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Aldesleukin for Non-Oncology Uses

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Overview

This policy supports medical necessity review for aldesleukin (Proleukin) for non-oncology uses. The use of aldesleukin (Proleukin) for oncology uses is addressed in a separate coverage policy. Please refer to the related coverage policy link above (Oncology Medications).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Aldesleukin (Proleukin) is considered medically necessary for the treatment of Chronic Graft-Versus-Host Disease when the individual meets ALL of the following criteria:

- 1. According to the prescriber, the individual has steroid-refractory disease
2. Proleukin will be used in combination with systemic corticosteroids

3. Proleukin will be prescribed by or in consultation with an oncologist or a physician associated with a transplant center

Dosing. Up to 1 million International Units/m² administered subcutaneously once daily.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy Criteria

Continuation of aldesleukin (Proleukin) is considered medically necessary for Chronic Graft-Versus-Host Disease when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration: up to 4 months.

Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other non-oncology use is considered experimental, investigational or unproven.

Coding Information

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J9015	Injection, aldesleukin, per single use vial

Background

OVERVIEW

Proleukin, a human recombinant interleukin-2 product, is indicated for the following conditions, in adults:

- **Metastatic melanoma.**
- **Metastatic renal cell carcinoma.**¹

Guidelines

Proleukin is addressed in the following National Comprehensive Cancer Network guidelines:

- **Cutaneous melanoma** (version 1.2023 – December 22, 2022) clinical practice guidelines recommend Proleukin for unresectable or metastatic disease as a single agent for second-line or subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy (category 2A).^{2,4} Proleukin may be considered for patients with small brain tumors and without significant peritumoral edema (category 2B) or for intralesional therapy as primary or second-line treatment of unresectable stage III disease with clinical or satellite/in-transit metastases, or local satellite/in-transit recurrence (category 2B).

- **Hematopoietic cell transplantation** (version 2.2022 – September 28, 2022) clinical practice guidelines recommend Proleukin as additional therapy, in combination with systemic corticosteroids, for steroid-refractory chronic graft-vs-host disease.^{2,5}
- **Kidney cancer** (version 3.2023 – September 22, 2022) clinical practice guidelines recommend Proleukin as a single agent for first-line (category 2B) and subsequent (category 2B) therapy for patients with relapsed or stage IV disease and clear cell histology.^{2,3}

References

1. Proleukin® intravenous infusion [prescribing information]. San Diego, CA: Prometheus Laboratories; September 2019.
2. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 10, 2023. Search term: aldesleukin.
3. The NCCN Kidney Cancer Clinical Practice Guidelines (version 3.2023 – September 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 10, 2023.
4. The NCCN Cutaneous Melanoma Clinical Practice Guidelines (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 10, 2023.
5. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines (version 2.2022 – September 28, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 10, 2023.

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