Aldesleukin (Proleukin®, IL-2, Interleukin)

Place of Service

Office Administration
Outpatient Facility Infusion Administration
Infusion Center Administration

HCPCS: J9015 per single-use vial

Conditions listed in policy (*see criteria for details*)

- Cutaneous melanoma – metastatic
- Graft versus host disease
- Neuroblastoma, high risk
- Renal cell carcinoma - metastatic

AHFS therapeutic class: Antineoplastic Agents

Mechanism of action: Aldesleukin, a human interleukin-2 derivative, is a biosynthetic (recombinant DNA origin) cytokine (i.e., lymphokine) with antineoplastic and immunomodulating activities.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Proleukin® (aldesleukin) not listed in section (3) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Cutaneous melanoma - metastatic

Covered Doses
Up to 720,000 IU/kg IV every 8 hours for a maximum of 14 doses (5 days) followed by at least 6 days of rest and a repeat of the 14 doses.
Each treatment course should be separated by at least 6 weeks.

Coverage Period
Indefinite

ICD-10:
C43.0, C43.10-C43.12, C43.20-C43.22, C43.30, C43.31, C43.39, C43.4, C43.51, C43.52, C43.59-C43.62, C43.70-C43.72, C43.8, C43.9
C43.111, C43.112, C43.121, C43.122

Graft versus host disease

1. Inadequate response to at least one prior drug for GVHD (i.e., systemic corticosteroids, immunosuppressants)

Covered Doses
up to $1x10^6$ IU/m^2 SC daily

Coverage Period
Indefinite

ICD-10:
D89.810-D89.813, T86.09

Neuroblastoma, high risk

1. Patient has received prior first-line therapy, **AND**
2. Used in combination with Unituxin (dinutuximab), Leukine (sargramostim), and isotretinoin

Covered Doses
3 MIU/m^2/day IV on days 1-4, and 4.5 MIU/m^2/day IV on days 8-11
IL-2 is given for 8 days (divided as above) during cycles 2 and 4 only of the 6-cycle chemotherapy regimen

Coverage Period
Cover 2 cycles (8 doses) in 1 year

ICD-10:
C74.90

Renal carcinoma - metastatic

Covered Doses
Up to 720,000 IU/kg IV every 8 hours for a maximum of 14 doses (5 days) followed by at least 6 days of rest and a repeat of the 14 doses.
Each treatment course should be separated by at least 6 weeks.

Coverage Period
Indefinite

ICD-10:
C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, Z85.528

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Proleukin® (aldesleukin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21): -

- HIV/AIDS Disease

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

22 million international units (single-use vial)

- After reconstitution, the vial provides **18 million international units**

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Cutaneous melanoma (Version 3.2022). Available at http://www.nccn.org
- National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (Version 2.2022). Available at http://www.nccn.org
- National Comprehensive Cancer network. Kidney cancer (Version 3.2023). Available at http://www.nccn.org
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Proleukin® (2023). Available by subscription at: http://www.nccn.org
- Proleukin® (aldesleukin) [Prescribing information]. Yardley, PA: Boehringer Ingelheim Pharma 11/2019.
- Unituxan® (dinutuximab) [Prescribing information]. Research Triangle Park, NC: United Therapeutics Corp. 9/2020.

(7) Policy Update

Date of last review: 1Q2023

Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee