Original Effective Date: 05/30/2026
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Last P&T Approval/Version: 07/29/2026
Next Review Due By: 07/2027
Policy Number: C30604-A

Voyxact (sibeprenlimab-szsi)

PRODUCTS AFFECTED

Voyxact (sibeprenlimab-szsi)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Primary Immunoglobulin A Nephropathy (IgAN)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered, and formulary preferencing. This clinical policy will be reviewed. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred.

A. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY:
   1. Documented diagnosis of Primary Immunoglobulin A Nephropathy (IgAN)
      AND

2. Documentation diagnosis was confirmed by kidney biopsy [DOCUMENTATION REQUIRED]
   AND
3. Documentation that member has failed to achieve a reduction in proteinuria under 1 gram/day while receiving maximally tolerate doses of a Renin-angiotensin-system (RAS) inhibitor (ACE inhibitor or ARB) for at least 3 months
   AND
4. Documentation that member has had a trial and failure of ONE formulary preferred glucocorticoid for at least 2 months
   AND
5. Documentation of baseline eGFR ≥ 30 mL/min/1.73 m2
   AND
6. Documentation that member's urine protein-to-creatinine ratio (UPCR) ≥ 0.75 g/g
   AND
7. Member is not currently receiving dialysis or has not undergone kidney transplant

CONTINUATION OF THERAPY:

A. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by stabilization of eGFR and decrease in UPCR from baseline

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Connecticut Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified nephrologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

400 mg subcutaneously every 4 weeks

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Subcutaneous

DRUG CLASS:

IgAN Agents - A Prolif Inducing Ligand (APRIL) Blocker

FDA-APPROVED USES:

Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Connecticut (Source: State of Connecticut)
"Sec. 38a-591o. Restrictions applicable to prospective or concurrent review of certain recurring prescription drugs. Exceptions…. (b) No health carrier shall require a prospective or concurrent review of a *recurring prescription drug to directly treat any autoimmune disorder, multiple sclerosis or cancer after such health carrier has certified such prescription drug through utilization review*. Nothing in this section shall require a health carrier to cover: (1) Any prescription drug to treat any autoimmune disorder, multiple sclerosis or cancer if the terms of coverage completely exclude such prescription drug from the policy's covered benefits; (2) a brand name drug when an equivalent generic drug is available; (3) a prescription drug that was certified through prospective or concurrent review (A) by such covered person's previous health carrier, or (B) under a previous employer's fully insured health plan administered by a third-party administrator that provided coverage to such covered person."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Immunoglobulin A (IgA) nephropathy is an immune mediated glomerular disease. The pathology of the disease begins with elevated circulating levels of galactose deficient IgA-1 (Gd-IGA1), which then results in the production of autoantibodies against Gd-IGA1. IgA-containing immune complexes form and deposit in the glomerular mesangium. These deposits trigger an inflammatory response leading to progressive loss of kidney function. Voyxact (sibeprenlimab-szsi) is humanized IgG2 monoclonal antibody. Voyxact (sibeprenlimab-szsi) inhibits A Proliferation Inducing Ligand (APRIL). Inhibiting APRIL results in reduced levels of galactose deficient IgA-1 (Gd-IGA1).

Typical manifestations of IgA nephropathy include hematuria, proteinuria and hypertension. Per the 2025 KDIGO Guideline, IgA nephropathy can only be diagnosed with a kidney biopsy as there are no validated serum or urine biomarkers for diagnosis. Once diagnosed, the goal of treatment is to reduce the rate of loss of kidney function. Urine protein excretion is a validated biomarker to guide treatment and clinical decisions. Rapidly progressive IgAN is a decline of at least 50% in estimated Glomerular Filtration Rate (eGFR) in less than or equal to three months.

KDIGO 2025 Guidelines for IgAN recommend simultaneously targeting optimized supportive care to slow or prevent nephron loss and pathogenic mechanism directed therapy. The KDIGO guidelines recommended treatments for patients with IgA nephropathy who are at risk of progressive loss of kidney function include systemic glucocorticoids. Additionally, Sodium-glucose co-transporter 2 inhibitors (SGLT2i) have been shown to reduce the rate of progressive kidney loss and reduce cardiovascular events. Other supportive care includes blood pressure control, including angiotensin-converting enzyme inhibitors (ACEis) or angiotensin receptor blockers (ARBs). Voyxact (sibeprenlimab-szsi) is not included in the guideline as there was not sufficient reported data at the cutoff time (April 2024).

The 2025 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for IgAN and IgA Vasculitis emphasizes that patients with proteinuria ≥0.5 g/day are at risk for progressive loss of kidney function and should be considered for treatment or additional treatment. The guideline further identifies reduction of proteinuria to <0.5 g/day, and ideally <0.3 g/day, as an important therapeutic goal. However, KDIGO acknowledges that treatment selection should be individualized and based on the totality of clinical evidence, including patient-specific risk factors, kidney function, histopathology, and the supporting evidence available for individual therapies.
While KDIGO 2025 lowers the threshold for identifying patients at risk of progression, the major clinical trials evaluating currently available disease-specific therapies for IgAN predominantly enrolled patients with higher levels of persistent proteinuria, generally exceeding 1 g/day despite optimized supportive care. Evidence demonstrating efficacy and long-term renal benefit in patients with lower levels of residual proteinuria remains limited. Therefore, persistent proteinuria greater than 1 g/day despite optimized supportive care continues to identify a population at substantial risk for progression and represents the patient population for whom the greatest clinical evidence supporting disease-specific pharmacologic intervention is currently available.
KDIGO 2025 recommends that all patients with IgAN receive optimized supportive care, including maximally tolerated renin-angiotensin system (RAS) blockade when appropriate, blood pressure control, lifestyle modification, and consideration of sodium-glucose cotransporter-2 (SGLT2) inhibitor therapy when clinically indicated. For patients who remain at risk of progressive kidney disease despite supportive care, additional disease-specific therapies may be considered. The guideline specifically discusses therapies such as targeted-release budesonide (Tarpeyo) and sparsentan while emphasizing ongoing assessment of proteinuria and kidney function as key measures of treatment response.
In alignment with the available clinical trial evidence and FDA-approved therapeutic development programs in IgAN, persistent proteinuria greater than 1 g/day despite optimized supportive care remains an appropriate threshold for identifying patients most likely to derive benefit from disease-specific pharmacologic therapy.

