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
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an FDA approved indication?	**Yes**: Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is this a request for continuation of therapy previously approved by fee-for-service (FFS)?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #54
4. Does the patient have Class III, Class IV, or Class V lupus nephritis AND is a baseline assessment with one of the following: • Urinary protein to creatinine ratio • eGFR	**Yes:** Go to #65	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the drug being prescribed by or in consultation with a rheumatologist, nephrologist, or a provider with experience treating lupus nephritis?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
6. Is the patient currently on cyclophosphamide? Note: Voclosporin safety and efficacy has not been established in combination with cyclophosphamide and use is not recommended.	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #7
7. Is the patient currently taking or have a contraindication to ALL of the following: • Mycophenolate OR Azathioprine • Glucocorticoids (e.g. prednisone) • Hydroxychloroquine	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Does the patient have proteinuria with a urine protein: creatinine ratio of >500 mg/g?	**Yes:** Go to #9	**No:** Go to #10
9. Is the patient currently taking, or have a contraindication to, either an angiotensin-converting enzyme inhibitor (ACEI) OR an angiotensin II receptor blocker (ARB)?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness.
10. Is the patient of childbearing potential?	**Yes:** Go to #11	**No:** Approve for 6 months
11. Is the patient pregnant or actively trying to conceive?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #12
12. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant?	**Yes:** Approve for 6 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Does the patient have an eGFR within past 60 days? Note: Should be monitored monthly per package labeling.	**Yes:** Go to #2 Record eGFR value & date _____	**No:** Pass to RPh. Deny; medical appropriateness
2. Has the voclosporin dose been adjusted appropriately based on baseline eGFR and current eGFR? • If eGFR <60 mL/min/1.73 m2 and reduced from baseline by >20% and <30%, reduce the dose by 7.9 mg twice a day. Reassess eGFR within two weeks; if eGFR is still reduced from baseline by >20%, reduce the dose again by 7.9 mg twice a day. • If eGFR <60 mL/min/1.73 m2 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. • 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.	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Has the patient's lupus nephritis improved or stabilized as assessed by one of the following: • Urinary protein to creatinine ratio • eGFR	**Yes:** Approve for 12 months.	**No:** Pass to RPh; Deny; medical appropriateness.