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)
- **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
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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.

<table>
<thead>
<tr>
<th>Label Name</th>
<th>GCN</th>
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<tbody>
<tr>
<td>IMCIVREE 10 MG/ML VIAI</td>
<td>48922</td>
</tr>
</tbody>
</table>

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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 #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 (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
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Clinical Criteria Logic Diagram

Initial request:

1. **Step 1**
   - Is the client < 6 years of age?
   - Yes: Approve Request (120 days)
   - No: Step 2

2. **Step 2**
   - Is the request for ≤ 1 injection per day?
   - Yes: Step 3
   - No: Deny Request (Manual)

3. **Step 3**
   - Does the client have a diagnosis of POMC, PCSK1 or LEPR deficiency confirmed by genetic testing? (Manual)
   - Yes: Step 5
   - No: Deny Request

4. **Step 4**
   - Does the client have a diagnosis of BBS in the last 730 days?
   - Yes: Deny Request
   - No: Step 6

5. **Step 5**
   - Does the client have a diagnosis of ESRD in the last 365 days?
   - Yes: Deny Request (365 days)
   - No: Step 1

6. **Step 6**
   - Does the client have a diagnosis of ESRD in the last 365 days?
   - Yes: Deny Request
   - No: Approve Request (365 days)
Renewal Request:

**Step 1**
Is the request for ≤ 1 injection per day?

- **Yes**: Go to Step 2
- **No**: Deny Request

**Step 2**
Has the client responded to Imcivree therapy? (Manual)

- **Yes**: Approve Request (365 days)
- **No**: Deny Request

- **Deny Request**
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#### Clinical Criteria Supporting Tables

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

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>Q8789</td>
<td>OTHER SPECIFIED CONGENITAL MALFORMATION SYNDROMES, NOT ELSEWHERE CLASSIFIED</td>
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**Step 5/6 (diagnosis of ESRD)**
- **Required quantity:** 1
- **Look back timeframe:** 365 days

<table>
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<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
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<td>END STAGE RENAL DISEASE</td>
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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.

<table>
<thead>
<tr>
<th>Publication Date</th>
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<tr>
<td>10/13/2023</td>
<td>Initial publication and presentation to the DUR Board</td>
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