Subject: Egrifta (tesamorelin)	**Original Effective Date:** 2/27/13
Policy Number: MCP-131	**Revision Date(s):** 6/15/2016;1/12/18
Review Date(s): 12/16/15; 6/15/2016; 3/21/2017	

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP document and provide the directive for all Medicare members.

SUMMARY OF EVIDENCE/POSITION STATEMENTS

Molina Healthcare reserves the right to update this Policy and revise coverage criteria to include or omit any off-label condition(s) as necessary based on medical literature and clinical studies that may become available.

This policy addresses the coverage of Egrifta™ (tesamorelin) for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Egrifta™ (tesamorelin) injections for HIV-associated abdominal lipodystrophy is not medically necessary ~~are not covered~~ by Molina Healthcare based on the current supporting evidence:

- While Egrifta™ (tesamorelin) is FDA-approved for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, an improvement in net health outcome has not been demonstrated. Specifically:
  - Long-term safety and potential long-term cardiovascular benefit of tesamorelin have not been studied and are not known[1]
  - Long-term risks of elevated IGF-1 levels are unknown[1]
  - There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking tesamorelin.[1]
  - Limited reduction on measurable waist circumstance decreased of 2 cm and the effects on the visceral adipose tissue (VAT) have been shown in clinical studies, however these effects have not been maintained beyond the duration of treatment:[4,5,6] Once Egrifta™ is discontinued, visceral adipose tissue (VAT) returns. Egrifta therapy will need to be continued indefinitely in order to maintain VAT reductions.
  - Effects on quality of life measures were not assessed.
  - Patient-reported outcomes related to belly image were inconsistent across trials

- Although waist circumference decreases and the effects on the visceral adipose tissue (VAT) are sustained during treatment, these benefits have not been shown to last beyond the duration of treatment. Additionally, there are no long-term studies demonstrating improved cardiovascular outcomes or long-term adverse events. Hence, the potential benefits do not outweigh the potential risks.
  - The long-term safety of tesamorelin is unknown particularly the risk of cancer associated with elevated IGF-1 levels. Tesamorelin may increase glycosylated hemoglobin; there is also concern for risk of retinopathy with long-term use. In the prescribing information, contraindications to tesamorelin include disruption of hypothalamic-pituitary axis, active malignancy, hypersensitivity to tesamorelin and/or mannitol and pregnancy. The warning and precaution section includes risk for neoplasm, elevated IGF-1, fluid retention, glucose intolerance, hypersensitivity reactions, injection site reactions and acute illness.

- The primary goal (and clinical study endpoints) is the reduction of visceral adipose tissue (VAT).[1,3,4,5] The reduction in VAT is to result in two clinically meaningful benefits. The therapy aims at reducing the cardiovascular risks in a population known to be at increased risk of cardiovascular morbidity/mortality due to further adverse effects of the antiretroviral therapy, such as increased insulin resistance or diabetes. Consequently, by counteracting the VAT increase, which is attributed to antiretroviral therapy, improve the patients' self-perception and by this increase patients' compliance to the antiretroviral regimen. Nevertheless, the clinical trials performed have not proven that the potential benefits of the reduction of VAT in HIV-infected patients contribute to long-term cardiovascular benefit and there are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking tesamorelin. Furthermore, despite the reduction in VAT, there were no robust or consistent changes in secondary supportive efficacy measures such as improved self-perception of body image or lipid abnormalities.[3,4,5]

- Long-term consequences and well-controlled drug trials for the syndrome have not been reported in HIV-associated lipodystrophy syndrome. It is reported that no studies have been conducted to determine the morbidity and mortality from the body morphologic changes of HIV-associated lipodystrophy.

