Texas Prior Authorization Program
Clinical Criteria

Imcivree (Setmelanotide)

Clinical Criteria Information Included in this Document

Imcivree (Setmelanotide)

- **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)
- **References**: clinical publications and sources relevant to this clinical criteria

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

Revision Notes

Initial publication and presentation for the DUR Board

Imcivree (Setmelanotide)

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX 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

RxPERT PAxpress

Imcivree (Setmelanotide)

Clinical Criteria Logic

Initial request:

1. Is the client less than (<) 6 years of age?
   [ ] Yes – Deny
   [ ] No – Go to #2

2. Is the request for less than or equal to (≤) 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 #6
   [ ] No – Deny

5. Does the client have a diagnosis of **end stage renal disease (ESRD)** in the last 365 days?
   [ ] Yes – Deny
   [ ] No – Approve (120 days)

6. 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:

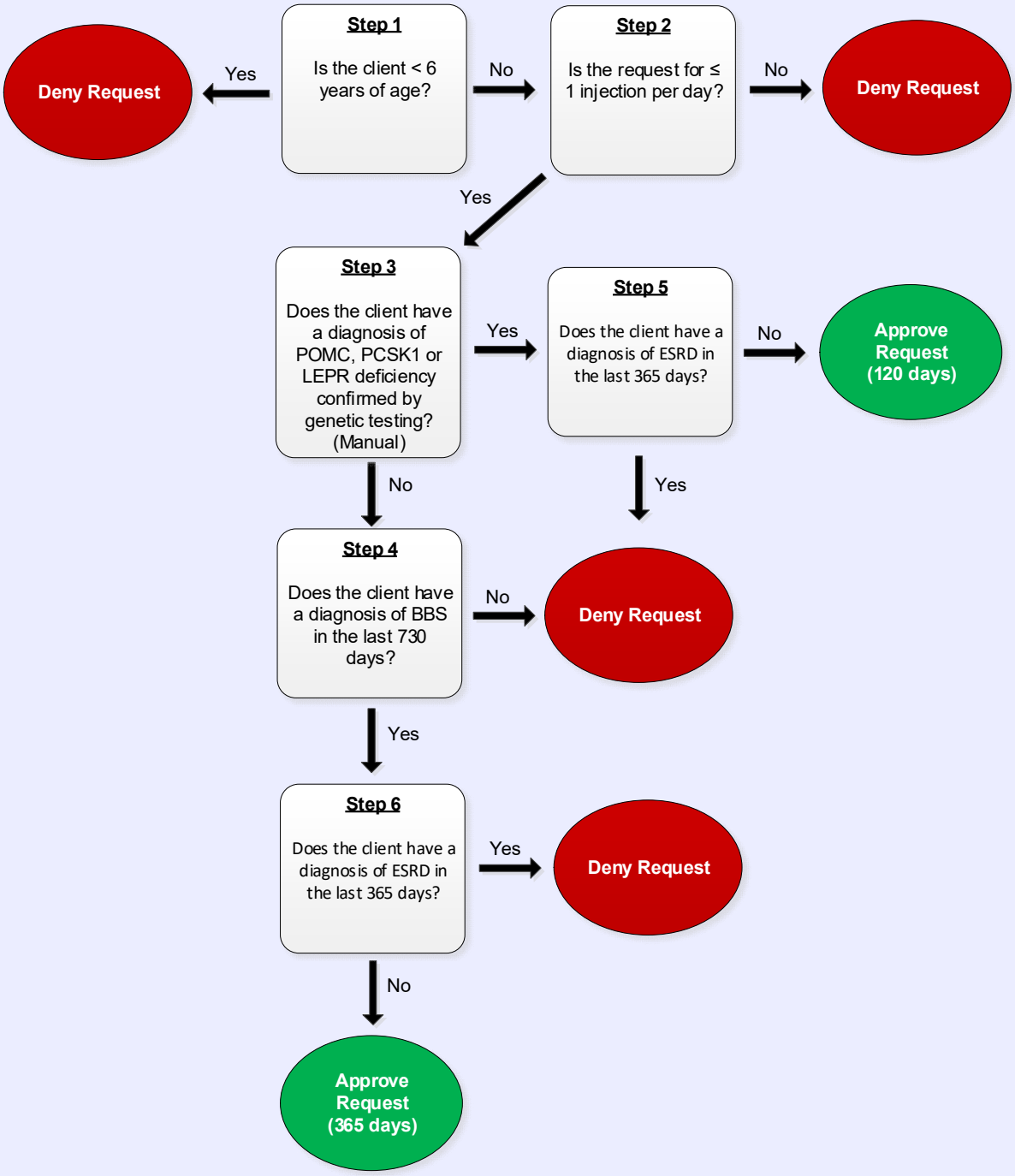
1. Is the request for less than or equal to (≤) 1 injection daily?
   [ ] Yes – Go to #2
   [ ] No - Deny

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 – Approve (365 days)
   [ ] No - Deny

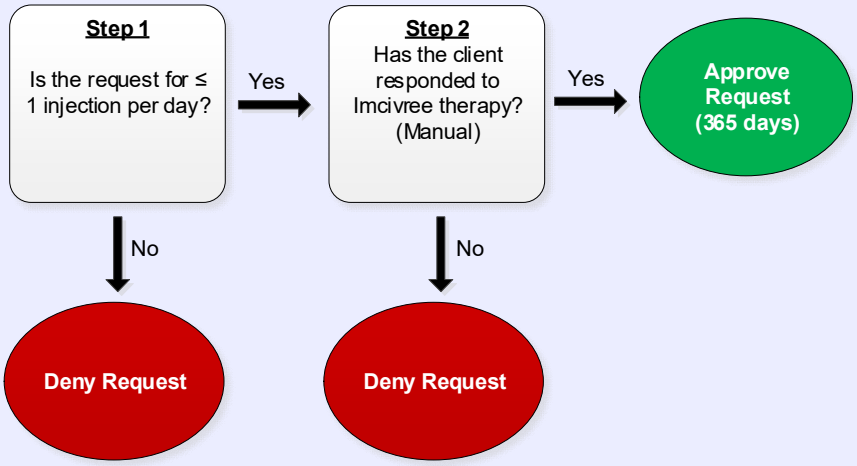
Imcivree (Setmalanotide)

Clinical Criteria Logic Diagram

Initial request:



Renewal Request:



Imcivree (Setmalanotide)

Clinical Criteria Supporting Tables

Step 4 (diagnosis of Bardet-Biedl syndrome) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
Q8783	BARDET-BIEDL SYNDROME
Q8789	OTHER SPECIFIED CONGENITAL MALFORMATION SYNDROMES, NOT ELSEWHERE CLASSIFIED

Step 5/6 (diagnosis of ESRD) **Required quantity:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
N186	END STAGE RENAL DISEASE

Imcivree (Setmalanotide)

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2023. Available at **www.clinicalpharmacology.com**. Accessed on October 13, 2023

2. 2023 ICD-10-CM Diagnosis Codes, Volume 1. 2023. Available at **www.icd10data.com**. Accessed on October 13, 2023.

3. Imcivree Prescribing Information. Boston, MA. Rhythm Pharmaceuticals, Inc. June 2022.

RxPERT® PAXPRESS™

Imcivree (Setmalanotide)

Publication History

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	Initial publication and presentation to the DUR Board