Sparsentan

Goal(s):

- To promote use that is consistent with medical evidence and product labeling in patients with immunoglobulin A nephropathy (IgAN).
- To ensure appropriate use of sparsentan in populations with clinically definite IgAN.
- To monitor for clinical response for appropriate continuation of therapy.

Length of Authorization:

- Up to 12 months

Requires PA:

- Sparsentan

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 the patient ≥ 18 years of age with diagnosis of IgAN confirmed by biopsy?	**Yes**: Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Does the patient have an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the request for continuation of therapy for a patient who has received ≥ 6 months of initial therapy with this agent?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #5
5. Is the medication going to be used in combination with any renin-angiotensin-aldosterone antagonists (e.g. angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists [ERAs], or aliskiren?	**Yes:** Pass to RPh. Deny; medical appropriateness Use of sparsentan and any these agents is contraindicated.	**No:** Go to #6
6. Is the prescriber a specialist in the management of IgAN (e.g. nephrologist)?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Is the patient at high risk of disease progression, defined as a 24-hour urine collection that indicates: • Proteinuria > 1.0 g/day; -OR- • Urine protein-to-creatinine ratio ≥ 1.5 g/g?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Will the prescriber attest that the patient received the maximum or maximally tolerated dose of ONE of the following for ≥ 12 weeks prior to starting sparsentan: • Angiotensin converting enzyme inhibitor • Angiotensin receptor blocker -OR- is there documentation that the patient has an intolerance or contraindication to renin-aldosterone-angiotensin system (RAAS) inhibitors?	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Has the patient received ≥ 3 months of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification, according to the prescriber?	**Yes**: Approve for 9 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Has the prescriber documented a positive patient response to sparsentan therapy such as: • eGFR that is not declining? • Stabilization or improvement of proteinuria? • No progression to dialysis?	**Yes**: Approve for 1 year	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 12/23
Implementation: 1/1/24