high-grade VUR. Appropriate outcomes for the comparison of bulking agents and other types of surgery are resolution of reflux and reduction in the rate of urinary tract infections (UTIs) and pyelonephritis. Because prophylactic antibiotic use does not treat the underlying reflux, reduction in the rate of UTIs and pyelonephritis are reasonable outcomes for studies comparing antibiotics and bulking agents. Differences in morbidity are also important outcomes for both proposed uses.

An initial literature search was performed in 2005. The evidence review has been updated regularly with a literature review using MEDLINE; most recently, the literature was reviewed through August 31, 2015. Following is a summary of key literature to date on use of periureteral bulking agents to treat VUR.
Efficacy of Bulking Agents for VUR

Systematic Reviews
A 2011 Cochrane review included randomized controlled trials (RCTs) on treatments for VUR. The Cochrane review addressed a variety of interventions including long-term antibiotic prophylaxis, open surgery, and use of bulking agents and, thus, had limited ability to evaluate the efficacy of bulking agents because studies on open surgery and bulking agents were combined in the analysis. The review, however, is useful for examining the assumption that VUR increases the risk of complications. The Cochrane review, last updated in 2011, included 20 trials with a total of 2324 children. No statistically significant differences were found in the overall risk of UTI or renal parenchymal injury between groups treated with surgery or bulking agents plus antibiotics versus antibiotic prophylaxis alone at any time point between 1 and 24 months. For example, a pooled analysis of data from 5 trials that evaluated repeat positive urine culture at 1 to 2 years found a nonsignificant risk ratio (RR) of 0.89 (95% confidence interval [CI], 0.55 to 1.44). In addition, a pooled analysis of 4 trials that evaluated the outcome of new renal parenchymal defects at 4 to 5 years after treatment calculated a pooled RR of 1.09 (95% CI, 0.79 to 1.49). One statistically significant finding was a reduction in febrile UTI by 5 years with surgery or bulking agent treatment compared with antibiotics alone in a pooled analysis of 2 studies (449 children) (RR=0.43; 95% CI, 0.27 to 0.70). These findings challenge the assumptions underlying the treatment of VUR, because one would expect a reduction in UTI if the hypothesis is correct that VUR is a modifiable risk factor for UTI and renal parenchymal damage.

A systematic review published in 2010 identified randomized trials and observational studies evaluating dextranomer/hyaluronic acid (Dx/HA) treatment for pediatric VUR. A total of 47 studies, mainly retrospective case series, met eligibility criteria. A key inclusion was that studies report the postoperative success rate after a single injection of Dx/HA. Success was defined as resolution of VUR and could also include downgrading to grade 1 VUR. Of 7303 ureters injected with Dx/HA, 5633 (77%) were considered treatment successes. There were higher rates of success in children with low-grade reflux compared with those with high-grade reflux. For example, the 164 children whose preoperative VUR was grade 1 had an 89% success rate compared with a 59% success rate among the 1109 children with initial grade IV VUR.

Randomized Controlled Trials

Periureteral Bulking Agents Versus Other Types of Surgery
The first RCT comparing periureteral bulking agents with ureteral reimplantation (UR) was published in 2013. Garcia-Aparicio et al in Spain randomized 41 children older than 1 year of age with VUR grades I to IV to receive endoscopic treatment with Dx/HA (n=22) or UR (n=19). Indications for surgery included recurrent UTIs, persistent VUR after 2 years of antibiotic prophylaxis, impairment of renal function, or another type of impairment due to VUR. A total of 35 refluxing ureters
were treated with bulking agents, and 32 refluxing ureters were treated with UR. One year after treatment, 32 of 35 ureters (91.4%) in the Dx/HA group and 32 of 32 ureters (100%) in the surgical reimplantation group were cured; the difference between groups was not statistically significant (p=0.23). Findings were similar at final follow-up. At 5 years, 30 of 35 ureters (85.7%) in the Dx/HA group and 100% in the UR group were free of VUR (p=0.48). One patient in the Dx/HA group and 2 patients in the UR group experienced treatment complications. Two patients in the Dx/HA group and none in the UR group experienced fevers posttreatment. Rates of complications and adverse events did not differ significantly between groups. The results of this trial support that there are no large differences between the 2 treatments, but the study was not powered to detect smaller differences in outcomes and was also likely too small to detect differences in complications and adverse events.

