Prior Authorization Criteria Update: Cannabidiol

Purpose of Update:
- Some clinicians have been prescribing cannabidiol at 30 mg/kg/day, which is an investigational dose. This maximum dose outlined in the cannabidiol prescribing information is 20mg/kg/day.¹

Recommendation:
- Update prior authorization criteria to include maximum dose limits.

References:

Appendix 1. Proposed Prior Authorization Criteria

Cannabidiol

Goal(s):
- To ensure appropriate drug use and restrict to indications supported by medical literature.

Length of Authorization:
- Up to 12 months

Requires PA:
- Cannabidiol

Covered Alternatives:
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Author: Deanna Moretz, PharmD, BCPS
## Approval Criteria

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes:</th>
<th>No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>What diagnosis is being treated?</td>
<td>Record ICD10 code.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Is the request for renewal of therapy previously approved by the FFS system?</td>
<td><strong>Yes:</strong> Go to Renewal Criteria</td>
<td><strong>No:</strong> Go to #3</td>
</tr>
<tr>
<td>3.</td>
<td>Is this an FDA approved indication? (Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older).</td>
<td><strong>Yes:</strong> Go to #4</td>
<td><strong>No:</strong> Pass to RPh. Deny; medical appropriateness</td>
</tr>
<tr>
<td>4.</td>
<td>Is the patient uncontrolled on current baseline therapy with at least one other antiepileptic medication? AND Is cannabidiol intended to be prescribed as adjuvant antiepileptic therapy?</td>
<td><strong>Yes:</strong> Go to #5</td>
<td><strong>No:</strong> Pass to RPh. Deny; medical appropriateness</td>
</tr>
<tr>
<td>5.</td>
<td>Is the prescribed dose greater than 20mg/kg/day?</td>
<td><strong>Yes: Pass to RPh. Deny; medical appropriateness</strong></td>
<td><strong>No:</strong> Go to # 6</td>
</tr>
<tr>
<td>5-6.</td>
<td>Are baseline liver function tests on file (serum transaminases and total bilirubin levels)?</td>
<td><strong>Yes:</strong> Approve for 12 months</td>
<td><strong>No:</strong> Pass to RPh. Deny; medical appropriateness</td>
</tr>
<tr>
<td></td>
<td>LFTs should be obtained at 1 month, 3 months, and 6 months after starting treatment with cannabidiol and periodically thereafter as clinically indicated, after cannabidiol dose changes, or addition of other medications that are known to impact the liver.</td>
<td>Document results here: Date of lab work________ AST___________________ ALT___________________ Total Bilirubin___________________</td>
<td>Note: dosage adjustment is recommended for patients with moderate or severe hepatic impairment. See Table 1 for dosing recommendations.</td>
</tr>
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Renewal Criteria

1. Are recent LFT’s documented in patient records?

   Yes: Go to # 2
   Document results here:
   Date of lab work_________
   AST___________________
   ALT___________________
   Total Bilirubin___________

   No: Pass to RPh. Deny; medical appropriateness

2. Has seizure frequency decreased since beginning therapy?

   Yes: Go to #3

   No: Pass to RPh. Deny for lack of treatment response.

3. Is the prescribed dose greater than 20mg/kg/day?

   Yes: Pass to RPh. Deny; medical appropriateness

   No: Go to # 4

3.4. Is cannabidiol intended to be prescribed as adjuvant antiepileptic therapy?

   Yes: Approve for 12 months

   No: Pass to RPh. Deny; medical appropriateness

Table 1: Dose Adjustments of Cannabidiol in Patients with Hepatic Impairment¹

<table>
<thead>
<tr>
<th>Hepatic Impairment</th>
<th>Starting Dosage</th>
<th>Maintenance Dosage</th>
<th>Maximum Recommended Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>2.5 mg/kg twice daily (5 mg/kg/day)</td>
<td>5 mg/kg twice daily (10 mg/kg/day)</td>
<td>10 mg/kg twice daily (20 mg/kg/day)</td>
</tr>
</tbody>
</table>

¹References:
1. Author: Deanna Moretz, PharmD, BCPS
   Date: March 2019
<table>
<thead>
<tr>
<th></th>
<th>Moderate</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>1.25 mg/kg twice daily (2.5 mg/kg/day)</td>
<td>2.5 mg/kg twice daily (5 mg/kg/day)</td>
<td>5 mg/kg twice daily (10 mg/kg/day)</td>
</tr>
<tr>
<td></td>
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P&T/DUR Review: 1/19 (DM)
Implementation: TBD; 3/1/19