# FORMULARY EXCLUSIONS

## Specific Exclusions

<table>
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<th>Exclusions</th>
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<td>Certain HIV Medications</td>
<td>Pifeltro (doravirine), Delstrigo</td>
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<tr>
<td>Antirheumatic injectables</td>
<td>Enbrel</td>
</tr>
<tr>
<td>Botulinum toxin</td>
<td>Botox, Myobloc</td>
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<tr>
<td>Compounded medications for infusion</td>
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<tr>
<td>(Active medication containing more than one ingredient)</td>
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<tr>
<td>Gonadotropin</td>
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<tr>
<td>Finasteride (Propecia)</td>
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<tr>
<td>(Approved for prostate disorders only)</td>
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<tr>
<td>Hyaluronic acid derivatives</td>
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<tr>
<td>Immune globulin intravenous (IGIV)</td>
<td>Hyalgan, Synvisc Sandoglobulin, Venoglobulin Lioresal</td>
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<tr>
<td>Injectable muscle relaxants</td>
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<tr>
<td>Mifepristone</td>
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<tr>
<td>Minoxidil (Rogaine)</td>
<td>Remicade, Synagis</td>
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<tr>
<td>Monoclonal antibodies</td>
<td></td>
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<tr>
<td>Nutritional supplements¹</td>
<td>Ensure</td>
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<tr>
<td>Propoxyphene</td>
<td>Geref, Humatrope</td>
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<tr>
<td>Recombinant human growth hormone (HGH)</td>
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<td>Synthetic growth hormone</td>
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<tr>
<td>Alirocumab (Praluent)</td>
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<tr>
<td>Evolocumab (Repatha)</td>
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## Class Exclusions

<table>
<thead>
<tr>
<th>Exclusions</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Durable Medical Equipment²</td>
<td>Test strips; Lancet, Meters</td>
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<tr>
<td>Cosmetic Medications</td>
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<tr>
<td>Erectile Dysfunction Pharmaceuticals</td>
<td>Viagra, Levitra, Cialis, Caverject</td>
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<tr>
<td>Female Sexual Dysfunction Pharmaceuticals</td>
<td></td>
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<tr>
<td>Fertility Drugs</td>
<td>Addyi (flibanserin)</td>
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<tr>
<td>Herbal Medications</td>
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<tr>
<td>Vaccines/Immunizing Biologicals</td>
<td>Zostavax</td>
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<tr>
<td>Weight Loss Medications</td>
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</tbody>
</table>

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)

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

¹ 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.

² Syringes are covered for insulin injection only.

Revised: 03/16/2020
PREScribing GuidELines

Drugs provided by the Medication Assistance Program (MAP), also known as the AIDS Drug Assistance Program (ADAP) MUST be prescribed in accordance with these guidelines. Revisions to prescribing guidelines may be made upon recommendations of either the Department’s Medical Director, HIV/AIDS Section Chief, or the ADAP Medical Issues Advisory Committee.

All medications must be ordered/shipped through the Department’s contracted dispensing pharmacy.

1. Anti-retroviral therapies should be prescribed in accordance with the latest Public Health Service guidelines. [http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf](http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf)

2. All newly FDA approved anti-retroviral therapies will be considered for addition to the formulary after the ADAP Medical Issues Advisory Committee has negotiated price on the medication. Please reference the ADAP Open Formulary Exclusions for the most current program exclusions ([https://iladap.providecm.net](https://iladap.providecm.net)).

3. ALL prescriptions for multi-source drugs (drugs available in a brand-name and equal or greater than one 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.
   a. 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 contracted dispensing pharmacy. In addition, this procedure will reduce the number of call-backs to prescribers by the dispensing pharmacy.

4. All prescriptions must be written for refills to follow the industry standard. However, prescriptions and refills should not supersede the client’s ADAP eligibility period.

5. HIV co-receptor (CCR5 and/or CXCR4) tropism assay must be run and submitted to ADAP prior to prescribing Selzentry.

6. Egrifta requires a “Statement of Medical Necessity” to be filled out and faxed to the Manufacturer to get an Authorization code to be given to ADAP for our contracted pharmacy to dispense the medication. Statement of Medical Necessity form is attached.

7. Ritonavir (Norvir) tablets will be dispensed unless other formations are required by the prescriber due to tolerance issues. ADAP may require prior approval for other formulations.

