

Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Imcivree (Setmelanotide)

Clinical Criteria Information included in this Document

- [Drugs requiring prior authorization](#): the list of drugs requiring prior authorization for this clinical criteria
- [Prior authorization criteria logic](#): a description of how the prior authorization request will be evaluated against the clinical criteria rules
- [Logic diagram](#): a visual depiction of the clinical criteria logic
- [Supporting tables](#): a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- [References](#): clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Revision Notes

Annual review by staff

Updated question 1 in the initial review criteria from 6 years of age to 2 years of age

Updated the approval duration to 365 days for initial approval for all indications

Added a check for end stage renal disease (ESRD) to renewal criteria

Updated references



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Drugs Requiring Prior Authorization

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
IMCIVREE 10 MG/ML VIAL	48922

**Imcivree (Setmelanotide)****Clinical Criteria Logic**

Initial request:

1. Is the client less than (<) 2 years of age?
☐ Yes – Deny
☐ No – Go to #2
2. Is the request for less than or equal to (\leq) 1 injection daily?
☐ Yes – Go to #3
☐ No – Deny
3. Does the client have a diagnosis of pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing? [Manual]
☐ Yes – Go to #5
☐ No – Go to #4
4. Does the client have a [diagnosis of Bardet-Biedl syndrome \(BBS\)](#) in the last 730 days?
☐ Yes – Go to #5
☐ No – Deny
5. Does the client have a [diagnosis of end stage renal disease \(ESRD\)](#) in the last 365 days?
☐ Yes – Deny
☐ No – Approve (365 days)

Renewal request:

1. Is the request for less than or equal to (\leq) 1 injection daily?
☐ Yes – Go to #2
☐ No – Deny
2. Has the client responded to Imcivree therapy (defined as at least 5% of baseline body weight or 5% of baseline BMI for patients with continued growth potential)? [Manual]
☐ Yes – Go to #3
☐ No – Deny
3. Does the client have a [diagnosis of end stage renal disease \(ESRD\)](#) in the last 365 days?

☐ Yes – Deny

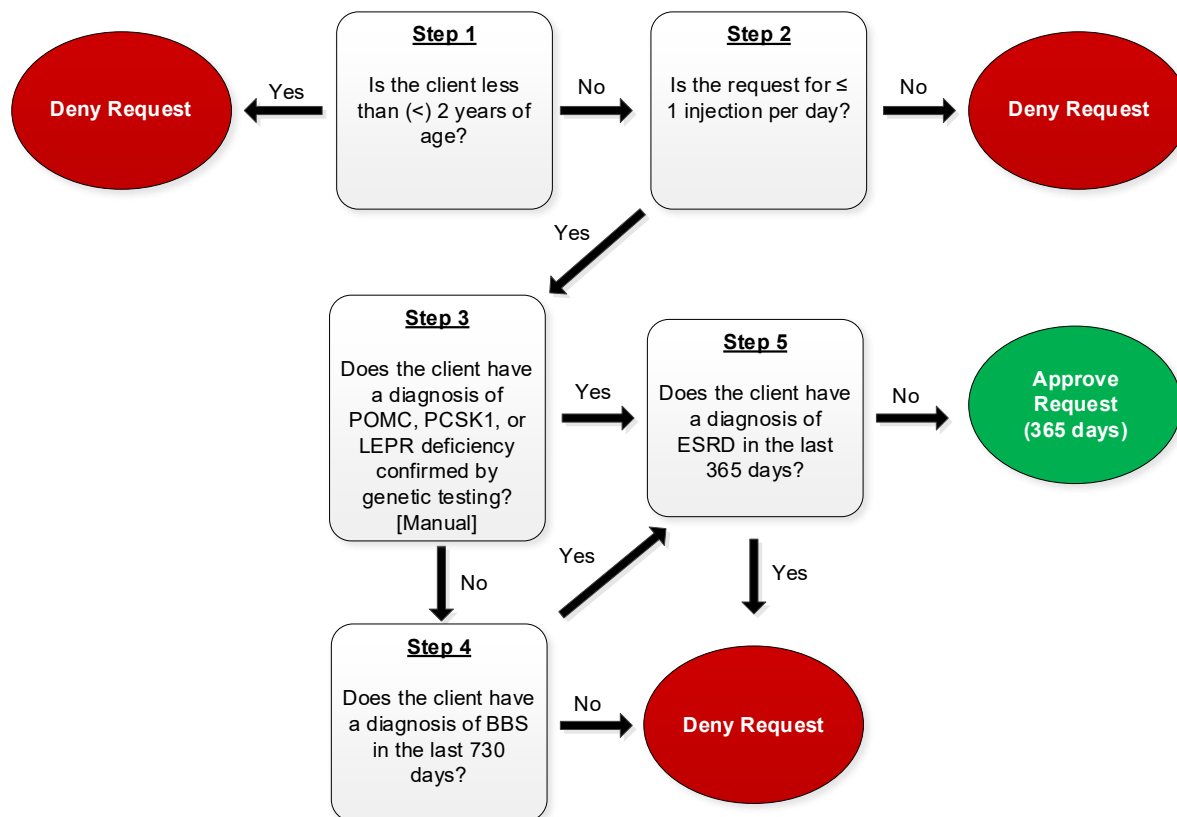
☐ No – Approve (365 days)



