Medical Policy:

Periurethral Bulking Agents for Urinary Incontinence

POLICY NUMBER	LAST REVIEW
MG.MM.ME.51aC3	May 13, 2022

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Stress urinary incontinence (SUI)	Stress urinary incontinence is a symptom that refers to leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending and even changing positions. There are two principle causes of this symptom — SUI and the rarer stress–induced detrusor overactivity (involuntary detrusor contractions that are caused by sudden increases in abdominal pressure). The distinction between these two can be determined by (in order of increasing specificity) patient history, physical examination (e.g., urinary loss after a stress event) and urodynamic studies.
Injectable bulking agents	Used predominantly to treat adult women with (SUI) due to intrinsic sphincteric deficiency (ISD), the agents are injected periurethrally to increase tissue bulk in order to increase resistance of urine outflow. Types of agents approved by the FDA include calcium hydroxylapatite, carbon coated spheres/beads, ethylene vinyl alcohol copolymer, glutaraldehyde crossed-linked collagen or polydimethylsiloxane. Injectable agents may provide immediate relief for some patients and are an option for patients who do not wish to undergo more invasive surgery and who understand that both efficacy and duration are inferior to surgery.

Guideline

A. Female members are eligible for coverage of periurethral injections with FDA approved bulking for persistent SUI.

B. Male members are eligible for coverage of periurethral injections with FDA approved bulking agents for post prostatectomy SUI.

Limitations and Exclusions

1. Repeat injections are no longer considered medically necessary when incontinence fails to improve (after 3 treatments), as progress is unlikely.
2. Bulking agents are not considered medically necessary for the treatment of urge incontinence, neurogenic bladder due to insufficient evidence of therapeutic value.
3. Bulking agents comprised of autologous fat, autologous ear chondrocytes or any other autologous cellular substances (e.g., myoblasts, fibroblasts, muscle derived stem cells, or adipose derived stem cells) are not considered medically necessary due to insufficient evidence of therapeutic value.

Procedure Codes

51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
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

ICD-10 Diagnoses

N36.42	Intrinsic sphincter deficiency (ISD)
N36.43	Combined hypermobility of urethra and intrinsic sphincter deficiency
N39.3	Stress incontinence (female) (male)
N39.42	Incontinence without sensory awareness
N39.43	Post-void dribbling
N39.44	Nocturnal enuresis
N39.45	Continuous leakage
N39.46	Mixed incontinence
N39.491	Coital incontinence
N39.492	Postural (urinary) incontinence
N39.498	Other specified urinary incontinence
N99.89	Other postprocedural complications and disorders of genitourinary system

References

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Specialty Matched Clinical Peer Review.

Revision History

Oct 14, 2020	ConnectiCare adopts clinical criteria of its parent corporation EmblemHealth