

Clinical Policy Title:	nivolumab and relatlimab-rmbw
Policy Number:	RxA.763
Drug(s) Applied:	Opdualag™
Original Policy Date:	07/18/2022
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Melanoma (must meet all):

1. Diagnosis of Stage III (unresectable) or Stage IV metastatic melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 12 years;
4. Weight \geq 40 kg;
5. Request meets one of the following (a or b):
 - a. Dose not exceeds 480 mg nivolumab and 160 mg relatlimab intravenously every 4 weeks.
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Melanoma (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
 - a. 480 mg nivolumab and 160 mg relatlimab intravenously every 4 weeks.
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration

Commercial: 6 months

Medicaid: 6 months

References

1. National Comprehensive Cancer Network. Melanoma: Cutaneous Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed June 29, 2023.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	05/31/2022	07/18/2022
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.4: Updated to include new weight criteria “Weight ≥ 40 kg”. 2. Initial Approval Criteria, I.A: Removed “Member meets all of the following: (a, b, c and d): a. No prior systemic therapy in the unresectable or metastatic setting including chemotherapy, immunotherapy, or targeted therapy; b. No active brain metastases or leptomeningeal metastases; c. No diagnosis of uveal melanoma; d. No active, known, or suspected autoimmune disease.” 3. Initial Approval Criteria, I.A: Removed “Member has Eastern Cooperative Oncology Group performance status of 0 or 1” 4. References were reviewed and updated. 	06/29/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023