PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Proleukin Prior Authorization Policy
- Proleukin® (aldesleukin intravenous infusion – Prometheus Laboratories)

REVIEW DATE: 01/18/2023

OVERVIEW
Proleukin, a human recombinant interleukin-2 product, is indicated for the following conditions, in adults:
- **Metastatic melanoma**.
- **Metastatic renal cell carcinoma**.[1]

Guidelines
Proleukin is addressed in the following National Comprehensive Cancer Network guidelines:
- **Cutaneous melanoma** (version 1.2023 – December 22, 2022) clinical practice guidelines recommend Proleukin for unresectable or metastatic disease as a single agent for second-line or subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy (category 2A).[2,4] Proleukin may be considered for patients with small brain tumors and without significant peritumoral edema (category 2B) or for intralesional therapy as primary or second-line treatment of unresectable stage III disease with clinical or satellite/in-transit metastases, or local satellite/in-transit recurrence (category 2B).
- **Hematopoietic cell transplantation** (version 2.2022 – September 28, 2022) clinical practice guidelines recommend Proleukin as additional therapy, in combination with systemic corticosteroids, for steroid-refractory chronic graft-vs-host disease.[2,5]
- **Kidney cancer** (version 3.2023 – September 22, 2022) clinical practice guidelines recommend Proleukin as a single agent for first-line (category 2B) and subsequent (category 2B) therapy for patients with relapsed or stage IV disease and clear cell histology.[2,3]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Proleukin. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Proleukin as well as the monitoring required for adverse events and long-term efficacy, approval requires Proleukin to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Proleukin is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Cutaneous Melanoma**. Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Intravenous Therapy. Approve if the patient meets the following criteria (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has metastatic or unresectable disease; AND

iii. Patient has tried at least one other systemic therapy; AND
iv. Proleukin will be used as a single agent; AND
v. Proleukin is prescribed by or in consultation with an oncologist.

B) Intralesional Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
i. Patient is ≥ 18 years of age; AND
ii. Proleukin will be directly injected into metastatic, recurrent, or unresectable cutaneous, subcutaneous, or nodal lesions; AND
iii. The medication is prescribed by or in consultation with an oncologist or dermatologist.

2. Kidney Cancer. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has relapsed or metastatic disease; AND
C) Patient has clear cell histology; AND
D) Proleukin will be used as a single agent; AND
E) Proleukin is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

3. Graft-Versus-Host Disease. Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
A) Patient has chronic graft-versus-host disease; AND
B) According to the prescriber, the patient has steroid-refractory disease; AND
C) Proleukin will be used in combination with systemic corticosteroids; AND
D) Proleukin will be prescribed by or in consultation with an oncologist or a physician associated with a transplant center.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Proleukin 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. Proleukin® intravenous infusion [prescribing information]. San Diego, CA: Prometheus Laboratories; September 2019.
2. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 10, 2023. Search term: aldesleukin.
3. The NCCN Kidney Cancer Clinical Practice Guidelines (version 3.2023 – September 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 10, 2023.
4. The NCCN Cutaneous Melanoma Clinical Practice Guidelines (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 10, 2023.
5. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines (version 2.2022 – September 28, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 10, 2023.