

## Voclosporin

**Goal(s):**

- Promote use that is consistent with medical evidence.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Voclosporin pharmacy claims

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an FDA approved indication?	<b>Yes:</b> Go to #3	<b>No:</b> Pass to RPh. Deny; medical appropriateness
3. Is the diagnosis funded by OHP?	<b>Yes:</b> Go to #4	<b>No:</b> Pass to RPh. Deny; not funded by the OHP.
4. Is this a request for continuation of therapy previously approved by fee-for-service (FFS)?	<b>Yes:</b> Go to <b>Renewal Criteria</b>	<b>No:</b> Go to #5
5. Does the patient have Class III, Class IV, or Class V lupus nephritis AND is a baseline assessment with one of the following: <ul style="list-style-type: none"> <li>• Urinary protein to creatinine ratio</li> <li>• eGFR</li> </ul>	<b>Yes:</b> Go to #6	<b>No:</b> Pass to RPh. Deny; medical appropriateness
6. Is the drug being prescribed by or in consultation with a rheumatologist, nephrologist, or a provider with experience treating lupus nephritis?	<b>Yes:</b> Go to #7	<b>No:</b> Pass to RPh. Deny; medical appropriateness

## Approval Criteria

<p>7. Is the patient currently on cyclophosphamide?</p> <p>Note: Voclosporin safety and efficacy has not been established in combination with cyclophosphamide and use is not recommended.</p>	<p><b>Yes:</b> Pass to RPh. Deny; medical appropriateness</p>	<p><b>No:</b> Go to #8</p>
<p>8. Is the patient currently taking or have a contraindication to ALL of the following:</p> <ul style="list-style-type: none"> <li>• Mycophenolate OR Azathioprine</li> <li>• Glucocorticoids (e.g. prednisone)</li> <li>• Hydroxychloroquine</li> </ul>	<p><b>Yes:</b> Go to #9</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
<p>9. Does the patient have proteinuria with a urine protein: creatinine ratio of &gt;500 mg/g?</p>	<p><b>Yes:</b> Go to #10</p>	<p><b>No:</b> Go to #11</p>
<p>10. Is the patient currently taking, or have a contraindication to, either an angiotensin-converting enzyme inhibitor (ACEI) OR an angiotensin II receptor blocker (ARB)?</p>	<p><b>Yes:</b> Go to #11</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness.</p>
<p>11. Is the patient of childbearing potential?</p>	<p><b>Yes:</b> Go to #12</p>	<p><b>No:</b> Approve for 6 months</p>
<p>12. Is the patient pregnant or actively trying to conceive?</p>	<p><b>Yes:</b> Pass to RPh. Deny; medical appropriateness</p>	<p><b>No:</b> Go to #13</p>
<p>13. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant?</p>	<p><b>Yes:</b> Approve for 6 months</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>

<b>Renewal Criteria</b>		
<p>1. Does the patient have an eGFR within past 60 days?</p> <p>Note: Should be monitored monthly per package labeling.</p>	<p><b>Yes:</b> Go to #2</p> <p>Record eGFR value &amp; date</p> <p>_____</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
<p>2. Has the voclosporin dose been adjusted appropriately based on baseline eGFR and current eGFR?</p> <ul style="list-style-type: none"> <li>• If eGFR &lt;60 mL/min/1.73 m<sup>2</sup> and reduced from baseline by &gt;20% and &lt;30%, reduce the dose by 7.9 mg twice a day. Reassess eGFR within two weeks; if eGFR is still reduced from baseline by &gt;20%, reduce the dose again by 7.9 mg twice a day.</li> <li>• If eGFR &lt;60 mL/min/1.73 m<sup>2</sup> and reduced from baseline by ≥30%, discontinue LUPKYNIS. Re-assess eGFR within two weeks; consider re-initiating LUPKYNIS at a lower dose (7.9 mg twice a day) only if eGFR has returned to ≥80% of baseline.</li> <li>• For patients that had a decrease in dose due to eGFR, consider increasing the dose by 7.9 mg twice a day for each eGFR measurement that is ≥80% of baseline; do not exceed the starting dose.</li> </ul>	<p><b>Yes:</b> Go to #3</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
<p>3. Has the patient's lupus nephritis improved or stabilized as assessed by one of the following:</p> <ul style="list-style-type: none"> <li>• Urinary protein to creatinine ratio</li> <li>• eGFR</li> </ul>	<p><b>Yes:</b> Approve for 12 months.</p>	<p><b>No:</b> Pass to RPh; Deny; medical appropriateness.</p>