- Presently, there are no specific guidelines regarding the tesamorelin as a treatment for lipodystrophy in patients with HIV. Policy and recommendations are not offered by The International Acquired Immune Deficiency Syndrome (AIDS)[D], The American Academy of HIV Medicine (AAHIVM)[B], nor by the National Institutes of Health (NIH)[C].It should be noted that any observed decreases in VAT were reversed, or returned to baseline, within 6 months of discontinuing tesamorelin therapy based on two unreliable extension studies.[3-5]

- Both peer-reviewed references, Hayes and UpToDate, addressed tesamorelin as a treatment for lipodystrophy in HIV-infected patients; however the recommendations of both references are limited to findings of the trials with data from only 6 months of treatment and 6 months of follow-up.
  - Hayes assigned a B-rating to its recommendation based on the evaluation of evidence which is defined as *"Some proven benefit. Published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations."*
  - UpToDate recognizes that tesamorelin has been shown to be efficacious in reducing visceral fat accumulation in clinical trials and recommends *"tesamorelin for the treatment of excess abdominal fat in HIV-infected patients who have not responded to exercise and dietary interventions and who are distressed by their* ***cosmetic appearance.****"* However advises that long-term safety data are lacking and the optimal duration of treatment remains unknown. The rapid re-accumulation of fat after treatment discontinuation, and the lack of long-term safety data, present challenges for defining the optimal use of tesamorelin.

- Tesamorelin as a treatment for lipodystrophy in HIV-infected patients has not been recommended nor approved by professional organizations in the European Union at this time.
  - The European AIDS Clinical Society[E] (EACS) Guidelines concluded that "pharmacological options for the management of lipodystrophy have not proven long-term effects and may cause new complications for patients."
  - The European Medicines Agency (EMA)[F], in October 2012, a recommendation for marketing authorization was not provided for the treatment of HIV infected patients with lipodystrophy and will not be evaluated at the present time due to major objections on quality, safety and efficacy.

FDA INDICATIONS

For the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.[1]

- Egrifta™ (tesamorelin) is not indicated for weight loss, and has been shown to have a weight-neutral effect.
- The long-term cardiovascular benefit and safety of Egrifta has not been studied.
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta.

Available as: 1 mg powder for injection (as package containing 60- 1 mg vials of tesamorelin); 2 mg powder for injection (as package containing 30- 1 mg vials of tesamorelin)

Approved by the FDA: *November 11, 2010*

FDA-approved indication does not, in itself, dictate coverage. Molina coverage Policy may not recommend coverage for all FDA-approved indications. Please review this Policy in its entirety for indications covered by Molina Healthcare.

The covered FDA-approved indications are conditions that are considered medically necessary; however it is not inclusive of all conditions which may be approved by the Medical Reviewer. At the discretion of the Medical Director and on a case-by-case basis, Molina Healthcare may consider authorization of the biologic therapy addressed in this Policy for members with exceptional circumstances and for members with severe disease who may fall outside of the defined criteria.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Egrifta™ (tesamorelin) is the first and only drug approved by the FDA for HIV-associated lipodystrophy. HIV-associated lipodystrophy is defined as physique changes and metabolic abnormalities commonly observed in HIV-infected patients.[1]

Egrifta is a growth hormone releasing factor (GRF) analog. It is a hypothalamic peptide that acts on pituitary cells in the brain to stimulate the production and release of endogenous growth hormone.[1] Growth hormone-releasing factor stimulates the pituitary to synthesize and secrete growth hormone, which is anabolic and lipolytic. Growth hormone plays an important role in the formation and function of fat cells as well as the overall regulation of fat metabolism. As a synthetic hormone releasing factor (GRF), its effect on visceral adipose tissue (VAT) is believed to be related to the anabolic and catalytic characteristic of growth hormone whose secretion is triggered by GRF; however the exact mechanism of Egrifta™ is unclear.