**Periureteral Bulking Agents Versus Antibiotic Prophylaxis**

Capozza and Caione reported on the results of a study of 61 children with VUR (grades II-IV) who were randomly assigned to receive an endoscopic subureteral implantation (n=40) of Deflux or 12 months of antibiotic prophylaxis (n=21). Entry criteria included grades II to IV reflux present for at least 6 months. The antibiotic therapy was not specified and presumably was variable. It was not reported whether patients had been receiving antibiotic therapy during the preceding 6 months and experienced breakthrough UTIs, were noncompliant, or showed no evidence of spontaneous resolution of VUR. Therefore it is unknown whether the Deflux treatment was primarily considered an alternative to medical therapy or to surgical therapy. In part, due to the small numbers in the antibiotic control group, the distribution of the different grades of VUR differed between the 2 groups. Outcomes included improvement in reflux grade and measures of renal function; incidence of UTIs was not reported. The only statistically significant outcome reported was improvement in reflux grade at month 12, with 69% of those in the Deflux group reporting a reflux grade of I or less, compared with only 38% in the antibiotic group. However, these results are not surprising, because antibiotic therapy itself is not intended to improve reflux grade but simply to sterilize the urine while awaiting the spontaneous resolution of VUR. Therefore, the only conclusion is that Deflux results in a higher incidence of VUR resolution than spontaneous resolution.

Findings from the Swedish Reflux trial in children were published in 2010. This nonblinded multicenter study included 203 children (128 girls, 75 boys) between the ages of 1 and 2 years with grade III to IV reflux. Participants were not required to have failed antibiotic prophylaxis; thus the trial evaluated injection of a bulking agent as an alternative to antibiotic therapy. Most participants (194 [96%]) were identified after a symptomatic UTI. Recruitment was more difficult than expected, and enrollment was stopped after 6 years. Participants were randomly assigned to 1 of 3 groups: antibiotic prophylaxis (n=69), endoscopic treatment with Deflux (n=66), or surveillance only (n=68).

The study aimed to simulate clinical practice, ie, prophylactic antibiotics were prescribed without monitoring compliance, rather than ensuring that study
participants took a known dose of antibiotics. Primary study outcomes included VUR status, and rates of febrile UTI and kidney damage after 2 years. Sixty-four of 66 patients randomly assigned to endoscopy received treatment. Fourteen of 19 patients with ongoing dilating VUR after 1 injection received a second injection; 2 patients received a third injection. Complications occurred in 6 (9%) of the 64 individuals who received endoscopic treatment. Overall, 187 participants (92%) completed at least 6 of the 8 follow-up visits; analysis was intention to treat. Two-year cystourethrography was done in 185 (91%) of the 203 patients. Findings from voiding cystourethrography were that VUR had resolved in 9 (13%) of 68 patients in the prophylaxis group, 20 (38%) of 52 in the endoscopy group, and 10 (15%) of 65 in the surveillance group. The proportion of patients in the 3 groups whose VUR was downgraded to grade I or II was 18 (26%) of 68, 17 (33%) of 52, and 21 (32%) of 65, respectively. There was a significantly greater proportion of patients whose VUR had resolved or had been downgraded in the endoscopy group than in the prophylaxis (p<0.001) and the surveillance groups (p=0.003), but no statistically significant differences were found between the prophylaxis and surveillance groups. Thirteen (20%) of the 66 patients randomly assigned to endoscopy whose VUR had initially resolved or been downgraded experienced recurrences and had stage III or IV VUR at 2 years.

Febrile UTI rates by treatment group in girls were 8 (19%) of 43, 10 (23%) of 43, and 24 (57%) of 42, respectively, in the prophylaxis, endoscopic, and surveillance groups. Rates were significantly higher in the surveillance group than either the prophylaxis group (p=0.002) or the endoscopic group (p=0.14); rates did not differ significantly in the prophylaxis versus the endoscopic groups. Rates of febrile UTI recurrence during follow-up were dramatically higher in girls (42/128 [33%]) than boys (7/75 [9%]).

Rates of febrile UTIs in boys were 2 (8%) of 26 in the prophylaxis group, 4 (17%) of 23 in the endoscopic group, and 1 (4%) of 26 in the surveillance group; there were no statistically significant differences between groups. The rate of new renal damage did not differ significantly among groups.

