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; **AND**
II. ECOG (Eastern Cooperative Oncology Group) performance status 0-1;

OR

III. Individual has metastatic renal cell cancer; **AND**
IV. ECOG (Eastern Cooperative Oncology Group) performance status 0-1;

OR

V. Individual is using in the treatment of high-risk neuroblastoma in pediatrics after response to induction therapy and stem cell transplantation (Unituxin 2020); **AND**
    A. Individual is using in combination with isotretinoin, dinutuximab, and sargramostim (Ladenstein 2018).

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 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:

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 23, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Koreth J, Kim HT, Jones KT, et al. Efficacy, durability, and response predictors of low-dose interleukin-2 therapy for chronic graft-versus-host disease. *Blood*. 2016;128(1):130-137. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937358/?report=printable.
5. Koreth J, Matsuoka K, Kim HT, et al. Interleukin-2 and regulatory T cells in graft-versus-host disease. *N Engl J Med.* 2011;365(22):2055-2066. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3727432/pdf/nihms342555.pdf
6. Ladenstein R, Potschger U, Valteau-Couanet D, et.al. Interleukin 2 with anti-GD2 antibody ch14.18/CHO (dinutuximab beta) in patients with high-risk neuroblastoma (HR-NBL1/SIOPEN): a multicentre, randomized, phase 3 trial. Lancet Oncol. 2018;19:1617-1629.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 23, 2022.
    a. Cutaneous Melanoma. V2.2022. Revised January 26, 2022.
    b. Hematopoietic Cell Transplantation (HCT). V1.2022. April 1, 2022.
    c. Kidney Cancer. V4.2022. Revised December 21, 2021.
9. Unituxin Package insert, 2015. Revised 2020. 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. Accessed on March 23, 2022.
10. Whangbo JS, Kim HT, Mirkovic N, et al. Dose-escalated interleukin-2 therapy for refractory chronic graft-versus-host disease in adults and children. *Blood Adv*. 2019;3(17):2550-2561. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6737411/pdf/advancesADV2019000631.pdf

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.