

MEDICAL POLICY

POLICY TITLE	PERIURETERAL BULKING AGENTS AS A TREATMENT OF VESICoureTERAL REFLUX
POLICY NUMBER	MP 1.109

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	11/1/2025

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I. POLICY

Periureteral bulking agents may be considered **medically necessary** as a treatment of vesicoureteral reflux grades II-IV when medical therapy has failed, and surgical intervention would be otherwise indicated.

The use of bulking agents as a treatment of vesicoureteral reflux in all other clinical situations is considered **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY GUIDELINES

The use of bulking agents is contraindicated in individuals with non-functioning kidney(s), Hutch diverticuli, active voiding dysfunction, and ongoing urinary tract infection. The International Reflux Study Group (IRSG) developed a classification system that grades the severity of VUR based upon the degree of retrograde filling and dilation of the renal collecting system demonstrated by voiding cystourethrogram. It is important to note the subjectivity of assigning VUR grades because there is not perfect concordance even among expert readers, especially when differentiating between intermediate grades (II and III). This has implications when interpreting the literature and when making individual treatment decisions. In addition, it is important to use a standardized protocol for VCUG as changes in test parameters can influence test results.

- Grade I – Reflux only fills the ureter without dilation.
- Grade II – Reflux fills the ureter and the collecting system without dilation.
- Grade III – Reflux fills and mildly dilates the ureter and the collecting system with mild blunting of the calices.
- Grade IV – Reflux fills and grossly dilates the ureter and the collecting system with blunting of the calices. Some tortuosity of the ureter is also present.

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- Grade V – Massive reflux grossly dilates the collecting system. All the calices are blunted with a loss of papillary impression, and intrarenal reflux may be present. There is significant ureteral dilation and tortuosity.

Cross-References:

MP 4.012 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

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Vesicoureteral Reflux

Vesicoureteral reflux (VUR) is the retrograde flow of urine from the bladder upward toward the kidney, and most commonly seen in children. The primary management strategies have been 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.

Vesicoureteral reflux (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 to 40 years. The estimated incidence of VUR is approximately 1% (0.4%-1.8%), but the precise figure, including asymptomatic cases, is unknown. The incidence of VUR is higher in children with a positive family history. A meta-analysis of more than 250 articles revealed its occurrence in 31.1% of children who were evaluated for a UTI and 17.2% in those with normal kidneys who underwent a voiding cystourethrogram for other indications, such as hydronephrosis.

Diagnosis

In most cases, VUR is diagnosed after a febrile UTI episode or abnormality seen on ultrasound imaging. Approximately one third of children with UTIs are found to have VUR. The average

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age for UTI onset 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 criterion standard for diagnosis is voiding cystourethrography, a procedure that involves catheterization of the bladder. According to the 2011 American Academy of Pediatrics guideline on the diagnosis and management of the initial UTI in febrile infants and children 2 to 24 months of age, voiding cystourethrography should not be performed routinely after the first febrile UTI. Voiding cystourethrography is indicated if renal and bladder ultrasonography reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy, as well as in other atypical or complex clinical circumstances. 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. Other factors found to be associated with the likelihood of spontaneous resolution of VUR and/or renal injury include age, sex, laterality, the presence of renal scars, the presence of voiding dysfunction, and history of UTI.

Treatment

Treatment strategies for VUR include bladder training, antibiotic prophylaxis, endoscopic injection of bulking agents, and surgical modification of the ureter to correct the underlying reflux. VUR is likely to resolve spontaneously over 1 to 5 years; lower grades of reflux (i.e., grades I and II) are associated with a higher probability of spontaneous resolution. The decision to administer prophylactic antibiotic treatment includes consideration of potential adverse events 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. Some centers have reported using laparoscopic anti-reflux 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.

Treatment of VUR remains controversial. There is a lack of good evidence that VUR increases the risk of pyelonephritis and renal scarring, and the long period of time before renal scarring,

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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. 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.

Bulking Agents

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 antibiotic and surgical therapy. Bulking agents have gained popularity due to several benefits including short operative time, short hospital stay, high efficacy, low complication rate and reduced cost. 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. More recently, the HIT (hydrodistension of the ureteric orifice and injection of bulking agents in the mid to distal submucosal tunnel at the 6 o'clock position) and double HIT (modified HIT with proximal and distal intraluminal submucosal injections) techniques have gained favor; a meta-analysis revealed that overall VUR resolution was 82.5% with HIT as compared to 71.4% with STING ($p < 0.00001$). These endoscopic procedures can be performed in an outpatient setting.

