Proleukin is a human recombinant interleukin-2 product, which effectively promotes the proliferation, differentiation, and recruitment of T and B cells, natural killer cells, and thymocytes. Proleukin stimulates lymphokine-activated kill cells and tumor-infiltrating lymphocyte cells. Proleukin also causes cytolytic activity in some lymphocytes and leads to interactions between the immune system and malignant cells.

**INDICATION(S):** Treatment of metastatic renal cell carcinoma or metastatic melanoma

**CRITERIA for APPROVAL:**
1. Patient has a diagnosis of metastatic renal cell carcinoma or metastatic melanoma
2. Patient is at least 18 years of age
3. Patient has normal cardiac function based on baseline thallium stress testing with documented normal ejection fraction and unimpaired wall motion
4. Patient has normal pulmonary function based on baseline pulmonary function tests with documented FEV₁ > 2 liters or ≥ 75% of predicted for height and age
5. Patient has a baseline CBC with differential and platelet counts, blood chemistries including electrolytes, renal function tests, and hepatic function tests, and a chest X-ray AND these tests will be performed daily during treatment with Proleukin
6. Patient’s serum creatinine is ≤ 1.5 mg/dL at baseline
7. Patient has had a normal brain scan with no brain metastases
8. Cardiac function and pulmonary function will be monitored on a regular basis during treatment
9. Dosing will be 600,000 units/kg IV every 8 hours for a maximum of 14 doses repeating after 9 days for a total of 28 doses per course.

**REASONS FOR DENIAL of BENEFIT:**
1. Patient does not meet above criteria
2. Patient has a known hypersensitivity to interleukin-2 or any other component of Proleukin
3. Patient has had an organ allograft
RENEWAL CRITERIA:

1. Patient did not experience any of the following drug-related toxicities during a previous course of Proleukin therapy:
   a. Sustained ventricular tachycardia (≥ 5 beats)
   b. Cardiac arrhythmias
   c. Chest pain with ECG changes
   d. Cardiac tamponade
   e. Intubation > 72 hours
   f. Renal failure requiring dialysis for > 72 hours
   g. Coma or toxic psychosis lasting > 48 hours
   h. Bowel ischemia or perforation
   i. GI bleeding requiring surgery

2. Patient is responding to treatment, as indicated by tumor shrinkage

3. Patient evaluated for response approximately 4 weeks after completion of a course of therapy and immediately prior to the start of the next treatment course

4. There is a rest period of at least 7 weeks from the date of hospital discharge before beginning the next round of treatment

BENEFIT APPROVAL:

Initial approval period: 12 weeks
Renewal approval period: Annually

References:

Lexi-Comp Online, Proleukin (aldesleukin), Hudson, Ohio: Lexi-Comp, Inc.; October 2, 2014.