



FEP Medical Policy Manual

FEP 7.01.102 Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux

Effective Policy Date: January 1, 2023

Original Policy Date: December 2012

Related Policies:

7.01.19 - Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether endoscopic treatment with periureteral bulking agents improves the net health outcome in individuals who have vesicoureteral reflux and (a) have failed medical therapy and are eligible for surgery or (b) have not failed medical therapy and may be ineligible for surgery.

POLICY STATEMENT

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

The use of bulking agents as a treatment of vesicoureteral reflux in other clinical situations is considered **investigational**.

POLICY GUIDELINES

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

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 VUR.¹¹ 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.

RATIONALE

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.

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 VUR in children.³¹ 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.

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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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2012	New policy	
March 2014	Replace policy	Policy updated with literature review, References 8-9, 17-19, and 23 added, other references renumbered. Policy statements unchanged.
March 2015	Replace policy	Policy updated with literature. Reference 17 added. Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through June 22, 2017; no references added. Policy statements unchanged but "not medically necessary" corrected to "Investigational" .
December 2018	Replace policy	Policy updated with literature review through June 7, 2018; no references added. Policy statements unchanged.
December 2019	Replace policy	Policy updated with literature review through May 31, 2019. no references added. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through June 29, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through June 29, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through May 16, 2022; references added. Policy statements unchanged.

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