Voyxact (sibeprenlimab-szsi) was assessed in the VISIONARY trial. VISIONARY was a multicenter, double-blind, placebo-controlled trial [NCT05248646]. Trial participants (n=510) with biopsy confirmed IgA nephropathy were randomized to sibeprenlimab 400 mg subcutaneous injection or placebo every 4 weeks for 26 doses. Participants in the trial were receiving maximally tolerated standard of care treatment. Key inclusion criteria includes age of 18 or older, biopsy confirmed IgAN, eGFR of at least 30 mL/min/1.73m^2, on stable, maximally tolerated ACEI or ARB for at least 3 months. The trial excluded patients with secondary forms of IgAN or IgA vasculitis, coexisting chronic kidney disease other than IgAN, chronic infectious disease, Type 1 of poorly controlled Type 2 diabetes, and any other kidney biopsy findings in addition to the IgAN. The primary endpoint of the trial was the 24-hour urine protein-to-creatinine ratio at 9 months, compared to baseline. The interim efficacy analysis included 320 participants who had completed 9 months of treatment. The observed geometric mean percent change from baselines was -50% (95% CI) in the treatment group compared to the placebo.

The most common adverse reactions were upper respiratory infection and injection site reactions.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Voyxact (sibeprenlimab-szsi) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Voyxact (sibeprenlimab-szsi) include serious hypersensitivity to sibeprenlimab-szsi or any of its excipients.

Exclusions/Discontinuation:
Treatment with Voyxact (sibeprenlimab-szsi) suppresses the immune system and increases the risk of infection. Patients should be assessed for active infection prior to initiation and throughout treatment. If a serious infection develops, consider interrupting Voyxact (sibeprenlimab-szsi) until the infection is controlled. Additionally, live vaccines should not be administered 30 days prior to or while on treatment with Voyxact (sibeprenlimab-szsi).

OTHER SPECIAL CONSIDERATIONS:

Voyxact (sibeprenlimab-szsi) received accelerated approval for reducing proteinuria. Its long-term effect on kidney function in IgAN patients is unconfirmed, and ongoing approval depends on clinical trial evidence of benefit. Per the package insert for Voyxact (sibeprenlimab-szsi), the product is intended for patient self-administration or for administration by a caregiver. Voyxact (sibeprenlimab-szsi) is injected subcutaneously in the front of the thigh or the abdomen. The back of the upper arm is also acceptable if a caregiver is administering the injection.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Voyxact SOSY 400MG/2ML single-dose prefilled syringe

REFERENCES

1. Voyxact (sibeprenlimab-szsi) injection, for subcutaneous use [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2025.
2. KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidney International, 108 (4), S1-S71.
3. Perkovic V, Barratt J, Lafayette R, Liew A, Suzuki Y, Carroll K, Cheung CK, Tesař V, Trimarchi H, Wong MG, Zhang H, Xia J, Fajardo C, Shah L, Hafkin J, Rizk DV. Evaluating Sibeprenlimab in IgA Nephropathy - Rationale and Baseline Data from the VISIONARY Trial. Kidney Int Rep. 2025 Oct 1;10(12):4207-4218.
4. ClinicalTrials.gov. (2022). Visionary study: Phase 3 trial of sibeprenlimab in immunoglobulin A nephropathy (IgAN) (NCT05248646). U.S. National Library of Medicine. https://clinicaltrials.gov/study/NCT05248646
5. Perkovic V, Trimarchi H, Tesar V, Lafayette R, Wong MG, Barratt J, Suzuki Y, Liew A, Zhang H, Carroll K, Jha V, Quevedo A, Han SH, Praga M, Chacko B, Sahay M, Cheung CK, Kooienga L, Walsh M, Xia J, Fajardo C, Shah L, Hafkin J, Rizk DV; VISIONARY Trial Investigators Group. Sibeprenlimab in IgA Nephropathy - Interim Analysis of a Phase 3 Trial. N Engl J Med. 2025 Nov 8. doi: 10.1056/NEJMoa2512133. Epub ahead of print. PMID: 41211929.
6. Srinivas S, Madhavaram SK, Bhanushali SA, Kalra K. The Immunoglobulin A Nephropathy Renaissance: From Pathogenesis to Personalized Therapy. Cureus. 2025 Nov 28;17(11):e97999. doi: 10.7759/cureus.97999. PMID: 41466967; PMCID: PMC12744310.
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8. Kidney Disease: Improving Global Outcomes (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(4S):S1–S71.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Duration of Approval FDA-Approved Uses Appendix Background References	Q3 2026
NEW CRITERIA CREATION	Q1 2026