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 ≥ 12 years;
4. Weight ≥ 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.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	05/31/2022	07/18/2022
Policy was reviewed: 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