8. The following drugs will require prior approval from the Department. All prior approval applications, including eligibility criteria and requirements, can be found at [https://iladap.providecm.net](https://iladap.providecm.net).
a. **Atovaquone (Mepron)** requires prior approval in all of the following situations:
   i. Used for more than 21 days.
   ii. Used as prophylaxis (rather than treatment).
   iii. More than one prescription per year is written for a patient not approved for use of Atovaquone as prophylaxis.

b. **Enfurvirtide (Fuzeon)** is limited to a cap of 15 clients concurrently. Eligibility is based on the following medical criteria:
   i. Failure of the current HAART regimen.
   ii. CD4 count less than 500.
   iii. Viral load greater than 500.

c. **Valganciclovir (Valcyte)** oral only, limited to a cap of 35 clients concurrently. Must meet one of the following:
   i. Prescribed for induction or maintenance treatment of cytomegalovirus (CMV) retinitis, or
   ii. Prescribed for a condition other than retinitis that is due to CMV.

d. **Ibalizumab-uiyk (Trogarzo)** requires pre-approval from the Department, as well as the attached Manufacturer's Enrollment Form. Trogarzo is limited to a cap of 20 clients concurrently. The Department encourages clients to be dually enrolled in RWPB Case Management for payment of Trogarzo infusion costs.
   i. Eligible patients must have a history of multi-drug resistant HIV infection.
   ii. Trogarzo must be shipped directly to a medical facility/infusion site.

e. **Hepatitis C** prior approval medications include:
   i. Harvoni (ledipasvir/sofosbuvir), Viekira Pak, Sovaldi (sofosbuvir), Ribavirin, Zepatier, Technivie, Daklinza, Epclusa, Vosevi, Mavyret
   ii. Hepatitis C prior approvals require documentation of baseline HCV RNA, HCV Genotype, and Fibrosis Staging. Zepatier also requires baseline NS5A resistance testing if Genotype 1a.
   iii. Physicians must review the Manufacturer’s 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.

f. **Hormone Therapy** - The following medications are available with pre-approval for clients who are currently in the process of gender transition, or in the maintenance stage from gender transition:
   i. Estradiol, Finasteride, Progestin, Spironolactone
ii. Guidance references for primary care protocol for hormone treatment for gender transition and maintenance:


g. **Serostim** may be prescribed for treatment of HIV-associated wasting only and requires a prior approval. The Program has implemented a cap of 15 clients concurrently.
**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.

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**Physician and Practice Information**

<table>
<thead>
<tr>
<th>Name</th>
<th>Office/Clinic/Institution</th>
<th>Street Address</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>Phone #</th>
<th>Fax</th>
<th>NPI #</th>
<th>Tax ID#</th>
<th>DEA#</th>
<th>Medicaid #</th>
<th>Email Address (optional)</th>
</tr>
</thead>
</table>

**Patient’s Personal Information**

<table>
<thead>
<tr>
<th>Name</th>
<th>Date of Birth</th>
<th>Gender</th>
<th>Last 4 Digits of SS# (optional)</th>
<th>Street Address</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>Primary Phone #</th>
<th>Cell Phone # (optional)</th>
<th>Email Address (optional)</th>
</tr>
</thead>
</table>

**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:  

\[
\text{Waist-to-hip ratio} = \frac{\text{Waist Circumference}}{\text{Hip Circumference}}
\]

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.

**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.

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**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**

**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.

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<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
</table>

**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 ________________________________
Primary Phone # ________________________
Date of Birth ___________________________

Street Address _________________________
Cell Phone # (optional) ___________________

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.

(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.

Visit EGRIFTA.com to download copies of this form.
**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 (e.g., >3 SDS), particularly if the efficacy response is not robust (e.g., 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 (e.g., 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 ≥ 6.5%). In clinical trials at week 26, a greater percentage of patients had elevated HbA1c (>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.

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**SAFETY INFORMATION**

**Indication and Important Risk Information for EGRIFTA®**

- Women who are pregnant; if pregnancy occurs during treatment, discontinue EGRIFTA®.
- Known hypersensitivity to tesamorelin and/or mannitol.
- Active malignancy (either newly diagnosed or recurrent). Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with EGRIFTA®.
- Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism or pituitary tumor/surgery, head irradiation or head trauma.
- Patients with active malignancy should not be treated with EGRIFTA®.
- Patients with a history of non-malignant neoplasms, EGRIFTA® therapy should be initiated after careful evaluation of the potential benefit of treatment.
- 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.
- The decision to start treatment with EGRIFTA® should be considered carefully based on the increased background risk of malignancies in HIV-positive patients.

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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).