Clinical Policy: Sibeprenlimab-szsi (Voyxact)

Reference Number: CP.PHAR.775
Effective Date: 06.01.26
Last Review Date: 05.26
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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 ≥ 1 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*):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   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;*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*

7. Failure of Filspari® or Vanrafia™ at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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

Drug Name	Maximum Dose
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	P&T Approval Date
Policy created	02.12.26	05.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.