

Illinois Medication Assistance Program – ADAP Open Formulary Exclusions

Specific Exclusions	Examples
Certain HIV Medications	Symtuza
Antirheumatic injectables	Enbrel
Botulinum toxin	Botox, Myobloc
Compounded medications for infusion (Active medication containing more than one ingredient)	
Gonadotropin	
Finasteride (Propecia) (Approved for prostate disorders only)	
Hyaluronic acid derivatives	Hyalgan, Synvisc
Immune globulin intravenous (IGIV)	Sandoglobulin, Venoglobulin
Injectable muscle relaxants	Lioresal
Mifepristone	
Minoxidil (Rogaine)	
Monoclonal antibodies	Remicade, Synagis
Nutritional supplements*	Ensure
Propoxyphene	
Recombinant human growth hormone (HGH)	Geref, Humatrope
Synthetic growth hormone	

Class Exclusions	Examples
Durable Medical Equipment**	Test strips; Lancet, Meters
Cosmetic Medications	
Erectile Dysfunction Pharmaceuticals	Viagra, Levitra, Cialis, Caverject
Female Sexual Dysfunction Pharmaceuticals	
Fertility Drugs	Addyi (flibanserin)
Herbal Medications	
Vaccines/Immunizing Biologicals	Zostavax

All Controlled Substances (C-II, C-III, C-IV, and C-V) are EXCLUDED with the exception of the following:

- Anabolic steroids used to treat testosterone deficiencies (depo-testosterone, aveed, axiron, oxandrolone, etc....)
- Anti-diarrheals (lomotil, diphenoxylate/atropine)
- Orexigenic (marinol, dronabinol)

*Vitamins (based on availability of State General Revenue Funds) and pain relievers (i.e. ibuprofen), sharps container, alcohol wipes and band aids are covered when prescribed by a physician. All other OTCs will be excluded. *

**Syringes for insulin injection only are covered.

*** All medications must be order/shipped through IDPH's contracted pharmacy.

**ILLINOIS DEPARTMENT OF PUBLIC HEALTH AIDS DRUG ASSISTANCE PROGRAM (ADAP)
PRESCRIBING GUIDELINES**

Drugs provided by the AIDS Drug Assistance Program (ADAP) **MUST** not exceed a \$2,000 per month benefits cap and **MUST** be prescribed in accordance with these guidelines. Revisions to prescribing guidelines may be made upon recommendations of the Department's ADAP Medical Issues Advisory Board.

CATEGORY I

- Category I anti-retroviral therapies should be prescribed in accordance with the latest Public Health Service guidelines. <http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf>
- All newly FDA approved anti-retroviral therapies will be considered for addition to the formulary, however:
 - **No more than five (5) drugs* from Category I (and Fuzeon)** prescribed concurrently (Up to two protease inhibitors or a protease inhibitor and an NNRTI may be provided concurrently), except with prior approval from ADAP. **There are no exceptions to this prescribing guideline**, except ritonavir (Norvir), at a reduced dosage may be prescribed for pharmacokinetic (PK) boosting, cobicistat (Tybust), and
 - Any change in Category I therapies will require a discontinuation order of the old prescription to be sent or faxed to CVS Caremark Pharmacy before the new order can be filled.
 - Combivir, Truvada, and Epzicom are fixed dose combinations and are considered two (2) drugs when ordered.
 - Trizivir, Atripla, Stribild, Complera and Triumeq are fixed-dosage combinations of 3 drugs and are considered three (3) drugs when ordered.
 - Kaletra contains Norvir at a reduced dosage and is considered one plus PK boosted drug when ordered.
- HIV co-receptor (CCR5 and/or CXCR4) tropism assay must be run and submitted to ADAP prior to prescribing Selzentry.

CATEGORY II

- Atovaquone (Mepron) prescriptions will require prior approval in all the following situations:
 - used for more than 21 days
 - used as prophylaxis (rather than treatment)
 - more than one prescription per year is written for a patient not approved for use of atovaquone as prophylaxis. Pre-approval form will be available on the IDPH website (www.idph.state.il.us).
- Ritonavir (Norvir) - tablets will be dispensed unless other formulations are required by prescriber due to tolerance issues. ADAP may require prior approval for other formulations.

CATEGORY V

- Enfuvirtide (Fuzeon); requires a separate application. Eligibility is based on medical criteria, with a cap limit of 15 clients. Prior approval by the Department will be faxed, via electronic file to the pharmacy as authorization. Fuzeon is considered one of the five (5) drugs along with those in Category 1.
- Valganciclovir (Valcyte) oral only: limited to a cap of 35 clients concurrently.

