

STANDARD MEDICARE PART B MANAGEMENT

PROLEUKIN (aldesleukin)

POLICY

I. 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.

A. FDA-Approved Indications

1. Proleukin is indicated for the treatment of adults with metastatic renal cell carcinoma (metastatic RCC).
2. Proleukin is indicated for the treatment of adults with metastatic melanoma.

B. Compendial Uses

1. Relapsed or stage IV renal cell carcinoma with clear cell histology; as high-dose single-agent therapy as first-line therapy
2. Metastatic or unresectable cutaneous melanoma; as high-dose single-agent therapy as second-line or subsequent therapy
3. Chronic graft-versus-host disease (GVHD)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. **Renal Cell Carcinoma**

Authorization of 12 months may be granted for treatment of relapsed or stage IV renal cell carcinoma for high-dose single-agent therapy.

B. **Cutaneous Melanoma**

Authorization of 12 months may be granted for treatment of metastatic or unresectable cutaneous melanoma for high-dose single-agent therapy as second-line or subsequent therapy.

C. **Chronic graft-versus-host disease (GVHD)**

Authorization of 12 months may be granted for treatment of chronic graft-versus host-disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following no response to first-line therapy options.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Reference number(s)
4239-A

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

- A. The member is currently receiving therapy with Proleukin.
- B. Proleukin is being used to treat an indication enumerated in Section II.
- C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Proleukin [package insert]. San Diego, CA: Prometheus Laboratories Inc.; September 2019.
2. The NCCN Drugs & Biologic Compendium 2020 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 6, 2020.