

# Specialty Guideline Management

## Niktimvo

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Niktimvo	axatilimab-csfr

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications<sup>1</sup>

Niktimvo is indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

#### Compendial Use<sup>2</sup>

Chronic graft-versus-host disease (GVHD)

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

### Coverage Criteria

#### Chronic Graft-Versus-Host Disease (cGVHD)<sup>1,2</sup>

Reference number(s)
6596-A

Authorization of 12 months may be granted for treatment of cGVHD when all of the following criteria are met:

- The member has had at least two prior lines of systemic therapy that failed to produce the desired response AND
- The member weighs at least 40 kg

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## References

1. Niktimvo [package insert]. Wilmington, DE: Incyte Corporation; January 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 7, 2025.