



## **Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence**

**Policy #** 00095

**Original Effective Date:** 01/27/2003

**Current Effective Date:** 05/08/2023

*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: Sacral Nerve Neuromodulation/Stimulation is addressed separately in medical policy 00108.*

*Note: Percutaneous Tibial Nerve Stimulation is addressed separately in medical policy 00415.*

### **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 the use of carbon-coated spheres, calcium hydroxylapatite (CaHA), polyacrylamide hydrogel, or polydimethylsiloxane to treat stress urinary incontinence (SUI) in men and women who have failed appropriate conservative therapy to be **eligible for coverage.\*\***

### **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 autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells or adipose-derived stem cells), autologous fat, and autologous ear chondrocytes to treat stress urinary incontinence (SUI) to be **investigational.\***

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## Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy # 00095

Original Effective Date: 01/27/2003

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Based on review of available data, the Company considers the use of any other periurethral bulking agents, including, but not limited to Teflon<sup>®</sup>† to treat stress urinary incontinence (SUI) to be **investigational**.\*

Based on review of available data, the Company considers the use of periurethral bulking agents to treat all other indications, including urge urinary incontinence, to be **investigational**.\*

Based on review of available data, the Company considers the use of perianal bulking agents to treat fecal incontinence to be **investigational**.\*

### **Policy Guidelines**

Individuals should have had an inadequate response to conservative therapy or therapies; in general, these treatments should have been used for at least 3 months. Conservative therapy for stress incontinence includes pelvic floor muscle exercises and behavioral changes, such as fluid management and moderation of physical activities that provoke incontinence. Additional options include intravaginal estrogen therapy, use of a pessary, and treatment of other underlying causes of incontinence in individuals amenable to these treatments.

### **Background/Overview**

#### **Incontinence**

Incontinence, especially urinary, is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence and 17% issues with fecal incontinence.

#### **Treatment**

##### **Urinary Incontinence**

Injectable bulking agents are space-filling substances used to increase tissue bulk. When used to treat stress urinary incontinence (SUI), bulking agents are injected periurethrally to increase tissue bulk and thereby increase resistance to the outflow of urine. The bulking agent is injected into the periurethral tissue as a liquid that solidifies into a spongy material to bulk the urethral wall. Bulking agents may be injected over a course of several treatments until the desired effect is achieved.

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Policy # 00095

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

Periurethral bulking agents have been widely used for incontinence in women. Men have also been treated, typically those with postprostatectomy incontinence.

Key factors in determining the optimal product are biocompatibility, durability, and absence of migration. A number of periurethral bulking agents to treat urinary incontinence have been cleared for marketing by the U.S. Food and Drug Administration (FDA); however, products developed to date have not necessarily met all criteria of the ideal bulking agents. The first FDA approved product was cross-linked collagen (e.g., Contigen). The agent was found to be absorbed over time and symptoms could recur, requiring additional injections. Contigen production was discontinued in 2011. Other periurethral bulking agents cleared by FDA for urinary incontinence include carbon-coated beads (eg, Durasphere), spherical particles of calcium hydroxylapatite (CaHA<sup>®†</sup>) in a gel carrier (Coaptite<sup>®†</sup>), polydimethylsiloxane (silicone, Macroplastique<sup>®†</sup>), cross-linked polyacrylamide hydrogel (Bulkamid<sup>®†</sup>), and ethylene vinyl alcohol copolymer implants (e.g., Tegress<sup>®†</sup>, formerly Uryx<sup>®†</sup>). Tegress was voluntarily removed from the market due to safety concerns.

### Fecal Incontinence

After the success of periurethral bulking agents for treating SUI, bulking agents injected into the anal canal have been proposed to treat fecal incontinence. In particular, bulking agents are a potential treatment for passive fecal incontinence associated with internal anal sphincter dysfunction. The bulking agent is injected into the submucosa of the anal canal to increase tissue bulk in the area, which narrows the opening of the anus. Current treatment options for fecal incontinence include conservative measures (e.g., dietary changes, pharmacotherapy, pelvic floor muscle exercises), sacral nerve stimulation, and surgical interventions to correct an underlying problem.

Several agents identical or similar to those used for urinary incontinence (e.g., Durasphere, silicone biomaterial) have been studied for the treatment of fecal incontinence. To date, only 1 bulking agent has been approved by FDA for fecal incontinence. This formulation is a non-animal-stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx), marketed by Q-Med as Solesta. A hyaluronic acid/dextranomer formulation (Deflux<sup>™†</sup>) from the same company has been commercially available for a number of years for the treatment of vesicoureteral reflux in children.