GENERAL INFORMATION

Lipodystrophy, or fat redistribution, is defined as an abnormal production, use, or storage of fat in the body. Lipodystrophy is a term commonly used to group the two conditions of lipoatrophy and lipohypertrophy, which includes either fat wasting or fat accumulation. Lipoatrophy presents with a loss of fat, usually in the face, buttocks, arms, and legs; while lipohypertrophy involves the build-up of fat viscerally in the abdomen, back of the neck, breasts, and suprapubic areas. Although patients may present with a combination of both lipoatrophy and lipohypertrophy, the processes behind these are viewed as two distinct conditions since the processes behind the development of these conditions are different. Egrifta is highly specific for reducing visceral fat in the abdomen with little effect on subcutaneous fat or fat in the extremities thereby not adding to lipoatrophy also seen in patients with HIV.[13,14,15]

Lipodystrophy in HIV-1-infected patients represents an adverse effect of antiretroviral therapy not limited to a specific drug or class of drugs.[9] In addition to being cosmetically disfiguring, HIV lipodystrophy syndrome is associated with metabolic disorders including hyperlipidemia, insulin resistance, hyperinsulinemia, and hyperglycemia. Long-term consequences of this syndrome are not known; however concern is growing that persistent lipid abnormality may lead to atherosclerotic cardiovascular disease and diabetes.

HIV-associated lipodystrophy is a progressive disease; its severity is directly proportional to age, duration of disease, and length of protease inhibitor (PI) and/or nucleoside reverse transcriptase inhibitor (NRTI) treatment. The development of lipohypertrophy has some adverse impacts for patients. Specifically, lipohypertrophy may have a negative impact on glucose tolerance and lipid metabolism which could lead to cardiovascular complications for these patients. Additional data and clinical studies are needed to determine if treatment with tesamorelin will improve cardiovascular outcomes and adherence to antiretroviral medications. Well-controlled drug trials for the syndrome have not been reported.

There is no standardized definition for diagnosing HIV-associated lipodystrophy at the time of this writing. Therefore, since there is no universally recognized clinical definition and assessment may be difficult in practice as risk factors can be divided into several groups: host factors (gender, age, race, genetic factors, initial total body fat content), environmental factors (nutrition, exercise level) antiretroviral therapy (duration of and drugs used), immunological response, HCV co-infection, as well as HIV-1 infection itself.[9]

Current prevalence estimates vary widely in the United States, approximately 14% to 40% of HIV-positive patients treated with highly active antiretroviral therapy (HAART) have HIV-associated lipodystrophy.[10]

Clinicians generally recognize that the condition is presented as abnormal body shape changes, including dorsocervical (commonly called "buffalo hump") fat pad enlargement, or buffalo hump; symmetric lipomatosis; breast enlargement; and/or abdominal obesity.[12] Thinning of the face, buttocks, and/or extremities, either alone or in combination with fat accumulation, has also been reported in HIV patients. Other potential indicators of lipodystrophy are metabolic abnormalities, including insulin resistance, glucose intolerance, elevated triglycerides, and elevated cholesterol levels. It is suggested that these abnormalities may be HAART-mediated; however, lipodystrophy may be unrelated to antiretroviral therapy since not all patients who exhibit abnormal fat distribution have been on HAART.

Objective criteria for diagnosing lipodystrophy are still not established.[9] There is no gold-standard method for measuring body fat. However, several techniques have been used: anthropometry, bioimpedance analysis, DEXA, computed tomography, magnetic resonance imaging and ultrasonography.However, it is noted that each of these techniques has limitations. Anthropometry and bioimpedance analysis cannot measure regional body fat. Computed tomography and magnetic resonance imaging are costly, therefore use may be limited. Ultrasonography is promising because of its simplicity, safety, availability and low cost, although it is more operator-dependent than other techniques. DEXA has gained popularity and may be currently the most widely utilized. Few data are available on the comparison of these objective techniques for measuring regional body fat.

Potential interventions for fat deposition (lipodeposition) include exercise, medical therapy, and surgical interventions. Refer to 'UpToDate' section below for recommendations.

