

Medical Policy HIV-Associated Lipodystrophy Syndrome

Policy Number: 026

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization required	X	X	Х
Notification within 24 hours of service or next business day			
No notification or authorization			

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical necessity for treatment of HIV-associated lipodystrophy syndrome. These criteria are also available through a custom subset accessible through InterQual®. To access the subset, log into Mass General Brigham Health Plan's provider website at MassGeneralBrighamHealthPlan.org and click the InterQual® Criteria Lookup link under the Resources Menu. The treating provider must request prior authorization and provide documentation as outlined in this policy.

Members must meet the general coverage criteria and the criteria for any specific procedure below:

Facial

- Dermal filler injections (Sculptra and Radiesse) for facial lipoatrophy
- Autologous fat transplantation

Chest

- Liposuction to reduce lipohypertrophy
- Gynecomastia Surgery to reduce lipohypertrophy

Ahdomen

Egrifta[™] for lipohypertrophy of the abdomen¹

Neck/Upper Back

Liposuction to reduce lipohypertrophy

General Coverage Criteria

Mass General Brigham Health Plan covers medically necessary treatments and procedures noted above for HIV-associated lipodystrophy syndrome when the following are met:

- 1. The member has a diagnosis of HIV or AIDS; and
- 2. The medical condition is well documented by clinical notes (photos may be required), that includes a diagnosis of HIV-associated lipodystrophy syndrome, and specifically states that the treatment is necessary for correcting, repairing, or ameliorating the effects of HIV-associated lipodystrophy syndrome; and
- 3. The requested procedure can be reasonably expected to treat the specific part of the body affected by HIV-associated lipodystrophy syndrome.

¹ Mass General Brigham Health Plan's retail pharmacy benefit covers Tesamorelin (Egrifta™) for the treatment of HIV-associated lipodystrophy syndrome, specifically lipohypertrophy of the abdomen through the pharmacy program.



Specific Criteria for Selected Procedures

Face

Mass General Brigham Health Plan considers Sculptra and Radiesse (the FDA-approved soft tissue fillers dermal injections for facial lipoatrophy due to HIV-associated lipodystrophy syndrome), as well as autologous fat transplantation, to be medically necessary when the general coverage criteria are met. In addition, the provider performing the procedure must be a contracted in-network provider.

Note: Subsequent injections with the above fillers or autologous fat transplantation may be considered medically necessary however prior authorization and clinical notes and documentation from the treating provider are required.

Exclusions

- 1. Semipermanent dermal fillers that are not approved by the FDA for the treatment of facial lipoatrophy due to HIV-associated lipodystrophy syndrome.
- 2. Semipermanent dermal fillers or autologous fat transplantation that is used for any indication other than facial lipoatrophy due to HIV-associated lipodystrophy syndrome.
- 3. See General Exclusions

Chest

Liposuction

Mass General Brigham Health Plan covers medically necessary liposuction to reduce lipohypertrophy of the chest caused by HIV-associated lipodystrophy syndrome when the member meets the general coverage criteria.

Gynecomastia Surgery

Mass General Brigham Health Plan covers medically necessary gynecomastia surgery to reduce lipohypertrophy of the chest caused by HIV-associated lipodystrophy syndrome when the member meets the general coverage criteria and when:

1. Liposuction is not indicated to treat HIV-associated lipohypertrophy of the chest.

Exclusions

- Breast surgeries or procedures performed outside the treatment of HIV-associated lipodystrophy syndrome solely to enhance a member's appearance or to counteract appearance that occurs through the natural aging process, in the absence of any signs or symptoms of functional abnormalities and/or associated medical complication is considered cosmetic and is not a covered benefit, unless specifically noted in the coverage criteria.
- 2. See General Exclusions

Abdomen

Egrifta™ Injections

Under Mass General Brigham Health Plan's retail pharmacy benefit, Tesamorelin (Egrifta™) is covered for the treatment of HIV-associated lipodystrophy syndrome, specifically lipohypertrophy of the abdomen when criteria are met and when authorized through the pharmacy program.

