Draft Revised Policy: Do Not Implement

Aldesleukin (Proleukin®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

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. Unresectable cutaneous melanoma
   2. Chronic graft-versus-host disease (GVHD)
   3. 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 metastatic renal cell carcinoma ~~with clear cell histology.~~

B. Cutaneous Melanoma

1. Authorization of 6 months may be granted as high-dose single-agent subsequent therapy for metastatic or unresectable disease.
2. Authorization of 3 months may be granted for treatment of unresectable or metastatic cutaneous melanoma for up to a maximum of 6 doses after administration of Amtagvi infusion.

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
Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for renal cell carcinoma or single agent subsequent treatment for 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Proleukin [package insert]. Philadelphia, PA: Iovance Biotherapeutics Manufacturing LLC.; January 2024.
2. The NCCN Drugs & Biologic Compendium 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 10, 2024.
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.
7. Amtagvi [package insert]. Philadelphia, PA: Iovance Biotherapeutics Manufacturing LLC; February 2024.

EFFECTIVE DATE

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