- Atovaquone (Mepron) – see notes under Category II.
- Neither enfuvirtide (Fuzeon) nor valganciclovir (Valcyte) are considered within the \$2,000 dollar monthly benefits cap.
- Hepatitis C – Harvoni (ledipasvir/sofosbuvir), Viekira Pak, Sovaldi (sofosbuvir), Ribavirin, Zepatier; Technivie, Daklinza
- Epclusa will be limited to a cap of 100 clients concurrently and then will move to a waiting list. Treatment is a 12, 16 or 24 week regimen. Hepatitis C drugs will not count toward the \$2,000 dollar monthly benefit cap. Hepatitis C drugs will require prior approval, which the prior approval form can be found [here](#). To be eligible one must meet the following:
 - Be currently enrolled in ADAP and eligible for ADAP assistance for the full duration of treatment
 - Be a patient who has Fibrosis Stage 2 (F2) and above
 - Have been denied medication coverage by their insurance plan (if they have insurance) – Documentation required
 - For Zepatier: If Genotype 1a – Need baseline NS5A resistance test and documentation.
 - Physician has reviewed the Manufacturers Prescribing Guidelines for possible drug interactions and issues associated with the Hepatitis C medication regimen they are prescribing in conjunction with their client’s current HIV regimen.
- **Egrifta** – assistance requires a “Statement of Medical Necessity” to be filled out and faxed to Manufacturer to get Authorization Code that needs to be given to ADAP for CVS to dispense the medication. You will find the form attached.

OTHER GENERAL GUIDELINES

- **All prescriptions** for multi-source drugs (drugs available in a brand-name and equal or greater than 1 generic formulation) will be filled with the lowest cost option available. Use of brand name drugs on the ADAP formulary is for informational purposes only.
- For coverage under ADAP, prescriptions for multi-source drugs should be written indicating “**product substitution permitted**” to ensure all efforts for fiscal stewardship are able to be implemented by ADAP through its dispensing pharmacy. In addition, this procedure will reduce the number of call-backs to prescribers by dispensing pharmacy.
- **All prescriptions** must be written for **no more than 3 refills**. Then the client will be required to re-visit their HIV Care Provider before a new prescription can be written.
- **All pre-approval** form can be located on the IDPH website (www.idph.state.il.us) for all prescriptions requiring pre- approval.

Guidance References for Primary Care Protocol for Hormone Treatment for Gender Transition and Maintenance:

The Center for Excellence for Transgender Health - *Primary Care Protocol -Hormone Administration*:
<http://transhealth.ucsf.edu/trans?page=protocol-hormones>

The World Professional Association for Transgender Health - *Standards of Care*:
http://www.wpath.org/uploaded_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf

***** All medications must be order/shipped through IDPH’s contracted pharmacy.**

STATEMENT OF MEDICAL NECESSITY

To help HIV-infected patients with excess abdominal fat obtain EGRIFTA® through EGRIFTA ASSIST®, you need to fax this completed form and the accompanying PATIENT AUTHORIZATION to:

FAX: 1-855-836-3069

EGRIFTA® is only available through specialty pharmacies.

All information is required unless otherwise noted.

Physician and Practice Information

Name _____
 Office/Clinic/Institution _____
 Street Address _____
 City _____ State _____ Zip _____
 Phone # _____ Fax _____
 NPI # _____ Tax ID# _____ DEA# _____
 Medicaid # _____
 Email Address (optional) _____

Office Contact

Name _____ Phone # _____

Medical History

The patient is currently receiving anti-retroviral therapy (ART) YES NO

Please provide the patient's:

Blood Fasting Glucose _____ mg/dL BMI _____ kg/m²

Waist Circumference _____ cm Hip Circumference _____ cm

Waist-to-hip Ratio _____

NOTE: Waist-to-hip ratio can be important for payor approval. Please use this formula: Waist-to-hip ratio = Waist Circumference ÷ Hip Circumference

Would the patient benefit from injection training? YES NO

NOTE: Patients who can benefit from injection training will receive a phone call to help guide them through the self-administration process. Additionally, patients may call EGRIFTA ASSIST® with medically related questions or visit EGRIFTA.com to view an instructional administration video.

