Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 257.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Opdualag (nivolumab and relatlimab-rmbw)

I. Policy:
Opdualag (nivolumab and relatlimab-rmbw)

II. Purpose/Objective:
To provide a policy of coverage regarding Opdualag (nivolumab and relatlimab-rmbw).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Relatlimab is a human IgG4 monoclonal antibody that binds to the LAG-3 receptor (Tawbi 2022) and blocks interaction between LAG-3 and its ligands (including MHC II) to reduce LAG-3 pathway-mediated immune response inhibition; antagonism of this pathway promotes T cell proliferation and cytokine secretion. Nivolumab is a human IgG4 monoclonal antibody that binds to the PD-1 receptor and blocks interaction with its ligands PD-L1 and PD-L2 and reduces PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors; therefore, signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. In animal tumor models, blocking PD-1 activity resulted in decreased tumor growth and blocking LAG-3 potentiated the antitumor effect of PD-1 blockade (inhibiting tumor growth and promoting tumor regression). Combining nivolumab (anti-PD-1) and relatlimab (anti-LAG-3) results in increased T-cell activation compared to the activity of either antibody alone.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Opdualag (nivolumab and relatlimab-rmbw) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation that Opdualag is written by a hematologist or oncologist **AND**
- Medical record documentation that patient is greater than or equal to 12 years of age **AND**
- For patients greater than or equal to 12 years and less than 18 years of age:
    - Medical record documentation of weight greater than or equal to 40 kg

  AND
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma

AUTHORIZATION DURATION: Initial approval will be for **12 months**. Subsequent approvals will be for an additional **12 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

QUANTITY LIMIT: 2 vials (40 mL) per 28 days

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Opdualag [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/17/22

Revised: 5/11/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added)

Reviewed: 5/10/24

MA UM Committee approval: 12/31/23