After stratifying findings by gender, the sample sizes in reported analyses were relatively small. There may have been insufficient power to evaluate some of the outcomes of interest (eg, kidney damage, febrile UTIs). Moreover, findings might not be applicable to children outside of the restricted age range included in the study and to those with lower grade VUR. Larger studies with a more representative sample of children with VUR are needed to further evaluate the effectiveness of this treatment.

**Comparison Between Bulking Agents**

Three RCTs have compared Deflux with Macroplastique for treatment of VUR in children. An earlier (2002) study by Oswald et al found similar rates of reflux correction in the 2 groups, but more recent RCTs have found higher success rates with Macroplastique than with Deflux. Studies varied in their eligibility criteria (eg, grade of VUR, previous use of antibiotics). The RCTs are described next.
Oswald et al (2002) randomly assigned 72 children with VUR to receive Deflux or Macroplastique in addition to antibiotic prophylaxis. Eligible children had grade II to IV reflux (International Reflux Study Group grading system). Because all patients continued to receive antibiotic therapy, presumably, the bulking procedure was primarily considered an alternative to surgical reimplantation of the ureter. However, the patient selection criteria do not indicate whether patients had failed prior antibiotic therapy or had unresolved VUR. Three months postinjection, VUR was corrected in 50 (86%) of 58 ureters in the Macroplastique group and 40 (71%) of 56 ureters in the Deflux group; the difference between groups was not statistically significant. Rates of maintaining reflux correction at 1 year was also similar in the 2 groups.

In 2011, Kim et al in Korea randomized 85 children aged 2 to 15 years with VUR (grades II-V) to receive subureteral injections of Macroplastique (n=42) or Deflux (n=43). Eligibility included breakthrough UTI in addition to persistent VUR; most patients (exact number not reported) had started immediately on antibiotic prophylaxis after diagnosis. Seventy-three (86%) of 85 children were available for the 3-month follow-up. The cure rate, defined as no evidence of reflux, was 69% in the Macroplastique group and 55% in the Deflux group. The difference between groups was statistically significant, favoring Macroplastique (p<0.05).

A 2014 RCT by Moore and Bolduc in Canada randomized 275 children (median age, 50 months) with grade I to V VUR to endoscopic treatment with Macroplastique or Deflux. Unlike previous trials, the study included patients with grade I VUR (9% of ureters), as well as higher grade disease; results were not stratified by VUR grade. Previous endoscopic treatment of VUR was an exclusion criterion but previous use of antibiotics was not reported. Three months after a single injection of bulking agents, VUR was corrected in 104 (85%) of 122 patients in the Macroplastique group and 101 (76%) of 133 patients in the Deflux group. As in the Kim et al study, the difference between groups was statistically significant, favoring Macroplastique (p<0.05).

**Children With Duplicated Ureters**

No controlled studies have been published comparing bulking agents with other treatments in children with duplicated ureters. However, several case series are available, and these uncontrolled studies suggest reasonable response rates and do not report high complication rates in this population of patients. The largest series to date was published in 2013 by Hunziker et al in Ireland. The study included 123 children with complete duplex systems who were treated with Dx/HA for grade II to V VUR. Mean age of participants was 3 years (range, 1 month to 12 years). Complete duplicated ureters were unilateral in 100 patients (81%) and bilateral in the remaining 13. A total of 136 refluxing units were treated with endoscopic injections of Dx/HA. Three months after treatment, children were evaluated with voiding cystourethrography and bladder ultrasound. The rate of VUR resolution after 1 injection was 68.4% (93/136 ureters). VUR resolved in an additional 35 ureters (25.7%) after a second injection and in the remaining 8 ureters (5.9%) after a third injection. There was 1 complication associated with the endoscopic injections, which was a case of frank hematuria. No patients
needed UR, and there was no evidence on ultrasound of delayed vesicoureteral junction obstruction. Five patients (4%) developed febrile UTIs during follow-up.

Other smaller case series have evaluated bulking agents as a treatment of VUR in patients with duplicated ureters. For example, Molitierno et al included 52 children with duplex ureters who had VUR grade II to V. Overall, VUR was cured in 44 (85%) of 52 patients after 1 or 2 treatments with Dx/HA. Moreover, Lackgren et al evaluated 68 children with duplex ureters and VUR. Forty-three children (63%) had a positive response to treatment, defined as having their reflux resolve to grade 0 or I. There were no complications associated with treatment. Seventeen (25%) children required open surgery.

