Keystone First
Family of Health Plans

Autologous Fat Grafting and Injectable Soft-Tissue Fillers

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Policy contains: autologous fat grafting, injectable fillers, breast reconstruction, systemic sclerosis, digital ulcers, chronic wounds, scar fibrosis, burn scars, fistula management, injection laryngoplasty, vocal fold paralysis, hyaluronic acid, poly-L-lactic acid, calcium hydroxylapatite, collagen, HIV-associated lipoatrophy

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Coverage policy

Autologous fat grafting and injectable soft-tissue fillers (e.g., collagen, Sculptra, Radiesse) are clinically proven and, therefore, may be medically necessary for the following indications:

Autologous fat grafting:

- Correcting contour irregularities and improving tissue quality after radiotherapy in post-mastectomy breast reconstruction (Zhong, 2025)
- Adjunctively treating systemic sclerosis digital ulcers to promote healing when combined with systemic therapy (Campochiaro, 2025; Suliman, 2023)

Injectable soft-tissue fillers:

- Restoring facial volume in human immunodeficiency virus-associated facial lipoatrophy with agents recognized by the Food and Drug Administration (e.g., poly-L-lactic acid, calcium hydroxylapatite), improving volume and quality-of-life outcomes (Jagdeo, 2015)

Additional uses for autologous fat grafting and injectable soft-tissues for vocal cord paralysis or glottic insufficiency are outlined in CCP.1157 Supraglottoplasty and laryngoplasty. All other uses of autologous fat grafting and injectable soft-tissue are considered investigational/not clinically proven and, therefore, not medically necessary. These include, but are not limited to:

- Using autologous fat grafting for generalized chronic wound management outside of systemic sclerosis digital ulcers; current evidence for generalized wounds is heterogeneous and characterized by very low certainty (Malik, 2020).
- Using injectable soft-tissue fillers for acne scar management, as the supporting evidence is characterized by heterogeneity and low quality (Albargawi, 2025).
- Using autologous fat grafting or injectable soft-tissue fillers for general aesthetic enhancement or to alter normal anatomic variation related to aging (cosmetic use).

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Implant or flap revision
- Capsulotomy/capsulectomy
- Local wound care
- Digital sympathectomy
- Revascularization procedures

Background

Autologous fat grafting is a surgical procedure involving the transplantation of an individual's own adipose tissue from one anatomical site to another for reconstructive or therapeutic purposes. The procedure involves harvesting adipose tissue via liposuction, processing the lipoaspirate using minimally manipulative techniques (e.g., centrifugation, filtration), and injecting the processed fat into the target area (Haddad, 2021). The mechanisms of action involve both structural replacement , restoring bulk in areas of volume loss (Lakhani, 2012) and regenerative effects, including the modulation of inflammation, promotion of angiogenesis, and remodeling of scar matrix (Schipper, 2024; Arena, 2025; Xiao, 2024). This policy addresses minimally manipulated autologous fat grafting, excluding enriched products such as stromal vascular fraction or nanofat.

Injectable soft tissue fillers are substances injected into the dermal or subcutaneous tissue. Common materials include hyaluronic acid, calcium hydroxylapatite, poly-L-lactic acid, and collagen. These agents serve as either physical fillers, providing immediate volume restoration (e.g., hyaluronic acid), or bio-stimulatory fillers, which stimulate natural collagen production (neocollagenesis) over time (e.g., poly-L-lactic acid, calcium hydroxylapatite) (Albargawi, 2025; Jagdeo, 2015).

While widely utilized for cosmetic enhancement (Amiri, 2024), both autologous fat grafting and injectable fillers are applied across diverse noncosmetic therapeutic and reconstructive indications. In reconstructive contexts, autologous fat grafting is used in post-mastectomy breast reconstruction to manage contour irregularities and address tissue damage from radiotherapy (Zhong, 2025). Fillers such as poly-L-lactic acid and calcium hydroxylapatite are employed to treat human immunodeficiency virus-associated facial lipoatrophy, restoring facial volume loss related to antiretroviral therapy to reduce social stigma and improve quality of life (Jagdeo, 2015). Furthermore, autologous fat grafting has applications in tissue regeneration for the management of

systemic sclerosis digital ulcers, chronic wounds, and burn scars (Campochiaro, 2025; Xiao, 2024; Lesmanawati, 2024).

Findings

Across noncosmetic indications, findings diverge by modality. Autologous fat transfer is endorsed for breast reconstruction and appears oncologically safe; in systemic sclerosis it improves short-term digital-ulcer healing, while effects on hand function and facial fibrosis are inconsistent and of lower certainty. Evidence for chronic wounds, scar fibrosis, and fistula care is low to very low, because studies are small and heterogeneous, and variable resorption limits durability. Injectable soft-tissue restore facial volume in human immunodeficiency virus–associated lipoatrophy, with hyaluronic acid safer but shorter-lived, poly-L-lactic acid longer-lasting but with more nodules, and calcium hydroxylapatite intermediate. Randomized trials remain scarce and technique variability limits generalizability, so conclusions distinguish guideline-supported practice from areas that remain investigational.

Guidelines

Autologous fat grafting in breast reconstruction

Society guidelines endorse autologous fat grafting as a reconstructive adjunct after oncologic breast surgery for contour correction, implant rippling, and irradiated skin improvement (Zhong 2025; American Society of Plastic Surgeons 2015). Ontario Health recommends fat grafting for these indications, citing improved patient-reported outcomes and no increased cancer recurrence based on a systematic review utilizing rigorous methodology, including the Appraisal of Guidelines for Research & Evaluation II framework (Zhong 2025). The American Society of Plastic Surgeons assigns a grade B recommendation based on consistent case-series evidence. They characterize the procedure as reconstructive, note its use for postmastectomy pain, and link coverage to the Women's Health and Cancer Rights Act while acknowledging insurer denials (American Society of Plastic Surgeons 2015).

Autologous fat grafting for systemic sclerosis

For digital ulcers in systemic sclerosis, the World Scleroderma Foundation conditionally advises autologous adipose tissue grafting as an adjunct to systemic therapy. This recommendation (evidence level three, expert opinion) is based on one randomized, controlled trial and cohort studies showing improved healing. The methodology included systematic reviews, Cochrane reviews, and the ROBINS-I (risk of bias in non-randomized studies of interventions) tool, and consensus procedures (Campochiaro 2025). The committee noted that other injectables, such as botulinum toxin for refractory ulcers, are supported mainly by observational data, highlighting evidence quality gaps that limit the strength of recommendations for those alternatives (Campochiaro 2025).

Systematic reviews and meta-analyses for autologous fat grafting

Breast reconstruction and oncologic safety

A large meta-analysis of 22 cohort studies (n = 9,971) provides moderate-certainty evidence regarding the oncologic safety of autologous fat grafting in individuals undergoing breast reconstruction after cancer treatment. The analysis found no increase in local recurrence, regional recurrence, distant metastasis, or mortality

associated with fat grafting compared with controls (Tian, 2022). These findings establish the safety of the procedure in this specific oncologic population, supporting its use for reconstructive indications (Tian, 2022).

Systemic sclerosis

Autologous fat grafting is effective for digital ulcer healing in systemic sclerosis, although evidence is less robust for improving hand function or facial fibrosis. Multiple systematic reviews, 13 studies (n = 170) and 29 studies (n = 704), synthesizing data from prospective cohorts and one randomized, sham-controlled trial reported high healing proportions and superiority of grafting over sham injection at eight weeks, supporting moderate certainty for short-term healing (Suliman, 2023); (Perrier, 2025). Regarding hand function and ischemic symptoms, reviews, 29 studies (n = 704), reported signals of reduced ischemic hand pain, but effects on mobility, grip measures, or range of motion were inconsistent, resulting in low certainty (Perrier, 2025). For facial fibrosis, improvements in mouth opening, mouth handicap scores, and subjective skin pliability were reported, but objective fibrosis measures were inconsistent, and the durability of effects remains uncertain due to variable graft resorption (Schipper, 2024).

Chronic wounds

The evidence regarding autologous fat grafting for generalized chronic wounds is characterized by significant heterogeneity and very low certainty, which is insufficient to establish the procedure as the standard of care. One systematic review of 10 observational studies (n = 389) analyzed various fat therapy techniques, attributing the very low certainty of evidence to the lack of controls, inconsistent reporting, and substantial procedural variations, despite noting a favorable safety profile (Malik, 2020). A separate meta-analysis of 21 randomized controlled trials (n = 1,119) suggested that human fat products, including minimally manipulated autologous fat grafting, accelerated wound healing rates, shortened time to complete healing, and reduced pain compared to conventional treatment (Xiao, 2024). However, the applicability of these findings to generalized chronic wound care remains limited by the very low certainty and heterogeneity noted across the broader literature.

Vocal fold insufficiency

Evidence regarding the efficacy of autologous fat grafting for vocal fold insufficiency is of very low certainty, primarily due to unpredictable graft durability and resorption. A Cochrane systematic review determined that no methodologically sound randomized controlled trials were available to compare the efficacy of autologous fat with other injectable materials for unilateral vocal fold paralysis (Lakhani, 2012). While systematic reviews of observational studies, 13 studies (n = 472), suggest short- to medium-term improvements, these studies are subject to significant bias, lack control groups, and frequently show a decline in effect requiring reintervention (Campagnolo, 2023). A meta-analysis of 49 observational studies (n = 1,166) found statistically significant short-term improvements in the Voice Handicap Index, clinician-rated perceptual voice analyses, maximum phonation time, and acoustic parameters at six months (Haddad, 2021). The analysis found no significant difference in outcomes based on the use of liposuction or incision as the harvest technique (Haddad, 2021).