Neck/Upper Back

Liposuction

Mass General Brigham Health Plan covers medically necessary liposuction to reduce lipohypertrophy of the neck caused by HIV-associated lipodystrophy syndrome when the member meets the general coverage criteria.

Exclusions

See General Exclusions



General Exclusions

- 1. When the member does not meet the general coverage criteria;
- 2. For members with a diagnosis of HIV-Associated Lipodystrophy syndrome, coverage of cosmetic surgery and procedures and non-surgical cosmetic dermatology procedures that are solely to enhance a patient's appearance in the absence of any signs or symptoms of functional abnormalities; and/or associated medical complication is considered cosmetic and is not a covered benefit, unless specifically noted otherwise in this coverage criteria. These include but are not limited to the following:
 - a. Hair removal
 - b. Facial implants
 - c. Skin tightening
 - d. Chemical peels
 - e. Laser skin resurfacing
 - f. Thyroid cartilage shaving surgeries
- 3. Procedures for facial or body augmentation/reduction not associated with HIV-associated lipodystrophy syndrome

MassHealth Variation

Mass General Brigham Health Plan uses guidance from MassHealth for coverage determinations for its MassHealth ACO members. At the time of Mass General Brigham Health Plan's most recent policy review, MassHealth did not have medical necessity guidance for treatment of HIV-associated lipodystrophy syndrome.

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has an NCD for Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (250.5).

Definitions

<u>Autologous fat transplantation</u> — Autologous fat transplantation involves harvesting of a small intact lump of fatty tissue from the abdomen, cervicodorsal area, or elsewhere, that can be processed into small fat "parcels" that are injected by a syringe with local anesthesia.

<u>HIV-associated Lipodystrophy Syndrome</u>: A syndrome that occurs in HIV-infected patients in response to some antiretroviral (ARV) drug therapy, characterized by abnormal fat metabolism and deposition. It is not a single syndrome but rather can be composed of three components that present together, or alone: lipoatrophy, lipohypertrophy, and metabolic disturbance (insulin resistance, hypercholesterolemia, and hypertriglyceridemia).

<u>Egrifta®</u> (<u>Tesamorelin injection</u>): Egrifta is a self-administered human growth hormone that was approved by the FDA in 2010 for the treatment of lipodystrophy in HIV infected adults. Egrifta induces and maintains a reduction of excess visceral abdominal fat.

<u>Facial Lipoatrophy</u>: Facial lipoatrophy is characterized by loss of the buccal and/or temporal fat pads, leading to facial skeletonization with concave cheeks, prominent nasolabial folds, periorbital hollowing, and visible facial musculature. Also referred to as facial lipodystrophy syndrome (LDS), and facial wasting. The two antiretroviral



drugs associated with causing HIV Facial Lipoatrophy are Zidovudine (Brand name: Retrovir; a component of Combivir and Trizivir) and Stavudine (Brand name: Zerit).

<u>Lipoatrophy</u>: Loss of fat from specific areas of the body, especially from the face, buttocks, and limbs.

<u>Lipohypertrophy</u>: Abnormal accumulation of fat, particularly within the abdomen, breast, dorsocervical region (back of neck and shoulders), front of the neck ("horse collar") and subcutaneous tissue (peripheral lipomatosis).

<u>Soft Tissue Fillers</u>: Soft tissue fillers, also known as injectable implants, dermal fillers, or wrinkle fillers are medical device implants approved by the FDA for use in helping to create a smoother and/or fuller appearance in the face, including nasolabial folds, cheeks, and lips and for increasing the volume of the back of the hand.

<u>Radiesse</u> (<u>Calcium hydroxylapatite</u>): Radiesse is a filler material for correction of moderate to severe facial wrinkles and folds. It was approved by the FDA in 2006 for facial lipoatrophy in people with HIV lipodystrophy. The effects of this material last approximately 18 months.

<u>Sculptra (Poly-L-lactic acid)</u>: Sculptra is a long lasting filler material that is given in a series of injections over a period of several months. The effects of Sculptra generally become increasingly apparent over time (over a period of several weeks) and its effects may last up to 2 years. In 2004 the FDA approved Sculptra as injectable filler to correct facial lipoatrophy in people with HIV lipodystrophy.

