



Proleukin® (aldesleukin) is indicated for the treatment of adults with metastatic renal cell carcinoma (mRCC) or metastatic melanoma (mM).



Current as of April 2020

Specialized Interleukin-2 (IL-2) Treatment Centers Nationwide

The following hospitals are listed as treatment centers because their medical and nursing staffs have experience in the administration of Proleukin therapy. However, the inclusion of a treatment center or physician should not be construed as a referral, endorsement, or recommendation, and the absence of any particular center or physician should not be interpreted as disapproval. Please contact the centers directly to learn about their individual experience and treatment guidelines.

Important Safety Information

WARNINGS

Therapy with Proleukin (aldesleukin) should be restricted to patients with normal cardiac and pulmonary functions as defined by thallium stress testing and formal pulmonary function testing. Extreme caution should be used in patients with a normal thallium stress test and a normal pulmonary function test who have a history of cardiac or pulmonary disease. Proleukin should be administered in a hospital setting under the supervision of a qualified physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available. Proleukin administration has been associated with capillary leak syndrome (CLS) which is characterized by a loss of vascular tone and extravasation of plasma proteins and fluid into the extravascular space. CLS results in hypotension and reduced organ perfusion which may be severe and can result in death. CLS may be associated with cardiac arrhythmias (supraventricular and ventricular), angina, myocardial infarction, respiratory insufficiency requiring intubation, gastrointestinal bleeding or infarction, renal insufficiency, edema, and mental status changes. Proleukin treatment is associated with impaired neutrophil function (reduced chemotaxis) and with an increased risk of disseminated infection, including sepsis and bacterial endocarditis. Consequently, preexisting bacterial infections should be adequately treated prior to initiation of Proleukin therapy. Patients with indwelling central lines are particularly at risk for infection with gram positive microorganisms. Antibiotic prophylaxis with oxacillin, nafcillin, ciprofloxacin, or vancomycin has been associated with a reduced incidence of staphylococcal infections. Proleukin administration should be withheld in patients developing moderate to severe lethargy or somnolence; continued administration may result in coma.

Please see accompanying full Prescribing Information including Boxed Warning.

**A multidisciplinary team
monitors patients 24/7
and manages expectations
throughout their hospital stay^{1,2}**



Not all centers have an equivalent amount of experience or the same monitoring and management guidelines.

Proleukin® (aldesleukin) for injection is administered routinely in a limited number of institutions throughout the United States. The treatment centers and physicians appearing on the following list are included because they have experience in the administration of Proleukin therapy. This list may not be a complete list of centers with experience in the administration of Proleukin therapy. No fees were paid, or other consideration provided, for inclusion on the list, and Clinigen has not independently investigated or evaluated these centers or physicians. Names, addresses, and telephone numbers are provided only as a resource and a starting point for you to find further information about Proleukin.

Just as the inclusion of a treatment center or physician should not be construed as a referral, endorsement, or recommendation, the absence of any particular center or physician should not be taken as disapproval in any way. Clinigen is not, and shall not be, liable to you or anyone else for the accuracy, reliability, timeliness, or efficacy of any information you obtain through the treatment centers or physicians on this list, nor for your reliance on any information you may learn from them and use to make any decisions or take any actions. Patients should always consult their own physicians, advisors, and healthcare providers when evaluating information related to any course of treatment.

Specialized IL-2 Treatment Centers Nationwide

ARIZONA

Banner Thunderbird Medical Center

5555 W. Thunderbird Road
Glendale, AZ 85306

Amol Rakkar, MD
Ph: 602-978-6255
arakkar@pvhomed.com

CALIFORNIA

Moores Cancer Center at UC San Diego Health

3855 Health Sciences Drive
La Jolla, CA 92037

Greg Daniels, MD, PhD
Associate Clinical Professor
Ph: 858-534-3804
gdaniels@ucsd.edu

