Common Drug Review
Patient Group Input Submissions

Tesamorelin (Egrifta) for lipodystrophy, HIV-infected patients

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Canadian Treatment Action Council (CTAC) — permission granted to post.

CADTH received patient group input for this review on or before March 28, 2016
CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter. This includes patient input received from individual patients and caregivers as part of that pilot project.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Canadian Treatment Action Council (CTAC)

Section 1 – General Information

Name of the drug CADTH is reviewing and indication(s) of interest	EGRIFTA (tesamorelin) for treatment of Lipodystrophy in HIV-infected patients.
Name of the patient group	[redacted]
Name of the primary contact for this submission:	[redacted]
Position or title with patient group	[redacted]
Email	[redacted]
Telephone number(s)	[redacted]
Name of author (if different)	
Patient group's contact information: Email	[redacted]
Telephone	[redacted]
Address	555 Richmond St. W. Ste 612.
Website	www.ctac.ca
Permission is granted to post this submission	Yes

1.1 Submitting Organization

The Canadian Treatment Action Council (CTAC) is Canada's national non-governmental organization addressing access to treatment, care and support for people living with HIV and hepatitis C. CTAC's organizational goals are to meaningfully engage community members, service providers, policymakers and other relevant stakeholders to identify, develop, and implement policy and program solutions. CTAC understands that treatment access should be considered in its holistic form, encompassing the range of treatment, care and support needs required to reach the most successful treatment experience possible for people living with HIV and/or viral hepatitis co-infection. Full CTAC membership is reserved for: a) individual people living with HIV (including HCV co-infection); b) organizations, groups or projects with a substantial HIV mandate (including HCV co-infection). Associate CTAC membership is open to any individual, organization, group or project that supports CTAC's mandate and objectives.

1.2 Conflict of Interest Declarations

CTAC received unrestricted organizational and/or educational grants from the following organizations in the 2015-2016 fiscal year: Abbott/Abbvie, Gilead Sciences, Janssen, and ViiV Healthcare.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

On March 15th, 2016, CTAC hosted a national patient input consultation webinar detailing some of the characteristics, properties, and major clinical findings associated with EGRIFTA. CTAC also related a helpful informational video overview of the Common Drug Review. The webinar was presented by policy researcher Adam Cook. Members of CTAC, organizational partners, and part webinar registrants were

invited to participate. In an attempt to secure the voice of more treatment-experienced individuals, principal investigators of the trials concerned were contacted and alerted to the Patient Input consultation. In total, 7 people registered for the webinar, 4 attended the live webinar, and the post-webinar survey received 7 responses. A link to the consultation webinar and web-based feedback survey was provided to webinar attendees and principal investigators by email and through CTAC's social media outlets (CTAC website, Youtube, Facebook, and Twitter). The survey was made available from March 16th, 2016 to March 28th, 2016. The Webinar video hosted on Youtube has accumulated 27 views as of this writing.

In total, CTAC has compiled data from 7 survey respondents. 4 respondents were female, 3 were male, and the respondents had a median age of 55. 4 were from Quebec and 3 were from Ontario. 6 identified as HIV positive, with one respondent being HIV negative, and all 6 HIV+ respondents reported that they were presently on HIV treatment. On average, respondents had been living with HIV for 25 years and been on treatment for 20 years. Most have been on their present treatment for at least 5 years. 4 different HAART regimens were represented amongst those with HIV treatment experience. 4 patients reported living with HIV-associated Lipodystrophy for an average of 12 years. 3 patients reported experience with EGRIFTA, while 3 patients reported they had no such treatment experience.

2.2 Impact of Condition on Patients

HIV is a serious, life-threatening illness that threatens the immune system. Over time, if left untreated, HIV can compromise a person's immune system to the point that the body may no longer be able to fight off opportunistic infections. As of 2011, 71 300 Canadians are living with HIV (Public Health Agency of Canada). Access, administration of and adherence to highly-active antiretroviral treatment (HAART) can control the progression of a person's HIV. In most cases, people taking HAART achieve an undetectable viral load (or viral suppression), the point at which there is so little HIV in the bloodstream (<50 copies/mL) that it cannot be detected by conventional medical technologies.

HIV-associated Lipodystrophy is the accumulation (lipohypertrophy) or loss (lipoatrophy) of fat in the body and it is unclear if this process is related to HIV infection or the use of HAART therapies to treat HIV infection. EGRIFTA is an injected therapy of thesamorelin that is designed to treat a specific form of lipohypertrophy resulting in increased Visceral Adipose Tissue (VAT). VAT is accumulated fat in the abdomen, or belly area, and is characterised by being "hard" fat. VAT accumulates deep in the abdomen in surrounds internal organs. VAT builds up over time and is very difficult to reduce with diet and exercise. Excessive VAT occurs in approximately 10% of people living with HIV, and can be diagnosed by a general physician based on physical measurements.

The psycho-social impact of VAT was reported by survey respondents very clearly. Many respondents reiterated that whether VAT was caused by HIV infection or HAART, it was a serious problem.

"My arms and legs have no fat and little muscle. My abdomen is huge. YOU PUT UP WITH THIS."

"having a fat gut with a treatment that is overly expensive and denied by those not infected is huge is the worst."

Research also shows that there are possible clinical consequences of HIV-associated Lipohypertrophy, such as neurocognitive disorders, increased overall mortality, decreased adherence to HAART, and

cardio-metabolic complications. Further, there is significant evidence suggesting that excess VAT is an indication of dysfunctional adipose tissue, which can itself indicated a larger metabolic problem.
"Less body fat will improve how I feel about myself. I have high tryclycerides and take medication for that. Perhaps having less body fat will improve that and help me fight any cardiovascular illness in the future."