Patient's Personal Information

Name _____
 Date of Birth _____
 Gender Male Female Last 4 Digits of SS# (optional) _____
 Street Address _____
 City _____ State _____ Zip _____
 Primary Phone # _____
 Cell Phone # (optional) _____
 Email Address (optional) _____

By providing your name, email address, or other personal information, you are giving Theratechnologies Inc. and companies working on our behalf permission to communicate with you about EGRIFTA® via mail, email, phone, or text. We will not sell or transfer your name, street address, or other personally identifiable information about you to any party for its own marketing use.

Insurance Information

Diagnosis _____ Diagnosis Code _____

The ICD-10 code for excess abdominal fat in HIV patients with lipodystrophy (the indication for EGRIFTA®) is E88.1.

NOTE: Without providing the above diagnosis and diagnosis code, this form cannot be processed.

Primary Insurance _____

Insurance ID _____

Copy of front and back of insurance card included

NOTE: Prescriptions cannot be processed unless copies of both sides of the insurance card are included.

For Office Use Only

EGRIFTA ASSIST® Patient ID# _____

Please see Important Safety Information for EGRIFTA® on pages 3 and 4.

Rx and Statement of Medical Necessity to be Completed and Signed by Physician

Prescription: EGRIFTA® (tesamorelin for injection) with injection kit

Ship to: Home Physician's Office

Number of Refills _____

Additional Instructions _____

Preferred Specialty Pharmacy (optional) _____

Physician Certification: I certify that the prescribed therapy is medically necessary, that the information in this Statement of Medical Necessity is accurate to the best of my knowledge, and that I am aware of the risks and benefits associated with the use of EGRIFTA®. I authorize Theratechnologies Inc. (1) to provide any information on this form to the insurer of the named patient and (2) forward the above prescription.

Name _____ Date _____ Signature _____

NOTE: Physician needs to sign and date in order for the prescription to be filled.

Visit EGRIFTA.com to download copies of this form.

PATIENT AUTHORIZATION

To help HIV-infected patients with excess abdominal fat obtain *EGRIFTA*® through *EGRIFTA ASSIST*®, you need to fax this completed form and the accompanying **STATEMENT OF MEDICAL NECESSITY** to:

FAX: 1-855-836-3069

EGRIFTA® is only available through specialty pharmacies.

Information to be Completed and Signed by Patient

Name _____

Street Address _____

Primary Phone # _____

Cell Phone # (optional) _____

Date of Birth _____

Authorization to Use and Disclose Protected Health Information

I authorize health care providers and their staff involved in my care to disclose my Protected Health Information (as hereafter defined), including but not limited to my medical record and other health information on my completed Statement of Medical Necessity form or other forms, records that may contain information created by other persons or entities, including physicians and other health care providers, as well as information regarding the use of drug and alcohol treatment services, confidential HIV/AIDS treatment, including HIV test results, and mental health services (excluding psychotherapy notes) (collectively, “Protected Health Information”), to Theratechnologies Inc. and its agents and representatives (collectively, “Theratechnologies”), so that Theratechnologies may, among other things:

- (1) facilitate the filling of my prescription for and the delivery and administration of *EGRIFTA*®;
- (2) assist me in obtaining insurance coverage for *EGRIFTA*®;
- (3) contact me by mail, email, and/or telephone to enroll me in, and administer, programs that provide *EGRIFTA*® support services;
- (4) provide me with free educational information and materials; and
- (5) conduct surveys to measure my satisfaction with *EGRIFTA*® and *EGRIFTA*® support services.

I understand that once my Protected Health Information is disclosed pursuant to this authorization, it may no longer be protected by the federal privacy law and regulations known as “HIPAA” or state privacy laws and may be subject to further disclosure by Theratechnologies and other third parties with whom Theratechnologies may share the information. However, other state and federal laws may prohibit the recipient from disclosing specially protected information such as substance abuse treatment information, HIV/AIDS-related information, and psychiatric/mental health information.

I understand that I may refuse to sign this authorization and such refusal will not affect my ability to receive *EGRIFTA*®, but it may limit my ability to receive certain support services for *EGRIFTA*® that are provided by Theratechnologies.

I understand that health care providers may receive compensation as a result of their disclosure of my Protected Health Information as described herein.

I understand that this authorization will remain in effect for 10 years from the date of my signature, unless I revoke it in writing earlier by contacting Theratechnologies c/o inVentiv Health, 500 Atrium Drive, Somerset, NJ 08873.

If I revoke this authorization, health care providers will stop using and disclosing my information for the purposes outlined herein as soon as possible, but the revocation will not affect prior use or disclosure of my information in reliance on this authorization, and my revocation will have no effect on any third parties who may have received my Protected Health Information pursuant to this authorization, including Theratechnologies.

