BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Dermal Fillers and Bulking Agents for Vocal Cord Insufficiency

Policy #: 216
Category: Medical

Latest Review Date: January 2020
Policy Grade: C

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

In accordance with Title XVIII of the Social Security Act, Section 1862 (a)(10) cosmetic surgery or expenses incurred in connection with such surgery is not covered except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after April 7, 2011:
Blue Advantage will treat **FDA approved injectable implants/bulking agents (e.g. Radiesse™)** as a **covered benefit** for the treatment of **unilateral vocal cord paralysis**.

Please refer to CMS NCD Dermal Injections for Treatment of Facial Lipodystrophy Syndrome (LDS) NCD250.5.

Effective for dates of service on or after November 17, 2009:
Blue Advantage will treat **dermal fillers** as a **non-covered** benefit for the use of **bilateral vocal cord paralysis, hoarseness, dysphonia or other conditions** of the vocal cords and as **investigational**.

Effective for dates of service on or after May 14, 2009:
Blue Advantage will treat **dermal fillers that are FDA approved for cosmetic purposes** as a non-covered benefit as they are considered **cosmetic.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Dermal Fillers for Cosmetic Purposes

Dermal fillers are products that are injected or placed into the dermis. There are also subdermal fillers and those placed underneath the dermis in the subcutis. They can be injected into areas with fine lines and wrinkles. Bovine collagen was the first FDA-approved dermal filler in the United States for more than a decade.

Vocal Cord Insufficiency

Under normal conditions, the mucosal vocal folds (vocal cords) open for breathing and close for voice vibration and swallowing. Loss of vocal fold closure due to paralysis, atrophy, or scar can affect voice, swallowing, and breathing. Injection of bulking agents has been reported for the treatment of vocal cord abnormalities. The objective of vocal fold injection augmentation (injection laryngoplasty) is to increase the size of the deficient vocal fold and reestablish symmetrical medial closure of both vocal folds.

Vocal fold paralysis occurs most frequently following surgery, and is a common complication of thyroid, cervical spine, esophagus, and lung surgeries. Examination on laryngoscopy shows impaired vocal fold motion, bowing of the fold, and incomplete glottis closure. Paresis refers to partial paralysis with preservation of gross mobility. The incidence of vocal fold paralysis has

increased with the increase in thyroidectomy and anterior cervical discectomy and fusion. However, many cases of unilateral vocal fold insufficiency will spontaneously recover if left untreated.

Surgical interventions for vocal fold paralysis include laryngoplasty, arytenoid adduction, and laryngeal re-innervation. Vocal fold injection augmentation (injection laryngoplasty) for the temporary treatment of vocal fold insufficiency was first reported over a century ago using paraffin, although injection augmentation has become more commonly reported in the past 2 decades. Injection of a bulking agent into the paraglottic space results in medialization of the vocal fold, and can be approached through the cricothyroid membrane or through the mouth.

The objective of vocal fold injection augmentation for the treatment of vocal cord insufficiency is to increase the size of the deficient vocal fold and reestablish symmetrical medial closure of both vocal folds. Materials used for vocal fold augmentation include Teflon, calcium hydroxylapatite (Prolaryn™ Plus/Radiesse™ Voice), carboxymethylcellulose (Prolaryn™ Gel/Radiesse™ Voice Gel), human collagen (CosmoPlast®), bovine collagen (Zyplast®), micronized dermis (Cymetra®), hyaluronic acid (Hylaform®, Restylane®), and autologous fat. All bulking agents cause some degree of inflammation. The duration of the inflammation varies according to the durability of the agent. Injection of bulking agents typically results in a transient increase in tissue volume, although Teflon, which has a high incidence of inflammation and granuloma formation, may result in a permanent increase in vocal fold volume.

KEY POINTS:

Literature review through January 2020.

Summary of Evidence:

For individuals who have vocal fold insufficiency (e.g. paralysis, paresis, atrophy, or scar) who receive vocal fold injection augmentation, the evidence includes 1 randomized controlled trial (RCT) and systematic reviews of case series and cohort studies. Relevant outcomes are change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Overall, the evidence is of low quality, with only 1 RCT in patients with unilateral vocal fold paralysis. This RCT showed a significant benefit of injection augmentation only in the first few months compared with observation, which could be related to the natural resolution of vocal fold paralysis over time. The systematic reviews have suggested comparable efficacy of vocal fold injection augmentation with surgical approaches, but interpretation is limited by a high potential for bias in the identified studies. Outcomes of the large case series and cohort studies have suggested a benefit in both objective and subjective outcomes related to the durability of the product injected.