USC Norris Comprehensive Cancer Center

1441 Eastlake Avenue
Los Angeles, CA 90033

David Quinn, MBBS, PhD
Associate Clinical Professor
Ph: 323-865-3360
diquinn@usc.edu

Kaiser Permanente Riverside Medical Center

10800 Magnolia Avenue
Riverside, CA 92505

Sam Yeh, MD
Ph: 951-353-4558
sam.s.yeh@kp.org

COLORADO

The University of Colorado—Anschutz Cancer Pavilion

1665 Aurora Court
Aurora, CO 80045

Karl Lewis, MD
Associate Professor,
Division of Medical Oncology
Ph: 720-848-0637
karl.lewis@ucdenver.edu

Rene Gonzalez, MD
Professor, Division of Medical Oncology
Ph: 720-848-0564
rene.gonzalez@ucdenver.edu

CONNECTICUT

Yale Cancer Center

20 York Street
New Haven, CT 06520

Harriet Kluger, MD
Ph: 203-200-6622
harriet.kluger@yale.edu

Mario Sznol, MD
Ph: 203-200-6622
mario.sznol@yale.edu

FLORIDA

Moffitt Cancer Center

12902 Magnolia Drive
Tampa, FL 33612

Nikhil Khushalani, MD
Cutaneous Oncology
Ph: 813-745-3437
nikhil.khushalani@moffitt.org

Ahmad Tarhini, MD, PhD
Senior Member and Director, Cutaneous
Clinical and Translational Research
Ph: 813-745-8581
ahmad.tarhini@moffitt.org

Orlando Health/UF Health Cancer Center

1400 South Orange Avenue
Orlando, FL 32806

Sajeve Thomas, MD
sajeve.thomas@orlandohealth.com

Sylvester Comprehensive Cancer Care/University of Miami

1475 NW 12th Avenue
Miami, FL 33136

Jose Lutzky, MD
Director, Melanoma Program
Ph: 305-243-5302

Joseph Pizzolato, MD
Director, GU Oncology
Ph: 305-243-5302

HAWAII

The Queen's Medical Center

1301 Punchbowl Street
Honolulu, HI 96813

Melvin Palalay, MD
Ph: 808-524-6115
melvin.palalay@hawaiihealthcare.com

ILLINOIS

Loyola University Medical Center

2160 S. First Avenue
Maywood, IL 60153

Joseph Clark, MD, FACP
Professor of Medicine
Ph: 888-584-7888
jclark@lumc.edu

Rush University Medical Center

1725 W. Harrison Street, Suite 1010
Chicago, IL 60612

Timothy Kuzel, MD
Professor of Medicine,
Chief Division of Hematology and
Oncology and Stem Cell Transplant
Ph: 312-226-2371
timothy_kuzel@rush.edu

INDIANA

Indiana University Melvin and Bren Simon Cancer Center

535 Barnhill Drive
Indianapolis, IN 46202

Theodore Logan, MD
Associate Professor of Clinical Medicine
Hematology/Oncology
Ph: 317-984-7449
tlogan@iupui.edu

KANSAS

The University of Kansas Cancer Center

3901 Rainbow Boulevard
Kansas City, KS 66160

Gary Doolittle, MD
Ph: 913-588-5000
gdoolittle@kumc.edu

Rahul Parikh, MD
Oncology office: 913-588-6029
Medical center: 913-588-5000
rparikh@kumc.edu

Menorah Medical Center—Sarah Cannon Cancer Institute

5721 W. 119th Street
Overland Park, KS 66209

Peter Van Veldhuizen, MD
Ph: 913-498-7409
peter.vanveldhuizen@hcahealthcare.com

KENTUCKY

University of Louisville/James Graham Brown Cancer Center

529 S. Jackson Street
Louisville, KY 40202

Jason Chesney, MD, PhD
Director, James Graham Brown
Cancer Center
Associate Vice President for Health Affairs
University of Louisville
Ph: 502-562-4673