A variety of bulking agents have been tested for biocompatibility and absence of migration. Some compounds used in clinical studies are collagen (Contigen® [Allergan, Coolock; note: this product is no longer commercially available], Zyderm®, Zyplast® [use discontinued due to immune reaction concerns, polytetrafluoroethylene paste (Teflon) [use discontinued due to concerns regarding particle migration polydimethylsiloxane (Macroplastique) [use discontinued due to concerns of malignant potential, calcium hydroxyapatite (Coaptite), dextranomer/hyaluronic acid copolymer (Deflux®, Dexell®, or Dx/HA), polyacrylamide hydrogel (Bulkamid® [Contura International A/S]), and polyacrylate-polyalcohol copolymer (Vantris®).

In 2017, the American Urological Association reviewed and confirmed the validity of its 2010 published guideline on the management of primary VUR in children. The Association recommended that patients older than 1 year of age 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 its authors acknowledged the lack of robust randomized controlled trial data.

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

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problem resolves. In comparison, on average, a 2% (range, 0%-9%) ureteral obstruction and reoperation rate has been reported following ureteral reimplantation. In 2019, Friedmacher and colleague estimated the incidence of ureteral obstruction following endoscopic injections of various substances (i.e., Dx/HA, polyacrylate polyalcohol, poldimethylsiloxane, calcium hydroxyapatite, polytetrafluoroethylene, or collagen) in twenty-five publications. Results revealed ureteral obstruction to be a rare complication after endoscopic correction of VUR, generally occurring in less than 1% of treated cases independent of the injected substance, volume, and technique.

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 three patients. There was no evidence of delayed vesicoureteral junction obstruction. Febrile UTIs occurred in 69 (5%) patients during follow-up; median follow-up was 5.6 years. Dwyer et al (2013) compared the rate of febrile UTIs in two 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]) ($p=0.24$). Lightfoot et al (2019) evaluated long-term outcomes after Dx/HA injection for primary VUR in ninety-nine patients (median follow-up: 8.4 years). Results revealed that a secondary surgery was performed in 13 (13.1%) patients, which was most commonly a repeat Dx/HA injection. Only 3 (3%) patients required open or laparoscopic surgery after Dx/HA injection. Additionally, of the 83 (84.7%) patients reporting ≥ 1 febrile UTIs preoperatively, only 9 (10.8%) reported postoperative occurrence of febrile UTIs.

Regulatory Status

In 2001, Deflux® was approved by the U.S. Food and Drug Administration (FDA) through the premarket application process for the "treatment of children with vesicoureteral reflux (VUR) grades II-IV" and remains the only FDA approved bulking agent for VUR¹¹. Contraindications include patients with nonfunctioning kidney(s), hutch diverticulum, ureterocele, active voiding dysfunction, and ongoing UTI. 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® (Merz Aesthetics), Macroplastique® (Cogentix Medical), and Tegress™ (CR Bard) are categorized by FDA as "Agent, Bulking, Injectable for Gastro-Urology Use." Tegress™ was voluntarily withdrawn from the market by CR Bard in January 2007.

FDA product code: LNM.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have VUR who have failed medical therapy and are eligible for surgery who receive endoscopic treatment with periureteral bulking agents, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. A meta-analysis showed that the rate of the resolution of reflux after the first endoscopic injection was 74%; the rates of resolution of grade II, grade III, and

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grade IV VUR were 79%, 72% and 63%, respectively. Overall, studies have reported similar rates of reflux resolution compared with ureteral reimplantation surgery and the body of evidence would suggest that morbidity rates are similar or lower with bulking agents. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have VUR who have not failed medical therapy and may be ineligible for surgery who receive endoscopic treatment with periureteral bulking agents, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The RCTs, which had relatively small sample sizes in each arm, compared periureteral bulking agents with antibiotic prophylaxis and/or surveillance only and reported 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.

V. DEFINITIONS

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N/A

VI. DISCLAIMER

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Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

VII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Code									
L8603	L8604	L8606	52327						

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ICD-10-CM Diagnosis Codes	Description
N13.70	Vesicoureteral-reflux, unspecified
N13.71	Vesicoureteral reflux without reflux nephropathy
N13.721	Vesicoureteral reflux with reflux nephropathy without hydroureter, unilateral
N13.722	Vesicoureteral reflux with reflux nephropathy without hydroureter, bilateral
N13.731	Vesicoureteral reflux with reflux nephropathy with hydroureter, unilateral
N13.732	Vesicoureteral reflux with reflux nephropathy with hydroureter, bilateral

VIII. REFERENCES

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IX. POLICY HISTORY

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MP 1.109	11/04/2020 Consensus Review. No change to policy statements. References updated.
	05/21/2021 Consensus Review. Updated Policy Guidelines, Background and References. No changes to coding.
	10/04/2022 Consensus Review. No change to policy stance. Updated background and references.
	09/20/2023 Consensus Review. No change to policy stance. Added VUR Grades to policy guidelines. New references.
	07/30/2024 Consensus Review. No change to policy stance. Updated references.
	07/17/2025 Consensus Review. No change to policy stance.
	10/08/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.

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