(Lichtenstein KA, *JAIDS* 2005; Kovacs, JAMA 2006.)
(U.S. Department of Health & Human Services. 2009; Schambelan M, et al. *J Acquir Immune Defic Syndr*. 2002.)
(Després J.P. and I. Lemieux, *Nature* 2006;444:881-87)

2.3 Patients' Experiences With Current Therapy

6 respondents identified as HIV positive, with one respondent being HIV negative, and all 6 HIV+ respondents reported that they were presently on HIV treatment. On average, respondents had been living with HIV for 25 years and been on treatment for 20 years. Most have been on their present treatment for at least 5 years. 4 different HAART regimens were represented amongst those with HIV treatment experience.

Most patients were pleased with their HIV treatment experience and present regimen.
"Very effective. Undetectable viral load, apart from a blip or two. I was undetectable when I started this treatment, switch due to tolerability. Previously on Sustiva, 3TC and Tenofovir (intolerant of the Sustiva...sleep issues) First treatment Crixivan, d4T and 3TC, source of my lipoaccumulation problem (apart from diet and exercise)"

"Health is better. I'm sure if I hadn't every gone on treatment wouldn't be here today."

However, some patients reported that their HIV therapy was still problematic.

"No! I'm in constant pain. Have no energy, and as a heterosexual, there is NO social events for me because of the stigma."

"Too soon to tell long term but huge headaches, muscle pain, bone pain."

"Low energy and increasingly lower - although is that related to the HIV treatment or other?"

Other than EGRIFTA, we are unaware of any other therapy available in Canada for the treatment of HIV-associated accumulation of excessive Visceral Adipose Tissue.

4 patients reported living with HIV-associated Lipodystrophy for an average of 12 years. 3 patients reported experience with EGRIFTA, while 3 patients reported they had no such treatment experience. Those who had experience with EGRIFTA noted its efficacy, but that it had to be used regularly and for the rest of a patient's life. That this meant regular injections as well as the possibility of a reversal of effects in the absence of use were concerns for patients with one patient noting that "*the complexity of Egrifta and the fact that it is a chronic treatment could outweigh those effects."* Further, a treatment-experienced patient reported an unanticipated social impact of using EGRIFTA that was problematic:

"difficulty of administering treatment (injection to prepare in several steps) and challenges to mobility

(travelling with syringes, water and freezer pack difficult for air travel and refrigeration away from home)."
Ultimately, however, patients with histories of using EGRIFTA were pleased with their experience, reporting that "*I did not have problems with side effects, not even injection site reactions,"* and *"the side effects already reported 'make sense' and are 'manageable.'"*

2.4 Impact on Caregivers

Respondents noted that most impacts of HIV-associated lipodystrophy, and specifically, excessive VAT, were associated with self-esteem issues, negative body image, impacts to quality of life, and problems socializing. Respondents reiterated a continuing issue with providing care for people living with HIV in rural areas, with one caregiver noting: *"The challenges involve the lack of rural medical staff. Ignorance and discrimination by LGBT agenda that refuses to include ALL people with HIV."* Suggesting that, within the HIV community itself, those living with excessive VAT and lipodystrophy suffer additional stigma. A Caregiver with experience in serving those with excessive VAT and HIV shared the following experience regarding the impact of lipodystrophy:

"As a health care provider and a researcher who has been conducting qualitative studies on lipodystrophy, I think Egrifta has the potential to positively impact body image, self-esteem, physical and mental health, quality of life and well-being. However, I don't think it is a quick and easy fix to abdominal lipohypertrophy. It is another medication people have to take. It is administrated SQ (which is complex on its own). Its effects are not permanent. Regardless of this, I think it should be made available and covered because it constitutes one option - the only one on the market - to address this problem."

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Information in this section was gathered in the same means and method as outlined in section 2.1.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

Patients with treatment experience using EGRIFTA noted that, as the *only* treatment option for HIV-associated VAT, they had every expectation that it would be recommended for public reimbursement.

"People who suffer from lipodystrophy have no options to address this problem. Coverage of poly-L-lactic acid (NewFill) for people who have facial lipoatrophy has never been achieved in Canada as opposed to other countries - this is something CTAC should consider working on. Coverage of Egrifta for people who have abdominal lipohypertrophy should be provided because it remains the only pharmacological option available."

Other patients noted that positive clinical benefits associated with reduced VAT were a bonus compared to the anticipated improvements to one's self-esteem that came with reduced lipohypertrophy, reporting "*If it will get rid of the lipodystrophy, then I will have my self esteem back*." However, the reduction in overall mortality associated with reduced VAT was an important factor to patients, several

of whom noted "*It is possible that the impact internally (VAT around the organs) is less perceivable to the individual, but impactful on health."*

Patients who had no experience with EGRIFTA nevertheless had high hopes for the medicine and its ability to address VAT and help improve existing self-esteem issues associated with negative body image.

"Less body fat will improve how I feel about myself. I have high tryclycerides and take medication for that. Perhaps having less body fat will improve that and help me fight any cardiovascular illness in the future."

Section 4 — Additional Information

CTAC continues to acknowledge and appreciate CADTH and CDEC suggestions as to how to improve patient input submissions, and is motivated to discuss revisions, reform, and refinements to the patient input process that can better represent the patient voice as well as improve the work of not only submitting organizations, but the CDR as a whole.