Practice Guidelines and Position Statements

American Academy of Otolaryngology-Head and Neck Surgery

The American Academy of Otolaryngology-Head and Neck Surgery (AAOHNS) published guidelines in 2013 on improving voice outcomes after thyroid surgery. AAOHNS made a strong recommendation for identifying the recurrent laryngeal nerve(s) during thyroid surgery, and recommendations to examine and document voice and vocal fold mobility both before and after

surgery. AAOHNS recommended that if patients have voice change or abnormal vocal fold mobility after surgery, surgeons should provide counsel on options for rehabilitation. Vocal fold injection medialization is described as a temporary intervention that may reduce the need for later surgical reconstruction.

National Institute for Health and Care Excellence
The U.K.'s National Institute for Health and Care Excellence (NICE) provided guidance in 2005 on collagen injection for vocal cord augmentation. NICE concluded that collagen injection is efficacious for short-term symptom relief and there were no major safety concerns.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:

Sculptra™, poly-L-lactic acid, injectable implant, lipoatrophy, HIV, collagen, Zyderm I, Zyderm II, Zyplast, CosmoDerm I, CosmoDerm II, CosmoPlast, porcine collagen, bovine collagen, Evolence, hyaluronic acid, Restylane, Perlane, Juvederm, Juvederm Ultra, Juvederm Ultra Plus, Hylaform, Hylaform Plus, Captique, Puragen and Puragen Plus, Prevelle Silk, Artefil, Radiesse, Elevess, Sculptra Aesthetic, Perlane, unilateral vocal cord paralysis, Coaptite™, Juliesse™, Prolaryn™ Plus/Radiesse™ Voice, carboxymethylcellulose (Prolaryn™ Gel/Radiesse™ Voice Gel), human collagen (CosmoPlast®), bovine collagen (Zyplast®), micronized dermis (Cymetra®), hyaluronic acid (Hylaform®, Restylane®), Juvederm Vollure XC, Juvederm Volbella XC, Refyne, Restylane Defyne, Belotero Balance, Artefill®, Fibrel, Evolence, glottal insufficency

APPROVED BY GOVERNING BODIES:

Multiple bulking agents have been approved by the U. S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of unilateral vocal cord paralysis. Manufacturers including but not limited to,Sofregen Medical (Medford, MA), Cytophil (East Troy, WI), Coapt Systems (Palo Alto, CA) and Bioform Medical (San Mateo, CA). According to the FDA, the product code dedicated to bulking agents for vocal cord medialization is MIX.

The Radiesse Laryngeal Implant (calcium hydroxylapatite) (BioForm Medical Inc.) obtained clearance from the FDA through the 510(k) approval process, as substantially equivalent to the predicate device on March 1, 2007. According to the FDA, the Radiesse Laryngeal Implant is indicated for vocal fold medialization and treatment of vocal fold insufficiency that can be improved by injection of a soft-tissue bulking agent. The Radiesse Laryngeal Implant is intended to augment the size of the displaced or deformed vocal fold so that it may meet the opposing vocal fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication for a Radiesse Laryngeal Implant (FDA, 2007). In February 2010, Merz Aesthetics Inc. acquired BioForm Medical Inc. Merz Aesthetics Inc. manufactures Radiesse Laryngeal Implant under the names Radiesse Voice and Radiesse Voice Injectable Implant (Merz Aesthetics Inc., 2012).

SCULPTRA™ (FDA approved July 2009) is indicated for use in immune-competent people as a single regimen for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

31513	Laryngoscopy, indirect; with vocal cord injection
31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic;
31571	With operating microscope or telescope
31574	Laryngoscopy, flexible; with injection(s) for augmentation (e.g., percutaneous, transoral), unilateral

HCPCS:

G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
J3490	Unclassified drugs
L8607	Injectable bulking agent for vocal cord medialization, 0.1ml, includes shipping and necessary supplies
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, Sculptra, 0.5mg
Q4112	Cymetra, Injectable, 1cc

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POLICY HISTORY:

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Medical Policy Group, January 2006
Medical Policy Group, January 2007
Medical Policy Group, January 2008
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Medical Policy Group, August 2009
Medical Policy Group, September 2009
Available for comment October 2-November 16, 2009
Medical Policy Update, July 2010 **(1)**
Medical Policy Group, April 2011 **(1)**
Available for comment April 13 – May 30, 2011
Medical Policy Group, October 2013 (1)
Medical Policy Group, December 2016
Medical Policy Group, September 2017
Medical Policy Group, January 2020

hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.