Chemotherapy: Melanoma

Proleukin (aldesleukin) J9015, Kimmtrak (tebentafusp-tebn) J9274, Opdualag (nivolumab/relatilmab-rmbw) J9298, Imlygic (talimogene laherparepvec) J9325

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).

Prior Authorization Group – Oncology: Melanoma Drugs PA

Drug Name(s):

PROLEUKIN	**KIMMTRAK**
OPDUALAG	**IMLYGIC**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months
Continuation: Approval will be for 12 months

FDA Indications:

Proleukin

- Metastatic malignant melanoma
- Metastatic renal cell carcinoma

Kimmtrak

- Uveal melanoma, Unresectable or metastatic, HLA-A*02:01-positive

Opdualag

- Melanoma, Unresectable or metastatic disease

Imlygic

Melanoma, Recurrent unresectable cutaneous, subcutaneous and nodal lesions following initial surgery

Off-Label Uses:

N/A

Age Restrictions:

Opdualag: 12 years or older
Others: Safety and efficacy not established in pediatric patients

Other Clinical Considerations:

Cancer diagnoses: Criteria as per NCCN or other FDA-approved cancer related guidelines.

CLINICAL / CMS ONLY

Proleukin

- Presence of organ allograft
- Significant cardiac (including those with an abnormal cardiac ejection fraction, impaired wall motion, or significant coronary artery disease), pulmonary (including those with an FEV1 less than or equal to 2 liters or less than 75% predicted for height and age), renal, hepatic, or CNS impairment
- Black Box Warning: Capillary Leak Syndrome (CLS), Neurologic Toxicities and Serious Infections
    - Capillary leak syndrome (CLS), including life threatening or fatal reactions, has occurred in patients treated with aldesleukin. Do not administer aldesleukin to patients with significant cardiac, pulmonary, renal, and hepatic impairment. Administer aldesleukin in a hospital setting with an intensive care facility. Withhold or discontinue aldesleukin as recommended.
    - Neurologic toxicities, which may be life-threatening or result in coma or permanent neurological deficits, have occurred in patients treated with aldesleukin. Withhold or discontinue aldesleukin as recommended.
    - Serious infections including sepsis and bacterial endocarditis have occurred in patients treated with aldesleukin. Treat pre-existing bacterial infections prior to initiation of aldesleukin therapy and withhold aldesleukin as recommended

Kimmtrak

- Black Box Warning: Cytokine Release Syndrome
- Cytokine Release Syndrome (CRS), which may be serious or life-threatening, occurred in patients receiving tebentafusp-tebn. Monitor for at least 16 hours following first three infusions and then as clinically indicated

Imlygic

- Immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS, or other clinical manifestations of infection with HIV, and those on immunosuppressive therapy; may cause life-threatening disseminated herpetic infection [3]
- Pregnancy

Resources:

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CLINICAL / CMS ONLY