EMCITATE® (tiratricol) Letter of Appeal

This sample letter of appeal is intended to help prescribers draft an appeal for a coverage denial of EMCITATE® (tiratricol) issued by a patient's health insurance plan. It is provided for informational purposes only and does not constitute medical, legal, or reimbursement advice.

Prescribers should always confirm whether the patient's health insurance plan has its own required template for submitting a letter of appeal. Individual health insurance policies are frequently updated, and it is the responsibility of the provider and/or their office staff to determine appropriate coding, medical necessity, site of service, and documentation requirements, and to submit appropriate codes, modifiers, and charges for services rendered, as specified by the patient's health insurance. This letter template represents no statement, promise, or guarantee of coverage or payment.

DIRECTIONS FOR USE:
Please create a letter on office/institution letterhead that must include patient-specific information and be signed by the prescriber. Always use professional judgment, provide clinical information, and consider the specific requirements of the patient's plan, which vary and may require different or additional information.

Please ensure all magenta fields are completed with black font. This page and the next are for your reference only and do not need to be sent to the insurance company. REMOVE BOTH PAGES BEFORE submitting to the patient's health insurance.

IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

EMCITATE® (tiratricol) is a thyroid hormone receptor agonist indicated for the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency (Allan-Herndon-Dudley syndrome).

Limitation of Use

EMCITATE is not recommended for the treatment of primary hypothyroidism.

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS
***See full prescribing information for complete boxed warning*.**
Thyroid hormones, including EMCITATE, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss.

CONTRAINDICATIONS

EMCITATE is contraindicated in patients with primary hyperthyroidism.

WARNINGS AND PRECAUTIONS

New Onset or Worsening of Thyrotoxicosis

Signs and symptoms of thyrotoxicosis (e.g., increased heart rate, elevated blood pressure, diarrhea, hyperhidrosis, irritability, insomnia, nightmares) have occurred with EMCITATE during treatment initiation and dose titration. Monitor and adjust the EMCITATE dose as indicated.

Not for Treatment of Obesity or Weight Loss

EMCITATE should not be taken for weight reduction as it may cause symptoms of thyrotoxicosis that could be serious or life-threatening.

Laboratory Test Interference for T3 Measurement

Tiratricol can cross-react with immunoassays for T3 leading to unreliable T3 results and cause an overestimation of T3.

ADVERSE REACTIONS

The most common adverse reactions with EMCITATE (reported in at least 5% of patients) were diarrhea, vomiting, rash, and hyperhidrosis.

For additional safety information, refer to the full Prescribing Information.

DRUG INTERACTIONS

Taking EMCITATE in combination with thyromimetic products or products used to treat thyroid conditions (e.g., levothyroxine, propylthiouracil, and carbimazole) may increase the risk of thyrotoxicosis or hypothyroidism and should be avoided.

See full Prescribing Information for drugs that may interact with EMCITATE and alter the therapeutic response.

REPORTING ADVERSE REACTIONS

To report suspected adverse reactions, contact Egetis Therapeutics US Inc. at 1-844-4EGETIS (1-844-434-3847). You may also report adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for EMCITATE, including the Boxed WARNING.

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EGETIS THERAPEUTICS™

Date: [MM/DD/YYYY]	Patient Name: [First and last name]
To: [Contact name]	Date of Birth: [MM/DD/YYYY]
[Name of health insurance plan or pharmacy benefit manager]	Caregiver Name: [First and last name]
[Insurance company address]	Policy/ID #: [Policy/ID number]
[City, State, Zip]	Group #: [Group number]
	Date(s) of Service: [MM/DD/YYYY]
	Case ID: [Case ID number]

Subject: Appeal for coverage denial of EMCITATE® (tiratricol)

To whom it may concern,

I am a specialist in [specialty/condition area] involved in the care of [Patient's Name]. I am writing this letter to appeal the coverage denial for [Patient's Name] to receive treatment with EMCITATE® (tiratricol), an FDA-approved therapy for the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter-8 (MCT8) deficiency. Coverage was denied on [date] for [list of reasons coverage was denied from denial letter].

Based on my clinical assessment, EMCITATE is the appropriate treatment option for [Patient Name]. This letter outlines [Patient's Name]'s medical history and clinical evidence that support my recommendation for treatment with EMCITATE:

- Provide reasons why EMCITATE is appropriate
- Address every denial reason stated in the denial letter
- Provide additional details about the patient's medical history, treatment needs, lab values, patient symptoms, and other pertinent information and where those details can be found in the attached documentation
- Reference any attachments, such as peer-reviewed studies

Based on the clinical data available, EMCITATE is appropriate and medically necessary for [Patient's Name]'s treatment of peripheral thyrotoxicosis in MCT8 deficiency. I would appreciate your urgent review of this request and ask that you reverse your decision and approve EMCITATE for my patient. If you have any questions or wish to conduct a peer-to-peer discussion, please contact me at [office phone number].

Sincerely,

[HCP name, credentials]
[NPI number]
[Contact information and address]
[Signature]

[Enclosures: Payer's prior authorization form, medical records, chart notes, copy of patient's insurance card, full Prescribing Information for EMCITATE (https://www.egetis.com/wp-content/uploads/emcitate-full-prescribing-information.pdf), FDA approval letter for EMCITATE to treat peripheral thyrotoxicosis in adults and pediatric patients with MCT8 deficiency (https://egetiscorpostg.wpenginepowered.com/news/egetis-therapeutics-announces-u-s-fda-approval-of-emcitate-tiratricol-for-patients-with-mct8-deficiency/)]