POLICY STATEMENT:

Based upon our criteria and review of the peer-reviewed literature, endoscopic injection of bulking agents specifically FDA approved (e.g., Deflux®) for vesicoureteral reflux is considered medically appropriate as an alternative to surgery for clinically severe vesicoureteral reflux Grade II-IV in children one year of age or older.

Refer to Corporate Medical Policy #7.01.22 Urethral Bulking Agents for the Treatment of Urinary Incontinence.

DESCRIPTION:

The endoscopic injection of bulking agents for correction of vesicoureteral reflux (VUR) is an outpatient procedure used to correct reflux in children. VUR is the retrograde flow of urine from the bladder to the ureter and, in some cases, the kidney. VUR predisposes the child to renal infection, injury, and scarring. Renal insufficiency, hypertension and end-stage renal disease may result.

On September 24, 2001 the FDA approved the use of dextranomer/hyaluronic acid copolymer (Deflux®) as a bulking agent for endoscopic subureteral injection for the treatment of VUR. Deflux is biodegradable, does not cause anaphylactic reactions, and does not migrate to distant organs. During the traditional endoscopic procedure, (also known as the STING procedure) Deflux is injected into the submucosal area next to the ureteral-bladder junction. A recently developed technique involving Deflux injection is a modification of the STING procedure. In this procedure the needle is placed within the ureteric tunnel and Deflux is injected into the submucosal intraureteric space along the entire length of the detrusor canal.

RATIONALE:

Deflux received premarket approval in 2001 and is currently the only substance approved in the United States for the endoscopic treatment of VUR, grades II-IV. Children with VUR face the possibility of pyelonephritis and renal damage. These endoscopic procedures have been demonstrated to decrease VUR. A number of other bulking materials have been investigated (e.g., Teflon, bovine collagen, autologous fat, silicone, chondrocytes) but have not received FDA approval for this indication.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>52327</td>
<td>Cystourethroscopy (including urethral catheterization) with subureteric injection of implant material</td>
</tr>
<tr>
<td>74420</td>
<td>Urography, retrograde, with or without KUB</td>
</tr>
<tr>
<td>74455</td>
<td>Urethrocytography, voiding, radiological supervision and interpretation</td>
</tr>
</tbody>
</table>

Proprietary Information of Excellus Health Plan, Inc.
SUBJECT: ENDOSCOPIC INJECTION OF BULKING AGENTS FOR THE TREATMENT OF VESICOURETERAL REFLUX

POLICY NUMBER: 7.01.68
CATEGORY: Technology Assessment

EFFECTIVE DATE: 07/02/99
REVISED DATE: 06/16/05, 05/18/06, 03/15/07, 02/21/08
ARCHIVED: 07/02/99-06/16/05, 02/19/09
EDITED DATE: 02/18/10, 2/17/11, 01/19/12, 01/17/13, 01/16/14

PAGE: 2 OF 3

HCPCS:
L8604 Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies
L8606 Injectable bulking agents, synthetic implant, urinary tract, 1 ml. syringe, includes shipping and necessary supplies

ICD9: 593.7-593.73 Vesicoureteral reflux (code range)
ICD10: N13.70-N13.739 Vesicoureteral-reflux (code range)
N13.9 Obstructive and reflex uropathy, unspecified

REFERENCES:


Proprietary Information of Excellus Health Plan, Inc.


* key article

KEY WORDS:
Deflux, STING

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Endoscopic Injection of Bulking Agents for the Treatment of Vesicoureteral Reflux.