Reference number(s)
2080-A

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 kidney cancer with clear cell histology; as high-dose single-agent therapy as first-line or subsequent therapy
2. Metastatic or unresectable cutaneous melanoma; as high-dose single-agent therapy as second-line or subsequent therapy
3. Neuroblastoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. Renal Cell Carcinoma
Authorization of 12 months may be granted for treatment of relapsed or metastatic renal cell carcinoma with clear cell histology for high-dose single-agent therapy as first-line or subsequent therapy.

B. 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. Neuroblastoma
Authorization of 12 months may be granted for the treatment of neuroblastoma.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II 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.

IV. REFERENCES

1. Proleukin [package insert]. San Diego, CA: Prometheus Laboratories Inc.; August 2018.
2. The NCCN Drugs & Biologic Compendium 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 31, 2019.
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.