

<Insurance Co Name>
<Insurance Co Address>
<Patient Name>
<Subscriber #>

<Date>

RE: Medical Necessity of Restorative Treatment for Facial Deformities from HIV-Associated Lipoatrophy

To Whom It May Concern:

This letter is written in regards to the medical necessity of restorative treatment for the facial deformities this patient suffers from secondary HIV-associated lipoatrophy.

Facial fat loss is the most devastating aspect of this condition, as it cannot be disguised by clothing or other means. Although the exact underlying mechanism of HIV-associated lipoatrophy is unknown¹, the devastating effects of this condition are known.^{2,3} Patients suffering from this condition are at an increased risk of depression, socially withdrawn and potentially suicidal. Furthermore, patients have even stopped their life-saving HAART therapy without consulting their physician in an attempt to stop this side effect. The implications for viral mutations, increasing viral load and worsening of patients' underlying condition requiring more expensive treatments cannot be stressed enough.

The ICD9 diagnosis code for lipodystrophy is 272.6. HIV-related lipodystrophy syndrome consists of lipohypertrophy (fat accumulation in the visceral area and dorsocervical pad) and lipoatrophy (subcutaneous fat loss in the face, extremities and buttocks).

Treatment of HIV-associated lipoatrophy with Sculptra (poly-L-lactic acid) has been shown to improve anxiety and depression scores⁴ as well as improve patient's quality of life as measured by visual analogue scale.⁵ The use of Sculptra is clearly indicated as a reconstructive procedure; that is, repair of abnormal facial structure caused by HIV or its treatment, in order to re-establish a normal appearance.

Due to the medical necessity of this treatment and the availability of a safe and effective treatment option, pre-approval is hereby requested for treatment of this patient's HIV-associated facial lipoatrophy with Sculptra.

The U.S. Food and Drug Administration has evaluated the safety and efficacy of Sculptra in restoring the normal facial contours of patients suffering from HIV-associated facial lipoatrophy.⁶ Based on the available scientific evidence,^{4,5} the FDA granted approval of Sculptra as a restorative medical device for the specific indication of HIV-associated facial lipoatrophy in August 2004. As this approval is relatively recent, I would be happy to further educate your company on this issue in any way that you might deem helpful. Please feel free to contact me at the above office with any questions you may have.

Sincerely,

<Signature>
<Printed Name>

¹ Montessori, V. CMAJ. 2004;170:229-238.

² James J, Carruthers, A. Dermatol Surg. 2002;28:979-986.

³ Martinez, E. Drug Saf. 2001;24:157-166.

⁴ Moyle, GJ. HIV Medicine. 2004;5:82-87.

⁵ Valantin, M. AIDS. 2003;17:2471-2477.

⁶ FDA Scientific Advisory Panel. March 25, 2004, Washington, D.C.