CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs

Opdualag™ (nivolumab and relatlimab-rmbw)

Effective: February 13, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Opdualag (nivolumab and relatlimab-rmbw) is a fixed-dose immune checkpoint inhibitor combining nivolumab, a programmed death 1 (PD-1)–blocking antibody, and relatlimab, a lymphocyte-activation gene 3 (LAG-3)-blocking antibody. This combination results in increased T-cell activation compared to the activity of either antibody alone.

Approval of Opdualag was based on the Phase 2/3 RELATIVITY-047 trial in which treatment with Opdualag compared to Opdivo alone, until disease progression or unacceptable toxicity, was evaluated in patients with previously untreated metastatic or unresectable melanoma. Results showed a median progression-free survival of 10.1 months in Opdualag-treated patients compared to 4.6 months in Opdivo monotherapy-treated patients.

Per the Food and Drug Administration-approved package labeling, Opdualag is administered intravenously every 4 weeks until disease progression or unacceptable toxicity occurs.

Food and Drug Administration - Approved Indications

Opdualag (nivolumab and relatlimab-rmbw) is a combination of nivolumab a programmed death receptor-1 (PD-1) blocking antibody, and relatlimab, a lymphocyte activation gene-3 (LAG-3) blocking antibody, indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Opdualag for Members when all of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The Member is at least 12 years of age

AND

3. The prescribing physician is an oncologist

Reauthorization Criteria

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The Member is at least 12 years of age

AND

3. The prescribing physician is an oncologist

AND

4. Documentation the Member has not experienced disease progression while receiving Opdualag.

Limitations

- Coverage of Opdualag will be authorized for 6 months.
- Members new to the Plan stable on Opdualag should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg

References:

1. Five-Year Outcomes with Nivolumab in Patients with Wild-Type BRAF advanced melanom. C. Robert, G. Long, et al. Journal of Clinical Oncology 38, no. 33 (November 20, 2020) 3937-3946.
2. Five-Year Survival with Combined Nivolumab and Ipilimumab in Advanced Melanoma. J Larkin, V Chiarion-Sileni, et al. N Engl J Med 2019; 381:1535-1546 (Oct. 17, 2019).
3. Melanoma. https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1410 Accessed 4/26/2022.
4. Opdualag (nivolumab and relatlimab-rmbw) [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. March 2022.
5. Tawbi HA, et al. Relatlimab and Nivolumab versus Nivolumab in Untreated Advanced Melanoma. N Engl J Med. 2022;386:24-34.

Approval And Revision History

April 19, 2023: year: Reviewed by the Medical Policy Approval Committee (MPAC).

May 9, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T), effective July 1, 2023.

Subsequent endorsement date(s) and changes made:

- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- February 13, 2024: No changes

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.