Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP090

Section: Medical Benefit Policy

Subject: Injectable Bulking Agents for Treatment of Urinary Incontinence

Applicable line of business:

Commercial	**x**	**Medicaid**	**x**
Medicare	**x**	**ACA**	**x**
CHIP	**x**		

I. Policy: Injectable Bulking Agents for Treatment of Urinary Incontinence

II. Purpose/Objective:

To provide a policy of coverage regarding Injectable Bulking Agents for Treatment of Urinary Incontinence

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
Periurethral injections of bulking agents such as collagen and synthetic agents (e.g. Durasphere™) are used for the management of patients with urinary incontinence resulting from intrinsic sphincter deficiency.

INDICATIONS:
The use of injectable bulking agents may be considered medically necessary when documented evidence of urinary incontinence refractory to prior non-invasive treatments (e.g., Kegel exercises and pharmacologic agents). Types of injectable bulking agents that have received FDA approval include but are not limited to the following:

1. Collagen implants (e.g., Contigen)
2. Carbon-coated beads (e.g., Durasphere)
3. Silicone elastomer (e.g., Macroplastique)
4. Spherical particles of calcium hydroxylapatite (e.g., Coaptite)

MEDICARE Business Segment: See also: National Coverage Determination 230.10 Incontinence Control Devices

LIMITATIONS:
A pre-treatment skin test for the bulking agent with no evidence of local bovine hypersensitivity is required prior to collagen implantation.

EXCLUSIONS:
There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of other agents, as periurethral bulking agents, including but not limited to Teflon®, autologous fat, or autologous ear chondrocytes. The Plan does **NOT** provide coverage of these agents because they are considered **unproven.**

There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of implantable, volume-adjustable balloon devices including but not limited to ProACT Adjustable Continence Therapy. These technologies are considered to be **unproven** and therefore **NOT COVERED**

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance
L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe
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, 1ml syringe
95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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ECRI Hotline Response: Injectable Urethral Bulking Agents for the Treatment of Urinary Stress Incontinence. 6/4/02

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/93 “Contigen Implant”

Revised: 6/96, 2/98, 12/02 revised as “Bulking Agents for Treatment of Urinary Incontinence”; 1/04 Coding, definition; 2/06; 2/07; 2/09 (key words); 2/20 (add product names); 2/25 (Add Medicare cross-reference); 2/26 (update Unproven language, add exclusion)

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