Name of Policy: Dermal Fillers

Policy #: 216       Latest Review Date: April 2011
Category: Medical       Policy Grade: C

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. 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.
**Description of Procedure or Service:**

A dermal filler is a product that is 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. The FDA approved indication for Zyderm is for the correction of contour deformities of the dermis in non-weight bearing areas. This product was marketed as **Zyderm I** and was extremely effective for correction of fine lines and shallow scars, with results often lasting three months. Other uses were for rhytides, deeper nasolabial folds and marionette lines but the effect only lasted about two months. There were issues with this product that included allergies to bovine collagen, lack of longer lasting results and disappointing results for its uses. Later **Zyderm II and Zyplast** were FDA approved with hopes of improving on the Zyderm I issues. Zyplast was indicated by the FDA approval for the correction of contour deficiencies of soft tissue and seemed to work well but some of the same issues existed with frequency of treatments, skin allergy testing and the poor response of deeper rhytides and folds.

Due to the risk of allergy to the bovine-derived collagen fillers, human-derived collagen dermal fillers were developed and labeled as bioengineered collagen. These products require no allergy testing. In March 2003, three bioengineered dermal fillers were FDA approved and are known as **CosmoDerm I & II, and CosmoPlast**. CosmoDerm I and II were indicated are injected into the superficial papillary dermis for correction of soft tissue contour deficiencies, such as wrinkles and acne scars. CosmoPlast is FDA approved for injection into the mid to deep dermis for correction of soft tissue contour deficiencies, such as wrinkles and acne scars.

Porcine collagen is naturally occurring collagen filler that is derived from porcine tendons. **Evolence** was FDA approved June 27, 2008. Evolence is indicated for correction of moderate-to-deep facial wrinkles and folds, such as nasolabial folds with duration of approximately six months.

Hyaluronic acid potently binds to water and, when injected into the skin, volumizes, softens and hydrates the skin. It also stabilizes intercellular structures and produces the viscoelastic network for collagen and elastin fibers to bind together. **Restylane** was FDA approved in February 2003. Restylane is relatively long-lasting, have minimal adverse effects was easy to use, was ready to use our of the box, did not require refrigeration, was cost effective, and did not require skin testing prior to treatment. If there are undesirable results, hyaluronidase can be injected to break down the unwanted hyaluronic acid dermal filler. Restylane is intended for temporary correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. Perlane is another hyaluronic acid product that is identical to Restylane except it is made up of larger particles. Both products will last about six months and Perlane my last up to nine months.

**Juvederm Ultra and Juvederm Ultra Plus** are non-animal stabilized hyaluronic dermal fillers that were FDA approved in June 2006. Juvederm Ultra Plus has a higher proportion of cross-linking of any of the hyaluronic acid fillers and thus has a smoother consistency. Indications are for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds). The duration of the effects of the Juvederm products range from six to 12 months.
**Hylaform and Hylaform Plus** are hyaluronic acid products derived from an avian source, rooster combs. They are similar in action to Restylane and Perlane but there needs to be aware of possible allergies to these avian proteins. These products are indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).

**Captique** is dermal filler that is the same as the Hylaform but is not animal based; it comes from a bacterial source through fermentation. Due to the bacterial source this makes Captique a stiffer form of dermal filler. This filler was FDA approved November 2004 and is indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) and duration of action is about 4 months.

**Puragen** is another bacterially derived hyaluronic but is not FDA approved in the United States at this time. This product is similar to Restylane in indications, precautions and duration as per the pilot studies.

**Prevelle Silk** was approved by the FDA in February 26, 2008 and is the only hyaluronic acid dermal filler that contains lidocaine. The indications for Prevelle Silk are injection into mid to deep dermis for correction of moderate to severe facial wrinkles and folds. The duration is approximately six months.

Polymethylmethacrylate with bovine collagen and marketed as **Artefill** is a dermal filler that is made of nonresorbable microspheres. Because of the bovine source, this product requires allergy testing. The FDA approval (October 2006) is only for correction of nasolabial folds. This product duration is listed as permanent support structure for wrinkle correction. This product must be injected directly beneath the skin fold in the deep dermis.

Calcium hydroxylapatite marketed as **Radiesse** was FDA approved in December 2006 for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and it is also intended for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV. This product may last as long as a year. In March, 2007, the FDA approved Radiesse for vocal fold medialization.

**Elevess** or Cosmetic Tissue Augmentation Product (CTA) is indicated for injection into the mid to deep dermis for the correction of moderate to severe facial wrinkles and folds (such as nasolabial folds). Elevess was FDA approved December 2006.