SUMMARY OF MEDICAL EVIDENCE

PUBLISHED CLINICAL TRIALS

The FDA approval of Egrifta was based on two multicenter, randomized, double-blind, placebo-controlled studies in HIV-infected patients with lipodystrophy and excess abdominal fat (abdominal lipohypertrophy). Both studies consisted of a 26-week Main Phase and a 26-week Extension Phase. The subjects were randomized to receive 2mg Egrifta or placebo subcutaneously daily for 26 weeks. The primary efficacy assessment for each of these studies was the percent change from baseline to Week 26 (Main Phase) in visceral adipose tissue (cm^2), as assessed by computed tomography (CT) scan at L4-L5 vertebral level. In both studies, Egrifta- treated patients completing the 26-week treatment period were re-randomized to blinded therapy with either daily placebo or 2 mg Egrifta for an additional 26-week treatment period (Extension Phase) in order to assess maintenance of VAT reduction and to gather long-term safety data.

Both studies (Study 1 and 2) consisted of a 26-week Main Phase and a 26-week Extension Phase. Main inclusion criteria were: [1]

- Age 18-65 years
- A waist circumference ≥ 95 cm (37.4 inches) and a waist-to-hip ratio ≥ 0.94 for men and ≥ 94 cm (37.0 inches) and ≥ 0.88 for women, respectively, and
- FBG <150 mg/dL (8.33 mmol/L)

Main exclusion criteria included BMI ≤ 20 kg/m^2, type 1 diabetes, type 2 diabetes, if previously treated with insulin.[1]

Study One

Main Phase

This study randomized 412 subjects. At Week 26, treatment with Egrifta resulted in a reduction from baseline in mean trunk fat of 1.0 kg compared with an increase of 0.4 kg in the placebo group. In addition, Egrifta resulted in an increase from baseline in mean lean body mass of 1.3 kg compared with a decrease of 0.2 kg in the placebo group.

Extension Phase

This study re-randomized 207 subjects. Those treated with Egrifta showed no change between Weeks 26 and 52 in mean trunk fat (increase of 0.1 kg vs. increase of 1.4 kg in placebo group) nor was there a change from Week 26 baseline in mean lean body mass (decrease of 0.1 kg vs. decrease of 1.8 kg in placebo group).

Study Two

Main Phase

This study randomized 404 subjects. At Week 26, treatment with Egrifta resulted in a reduction from baseline in mean trunk fat of 0.8 kg compared with an increase of 0.2 kg in the placebo group. In addition, Egrifta resulted in an increase from baseline in mean lean body mass of 1.2 kg compared with a decrease of 0.03 kg in the placebo group.

Extension Phase

This study re-randomized 177 subjects. Those treated with Egrifta showed no change between Weeks 26 and 52 in mean trunk fat (decrease of 0.5 kg vs. an increase of 1.09 kg in placebo group) nor was there a change from Week 26 baseline in mean lean body mass (increase of 0.1 kg vs. decrease of 1.7 kg in placebo group).

In both studies, there was no adverse effect of Egrifta on lipids or subcutaneous adipose tissue and Efrifta did not adversely alter antiretroviral effectiveness, such as mean circulating levels of CD4 counts or HIV-1 RNA (viral load).

Summary of efficacy findings[3-8]

- In the first 26 weeks, tesamorelin reduced visceral adipose tissue assessed by computed tomography scan by an average of 24 cm^2, which was enough to improve patient body image, compared to a gain of 2 cm^2 with placebo; waist circumference decreased by 2.4 cm.
- In the second 26 weeks, the improvement was maintained among the patients who continued treatment with tesamorelin (reduction in waist circumference of 3.4 cm at 52 weeks), but the patients re-randomized to placebo returned rapidly to baseline fat accumulation.[6]
- There are no controlled data beyond 26 weeks of continuous exposure and only 209 subjects were exposed for 52 weeks adds to the uncertainty regarding the risks involved with tesamorelin treatment. No assessment of long-term safety can be performed.[F]
- In the two pivotal, Phase III clinical trials, tesamorelin compared to placebo significantly lowered visceral adipose tissue at both 26 and 52 weeks; however, these results were not maintained in patients who were switched to placebo in the extension arm. Both the tesamorelin and placebo arms experienced relatively high drop-out rates. Adverse events occurred more frequently in the tesamorelin group than placebo and the most commonly reported were injection site reactions, peripheral edema, discomfort, and pain in extremities. Higher levels of insulin-like growth factor I (IGF-1) occurred in tesamorelin compared to placebo.