**Adverse Events**

According to case series data, injection of periureteral bulking agents is associated with low morbidity rates. Temporary postoperative ureteral obstruction may occur in less than 0.7% of patients following injection of bulking agents; this can be treated with ureteral stenting until the problem resolves. In comparison, an average 2% (range, 0%-9%) ureteral obstruction and reoperation rate have been reported following ureteral reimplantation. A large series published by Puri et al (2012) retrospectively reported on 1551 children injected with Dx/HA for high-grade VUR. The only reported procedure-related complication was hematuria lasting up to 12 hours in 3 patients. There was no evidence of delayed vesicoureteral junction obstruction. Febrile UTIs occurred in 69 patients (5%) during follow-up; the median length of follow-up was 5.6 years. Dwyer et al compared the rate of febrile UTIs in 2 cohorts of patients with VUR. The incidence of febrile UTI did not differ significantly between patients who had ureter reimplantation (8% [16/210 cases]) and those who had endoscopic injections of Dx/HA (4% [4/106 patients]) (p=0.24).

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

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<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>Ongoing</td>
<td>A Prospective Study Comparing the Success Rate of Injection of (DefluxR) Versus (VantrisR) for VUR in children</td>
<td>100</td>
<td>Dec 2015</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

**Summary of Evidence**

The evidence for endoscopic treatment with periureteral bulking agents in individuals with VUR who have failed medical therapy and are eligible for surgery includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Overall, studies found similar rates of reflux resolution compared with ureteral reimplantation surgery and the body of evidence suggests that morbidity rates are
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**Practice Guidelines and Position Statements**

In 2012, The European Association of Urology (EAU) published a guideline on the diagnosis and treatment of VUR in children. EAU recommends continuous antibiotic prophylaxis as initial treatment for children diagnosed with VUR in the first year of life and for children age 1 to 5 years who present with high-grade VUR. For children age 1 to 5 with lower grade VUR and no symptoms, surveillance without antibiotic prophylaxis is considered a reasonable option. The document states that surgical correction is a treatment option for patients with persistent symptoms and that endoscopic injection of bulking materials can have satisfactory results in children with lower grades of VUR.

In 2010, the American Urological Association published an updated guideline on management of primary VUR in children. It recommended that patients older than 1 year who have a febrile breakthrough urinary tract infection while receiving continuous antibiotic prophylaxis be considered for open surgery or endoscopic injection of bulking agents. Specific bulking agents mentioned were Deflux and Macroplastique. The guideline was based on a review of the evidence, but the authors acknowledged the lack of robust randomized controlled trials.

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force has not addressed use of injectable bulking agents to treat VUR.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References


**Billing Coding/Physician Documentation Information**

**CPT code 52327**
- Cystourethroscopy (including ureteral catheterization); with subureteric injection of implant material

**L8603**
- Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies

**L8604**
- Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies

**L8606**
- Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

**ICD10 Codes**

**N11.0**
- Nonobstructive reflux-associated chronic pyelonephritis

**N13.70- N13.739**
- Vesicoureteral-reflux code range

**Coding Issues**

CPT code 52327 would apply to the use of any bulking agent, including Deflux, to treat VUR:

Effective 1/1/09, there is a specific HCPCS code for Deflux:
- L8604: Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies

Prior to 2009, HCPCS Code L8606 was sometimes used to describe the use of Deflux; however, the code was not a perfect match, since Deflux is a copolymer that includes some non-synthetic material. HCPCS code L8606 was created for totally synthetic bulking agents (i.e., Macroplastique), while HCPCS code L8603 describes the use of collagen. These codes were originally designed to address the use of bulking agents as a treatment of urinary incontinence.

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

- **5/1/06** New policy; considered investigational.
- **5/1/07** Policy statement revised adding a medically necessary statement for periureteral bulking agents.
- **5/1/08** No policy statement changes.
- **5/1/09** No policy statement changes
5/1/10  Policy statement revised to change the medically necessary from “open
surgical procedure” to “surgical procedure.” Also added failed medical
therapy to the medically necessary policy statement.
5/1/11  No policy statement changes.
5/1/12  No policy statement changes.
5/1/13  No policy statement changes.
5/1/14  Duplicated ureter removed as contraindication in Policy Guidelines.
5/1/15  No policy statement changes.
5/1/16  No policy statement changes.
5/1/17  No policy statement changes.

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