

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Proleukin (aldesleukin)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Proleukin (aldesleukin)

### APPROVAL CRITERIA

Requests for Proleukin (aldesleukin) may be approved if the following criteria are met:

I. Individual has metastatic malignant melanoma;

**OR**

II. Individual has metastatic renal cell cancer;

**OR**

III. Individual is using in the treatment of high-risk neuroblastoma in pediatrics after response to induction therapy and stem cell transplantation (Unituxin 2015); **AND**  
 A. Individual is using in combination with isotretinoin, dinutuximab, and sargramostim.

Proleukin (aldesleukin) may **not** be approved for any of the following:

- I. Individual has an abnormal thallium stress test; **OR**
- II. Individual has an abnormal pulmonary function test; **OR**
- III. Individual with organ allografts; **OR**
- IV. Individual has active systemic infections; **OR**
- V. When the above criteria are not met, and for all other indications.

### **Note:**

Proleukin has black box warnings that limits its use to only administration in a hospital setting under the supervision of a qualified physician. These box warnings include use restricted to patients with normal cardiac and pulmonary functions as defined by thallium stress testing and formal pulmonary function testing, and adverse effects, such as capillary leak syndrome resulting in cardiac issues and other abnormalities, and impaired neutrophil function leading to

CRX-ALL-0496-20

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 New Program Date 05/21/2018

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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increased risk of disseminated infection. Proleukin should also not be given to patients who develop moderate or severe lethargy or somnolence due to risk of coma.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 26, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 26, 2019.
  - a. Cutaneous Melanoma. V2.2019. Revised March 12, 2019.
  - b. Kidney Cancer. V2.2020. Revised August 5, 2019.
6. Unituxin Package insert, 2015. U.S. Food and Drug Administration. U.S. Department of Health and Human Services. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/125516s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125516s000lbl.pdf). Accessed on September 26, 2019.
- 7.

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