ADAP Advocacy Association
PO Box 15275
Washington, DC 20003

adapadvocacyassociation.org

November 21, 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+®), as well as the 52 undersigned national, state, and local organizations to request that the HIV/AIDS Bureau make a correction to the section "Abnormalities of Body-Fat Distribution" in the **Guide for HIV/AIDS Clinical Care** (hereafter, "The Guide") published in September 2016.[1] 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 correct the following statement regarding growth hormone-releasing factor.

> "*Unfortunately, when tesamorelin was discontinued, patients' visceral fat returned to baseline levels within 13 weeks. That, along with its expense and the fact that it requires subcutaneous injection, has limited the use of tesamorelin.*"

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" is 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."[2]

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) went 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.[3]

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."[4]

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

SUPPORTING ORGANIZATIONS:
AcadianaCares – Lafayette, LA
ACRIA – New York, NY
ADAP Educational Initiative – Columbus, OH
AIDS Action Committee of Massachusetts – Boston, MA
AIDS Alabama – Birmingham, AL
AIDS Support Group of Cape Cod – Hyannis, MA
All Under One Roof LGBT Advocates of Southeastern Idaho, Inc. – Poctello, ID
ALSO Youth, Inc. – Sarasota, FL
Anthony's Plot Community – Winston Salem, NC
Bradbury-Sullivan LGBT Community Center – Allentown, PA
CAEAR Coalition – Washington, DC
CenterLink: The Community of LGBT Centers -- Fort Lauderdale, FL
Community Access National Network (CANN) – Washington, DC
Community Research Initiative – Boston, MA
Demand Universal Healthcare (DUH) – Springfield, IL
Empower U Community Health Center – Miami, FL
Equality Weddings – Wilton Manors, FL
Fenway Health – Boston, MA

Foodexperience – Asheville, NC
Gay Men's Health Crisis (GMHC) – New York, NY
Georgia Equality – Atlanta, GA
GLBTQ Legal Advocates & Defenders – Boston, MA
HealthHIV – Washington, DC
Health Education Services – Durham, NC
Hepatitis Foundation International – Silver Spring, MD
HIV Dental Alliance – Atlanta, GA
HomeCare for the Carolinas – Charlotte, NC
Housing Works – Brooklyn, NY
Let's Kick ASS (AIDS SURVIVOR SYNDROME) – San Francisco, CA
LGBT Center of Raleigh – Raleigh, NC
Los Angeles LGBT Center – Los Angeles, CA
Miami Valley Positives for Positives – Dayton, OH
Miracle of LoVe – Leesburg, FL
Moveable Feast, Inc. – Baltimore, MD
Napo Pharmaceuticals – San Francisco, CA
National Association of Social Workers - Massachusetts Chapter – Boston, MA
NC AIDS Action Network – Raleigh, NC
New England AIDS Education and Training Center – Worcester, MA
Pride Center of Western New York – Buffalo, NY
Priority Health Care – Marrero, LA
PWN-USA-Louisiana – Baton Rouge, LA
Reaching All HIV+ Muslims In America (RAHMA) – Washington, DC
RiseUpToHIV, Inc. – Columbus, OH
Sacramento LGBT Community Center – Sacramento, CA
Salaam Legal Network & Citizens Council for Human Rights – Memphis, TN
SFAN South Florida AIDS Network of Broward County – Fort Lauderdale, FL
South Carolina HIV Task Force – Columbia, SC
The Center: 7 Rivers LGBTQ Connection – La Crosse, WI
The SOURCE LGBT+ Center – Visalia, CA
TPAN – Chicago, IL
Victory Programs – Boston, MA
Washington County Gay Straight Alliance, Inc. – Washington, PA

References

[1] Guide for HIV/AIDS Clinical Care, Section "Abnormalities of Body-Fat Distribution" (https://aidsetc.org/guide/abnormalities-body-fat-distribution). Accessed October 27, 2016.
[2] Klein, Ben, GLBTQ Legal Advocates & Defenders, "Mandating Treatment for HIV-Related Lipodystrophy: The Massachusetts experience and a call for national action," August 25, 2016.
[3] The Commonwealth of Massachusetts, 189th General Court, "Bill S.2137: An Act relative to HIV-associated lipodystrophy syndrome treatment," 2016.
[4] U.S. Food & Drug Administration, "FDA approves Egrifta to treat Lipodystrophy in HIV patients," November 10, 2010.