Scar fibrosis and burns

Systematic reviews examining autologous fat grafting for scar fibrosis suggest potential improvements in appearance but limited functional benefits, resulting in low certainty evidence. For chronic burn scars, synthesized evidence from six studies (n = 241) indicates improvements in clinician-rated scar scales and histologic architecture when injected fat grafting is used, particularly when combined with fractional laser for

facial scars (Lesmanawati, 2024). Symptomatically, higher satisfaction and some improvements in hand movement were reported in six studies (n = 241), but effects on function, pain, or itch were mixed (Lesmanawati, 2024). Divergent findings were noted in pediatric populations within a synthesis of six studies (n = 241), where one randomized trial found no improvement compared to saline (Lesmanawati, 2024). Evidence for acute burns was confounded by the use of topical nanofat, which is outside the scope of minimally manipulated grafting (Lesmanawati, 2024).

Fistula management

The available systematic reviews provide insufficient evidence regarding the efficacy of minimally manipulated autologous fat grafting for fistula management. Reviews addressing perianal Crohn's fistulas and nonenteric cutaneous fistulas, four studies (n = 49) and seven studies (n = 13) respectively, predominantly synthesized studies that utilized techniques involving more than minimal manipulation, such as microfragmented fat or stromal vascular fraction (De Gregorio, 2023; Bonomi, 2025). Furthermore, in four studies (n = 49), the frequent use of concomitant surgical maneuvers confounds the attribution of effects (De Gregorio, 2023). Consequently, these reviews do not permit conclusions specific to minimally manipulated autologous fat grafting for these indications.

Systematic reviews and meta-analyses for injectable soft-tissue fillers

Vocal fold insufficiency (injection laryngoplasty)

Injectable soft tissue fillers consistently provide measurable functional gains in the treatment of unilateral vocal fold paralysis. A meta-analysis of 32 studies (n = 1,917) showed short- to medium-term improvement in patient-reported quality of life, maximal phonation time, and normalized glottal gap, with adverse events rare and transient (Alkhalifah, 2025). A broader meta-analysis of 82 studies reported a mean maximal phonation time gain of 4.71 seconds (postop: n = 1,781; pre n = 1,981), along with significant reductions in jitter and shimmer (Safia, 2024).

The timing of intervention and the material used are major predictors of benefit (Safia, 2024). Early injection laryngoplasty, six months or less, reduced the relative risk of subsequent permanent thyroplasty to 0.25 across 275 pooled cases, with mean injection time 4.5 months (Vila, 2018; Safia, 2024). Reviews focused on hyaluronic acid confirm durability clustered at six to 12 months with inflammatory complications in 1.47% of 476 treated individuals (Švejdová, 2022). Comparative studies reinforce clinical effectiveness relative to alternatives; 17 head-to-head studies showed no consistent superiority of injection laryngoplasty versus thyroplasty, arytenoid adduction, or reinnervation across perceptual, acoustic, or laryngoscopic outcomes (Siu, 2016; Safia, 2024).

Human immunodeficiency virus-associated facial lipoatrophy

Injectable soft tissue fillers demonstrate consistent safety, efficacy, and durability for restoring facial volume in human immunodeficiency virus-associated facial lipoatrophy. Multiple fillers improve contour and quality of life but differ in durability and complication profiles (Jagdeo, 2015). Six observational studies of hyaluronic acid showed consistent volume restoration at six and 12 months, offering a safe, reversible option for short- to medium-term use (Jagdeo, 2015).

Longer-lasting fillers extend benefit but may increase complication rates. Poly-L-lactic acid, supported by three randomized trials and 20 observational studies, provides more durable correction, sustaining tissue depth gains

at 48 weeks in randomized cohorts (n = 130), but carried a higher risk of nodule formation (Jagdeo, 2015). Calcium hydroxylapatite also offers predictable medium-term benefit (Jagdeo, 2015). In contrast, polyalkylimide gel demonstrated high infectious complication rates, 3.3% to 19%, in long-term observational series (Jagdeo, 2015).

References

On 9/9/2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were Autologous fat grafting, fat transfer, lipofilling, adipose tissue graft, dermal fillers, injectable fillers, soft tissue fillers, hyaluronic acid, poly-L-lactic acid, calcium hydroxylapatite, collagen injection. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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10/2025: Policy active.