



Louisiana

Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux

Policy # 00899

Original Effective Date: 01/01/2025

Current Effective Date: 01/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence is addressed separately in medical policy 00095.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider periureteral bulking agents as a treatment of vesicoureteral reflux grades II, III, or IV when medical therapy has failed (i.e., continuous antibiotic prophylaxis) and surgical intervention is otherwise indicated to be **eligible for coverage**** (see Policy Guidelines for contraindications).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of bulking agents as a treatment of vesicoureteral reflux in other clinical situations to be **investigational.***

Policy Guidelines

The use of bulking agents is contraindicated in individuals with nonfunctioning kidney(s), Hutch diverticuli, active voiding dysfunction, and ongoing urinary tract infection.

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The International Reflux Study Group (IRSG) developed a classification system that grades the severity of vesicoureteral reflux (VUR) based upon the degree of retrograde filling and dilation of the renal collecting system demonstrated by voiding cystourethrogram (VCUG). The subjectivity of assigning VUR grades has been described. Some centers utilize the protocol developed by the American Academy of Pediatrics:

- 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.
- 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.

The severity of reflux can be classified as mild (Grades I and II), moderate (Grade III) and severe (Grades IV and V).

Background/Overview

Vesicoureteral Reflux

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. Although the exact prevalence of VUR in the general population is unknown, 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 age

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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; therefore, 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 (reaffirmed in 2016), 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 (ie, 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, and surgical modification of the ureter to correct the underlying reflux. Vesicoureteral reflux is likely to resolve spontaneously over 1 to 5 years; lower grades of reflux (ie, 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 therapy, 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

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lower grades of reflux. Advances in surgical technique, including the use of a lower abdominal transverse incision, have led to smaller scars. 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 antireflux surgery, but this is technically difficult and not 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 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 (>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 is suggested as an alternative to antibiotic and 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 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 coated 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 ($p < .00001$). These endoscopic procedures can be performed in an outpatient setting.

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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^{®†} and 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^{®†} [Axonics]), and polyacrylate-polyalcohol copolymer (Vantris^{®†} [Promedon]).

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, on average, a 2% (range, 0% to 9%) ureteral obstruction and reoperation rate has been reported following ureteral reimplantation. In 2019, Friedmacher and Puri estimated the incidence of ureteral obstruction following endoscopic injections of various substances (ie, Dx/HA, polyacrylate polyalcohol, polydimethylsiloxane, calcium hydroxyapatite, polytetrafluoroethylene, or collagen) in 25 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 3 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 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=.24). Lightfoot et al (2019) evaluated long-term outcomes after Dx/HA injection for primary VUR in 99 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.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 VUR. 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.

FDA product code: LNM.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Most commonly seen in children, vesicoureteral reflux (VUR) is the retrograde flow of urine from the bladder upward toward the kidney. 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.

Summary of Evidence

For individuals who have vesicoureteral reflux (VUR) who have failed medical therapy and are eligible for surgery who receive endoscopic treatment with periureteral bulking agents, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Overall, studies have reported 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 that the technology results in an improvement in the net health outcome.

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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 that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association

In 2017, the American Urological Association reviewed and confirmed the validity of its 2010 published guideline on the management of primary vesicoureteral reflux (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 Macropastique. The guideline was based on a review of the evidence, but its authors acknowledged the lack of robust randomized controlled trial data.

U.S. Preventive Services Task Force Recommendations

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

Medicare National Coverage

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

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Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov did not reveal any relevant ongoing clinical trials as of June 12, 2024.

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10/03/2024 Medical Policy Committee review

10/08/2024 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 10/2025

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	52327
HCPCS	L8604
ICD-10 Diagnosis	N11.0, N13.70- N13.739

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux

Policy # 00899

Original Effective Date: 01/01/2025

Current Effective Date: 01/01/2025

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: 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.

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