Autologous fat and autologous ear chondrocytes have also been used as periurethral bulking agents; autologous substances do not require FDA approval. Polytetrafluoroethylene (Teflon<sup>®†</sup>) has been

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Policy # 00095

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

investigated as an implant material but does not have FDA approval. A more recently explored alternative is cellular therapy with myoblasts, fibroblasts, or stem cells (muscle-derived or adipose-derived). In addition to their use as periurethral bulking agents, it has been hypothesized that transplanted stem cells would undergo self-renewal and multipotent differentiation, which could result in the regeneration of the sphincter and its neural connections.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Several periurethral bulking agents have been approved by FDA through the premarket approval process for the treatment of SUI due to intrinsic sphincter deficiency; other than Contigen<sup>®</sup>, approval is only for use in adult women. Products include:

- In 1993, Contigen (Allergan), a cross-linked collagen, was approved. A supplemental approval in 2009 limited the device's indication to the treatment of urinary incontinence due to intrinsic sphincter deficiency in patients (men or women) who have shown no improvement in incontinence for at least 12 months. Allergan ceased production in 2011; no reason for discontinuation was provided publicly.
- In 1999, Durasphere (Advanced UroScience), a pyrolytic carbon-coated zirconium oxide sphere, was approved.
- In 2004, Uryx (CR Bard), a vinyl alcohol copolymer implant, was approved. In 2005, approval was given to market the device under the name Tegress. In 2007, Tegress<sup>®</sup> was voluntarily removed from the market due to safety concerns.
- In 2005, Coaptite (Merz Aesthetics, previously BioForm Medical), spherical particles of calcium hydroxylapatite, suspended in a gel carrier, was approved.
- In 2006, Macroplastique (Cogentix Medical), polydimethylsiloxane, was approved.
- In 2020, Bulkamid Urethral Bulking System (Axonics Modulation Technologies, Inc.), a soft hydrogel that consists of 97.5% water and 2.5% polyacrylamide, was approved

In 2011, NASHA Dx, marketed as Solesta (Q-Med), was approved by FDA through the premarket approval process as a bulking agent to treat fecal incontinence in patients 18 years and older who have failed conservative therapy. FDA product code: LNM.

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## Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy # 00095

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

### **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.

Bulking agents are injectable substances used to increase tissue bulk. They can be injected periurethrally to treat urinary incontinence and perianally to treat fecal incontinence. The U.S. Food and Drug Administration (FDA) has approved several bulking agent products for treating urinary incontinence and 1 for treating fecal incontinence.

### **Summary of Evidence**

For individuals who have stress urinary incontinence who receive injectable bulking agents, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trials vary by bulking agents used and comparator interventions (e.g., placebo, conservative therapy, surgical procedure, another bulking agent). Due to this heterogeneity across studies, and the small number of studies in each category, Cochrane reviewers were unable to draw specific conclusions about the efficacy of specific bulking agents compared with alternative treatments. Additionally, authors of another recent systematic review concluded that bulking agents were less effective than surgical procedures regarding subjective improvement after treatment, with no difference between the interventions with regard to complications. Studies have shown that cross-linked collagen improves the net health outcome (i.e., it is effective in some patients who have failed conservative treatment with fewer adverse events than surgery), although products that cross-link in such a way are no longer commercially available. There is evidence that FDA-approved carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel, and polydimethylsiloxane have efficacy for treating incontinence, and further that they produce outcomes with a safety profile similar to cross-linked collagen. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fecal incontinence who receive injectable bulking agents, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional

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Policy # 00095

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

outcomes, quality of life, and treatment-related morbidity. A comparative effectiveness review from the Agency for Healthcare Research and Quality evaluated 2 RCTs with the FDA-approved product NASHA Dx (Solesta<sup>®†</sup>) and 2 RCTs with Durasphere<sup>®‡</sup> (off-label in the United States). One RCT comparing NASHA Dx with sham found that NASHA Dx improved some outcomes but not others. The other RCT did not find a significant difference in efficacy between NASHA Dx and biofeedback. Two additional RCTs evaluating Durasphere found only short-term improvements in fecal incontinence severity. Controlled trials with longer follow-up are needed to determine the durability of any treatment effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Supplemental Information**

#### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 physician specialty societies and 4 academic medical centers while this policy was under review in 2013. There was consensus agreement with all of the policy statements among reviewers who provided responses. In particular, there was unanimous agreement among respondents for the statement that use of perianal bulking agents to treat fecal incontinence is considered investigational.

#### **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.

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Policy # 00095

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

### Urinary Incontinence

#### **American Urological Association and Society of Urodynamics**

The 2017 joint guidelines on the surgical treatment of female stress urinary incontinence (SUI) from the American Urological Association and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction stated that bulking agents are an option for patients considering surgery for SUI. The guidelines also stated that there are few long-term data on the efficacy of bulking agents and that retreatment is common.

#### **National Institute for Health and Care Excellence**

In 2015, the National Institute for Health and Care Excellence updated its guidance on urinary incontinence in women. The updated guidance recommended considering "intramural bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI [urinary incontinence] if conservative management has failed. Women should be made aware that:

- repeat injections may be needed to achieve efficacy
- efficacy diminishes with time
- efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings."

#### **American College of Obstetricians and Gynecologists**

In 2016 (reaffirmed in 2019), the American College of Obstetricians and Gynecologists updated its practice bulletin on urinary incontinence in women. The practice bulletin stated that "urethral bulking injections are a relatively noninvasive treatment for stress urinary incontinence that may be appropriate if surgery has failed to achieve adequate symptom reduction, if symptoms recur after surgery, in women with symptoms who do not have urethral mobility, or in older women with comorbidities who cannot tolerate anesthesia or more invasive surgery. However, urethral bulking agents are less effective than surgical procedures such as sling placement and are rarely used as primary treatment for stress urinary incontinence." There was insufficient evidence to recommend any specific bulking agent.