Post-marketing Safety Experience[1b,1c]

According to FDA documents, the following post-marketing clinical studies will be conducted:

1) Observational study with a minimum duration of 10 years will conducted to determine the occurrence of glucose intolerance/diabetes mellitus, hypersensitivity reactions, malignancies, liver abnormalities, kidney abnormalities, diabetic retinopathy, and major adverse cardiovascular events.
2) Randomized, placebo-controlled, double-blind clinical trial in patients with HIV-lipodystrophy and type 2 diabetes must be conducted to assess the risk of retinopathy.

HAYES DIRECTORY

A Hayes Directory report on "Recombinant Growth Hormone Treatment for AIDS/HIV-Associated Wasting and Lipodystrophy" was available at the time of this writing in December 2013.

The evaluation of evidence for tesamorelin treatment of lipodystrophy in HIV-infected adult patients was assigned a **B-rating.*** This rating takes into consideration the combined findings from two large, multicenter, double-blind RCTs that evaluated daily treatment with 2 mg tesamorelin versus placebo in a total of 806 patients who had lipodystrophy. Patients treated with tesamorelin had increases in lean body mass combined with reductions in visceral adipose tissue, triglycerides, and non-high-density lipoprotein cholesterol, without inordinate risk.

It was noted that the specific strengths of evidence from the pooled analysis of the two RCTs are large study population, multicenter design, randomization of patients to treatment groups, placebo control, and blinding of patients and assessors to the treatment being administered. The weakness of this pooled analysis is that it is limited to only 6 months of treatment and 6 months of follow-up.

**Hayes Rating B is defined by The Hayes Rating system, developed by Winifred S. Hayes, Inc., as "Some proven benefit. Published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations. Drugs, biologics, and devices with a B rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration."*

UPTODATE[9]

- The review suggests standard methods of weight reduction, such as aerobic exercise training, in patients with abdominal fat accumulation. (Grade 2C).

- Aerobic exercise training with preferential use of metformin for glycemic control is recommended for patients with concomitant diabetes, (Grade 2C). The review notes that metformin is a judicious treatment option for diabetic patients, especially those with increased truncal fat who have intact renal and hepatic function. However, metformin should be avoided in patients who primarily have lipoatrophy of moderate to severe severity since it may further reduce subcutaneous fat.

- UpToDate recognizes that tesamorelin has been shown to be efficacious in reducing visceral fat accumulation in clinical trials and recommends "tesamorelin for the treatment of excess abdominal fat in HIV-infected patients who have not responded to exercise and dietary interventions and who are distressed by their cosmetic appearance." However advises that long-term safety data are lacking and the optimal duration of treatment remains unknown. The rapid re-accumulation of fat after treatment discontinuation, and the lack of long-term safety data, present challenges for defining the optimal use of tesamorelin.

COCHRANE DATABASE OF SYSTEMATIC REVIEWS

A Cochrane review was not available for tesamorelin treatment of lipodystrophy in HIV-infected adult patients at the time of this writing in December 2012; however there is a review at the protocol stage, "Drug interventions for the treatment of lipodystrophy in patients with HIV infection." At this time there is no abstract or plain language summary for this review. The objectives for the review are as follows: To examine the efficacy of non-ART drug interventions for the treatment of lipodystrophy in adult patients infected with HIV.

PROFESSIONAL ORGANIZATIONS

Guidelines

At the time of this writing in December 2012, there are no specific guidelines regarding the treatment of lipodystrophy in patients with HIV.

