Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Opdualag™ (nivolumab and relatlimab-rmbw)

Effective: January 13, 2026

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

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 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

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 or older

AND

3. The prescribing physician is an oncologist

AND

4. Documentation the Member has no prior treatment history with PD-1 inhibitors or PD-L1 inhibitors within the previous 6 months

AND

5. Documentation Opdualag will not be used in combination with other antineoplastic agents

Reauthorization Criteria

1. Documented diagnosis of unresectable or metastatic melanoma

AND

2. The Member is at least 12 years of age or older

AND

3. The prescribing physician is an oncologist

AND

4. Documentation Opdualag will not be used in combination with other antineoplastic agents

AND

5. 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 2024.

Approval And Revision History

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

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

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: May 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- May 17, 2023: Annual review removed initial authorization criteria of documented clinical inappropriateness for Keytruda and Opdivo to align with NCCN effective July 1, 2023
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- February 13, 2024: No changes. Tufts Health Together added to Medical Necessity Guideline (effective 2/13/2024).
- January 14, 2025: No changes. Removed Tufts Health Together from the Medical Necessity Guideline. Coverage for Tufts Health Together will fall under the Unified Medical Policies Medical Necessity Guideline (eff 2/18/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- January 13, 2026: No changes.
- February 2026: Administrative update to remove Carelink from template.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21

under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.