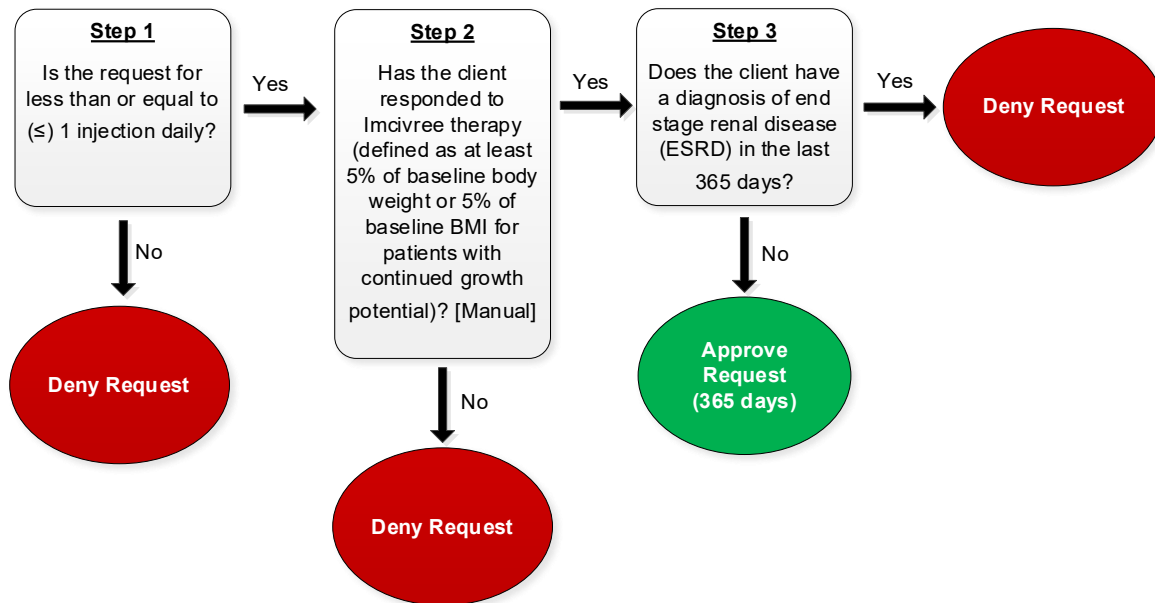
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Clinical Criteria Logic Diagram

Initial request:



Renewal request:





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Clinical Criteria Supporting Tables

Table 4 (diagnosis of Bardet-Biedl syndrome)**Required diagnosis: 1****Look back timeframe: 730 days**

ICD-10 Code	Description
Q8783	BARDET-BIEDL SYNDROME
Q8789	OTHER SPECIFIED CONGENITAL MALFORMATION SYNDROMES, NOT ELSEWHERE CLASSIFIED

Table 5 / 3 (diagnosis of ESRD)**Required diagnosis: 1****Look back timeframe: 365 days**

ICD-10 Code	Description
N186	END STAGE RENAL DISEASE

**Imcivree (Setmelanotide)****Clinical Criteria References**

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2025. Available at www.clinicalpharmacology.com. Accessed on May 14, 2025.
2. 2025 ICD-10-CM Diagnosis Codes, Volume 1. 2025. Available at www.icd10data.com. Accessed on May 14, 2025.
3. Imcivree Prescribing Information. Boston, MA. Rhythm Pharmaceuticals, Inc. March 2025.
4. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on May 14, 2025.
5. Perreault L, Rosenbaum M. Obesity: Genetic contribution and pathophysiology. UpToDate, Pi-Sunyer X, Hussain Z (Ed) [Internet]. Waltham, MA: UpToDate; January 9, 2025. Available from: www.uptodate.com.

**Imcivree (Setmelanotide)****Publication History**

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the [Revision Notes](#) on the first page of this document.

Publication Date	Notes
10/13/2023	<ul style="list-style-type: none">Initial publication and presentation to the DUR Board
6/30/2025	<ul style="list-style-type: none">Annual review by staffUpdated question 1 in the initial review criteria from 6 years of age to 2 years of ageUpdated the approval duration to 365 days for initial approval for all indicationsAdded a check for end stage renal disease (ESRD) to renewal criteriaUpdated references