EMCITATE®
tiratricol tablets, 350 µg

EGETIS rarelink™

Prior Authorization (PA) Checklist for EMCITATE® (tiratricol)

For the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency

(Limitation of use: EMCITATE is not recommended for the treatment of primary hypothyroidism)

Most health plans require a prior authorization (PA) before approving EMCITATE. Egetis RareLink™ works alongside your practice to navigate coverage requirements, address access barriers, and support patients and caregivers throughout their EMCITATE journey.

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.

SELECT 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.

Please see Important Safety Information for EMCITATE, including Boxed WARNING, on the last page.

Please see full Prescribing Information, including Boxed WARNING, at emcitatehcp.com.

PA Authorization Best Practices

Tips for preparing and tracking your PA from start to finish

Preparation & submission

- Confirm patient's insurance information
- Gather all required documentation (see page 2 checklist)
- Complete all sections of the PA form
- Work with Egetis RareLink™ to determine the appropriate PA submission pathway
- Keep a copy of the submission documentation for your records

Follow-up

- Track PA status with Egetis RareLink
- Respond to requests for additional clinical information or documentation, as needed
- Connect with your Patient Support Liaison (PSL) for education and support throughout the process

Determination

- Record the approval code and effective dates in the patient's medical record
- Note the expiration date (you may need to resubmit before it expires)
- Check that the approval reflects the correct prescribed quantity
- Share approval information with the specialty pharmacy

Complete, accurate forms are the best way to help get coverage approval. Read and fill out the PA form carefully, and review any guidance provided by the specialty pharmacy before submitting.

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PA Document Checklist

Use this list as a guideline to gather what's commonly needed for a complete PA submission

Comprehensive clinical documentation is critical to have a complete submission for EMCITATE. Requirements vary by plan, so check that you have an accurate list of criteria from your patient's health plan before you submit.

Clinical diagnosis

- ☐ **Genetic test results for MCT8 deficiency**
- ☐ **Thyroid panel results** (include specific values, reference ranges, and collection dates)
  - ☐ Total T3
  - ☐ fT4
  - ☐ TSH

Supporting documentation

- ☐ Patient insurance policy number
- ☐ Patient date of birth
- ☐ Patient weight and the date of measurement
- ☐ Completed PA request form for EMCITATE (Some payers may require specific forms to be completed for EMCITATE)
- ☐ Treatment history (Not currently taking thyromimetic products or other thyroid medications, such as levothyroxine, propylthiouracil, and carbimazole)
- ☐ Relevant laboratory results
- ☐ Letter of medical necessity, supported by medical records, relevant diagnoses (with ICD-10 codes, if applicable), chart notes, lab results, published peer-reviewed literature, and/or full Prescribing Information
- ☐ Patient participation in clinical trials and/or expanded access program (if applicable)
- ☐ Prescription in consultation with a pediatric endocrinologist
- ☐ Symptoms observed during clinical visits and/or reported by the patient's caregiver



For personalized support, contact **Egetis RareLink™** at:

1-844-4EGETIS / 1-844-434-3847 (Option 1)

8 AM–8 PM ET, Monday through Friday

emcitatehcp.com

Note: Following this checklist does not guarantee that the patient's health plan will provide reimbursement for EMCITATE. It is also not intended to substitute for, or influence, the physician's independent medical judgment. The information in this checklist is for guidance and is not intended to be a complete list of all possible information needed or requested by a health insurance plan.

FDA, US Food and Drug Administration; fT4, free thyroxine; ICD-10, International Classification of Diseases, Tenth Revision; T3, triiodothyronine; TSH, thyroid-stimulating hormone.

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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.

EGETIS THERAPEUTICS™

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