Clinical Policy: Sibeprenlimab-szsi (Voyxact)

Reference Number: PA.CP.PHAR.775
Effective Date: 05/2026
Last Review Date: 04/2026

Description

Sibeprenlimab-szsi (Voyxact®) is an A Proliferation Inducing Ligand (APRIL) blocker.

FDA Approved Indication(s)

Voyxact is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.*

**This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether Voyxact slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.*

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Voyxact is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Immunoglobulin A Nephropathy (must meet all)**:**

1. Diagnosis of IgAN confirmed via kidney biopsy;
2. Prescribed by or in consultation with a nephrologist;
3. Age ≥ 18 years;
4. Documentation of both of the following (a and b):
   a. Proteinuria of ≥ 0.5 g/day or urine protein-to-creatinine ratio (UPCR) ≥ 0.75 g/g;
   b. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2;
5. Member meets both of the following, unless contraindicated or clinically significant adverse effects are experienced (a and b, *see Appendix D*):
   a. Failure of a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g., irbesartan, losartan, lisinopril, benazepril) for at least 12 weeks;
   b. RAAS inhibitor therapy dose was at least 50% of maximum labeled dose;
6. Failure of a sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., empagliflozin, dapagliflozin) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
7. Failure of Filspari® or Vanrafia™ at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
8. Dose does not exceed both of the following (a and b):
   a. 400 mg every 4 weeks;
   b. 1 prefilled syringe per 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Immunoglobulin A Nephropathy (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. Decrease in UPCR from baseline;
   b. Reduction of proteinuria as evidence by a lower total urine protein per day from baseline;
3. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 400 mg every 4 weeks;
   b. 1 prefilled syringe per 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACEI: angiotensin-converting-enzyme inhibitor
ARB: angiotensin receptor blocker
eGFR: estimated glomerular filtration rate
FDA: Food and Drug Administration
IgAN: immunoglobulin A nephropathy
RAAS: renin-angiotensin-aldosterone system
SGLT2: sodium-glucose cotransporter-2
UPCR: urine protein-to-creatinine ratio

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Maximum Dose
Angiotensin/Endothelin-Receptor Antagonists	
Filspari (sparsentan)	400 mg/day
Vanrafia (atrasentan)	0.75 mg/day
ACEIs	
benazepril (Lotensin®)	80 mg/day
captopril (Capoten®)	450 mg/day
enalapril (Vasotec®, Epaned®)	40 mg/day
fosinopril (Monopril®)	80 mg/day
lisinopril (Prinivil®, Zestril®, Qbrelis®)	80 mg/day
moexipril (Univasc®)	30 mg/day
perindopril (Aceon®)	16 mg/day
quinapril (Accupril®)	80 mg/day
ramipril (Altace®)	20 mg/day
trandolapril (Mavik®)	8 mg/day
ARBs	
azilsartan (Edarbi®)	80 mg/day
candesartan (Atacand®)	32 mg/day
eprosartan (Teveten®)	900 mg/day
irbesartan (Avapro®)	300 mg/day
losartan (Cozaar®)	100 mg/day
olmesartan (Benicar®)	40 mg/day
telmisartan (Micardis®)	80 mg/day
valsartan (Diovan®)	320 mg/day
SGLT2 Inhibitors	
dapagliflozin (Farxiga®)	10 mg/day
Jardiance® (empagliflozin)	10 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): serious hypersensitivity to sibeprenlimab-szsi or any of the excipients of Voyxact
- Boxed warning(s): none reported

Appendix D: General Information

- The 2025 Kidney Disease Improving Global Outcomes (KDIGO) recommends initial therapy with a RAAS inhibitor (ACEI or ARB), singly or in combination with an SGLT2 inhibitor, for patients with proteinuria > 0.5 g per day, regardless of whether the patient has hypertension.
- Patients with IgAN who are considered high risk for progressive chronic kidney disease despite maximum supportive care (defined as blood pressure control, reduction of proteinuria, and lifestyle modifications) may consider treatment with corticosteroids or immunosuppressive drugs; however, there is current uncertainty over the safety and efficacy of existing immunosuppressive treatment choices. For all patients in whom immunosuppression is being considered, a detailed discussion of the risks and benefits of

each drug should be undertaken with the patient recognizing that adverse treatment effects are more likely in patients with eGFR < 50 mL/min/1.73 m^2.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IgAN	400 mg SC every 4 weeks	400 mg/month

VI. Product Availability

Prefilled syringe: 400 mg/2 mL

VII. References

1. Voyxact Prescribing Information. Rockville, MD: Otsuka Pharmaceutical, Inc.; November 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761434s000lbl.pdf. Accessed February 12, 2026.
2. Rovin BH, Barratt J, Cook HT, et al; KDIGO IgAN and IgAV Work Group. KDIGO 2025 clinical practice guideline for the management of immunoglobulin A nephropathy (IgAN) and immunoglobulin A vasculitis (IgAV). Kidney Int. 2025;108(4 Suppl):S1-S71. doi:10.1016/j.kint.2025.04.004

Reviews, Revisions, and Approvals	Date
Policy created	04/2026