### Fecal Incontinence

#### **American College of Obstetricians and Gynecologists**

In 2019, the American College of Obstetricians and Gynecologists published a practice bulletin on the clinical management of fecal incontinence in women. The College stated that "anal sphincter

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## Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy # 00095

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

bulking agents may be effective in decreasing fecal incontinence episodes up to 6 months and can be considered as a short-term treatment option for fecal incontinence in women who have failed more conservative treatments." This recommendation is based on limited or inconsistent scientific evidence.

### **American Society of Colon and Rectal Surgeons**

In 2015, the American Society of Colon and Rectal Surgeons updated its practice parameters for the treatment of fecal incontinence. The Society gave a weak recommendation based on moderate-quality evidence (2B) that injection of bulking agents into the anal canal may help to decrease episodes of passive fecal incontinence. Studies reviewed showed modest short-term improvements, and no study identified showed a long-term benefit of bulking agents.

### **National Institute for Health and Care Excellence**

In 2007, the National Institute for Health and Care Excellence published guidance on injectable bulking agents for treating fecal incontinence. The guidance stated that there is insufficient evidence to support the safety and efficacy of injectable bulking agents for fecal incontinence.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

The 1996 Medicare National Coverage Determination for Incontinence Control Devices (230.10) addressed collagen implants but not other types of bulking agents. Specific coverage information on collagen implants is as follows:

"Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary incontinence due to ISD [intrinsic sphincteric deficiency]:

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male patients following trauma, including prostatectomy and/or radiation; and
- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H<sub>2</sub>O or less.

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Policy # 00095

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Current Effective Date: 05/08/2023

Patients whose incontinence does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by collagen implant is covered. Patients who have a recurrence of incontinence following successful treatment with collagen implants in the past (e.g., 6 to 12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification."

No national coverage determination was identified on injectable bulking agents for treating fecal incontinence.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT01115465	Real-time Observation of Safety and Effectiveness in the Treatment of Female Stress Urinary Incontinence	276	Feb 2022
NCT02538991	TVT Versus Bulkamid <sup>®</sup> †-Injections in Treatment of Stress Urinary Incontinence - Patient Satisfaction and Complications of the Treatment	224	Dec 2022
NCT03474653	Latitude-An Observational Study of Patient Choice and the Urethral Bulking Agent, Bulkamid <sup>®</sup> †, Used for the First Line Treatment for Stress Urinary Incontinence and the Impact on a Subsequent Mid Urethral Sling	399	Jun 2023
NCT03811821	Comparative Effectiveness of Biofeedback and Injectable Bulking Agents for Treatment of Fecal Incontinence: The Fecal Incontinence Treatment (FIT) Study	285	Dec 2023

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## Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy # 00095

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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## Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy # 00095

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Current Effective Date: 05/08/2023

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## Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy # 00095

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Current Effective Date: 05/08/2023

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## Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy # 00095

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

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## **Policy History**

Original Effective Date: 01/27/2003

Current Effective Date: 05/08/2023

01/27/2003	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
01/31/2005	Managed Care Advisory Council approval
01/04/2006	Medical Director review
01/17/2006	Medical Policy Committee review. Format revision.
02/23/2006	Quality Care Advisory Council approval
01/10/2007	Medical Director review
01/17/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
01/09/2008	Medical Director review

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01/23/2008	Medical Policy Committee approval. Policy statement revised to include newly FDA-approved bulking agents.
01/07/2009	Medical Director review
01/14/2009	Medical Policy Committee approval. Autologous cellular therapy was added as investigational.
01/07/2010	Medical Director review
01/20/2010	Medical Policy Committee approval. Ethylene vinyl alcohol copolymers were deleted from coverage.
01/06/2011	Medical Director review
01/19/2011	Medical Policy Committee approval. No change to coverage.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Added "Urinary" to the policy title. Added that men and women who have failed appropriate conservative therapy are eligible for coverage to treat stress urinary incontinence. Stress urinary incontinence added to the investigational statements. The use of periurethral bulking agents to treat all other indications, including urge urinary incontinence, is considered investigational.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. Changed the policy title from "Periurethral Bulking Agents for the Treatment of Urinary Incontinence" to "Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence". Added that the use of perianal bulking agents to treat fecal incontinence is considered to be investigational.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Contigen (cross-linked collagen) removed from eligibility statement as it has been withdrawn from the market.
10/01/2016	Coding update
11/03/2016	Medical Policy Committee review

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11/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Added Policy Guidelines section.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Added polyacrylamide hydrogel as Medically Necessary due to FDA approval in 2020.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2024

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of*

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*descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

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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	46999, 51715
HCPCS	L8603, L8604, L8605, L8606
ICD-10 Diagnosis	All related diagnoses

\*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 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

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- 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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**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

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recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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