Vikas Singh, MD
Assistant Professor of Medicine Division
of Medical Oncology & Hematology
James Graham Brown Cancer Center
University of Louisville, KY
Ph: 502-562-4358
vikas.singh@louisville.edu

LOUISIANA

Baton Rouge General Hospital

8585 Picardy Avenue
Baton Rouge, LA 70809

Gerald Miletello, MD
Chief of Oncology
Ph: 225-237-1600
gpmile@cox.net

MARYLAND

Johns Hopkins—Sidney Kimmel Comprehensive Cancer Center

Viragh Building, Rm. 9150
401 North Broadway
Baltimore, MD 21287

Michael Carducci, MD, FACP (mM; mRCC)
Professor of Oncology and Urology
Ph: 410-614-6321
Referrals: 410-955-8964
carducci@jhmi.edu

University of Maryland Greenebaum Cancer Center

22 South Greene Street
Baltimore, MD 21201

Heather Mannuel, MD (mM; mRCC)
Ph: 410-328-2567
hmannuel@umm.edu

Arif Hussain, MD (mM; mRCC)
Ph: 410-328-7225
ahussain@som.umaryland.edu

MASSACHUSETTS

Beth Israel Medical Center

330 Brookline Avenue
Boston, MA 02215

David McDermott, MD
Clinical Director, Hematology/Oncology
Ph: 617-667-2100
dmcdermo@bidmc.harvard.edu

MICHIGAN

The University of Michigan Rogel Cancer Center

1500 E. Medical Center Drive
Ann Arbor, MI 48109

Ajjai Alva, MBBS
Assistant Professor of Medicine
Academic office: 734-936-0091
Clinic: 734-647-8903
ajjai@umich.edu

MINNESOTA

University of Minnesota Medical Center

909 Fulton Street SE
Minneapolis, MN 55455

Evidio Domingo-Musibay, MD
Assistant Professor of Medicine
Ph: 612-624-5373
musib024@umn.edu

Gautam Jha, MBBS
Ph: 855-486-7226
jhaxx014@umn.edu

NEBRASKA

Nebraska Cancer Specialists

17201 Wright Street, Suite 101
Omaha, NE 68130

Ralph Hauke, MD, FACP
Ph: 402-955-2986
rhauke@nebraskacancer.com

NEW JERSEY

Hackensack University Medical Center/John Theurer Cancer Center

92 Second Street
Hackensack, NJ 07601

Robert Alter, MD
Ph: 551-996-5865
Cell: 973-715-8131
raltermd@aol.com

NEW YORK

Montefiore Einstein Center for Cancer Care

1521 Jarrett Place
Bronx, NY 10461

Katia Papalezova, MD
Ph: 718-862-8840
kpapalez@montefiore.org

Columbia University Medical Center

630 W. 168th Street
New York, NY 10032

Bret Taback, MD
Cell: 646-763-2201
bt2160@columbia.edu

Roswell Park Comprehensive Cancer Center

Elm and Carlton Streets
Buffalo, NY 14263

Marc Ernstoff, MD
Ph: 716-845-5899
marc.ernstoff@roswellpark.org

Igor Puzanov, MD, MSCI, FACP
Cell: 615-545-1041
igor.puzanov@roswellpark.org

NYU Clinical Cancer Center—Perlmutter Cancer Center

160 E. 34th Street
New York, NY 10016

Daniel Cho, MD
Ph: 212-731-5445
daniel.cho@nyumc.org

NORTH CAROLINA

Duke University—Duke Cancer Center

20 Duke Medicine Circle
Durham, NC 27710

Brent Hanks, MD, PhD
Assistant Professor, Division of Medical
Oncology, Department of Medicine
Ph: 919-684-1995
www.thehankslab.com

Michael Morse, MD, FACP, MHS
Professor of Medicine in the Division
of Medical Oncology
Ph: 919-971-0276
michael.morse@duke.edu

