AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Voyxact	Page:	1 of 3
Effective Date:	3/9/2026	Last Review Date:	1/2026

Applies to:	☒Illinois	☐Florida	☒Florida Kids
	☒New Jersey	☒Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Voyxact under the patient's prescription drug benefit.

Description:

FDA-approved Indications[1]

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

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Voyxact

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Initial requests:
  - Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
  - Laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 0.5 grams per day (g/day) or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 grams per gram (g/g) obtained within 3 months prior to initiation of the requested drug.
- Continuation requests:
  - Laboratory report and/or chart note(s) indicating the member has decreased levels of proteinuria or UPCR from baseline.

Prescriber Specialties

This medication must be prescribed by or in consultation with a nephrologist.

Coverage Criteria

Primary Immunoglobulin A Nephropathy (IgAN)[1-4]
Authorization of 12 months may be granted when all of the following criteria are met:

- Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.
- Member has either of the following obtained within 3 months prior to initiation of the requested drug:
  - Proteinuria greater than or equal to 0.5 g/day
  - UPCR greater than or equal to 0.8 g/g
- Member has received a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor blocker [ARB]) for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to RAS inhibitors.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in all members (including new members) who are currently receiving the requested medication and who are experiencing benefit from therapy as evidenced by either of the following:

- Decreased levels of proteinuria from baseline.
- Decrease in UPCR from baseline.

Approval Duration and Quantity Restrictions:
Approval: 12 months

Quantity Level Limit:
- Voyxact (sibeprenlimab-szsi) 400 mg per 2 mL prefilled syringe for subcutaneous injection: 1 prefilled syringe per 28 days

References:
1. Voyxact [package insert]. Tokyo, Japan: Otsuka Pharmaceutical Company, Ltd.; November 2025.
2. ClinicalTrial.gov. National Library of Medicine (US). Identifier NCT05248646 Visionary Study: Phase 3 Trial of Sibeprenlimab in Immunoglobulin A Nephropath (IgAN). July 10, 2025. Available from: https://clinicaltrials.gov/study/NCT05248646.
3. Fellstrom BC, Baratt J, Cook H, et al. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomized, placebo-controlled phase 2b trial. Lancet. 2017 May 27;389 (10084): 2117-2127.

4. Kidney Disease: Improving Global Outcomes (KDIGO). KDIGO 2025 Clinical Practice Guideline for the Management of Immnoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidney Int. 2025 Oct; 108 (4S): S1-S71.