PRIOR AUTHORIZATION POLICY

POLICY: Niktimvo Prior Authorization Policy
- Niktimvo™ (axatilimab-csfr intravenous infusion – Incyte/Syndax)

REVIEW DATE: 10/23/2024

OVERVIEW

Niktimvo, a colony stimulating factor-1 receptor-blocking antibody, is indicated for the treatment of chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

Guidelines

Niktimvo has been addressed in the National Comprehensive Cancer Network Hematopoietic Cell Transplantation guidelines (version 1.2024 – August 30, 2024). Options for first-line therapy for chronic GVHD including restarting, continuing, or escalating the original immunosuppressive agent(s) and/or administering systemic corticosteroids (0.5 to 1 mg/kg day of methylprednisolone or prednisone dose equivalent). Among the agents FDA-approved for use in chronic GVHD, Jakafi® (ruxolitinib tablets) is the only agent given a category 1 recommendation for chronic GVHD. Niktimvo, Rezurock® (belumosudil tablets), and Imbruvica® (ibrutinib tablets, capsules, and oral suspension) each have a category 2A recommendation. The guidelines cite that each of these FDA-approved agents should be used following failure of one or two lines of systemic therapy (depending on the agent). Other medication alternatives include Orencia® (abatacept intravenous [IV] infusion and subcutaneous [SC] injection), Lemtrada® (alemtuzumab IV infusion), calcineurin inhibitors (e.g., tacrolimus, cyclosporine), Enbrel® (etanercept SC injection), extracorporeal photopheresis, hydroxychloroquine, imatinib, Proleukin® (aldesleukin IV infusion and SC injection), low-dose methotrexate, mammalian target of rapamycin inhibitors (e.g., sirolimus), mycophenolate mofetil, pentostatin, and rituximab.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Niktimvo. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Niktimvo is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Graft-Versus-Host Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 40 kg; AND
   - **B)** Patient has chronic graft-versus-host disease; AND
   - **C)** Patient has tried at least two conventional systemic treatments for chronic graft-versus-host disease. Note: Examples of systemic therapy may include Jakafi (ruxolitinib tablets), Rezurock (belumosudil tablets), Imbruvica (ibrutinib tablets, capsules, and oral suspension), imatinib,

hydroxychloroquine, methotrexate, rituximab, pentostatin, interleukin-2 (e.g., Proleukin [aldesleukin intravenous infusion]), methylprednisolone, cyclosporine, tacrolimus, sirolimus, and mycophenolate mofetil.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Niktimvo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Niktimvo™ intravenous infusion [prescribing information]. Wilmington, DE: Incyte; August 2024.
2. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 2.2024 – August 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 9, 2024.