

SPECIALTY GUIDELINE 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)
4. Neuroblastoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Renal Cell Carcinoma**

Authorization of 6 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 6 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 6 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.

D. **Neuroblastoma**

Authorization of 6 months may be granted for the treatment of neuroblastoma.

III. CONTINUATION OF THERAPY

A. **Renal Cell Carcinoma or Cutaneous Melanoma**

Reference number(s)
2080-A

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for renal cell carcinoma or cutaneous melanoma when all of the following criteria are met:

1. The member must be evaluated for response approximately 4 weeks after completion of a course of therapy and again immediately prior to the scheduled start of the next treatment course,
2. Additional courses of treatment should be given only if there is some tumor shrinkage following the last course,
3. Retreatment is not contraindicated,
4. Each treatment course should be separated by a rest period of at least 7 weeks from the date of hospital discharge.

B. Chronic graft-versus-host disease (GVHD)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for chronic graft-versus-host disease (GVHD) who have improvement in symptoms and no unacceptable toxicity.

C. Neuroblastoma

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for neuroblastoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Proleukin [package insert]. San Diego, CA: Prometheus Laboratories Inc.; September 2019.
2. The NCCN Drugs & Biologic Compendium 2021 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 3, 2021.
3. Pistoia V, Bianchi G, Borgonovo G, Raffaghello L. Cytokines in neuroblastoma: From pathogenesis to treatment. *Immunotherapy*. 2011;3(7):895-907.
4. Russell HV, Shohet JM, Nuchtern JG. Treatment and prognosis of neuroblastoma. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed September 2012.
5. Levy G, Bonnevalle M, Rocourt N, et al. Necrotizing enterocolitis as an adverse effect of recombinant interleukin-2 and Ch14.18 in maintenance therapy for high-risk neuroblastoma. *J Pediatr Hematol Oncol*. 2015;37(4):e250-e252.
6. Unituxin [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; September 2020.