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October 31, 2016

Laura Cheever, MD, ScM
Associate Administrator
HIV/AIDS Bureau
US Department of Health and Human Services
Health Resources and Services Administration

RE: Needed Update to the Guide for HIV/AIDS Clinical Care

Dr. Cheever,

I'm writing to you on behalf of the ADAP Advocacy Association (aaa+®) and its board of directors, as well as the ___ undersigned national, state, and local community organizations to request that the Bureau publish another update to the **Guide for HIV/AIDS Clinical Care** (hereafter, "The Guide"). The Guide outlines HIV-related protocols and clinical practices in HIV/AIDS treatment, but the current version doesn't accurately reflect the most up-to-date information about the treatment for lipodystrophy disease.

The Guide was last published in April 2014. In your commitment to continuously improve HIV/AIDS clinical care and provide updated information of importance to HIV/AIDS patients and clinicians, we urge you to update Section 6: Comorbidities, Co-infections, and Complications, Subsection: Abnormalities of Body-Fat Distribution, found on page 336 regarding the treatment of growth hormone-releasing factor.

> *Guide for HIV/AIDS Clinical Care*
> *April 2014*
> *Page 336*
>
> *"Abnormalities of Body-Fat Distribution*
> *Growth hormone-releasing factor*
> *Tesamorelin, a synthetic growth hormone-releasing factor analogue, is approved by the U.S. Food and Drug Administration (FDA) for the treatment of excess abdominal fat in HIV-infected persons with lipodystrophy. It has been shown to reduce central fat accumulation by about 18% over the course of 12 weeks, without adverse effects on glucose or lipid parameters. Unfortunately, patients rapidly regain visceral fat when tesamorelin is discontinued. That, along with its expense, has limited the use of tesamorelin. No long-term safety data are available."*

This section, as currently written, does a disservice to the needs of patients living with HIV-infection, and diagnosed with HIV-related abnormal accumulation of visceral adipose tissue (VAT) by concluding that the potential discontinued use of tesamorelin and its "expense" has limited its use. That is not the appropriate conclusion for a clinical reference guide for physicians, clinicians or patients.

As you may know, for any treatment to be effective, patients must remain on therapy. Patients with HIV-infection – and most notably those patients who are HIV/AIDS long-term survivors – know all too well how valuable compliance is to long-term health outcomes.

Ben Klein, Senior Attorney and AIDS Law Project Director, GLBTQ Legal Advocates & Defenders, accurately outlines the medical necessity associated with long-term therapy to combat lipodystrophy disease. According to Klein, "There is a debilitating and disfiguring side effect of early HIV medications that causes profound suffering among our longest-term survivors of the HIV epidemic. For some, it is so severe that they do not leave their homes and become shut-ins, depressed, and suicidal. For others it causes chronic physical pain and structural damage, including spine and neck problems. And for many it is an involuntary public disclosure of HIV, still the most stigmatized health condition in America. Most public and private insurers refuse to cover the simple, inexpensive, and effective medical treatments available to remedy it."[1]

Research has shown that between 20% and 30% of HIV-positive patients are experiencing excess VAT. For years, there's been a common misconception that this belly fat is just a physical cosmetic issue that is a side effect of earlier HIV treatments -- something that must be accepted as a reality of now living longer with HIV-infection. Recent research dispels that myth so that even with newer anti-retro viral regimens this condition continues to exist.

This research is already being reflected at the state level, particularly in Massachusetts. On November 9, 2016, "**An Act relative to HIV-associated lipodystrophy syndrome treatment**" (formerly, Bill S.2137) will go into effect in Massachusetts, and it shall guarantee "coverage for medical or drug treatments to correct or repair disturbances of body composition caused by HIV associated lipodystrophy syndrome including, but not limited to, reconstructive surgery, such as suction assisted lipectomy, other restorative procedures and dermal injections or fillers for reversal of facial lipoatrophy syndrome."[2]

It is also consistent with the findings by the U.S. Food & Drug Administration (FDA), upon approving tesamorelin as treatment for lipodystrophy. On November 10, 2010, Curtis Rosebraugh, M.D., M.P.H., director of the Office of Drug Evaluation II in the FDA's Center for Drug Evaluation and Research said, "The FDA recognizes the need for therapies to treat patients with HIV-lipodystrophy. The presence of excess fat with this condition may contribute to other health problems as well as affect a patient's quality of life, so treatments that demonstrate they are safe and effective at treating these symptoms are important."[3]

Therefore, we, the undersigned organizations urge The Bureau of HIV/AIDS to revise the Guide for HIV/AIDS Clinical Care to provide more accurate and detailed information regarding the treatment of tesamorelin on visceral adipose tissue (VAT).

Sincerely,

Brandon M. Macsata
CEO

[1] Klein, Ben, *GLBTQ Legal Advocates & Defenders, "Mandating Treatment for HIV-Related Lipodystrophy: The Massachusetts experience and a call for national action," August 25, 2016.*
[2] The Commonwealth of Massachusetts, 189th General Court, "*Bill S.2137*: *An Act relative to HIV-associated lipodystrophy syndrome treatment*," 2016.
[3] U.S. Food & Drug Administration, "*FDA approves Egrifta to treat Lipodystrophy in HIV patients*," November 10, 2010.

NATIONAL ADVOCACY/PROVIDER ORGANIZATIONS:

STATEWIDE ADVOCACY/PROVIDER ORGANIZATIONS:

LOCAL ADVOCACY/PROVIDER ORGANIZATIONS: