Mass General Brigham
Health Plan

Niktimvo (axatilimab-csfr)
Effective 06/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Niktimvo (axatilimab-csfr) is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody 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 kilograms.

In the AGAVE-201 tria,l refractory disease was defined as meeting any of the following:

a. Development of ≥ 1 new sites of disease while being treated for cGVHD
b. Progression of existing sites of disease despite ≥ 1 month of standard or investigational therapy for cGVHD
c. Participants who have not achieved a response within 3 months on their prior therapy for cGVHD and for whom the treating provider believes a new systemic therapy is required.

Additionally, recurrent disease was defined as the following:

a. Active, symptomatic disease (after an initial response to prior therapy) as defined, based on the NIH 2014 consensus criteria, by organ-specific or global assessment or for which the provider believes that a new line of systemic therapy is required.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

1. Documented diagnosis of chronic graft-versus-host disease (cGVHD) post allogeneic hematopoietic cell transplantation (aHSCT)
2. Documented failure of at least two prior lines of systemic therapy
3. Member weight is at least 40 kilograms

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation of positive clinical response to therapy

Limitations

1. Initial and reauthorization requests will be approved for 12 months

References

1. Niktimvo (axatilimab-csfr) [prescribing information]. Wilmington, DE: Incyte Corporation; January 2025.

Review History

04/09/2025 – Reviewed at April P&T. Effective 06/01/2025.