EMCITATE® (tiratricol) Letter of Medical Necessity

This sample letter of medical necessity is intended to help prescribers document the medical necessity of EMCITATE® (tiratricol) for patients who have been prescribed the therapy. It is provided for informational purposes only and is not based on legal advice or official guidance from payers.

There is no requirement that a patient or healthcare provider use any Egetis Therapeutics™ product in exchange for this information. Additionally, this letter template is not meant to be a substitute for a prescriber's independent medical decision-making and represents no statement, promise, or guarantee of coverage or payment.

Payers may request a letter of medical necessity as part of a prior authorization (PA) request to support approval efforts. The letter should explain why the therapy is medically necessary for the specific patient and may include supporting documentation (eg, medical records, peer-reviewed literature, and clinical treatment history).

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 page 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: Letter of medical necessity for EMCITATE® (tiratricol)

To whom it may concern,

I am writing on behalf of my patient, [Patient's name], to document the medical necessity of EMCITATE® (tiratricol) for the treatment of peripheral thyrotoxicosis in monocarboxylate transporter-8 (MCT8) deficiency. MCT8 deficiency is a rare, devastating, life-shortening, X-linked disorder characterized by neurodevelopmental impairment and systemic metabolic and cardiovascular disturbances, with increased morbidity and mortality. EMCITATE is the first and only treatment for this condition in adults and pediatric patients and was approved by the US Food and Drug Administration on September 28, 2026.

[Patient's name] has been diagnosed with peripheral thyrotoxicosis in MCT8 deficiency [based on genetic testing and clinical symptoms] as of [MM/DD/YYYY] and has been in my care for it since [MM/DD/YYYY].

I am a board-certified [specialty (eg, pediatric endocrinologist, geneticist) and credentials] with [#] years of experience, and I'm confident in the medical necessity of EMCITATE for this patient. I have prescribed EMCITATE (XX mcg) based on the dosing regimen in the full Prescribing Information.

Please review my clinical rationale and the attached documentation to substantiate the medical need for treatment with EMCITATE. [Consider including:]

- Rationale for why this is medically necessary
- Genetic test results
- Lab results (T3, T4)
- Description of symptom presentation
- Any applicable medical records that support your decision to prescribe EMCITATE
- Published data that supports the use of EMCITATE for the patient's condition
- Additional required documentation outlined in the specific payer policy
- For reauthorization, please include XXXX

If you have any further questions, please feel free to call me at [HCP phone number] to discuss.

Thank you in advance for your immediate attention to this request,

[HCP name, credentials]
[NPI number]
[Contact information and mailing 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/)]