Related Policies

- Breast Surgeries Medical Policy
- Reconstructive and Cosmetic Procedures

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or payment.

The following list of codes applies to commercial and MassHealth plans only.

Authorized CPT/HCPCS Codes	Code Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, sculptra, 0.5 mg

Summary of Evidence

HIV-associated lipodystrophy syndrome includes both facial lipoatrophy and central fat accumulation, which require different treatment approaches, and associated metabolic abnormalities including dyslipidemia, insulin resistance, and diabetes mellitus, as described by Brown (2008). The literature spans clinical manifestations, diagnostic criteria, and various therapeutic approaches, with observational studies by Santos et al. (2019) and Dos Santos et al. (2018) establishing anthropometric criteria for diagnosis of the lipodystrophy syndrome. Several papers, including Thet and Siritientong (2020), explore the relationship between antiretroviral therapy and metabolic complications. The psychosocial impact of LDS is documented by Power et al. (2003) and Verolet



et al. (2015), highlighting its effects on quality of life and mental health. Coverage of medical, surgical, and drug treatments to correct or repair disturbances of body composition caused by HIV-associated lipodystrophy syndrome is mandated by Massachusetts General Laws Part I, Title XXII, Chapter 175, Section 47II for certain plans.

Treatment options for central fat accumulation include liposuction and excisional lipectomy. An early case series by Connolly et al (2004) suggested that liposuction could be effective for cervical lipohypertrophy ("buffalo hump"). Gold and Annino (2009) presented a small case series suggesting efficacy and safety of ultrasonic tumescent liposuction for cervical lipohypertrophy. A retrospective study by Barton et al. (2021) concluded that excisional lipectomy was generally superior to liposuction, with lower risks of recurrence, reoperation, and seroma formation.

Treatment options for lipoatrophy include autologous fat transfer and injection of synthetic dermal fillers. An early report by Comite et al. (2004) on the use of the facial filler calcium hydroxyapatite (Radiesse) showed initial improvement but need for retreatment at 1 month and decreased efficacy by 9 months. A larger single-arm trial of calcium hydroxyapatite by Silvers et al. (2006) showed that efficacy persisted at 1 year and at 18 months. A prospective case series by Duracinsky et al. (2014) showed that the dermal filler poly-L-lactic acid required up to 5 monthly treatments, and adverse events were noted in 18%. A nonrandomized prospective cohort study by Rozelar et al. (2014) showed that both calcium hydroxyapatite and poly-L-lactic acid treating yielded improvements at 1 year in quality of life and in total subcutaneous thickness in the injected areas on MRI. A nonrandomized prospective trial by Negredo et al. (2006) suggested that autologous fat transfer, poly-lactic acid, and polyacrylamide hydrogel were all safe and effective in treating facial lipoatrophy. Another nonrandomized prospective trial by Pavlidis et al. (2018) found that dermal fillers and autologous lipotransfer were both effective in the treatment of lipoatropy in the short term (at 1-2 months), but that autologous lipotransfer was more cost-effective than synthetic dermal fillers because of better durability at 1- and 2-year follow-up.

Based on the studies above, Mass General Brigham Health Plan covers dermal fillers, autologous fat transfer, drug therapy, liposuction, and surgical lipectomy for specific indications associated with HIV lipodystrophy syndrome in which those therapies have shown safety and efficacy.

Effective

March 2025: Off-cycle update. Summary of evidence added. References updated.

January 2025: Annual Review.

November 2024: Off-cycle update. MassHealth Variation language added. Added criteria from custom subset in InterQual®.

January 2024: Annual Review. Medicare Advantage added to table 1. Medicare Variation language added. References updated.

November 2023: Off-cycle update. Code added.

January 2023: Annual Review. References updated.

January 2022: Annual Review. References updated.

January 2021: Annual Review. Revised exclusions. References updated.

January 2020: Annual Review. References updated.

September 2018: Removed exclusion: liposuction for HIV associated lipodystrophy of the abdomen.

December 2017: Annual Review. November 2016: Effective date.

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