UNC Lineberger Comprehensive Cancer Center

101 Manning Drive
Chapel Hill, NC 27514

Stergios Moschos, MD
Clinical Associate Professor
Ph: 412-915-5014
stergios_moschos@med.unc.edu

OHIO

Good Samaritan Hospital

375 Dixmyth Avenue
Cincinnati, OH 45220

James Maher, MD
Medical Oncologist
Ph: 513-853-1300



**The Ohio State University
Comprehensive Cancer
Center—Arthur G. James
Cancer Hospital**

300 W. 10th Ave
Columbus, OH 43210
Ph: 614-293-6196
jamesline@osumc.edu

J. Paul Monk, MD
Associate Professor of Medical Oncology

Edmund Folefac, MBCHB
Medical Oncology
Ph: 614-293-1870

Kari Kendra, MD PhD
Associate Professor of Medical Oncology

OREGON

Providence Cancer Institute

4805 NE Glisan Street, Suite 11N-1
Portland, OR 97213

Brendan Curti, MD
Director of Genitourinary Oncology
Research and Melanoma Program
Ph: 503-215-5696
brendan.curti@providence.org

PENNSYLVANIA

Penn State Cancer Institute

400 University Drive
Hershey, PA 17033

Monika Joshi, MD (mRCC)
Ph: 717-531-8678
mjoshi@pennstatehealth.psu.edu

Joseph Drabick, MD, FACP (mM; mRCC)
Ph: 717-531-8678
jdrabick@pennstatehealth.psu.edu

Sheldon Holder, MD, PhD (mRCC)
Ph: 717-531-8678
sholder@pennstatehealth.psu.edu

**Thomas Jefferson University
Medical Center**

1025 Walnut Street, College Bldg
Philadelphia, PA 19107

Nathan Handley, MD
Ph: 215-955-8874
nathan.handley@jefferson.edu

Important Safety Information

Because of the severe adverse events which generally accompany Proleukin® therapy at the recommended dosages, a thorough clinical evaluation should be performed to identify patients with significant cardiac, pulmonary, renal, hepatic, or CNS impairment in whom Proleukin is contraindicated. Patients with normal cardiovascular, pulmonary, hepatic, and CNS function may experience serious, life threatening or fatal adverse events. Adverse events are frequent, often serious, and sometimes fatal. The following adverse events (Grades 1-4) were seen in ≥ 30% of 525 patients (255 with metastatic renal cell cancer and 270 with metastatic melanoma) treated with Proleukin: hypotension (71%), diarrhea (67%), oliguria (63%), chills (52%), vomiting (50%), dyspnea (43%), rash (42%), bilirubinemia (40%), thrombocytopenia (37%), nausea (35%), confusion (34%), and creatinine increase (33%).

Please see accompanying full Prescribing Information and complete Boxed Warning on cover.

William Tester, MD
Ph: 215-955-8874
william.tester@jefferson.edu

Melissa Wilson, MD, PhD (mM)
Ph: 215-955-8874
melissa.wilson@jefferson.edu

UPMC Hillman Cancer Center

5150 Centre Avenue
Pittsburgh, PA 15232

Diwakar Davar, MD, MBBS, MSc
Ph: 412-623-7368
Fax: 412-623-7704
Cell: 412-427-2404
davar@upmc.edu

Leonard Appleman, MD, PhD
Ph: 412-692-4724
Fax: 412-692-4505
Cell: 617-543-7763
applemanlj@upmc.edu

RHODE ISLAND

Roger Williams Medical Center

825 Chalkstone Avenue
Providence, RI 02908

Steven Katz, MD, FACS
Ph: 401-456-2077
skatz@chartercare.org

TEXAS

**The University of Texas MD
Anderson Cancer Center**

1515 Holcombe Boulevard
Houston, TX 77030

Michael Wong, MD, PhD, FRCPC
Professor of Medicine
Ph: 713-792-3798
mkwong@mdanderson.org