I understand that the support services provided by Theratechnologies that are described in this authorization can be changed at any time, without prior notification.

I have the right to receive a copy of this authorization.

 Patient Name or Authorized Representative Date
 (please print)

 Patient Signature

If Authorized Representative please state basis for authority:

NOTE TO RECIPIENT OF INFORMATION:

HIV Related Information: To the extent that HIV-related information has been provided to you, such information has been disclosed to you from records whose confidentiality may be protected by federal and state law. Such laws may prohibit you from making any further disclosure of the HIV-related information without the specific written consent of the person to whom it pertains, or as otherwise permitted by said laws. When obtaining such written consent, you must expressly identify that HIV-information is being disclosed (a general authorization for the release of the entire medical file, for example, is **NOT** sufficient for this purpose). An oral disclosure shall be accompanied or followed by such notice within ten days.

Indication and Important Risk Information for EGRIFTA[®]

Indication

EGRIFTA[®] is indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Limitations of Use:

- Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of EGRIFTA[®] treatment have not been studied and are not known, careful consideration should be given whether to continue EGRIFTA[®] treatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan
- EGRIFTA[®] is not indicated for weight loss management (weight neutral effect)
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking EGRIFTA[®]

Contraindications

- Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism or pituitary tumor/surgery, head irradiation or head trauma
- Active malignancy (either newly diagnosed or recurrent). Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with EGRIFTA[®]
- Known hypersensitivity to tesamorelin and/or mannitol
- Women who are pregnant; if pregnancy occurs during treatment, discontinue EGRIFTA[®] therapy

Warnings and Precautions

Neoplasms: EGRIFTA[®] induces the release of endogenous growth hormone (GH), a known growth factor. Thus, patients with active malignancy should not be treated with EGRIFTA[®]. For patients with a history of non-malignant neoplasms, EGRIFTA[®] therapy should be initiated after careful evaluation of the potential benefit of treatment. For patients with a history of treated and stable malignancies, EGRIFTA[®] therapy should be initiated only after careful evaluation of the potential benefit of treatment relative to the risk of re-activation of the underlying malignancy. In addition, the decision to start treatment with EGRIFTA[®] should be considered carefully based on the increased background risk of malignancies in HIV-positive patients.

Elevated IGF-1: EGRIFTA[®] stimulates GH production and increases serum IGF-1. Given that IGF-1 is a growth factor and the effect of prolonged elevations in IGF-1 levels on the development or progression of malignancies is unknown, IGF-1 levels should be monitored closely during EGRIFTA[®] therapy. Careful consideration should be given to discontinuing EGRIFTA[®] in patients with persistent elevations of IGF-1 levels (eg, >3 SDS), particularly if the efficacy response is not robust (eg, based on visceral adipose tissue changes measured by waist circumference or CT scan). During the clinical trials, patients were monitored every three months. Among patients who received EGRIFTA[®] for 26 weeks, 47.4% had IGF-1 levels greater than 2 standard deviation scores (SDS), and 35.6% had SDS >3, with this effect seen as early as 13 weeks of treatment. Among those patients who remained on EGRIFTA[®] for a total of 52 weeks, at the end of treatment 33.7% had IGF-1 SDS >2 and 22.6% had IGF-1 SDS >3.

Fluid Retention: Fluid retention may occur during EGRIFTA[®] therapy and is thought to be related to the induction of GH secretion. It manifests as increased tissue turgor and musculoskeletal discomfort resulting in a variety of adverse reactions (eg, edema, arthralgia, carpal tunnel syndrome) which are either transient or resolve with discontinuation of treatment.

Glucose Intolerance: EGRIFTA[®] treatment may result in glucose intolerance. Patients treated with EGRIFTA[®] are at an increased risk of developing diabetes (HbA1c \geq 6.5%). In clinical trials at week 26, a greater percentage of patients had elevated HbA1c (\geq 6.5%) in the EGRIFTA[®] group than in the placebo group (4.5% vs 1.3%). Glucose status should be carefully evaluated prior to initiating EGRIFTA[®] treatment and monitored periodically for changes in glucose metabolism to diagnose those who develop impaired glucose tolerance or diabetes. Caution should be exercised in treating patients with EGRIFTA[®] if they develop these conditions and discontinuation of treatment should be considered in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue by waist circumference or CT scan measurements. Since EGRIFTA[®] increases IGF-1, patients with diabetes who are receiving ongoing treatment with EGRIFTA[®] should be monitored at regular intervals for potential development or worsening of retinopathy.