**Sculptra** is an injectable implant that contains microparticles of poly-L-lactic acid. It is a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family. In August 2004, the FDA approved Sculptra as injectable filler to correct facial fat loss in HIV patients. Sculptra works by temporarily adding volume to facial tissue and restoring a smoother, fuller appearance to the face. The initial treatment series may consist of four to five injection sessions conducted at approximately two-week intervals. Repeat treatments may be needed to maintain the effect which may range from several months to about a year. On July 29, 2009, the FDA approved Sculptra Aesthetic for correction of shallow to deep nasolabial fold contour.
deficiencies and other facial wrinkles which are treated with the appropriate injection technique in healthy patients.

**Perlane®** injectable gel is biotechnologically engineered, non-immunogenic, stabilized hyaluronic acid gel particles. The three-dimensional gel particles in Perlane are hydrophilic molecules, attracting and binding to water molecules as they degrade, helping to maintain volume augmentation for about six months. On May 2, 2007, Perlane was approved by the FDA for implantation into the deep dermis to superficial subcutis for the correction of moderate to severe facial folds and wrinkles, such as the nasolabial folds. Perlane is a Class III restricted medical device and should only be administered under the supervision of a licensed practitioner. Perlane has also been used for other facial issues that may include lip enhancement, chin augmentation, and softening acne scar.

**Policy:**

**Effective for dates of service on or after March 3, 2011:**

*Radiesse™, Sculptra™, and other FDA approved injectable implant devices meet* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of **unilateral vocal cord paralysis**.

Dermal fillers that are FDA approved for cosmetic purposes do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and **are not covered** as they are considered **cosmetic and a contract exclusion**.

**Poly-L-lactic acid, (Sculptra™), an injectable implant device used to treat facial lipoatrophy is considered cosmetic.**

**Effective for dates of service on or after July 1, 2009:**

Dermal fillers do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the use of **bilateral vocal cord paralysis, hoarseness, dysphonia or other conditions** of the vocal cords and are considered **investigational**.

*Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate 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.*

**Key Points:**
The Vega Study, from France, was a 96-week open-label, non-comparative, single-center study in 50 HIV patients. Patients had a mean age of 45 years, 84% were Caucasian, and 98% were male. Most patients had four to five injection sessions. The results showed all patients experienced increases in skin thickness in the treatment area in weeks eight to 96 during the
study and the changes persisted for up to two years. The results also showed 3% had bruising, 30% had hematoma, and 52% had a nodule at the injection site.

The Chelsea and Westminster (C&W) Study, from England, was a 24 week, open-label, single-center, randomized study in 30 HIV patients. Patients were randomized to the delayed treatment group (treatment delayed by 12 weeks) or immediate treatment group, and received 12 or 24 weeks, respectively, of follow up. The immediate treatment group received injections on day one and at weeks two and four. The delayed treatment group received injections at weeks 12, 14, and 16. The results showed all patients had significant changes from baseline in mean skin thickness in the areas treated. A mean increase in dermal thickness of approximately 4 to 6 mm was observed in both groups 12 weeks after the initiation of treatment. The adverse events at the injection site included 38% with bruising, 10% with discomfort, 10% with erythema, 10% with inflammation, and 31% with a nodule.

The Apex 002 Study and the Blue Pacific Study were two, single-center, open-label, 12-month investigator-initiated studies in the U.S. in HIV positive patients with facial lipoatrophy. There were 99 pts in each study, and the majority was Caucasian males. Patients received up to six injection sessions at three to six week intervals and were followed for one year. The adverse events for the Apex study included discomfort in 19%, edema in 3%, bruising in 1%, and injection site papule in 6%. The adverse events for the Blue Pacific Study included bruising in 30%, edema in 17%, discomfort in 15%, erythema in 3% and injection site papule in 13%.

The final results of the U.S. Studies have not been published. The long-term safety and effectiveness beyond two years have not been investigated. The uses of poly-L-lactic acid injectable implant devices for the treatment of other diseases/conditions (e.g., facial wrinkles and folds due to ageing) have not been done in the U.S.

January 2007 Update
There is no new information available to change the policy statement.

January 2008 Update
The FDA indications have not been changed for this device. The only FDA approved indication remains for restoration and/or correction of signs of facial fat loss in HIV patients. A literature review indicated that studies are being performed for other uses of this device that are off-label uses. There is no new information to alter the coverage statement of this policy.

March 2009 Update
This policy has been updated to include multiple dermal fillers. Information has been added to include the FDA approved indications in the description regarding these products.

August 2009 Update
Sculptra Aesthetic was FDA approved on July 29, 2009 for correction of nasolabial folds and other facial wrinkles. The approval was based on results from a randomized, comparative, valuator-blinded, parallel group, multicenter study of 233 patients. Patients received Sculptra Aesthetic or an approved human derived collagen for the treatment of their nasolabial fold wrinkles. Sculptra Aesthetic was administered in a single treatment regimen, at three week
intervals, for up to four treatment sessions for the correction of shallow to deep dermal grid pattern (cross-hatch) injection technique. The Sculptra Aesthetic patients were followed for an additional 12 months. Treatment effects were maintained up to 25 months after the last treatment session, while the human derived collagen was effective up to three months.