International Acquired Immune Deficiency Syndrome (AIDS)[D]

The United States Panel of the International Acquired Immune Deficiency Syndrome (AIDS) Society provides recommendations regarding the treatment of this condition; however these recommendations do not include Egrifta since it was not available when the recommendations were made in 2002.

American Academy of HIV Medicine (AAHIVM)[B]

The AAHIVM, in conjunction with the American Geriatric Society and the AIDS Community Research Initiative of America, published guidelines concerning HIV and aging. This guideline lists modification of antiretroviral therapy, surgical fat removal, and use of GH or GH analogs as options for management of lipoatrophy and lipohypertrophy in older patients infected with HIV; however do not address tesamorelin as a treatment for lipodystrophy (AAHIVM, 2011).

National Institutes of Health (NIH)[C]

NIH updated guidelines in 2012 to address the use of antiretroviral agents in adults and adolescents infected with HIV list lipodystrophy as a potential complication of treatment, but do not address treatment of lipodystrophy (NIH, 2012).

European AIDS Clinical Society[E] (EACS)

As of this writing in December 2012, there is no medical therapy that has been approved in the European Union for the treatment of excess visceral adipose tissue (VAT) in HIV infection.[E,F] The European AIDS Clinical Society Guidelines concluded that "pharmacological options for the management of lipodystrophy have not proven long-term effects and may cause new complications for patients."

The European Medicines Agency (EMA)[F]

In the 'Withdrawal Assessment Report' released by the EMA in October 2012, it was concluded Egrifta remained not approvable the treatment of HIV infected patients with lipodystrophy and will not be evaluated at the present time due to major objections on quality, safety and efficacy. The assessment was determined based on the review of the data and the manufacturer's response to the Committee for Medicinal Products for Human Use (CHMP) on quality, safety and efficacy. Therefore, a recommendation for marketing authorization was not provided.

The European Medicines Agency (EMA) concluded that the overall benefit to risk of Egrifta was negative based on the evaluation of the available data. The effects of tesamorelin on IGF-1 levels, antibody formation, and glucose metabolism clearly outweigh the beneficial effects reported with tesamorelin.

The EMA noted that "it is currently not clear whether patients on tesamorelin will develop neutralizing antibodies and cross-reactivity to hGRF with long-term exposure. Adverse effects on the physiological process cannot be excluded. Also, it is currently not clear whether tesamorelin might induce other AEs related to GH therapy and the occurrence of anaphylactic reactions is considered very likely."

The EMA report noted that the use of pharmacological doses of growth hormone indicated possible beneficial effects of reduced trunk fat and VAT and increased lean body mass (Wanke et al., 1999; Lo et al., 2001; Engelson et al., 2002; Kotler et al., 2004b), but was also associated with significant side effects, including symptoms of interstitial fluid retention and hyperglycemia. Metformin has also been investigated in small studies. Dietary and exercise intervention may also be important in some patients, however there are no large-scale studies to look at the effect of this on VAT. Some recent studies have looked at switching antiretroviral treatments as a strategy to reduce VAT.

DEFINITIONS

HAART: Highly active antiretroviral therapy
ART: Antiretroviral therapy
HIV: Human Immunodeficiency Virus
IGF-1: Insulin-like Growth Factor 1
VAT: Visceral Adipose Tissue
HPA: Hypothalamic-Pituitary Axis
Waist-to-hip ratio: The waist circumference divided by the circumference of the hips

APPENDIX

N/A

CODING INFORMATION

CPT	Description
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

HCPCS	Description
J3490	Unclassified Drug

ICD-9	Description [For dates of service prior to 10/01/2015]
272.6	Lipodystrophy
O42	Human immunodeficiency virus [HIV] disease
ICD-10	**Description [For dates of service on or after 10/01/2015]**
E88.1	Lipodystrophy, not elsewhere classified
B20	Human immunodeficiency virus [HIV] disease

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Reviews, Revisions, and Approvals	Date	MCPC
Policy Developed	2/27/13	