BlueCross BlueShield
Federal Employee Program

# OPDUALAG
# (nivolumab and relatlimab-rmbw)

## RATIONALE FOR INCLUSION IN PA PROGRAM

### Background

Opdualag is a human IgG4 monoclonal antibody and 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. Antagonism of the LAG-3 pathway promotes T-cell proliferation and cytokine secretion. Upregulation of PD-1 ligands occurs in some tumors which inhibits T-cell proliferation and cytokine production. PD-1 blocking by nivolumab decreases tumor growth. LAG-3 blockade potentiates the anti-tumor activity of PD-1 blockage, inhibiting tumor growth and promoting tumor regression (1).

### Regulatory Status

FDA-approved indication: Opdualag is indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma (1).

Opdualag carries warnings regarding severe and fatal immune-mediated adverse reactions, infusion-related reactions, and complication of allogenic hematopoietic stem cell transplantation (1).

Opdualag can also cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Opdualag and for at least 5 months after the last dose of Opdualag (1).

The safety and effectiveness of Opdualag have not been established in pediatric patients less than 12 years of age or in pediatric patients 12 years or older who weigh less than 40 kg (1).

### Summary

Opdualag is a combination of nivolumab and relatlimab and is indicated for unresectable or metastatic melanoma. Opdualag has warnings including severe and fatal immune-mediated adverse reactions and infusion-related reactions. The safety and effectiveness of Opdualag have not been established in pediatric patients less than 12 years of age or in pediatric patients 12 years or older who weigh less than 40 kg (1).

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Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Opdualag while maintaining optimal therapeutic outcomes.

**References**


1. Opdualag [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2024.
2. NCCN Drugs & Biologics Compendium® Nivolumab and relatlimab-rmbw 2025. National Comprehensive Cancer Network, Inc. Accessed on January 27, 2025.