**September 2009 Update**
The use of dermal fillers for the treatment of vocal cord paralysis is not an FDA approved indication and therefore does not meet TEC criteria. The American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) published national clinical practice guidelines in September 2009.

Key features of the new guideline include:

- Most, but not all, hoarseness is the result of benign underlying or self-limiting factors; however, clinicians should consider the possibility of a serious underlying condition (growth or tumor of the larynx) or medication side effects as a cause.

- Laryngoscopy is an office procedure to visualize the larynx (voice box and vocal cords) that should be performed if hoarseness persists or if the cause is uncertain.

- Imaging studies, such as a CT or MRI scans, should not be obtained for a primary complaint of hoarseness prior to visualizing the larynx; laryngoscopy is the primary diagnostic modality and should be done first.

- Anti-reflux medicines should not be prescribed for hoarseness unless there are (a) signs or symptoms of gastroesophageal reflex disease (GERD), such as heartburn or regurgitation, or (b) signs of inflammation of the larynx seen during laryngoscopy.

- Steroids or antibiotics given by mouth are not recommended for hoarseness and should not be used routinely.

- Voice therapy is a well-established intervention for hoarseness that can be performed at any age. Laryngoscopy should be performed prior to voice therapy and results communicated to the speech-language pathologist. Therapy for hoarseness usually includes one to two sessions per week for four to eight weeks.

- Surgery is not the primary treatment for most hoarseness, but may be indicated for suspected cancer, other tumors or growths, abnormal movement of the vocal cords, or abnormal tone of the vocal cord muscles.

- The risk of hoarseness may be reduced by preventive measures such as staying well-hydrated, avoiding irritants (especially tobacco smoke), voice training, and amplification during heavy voice use.

In an article published in 2003 by Karpenko et al, Cymetra was used as injection for unilateral vocal cord paralysis. The goal was to demonstrate that injections for glottal incompetence would lead to long term improvement in voice quality and glottal gap closure. Ten patients were in the
study and underwent injection of Cymetra into the thyroarytenoid muscle. Significant improvements were identified in maximum phonation time, relative glottal area, and subjective judgment of glottal competency. The results were not maintained at the three-month study interval. No significant change in quantitative or subjective voice quality was noted for the study group during the investigation. Resorption of Cymetra was thought to play a significant role in contributing to these findings.

April 2011 update
Calcium hydroxylapatite (CaHA), known by the trade name Radiesse Voice, is currently a FDA approved substance for potentially long-term vocal fold injection. It is comprised of microspheres of CaHA in a carboxymethylcellulose carrier. Rosen, et al, (2009) reported that a recent multi-institutional clinical trial revealed excellent results of 80% improvement at 12 month follow-up. Also, Carol, et al (2010) reported that long term clinical results show that persistent medialization after CaHA injection may be present up to two years or more, with an average duration of 18 months.

Vocal fold injection is a surgical treatment alternative to laryngeal framework surgery. In a study by Morgan, et al (2007) injection and medialization laryngoplasty were comparable in their improvement of subjective and objective voice outcomes. Both treatment modalities should be included in the otolaryngologist’s armamentarium for managing unilateral vocal fold paralysis.

Key Words: 

Approved by Governing Bodies:
Poly-L-lactic Acid (aka Sculptra™) received FDA approved August 3, 2004 for use as an injectable filler to correct facial fat loss in HIV patients.
See description for FDA approval dates of each of the dermal filler products.

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity
Pre-certification/Pre-determination requirements: Not applicable
Current Coding:
CPT codes:

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<td>31570</td>
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HCPCS:

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Previous Coding:

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References:

4. Carrol T, Rosen CA. Long-term Results of Calcium Hydroxylapatite (CaHA) Vocal Fold Injection for Glottal Incompetence; Combined Otolaryngology Spring Meeting, ALA Section; 2010 Apr 28-May 2; Las Vegas, NV, USA.

Policy History:
Medical Policy Group, January 2005 (1)
Medical Policy Administration Committee, January 2005
Available for comment February 14-March 30, 2005
Medical Policy Group, January 2006 (1)
Medical Policy Group, January 2007 (1)
Medical Policy Group, January 2008 (1)
Medical Policy Group, March 2009 (1)
Medical Policy Administration Committee, April 2009
Available for comment April 3-May 18, 2009
Medical Policy Group, August 2009 (1)
Medical Policy Group, September 2009 (1)
Medical Policy Administration Committee, October 2009
Available for comment October 2, November 16, 2009
Medical Policy Update, July 2010 (1): August, 2010 Added Perlane to policy as not covered.
Medical Policy Group, April 2011 (1): Update to Description, Policy, Key Points, Key Words Coding and References to include coverage for unilateral vocal cord paralysis
Medical Policy Administration Committee Meeting, April 2011
Available for comment April 13 – May 30, 2011
Medical Policy Group, October 2013 (1): Removed ICD-9 Diagnosis codes; no change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date 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.