Hypersensitivity Reactions: Hypersensitivity reactions may occur in patients treated with EGRIFTA[®]. Hypersensitivity reactions occurred in 3.6% of patients with HIV-associated lipodystrophy treated with EGRIFTA[®] in the Phase 3 clinical trials. These reactions included pruritus, erythema, flushing, urticaria, and other rash. In cases of suspected hypersensitivity reactions, patients should be advised to seek prompt medical attention and treatment with EGRIFTA[®] should be discontinued immediately.

Important Risk Information for EGRIFTA[®] (continued)

Injection-Site Reactions: EGRIFTA[®] treatment may cause injection-site reactions, including injection-site erythema, pruritus, pain, irritation, and bruising. The incidence of injection-site reactions was 24.5% in EGRIFTA[®]-treated patients and 14.4% in placebo-treated patients during the first 26 weeks of treatment in the Phase 3 clinical trials. For patients who continued EGRIFTA[®] for an additional 26 weeks, the incidence of injection-site reactions was 6.1%. In order to reduce the incidence of injection-site reactions, it is recommended to rotate the site of injection to different areas of the abdomen.

Acute Critical Illness: Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic amounts of growth hormone. EGRIFTA[®] has not been studied in patients with acute critical illness. Since EGRIFTA[®] stimulates growth hormone production, careful consideration should be given to discontinuing EGRIFTA[®] in critically ill patients.

Adverse Reactions

- The most commonly reported adverse reactions are hypersensitivity (eg, rash, urticaria) reactions due to the effect of GH (eg, arthralgia, extremity pain, peripheral edema, hyperglycemia, carpal tunnel syndrome), injection-site reactions (injection-site erythema, pruritus, pain, urticaria, irritation, swelling, hemorrhage)
- During the first 26 weeks of treatment (main phase), discontinuations as a result of adverse reactions occurred in 9.6% of patients receiving EGRIFTA[®] and 6.8% of patients receiving placebo. Apart from patients with hypersensitivity reactions identified during the studies and who were discontinued per protocol (2.2%), the most common reasons for discontinuation of EGRIFTA[®] treatment were adverse reactions due to the effect of GH (4.2%) and local injection-site reactions (4.6%)
- During the following 26 weeks of treatment (extension phase), discontinuations as a result of adverse events occurred in 2.4% of patients in the T-T group (patients treated with tesamorelin for Week 0-26 and with tesamorelin for Week 26-52) and 5.2% of patients in the T-P group (patients treated with tesamorelin for Week 0-26 and with placebo for Week 26-52)

Immunogenicity

Antibody formation may occur with the use of therapeutic peptide products. Anti-tesamorelin IgG antibodies were detected in approximately half of patients treated with EGRIFTA[®] and generally disappeared over time after discontinuation of treatment. Antibodies did not appear to impact the efficacy of EGRIFTA[®].

Drug Interactions

Cytochrome P450-Metabolized Drugs: Co-administration of EGRIFTA[®] with simvastatin, a sensitive CYP3A substrate, showed that EGRIFTA[®] had no significant impact on the pharmacokinetic profiles of simvastatin in healthy subjects. Because tesamorelin stimulates GH production, careful monitoring is advisable when EGRIFTA[®] is administered in combination with other drugs known to be metabolized by CYP450 liver enzymes.

For information about additional drug interactions, please refer to the provided full Prescribing Information.

Use in Specific Populations

Nursing Mothers: Because of both the potential for HIV-1 infection transmission and serious adverse reactions in nursing infants, mothers receiving EGRIFTA[®] should be instructed not to human milk-feed. It is not known whether EGRIFTA[®] is excreted in human milk.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established. EGRIFTA[®] should not be used in children with open epiphyses, among whom excess GH and IGF-1 may result in linear growth acceleration and excessive growth.

Geriatric Use: There is no information on the use of EGRIFTA[®] in patients greater than 65 years of age with HIV and lipodystrophy.

Renal and Hepatic Impairment: Safety, efficacy, and pharmacokinetics of EGRIFTA[®] in patients with renal or hepatic impairment have not been established.

For complete disclosure of EGRIFTA[®] product information, please read the Full Prescribing Information, Patient Information, and Instructions for Use.

For more information about EGRIFTA[®], please visit EGRIFTA.com or contact the EGRIFTA ASSIST[®] program toll-free at 1-844-EGRIFTA (1-844-347-4382).