**Harold C. Simmons
Comprehensive Cancer
Center—University of
Texas Southwestern
Medical Center**

5323 Harry Hines Boulevard
Dallas, TX 75390

James Brugarolas, MD, PhD
Ph: 214-645-4673
james.brugarolas@utsouthwestern.edu

Hans Hammers, MD, PhD
Ph: 214-645-4673
hans.hammers@utsouthwestern.edu

UTAH

Huntsman Cancer Institute

1950 Circle of Hope
Salt Lake City, UT 84112

Benjamin Maughan, MD, PharmD
Instructor, Division of Medical Oncology
Ph: 801-581-8915
benjamin.maughan@hci.utah.edu

Neeraj Agarwal, MD
Associate Professor, Division of Oncology
Ph: 801-585-0250
neeraj.agarwal@hci.utah.edu

VIRGINIA

**VCU Massey Cancer
Center**

401 College Street
Richmond, VA 23298

Giao Phan, MD, FACS
Ph: 804-828-9325
gqphan@vcu.edu

WASHINGTON

**Seattle Cancer Care Alliance—
UW Medicine**

825 Eastlake Avenue East
Seattle, WA 98109

Scott Tykodi, MD, PhD
Associate Professor, Division of Oncology
Ph: 206-288-6326
stykodi@fredhutch.org

WISCONSIN

**Ascension St. Francis Reiman
Cancer Center**

7410 W. Rawson Avenue
Franklin, WI 53132

Jonathan Treisman, MD
Medical Director, Cancer Care—
Wheaton Franciscan Cancer Care
Ph: 414-427-2360
jonathan.treisman@ascension.org

For any questions regarding this list, please contact the Proleukin Product Information line at 1-877-PROLEUKIN (776-5385), or visit www.proleukin.com.

Proleukin[®] Patient Selection Considerations

If you check all of these boxes, consider referring your patient to a specialized IL-2 Treatment Center to confirm eligibility

1 PERFORMANCE STATUS:

ECOG PS of 0 or I,¹ or an equivalent Karnofsky score

2 NEGATIVE FOR¹:

Active central nervous system (CNS) metastases

Any organ transplant

Autoimmune diseases, including scleroderma, bullous pemphigoid, and myasthenia gravis

Inflammatory disorders, including Crohn's disease, inflammatory arthritis, and thyroiditis

Infection

3 ORGAN FUNCTION:

Pulmonary: FEV₁ > 2 liters or ≥ 75% of predicted for height or age¹

Cardiac: normal ejection fraction and unimpaired wall motion on thallium stress test¹

Renal: serum creatinine ≤ 1.5 mg/dL and creatinine clearance > 60 mL/min^{1,3}

Hepatic: bilirubin ≤ 2 mg/dL⁴

CNS: normal CNS function¹



Important Safety Information

Careful patient selection is mandatory prior to the administration of Proleukin. See “CONTRAINDICATIONS,” “WARNINGS,” and “PRECAUTIONS” sections, in the accompanying full Prescribing Information, regarding patient screening, including recommended cardiac and pulmonary function tests and laboratory tests.

Please see accompanying full Prescribing Information and complete Boxed Warning on cover.

References: **1.** Proleukin [package insert]. Yardley, PA: Clinigen, Inc; 2019. **2.** Atkins MB, Lotze MT, Dutcher JP, et al. High-dose recombinant interleukin 2 therapy for patients with metastatic melanoma: analysis of 270 patients treated between 1985 and 1993. *J Clin Oncol.* 1999;17(7):2105-2116. **3.** Jarkowski A III, Wong MKK. A re-assessment of the safety and efficacy of interleukin-2 for the treatment of renal cell carcinoma. *Clin Med Ther.* 2009;1:527-540. **4.** Schwartzentruber DJ. Guidelines for the safe administration of high-dose interleukin-2. *J Immunother.* 2001;24(4):287-293.

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CLINIGEN
Clinigen, Inc. Yardley, PA 19067