Opdualag (nivolumab and relatlimab-rmbw)

Humana

Pharmacy Coverage Policy

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

Description

Opdualag (nivolumab and relatlimab-rmbw) is the combination of nivolumab and relatlimab, administered as a single intravenous infusion, are two distinct inhibitory immune checkpoints that are often co-expressed on tumor-infiltrating lymphocytes, thus contributing to tumor-mediated T-cell exhaustion.

Opdualag is indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

Nivolumab and relatlimab-rmbw is available as Opdualag in 240 mg - 80 mg/20 mL vials.

Please note the following regarding medically accepted indications:

Coverage Determination

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or

approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are

subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- **American Hospital Formulary Service-Drug Information (AHFS-DI)**
- **National Comprehensive Cancer Network (NCCN) Drugs and Biologics**
- **Compendium**
- **Truven Health Analytics Micromedex DrugDEX**
- **Elsevier/Gold Standard Clinical Pharmacology**

Wolters Kluwer Lexi-Drugs

Opdualag (nivolumab and relatlimab-rmbw) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Melanoma: Unresectable or metastatic melanoma

- **The member must have a diagnosis of unresectable or metastatic melanoma**
- **AND**
- **The member must be 12 years of age or older AND**
- **Opdualag is administered as monotherapy AND**

There is a medical reason why Keytruda or Opdivo as monotherapy or Opdivo in combination with Yervoy cannot be initiated or continued

Opdualag (nivolumab and relatlimab-rmbw) will be approved in sixmonth durations or as determined through clinical review.

Coverage Limitations

Opdualag (nivolumab and relatlimab-rmbw) therapy is not considered medically necessary for members with the following concomitant conditions:

- **Disease progression while on or following prior anti-PD-1/PD-L1 therapy (e.g., nivolumab, atezolizumab)**

- **Members on concomitant Zelboraf (vemurafenib), Tafinlar (dabrafenib), Mekinist (trametinib) or Cotellic (cobimetinib) therapy. Safety and efficacy have not been established.**

- **Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature. Background This is a prior authorization policy about Opdualag (nivolumab and relatlimab-rmbw).**

- **Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment-producing cells (melanocytes) located in the skin. Metastatic melanoma is the deadliest form of the disease and occurs when cancer spreads beyond the surface of the skin to other organs. The incidence of melanoma has been increasing steadily for the last 30 years. In the United States, approximately 99,780 new diagnoses of melanoma and about 7,650 related deaths are estimated for 2022. Melanoma can be mostly treatable when caught in its very early stages; however, survival rates can decrease as the disease progresses.**

- **Warnings and Precautions:**
  - **Immune-Mediated Adverse Reactions: Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immunemediated dermatologic adverse reactions, immune-mediated nephritis with renal dysfunction, and immune-mediated myocarditis. Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. o Withhold or permanently discontinue based on severity and type of reaction.**
  - **Infusion-related reactions: Interrupt, slow the rate of infusion, or permanently discontinue OPDUALAG based on severity of reaction.**

- **Complications of allogeneic HSCT: Fatal and other serious complications can occur in patient who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody.**

- **Embryo-fetal toxicity: Can cause fetal harm. Advise females of reproductive potential of potential risk to a fetus and to use effective contraception.**

- **Evaluation of disease progression while on or following immunotherapy will assess direct PD-1/PD-L1 treatment effects**
  - **Progressive disease off therapy is not equivalent to progressive disease while on therapy**
- **Assessment of treatment response will be evaluated on individual case basis utilizing various resources (e.g., NCCN Guidelines, iRECIST criteria)**

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Opdualag; Nivolumab; Relatlimab; Melanoma; Pharmacy

References

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Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.

NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

Opdualag [Package Insert]. Princeton, NJ. Bristol-Myers Squibb. March 2022.