

## Proleukin® (aldesleukin, IL-2)

**Date of Origin:** 9/27/17

**Last Review Date:** 9/27/17

**Effective Date:** 12/1/2017

**Dates Reviewed:** 9/27/17

**Developed By:** Medical Necessity Criteria Committee

### I. Length of Authorization

Coverage is provided for 2 months and may be renewed.

### II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 22 million IU single-use vial: 112 vials per 68 days (4 vials per dose x 28 doses)

B. Max Units (per dose and over time) [Medical Benefit]:

- 88 billable units per 68 days

### III. Initial Approval Criteria

- Patient is 18 years or older; **AND**
- Patient must have normal cardiac function determined by thallium stress testing; **AND**
- Patient must have normal pulmonary function determined by formal pulmonary function testing; **AND**
- Proleukin should be administered in a hospital setting under close supervision; **AND**
- Pre-existing bacterial infections should be adequately treated prior to initiation of therapy; **AND**
- Patient must not have an organ allograft; **AND**

Coverage is provided in the following conditions:

#### **Renal Cell Carcinoma †**

- Patient must have relapsed or metastatic disease; **AND**
- Must be used as first-line therapy; **AND**
- Must be used as a single agent; **AND**
- Patient must have predominant clear cell histology

#### **Melanoma †**

- Patient must have unresectable or metastatic disease; **AND**
- Used as first-line therapy†; **AND**
  - Patient must have an ECOG performance status of 0-1; **OR**
- Used as second-line or subsequent therapy‡; **AND**
  - Patient has disease progression or achieved maximum clinical benefit from BRAF targeted therapy; **AND**
  - Patient must have an ECOG performance status of 0-2; **AND**
    - Used as a single agent; **OR**
    - Used in combination with:
      - Interferon alfa and dacarbazine; **OR**
      - Temozolomide and cisplatin or carboplatin
- Patient must not have active, untreated brain metastases

† FDA-labeled indication(s); ‡ Compendia approved indication(s)

**IV. Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria in Section III; **AND**
- Disease response with treatment as defined by decrease in tumor size; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include sustained ventricular tachycardia (≥5 beats); cardiac arrhythmias not controlled or unresponsive to management; chest pain with ECG changes, consistent with angina or myocardial infarction; cardiac tamponade; intubation for > 72 hours; renal failure requiring dialysis > 72 hours; coma or toxic psychosis lasting > 48 hours; repetitive or difficult to control seizures; bowel ischemia/perforation; GI bleeding requiring surgery, etc.; **AND**
- Patient must not have developed moderate to severe lethargy or somnolence

**V. Dosage/Administration**

Indication	Dose
All indications	600,000 IU/kg administered every 8 hours IV for a maximum of 14 doses. Following 9 days of rest, the schedule is repeated for another 14 doses, for a maximum of 28 doses per course, as tolerated. Each treatment course should be separated by a rest period of at least 7 weeks from the date of hospital discharge.

## VI. Billing Code/Availability Information

### Jcode:

- J9015 – Injection, aldesleukin, per single use vial

### NDC:

- Proleukin 22 million IU single-use vial – 65483-0116-07

## VII. References

1. Proleukin [package insert]. San Diego, CA; Prometheus Laboratories, Inc.; January 2015. Accessed September 2017.
2. NCCN Clinical Practice Guidelines in Oncology™. Kidney Cancer v.1.2018. [cited 9/20/2017]; Available from: [https://www.nccn.org/professionals/physician\\_gls/pdf/kidney.pdf](https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf)
3. NCCN Clinical Practice Guidelines in Oncology™. Melanoma v.1.2017. [cited 9/20/2017]; Available from: [https://www.nccn.org/professionals/physician\\_gls/pdf/melanoma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/melanoma.pdf)
4. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD) for Chemotherapy Drugs and their Adjuncts (L35053). Centers for Medicare & Medicaid Services, Inc. Updated on 11/22/2016 with effective date 1/1/2017. Accessed December 2016.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
Z85.528	Personal history of other malignant neoplasm of kidney
Z85.820	Personal history of malignant melanoma of skin

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

<b>Jurisdiction(s): 5, 8</b>	<b>NCD/LCD Document (s): L35053</b>
<a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35053&amp;bc=gAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35053&amp;bc=gAAAAAAAAAAAAA==</a>	

<b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b>		
<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corporation (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC