Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 92.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Off-label Drug Use for Oncologic Indications

I. Policy:
Off-label Drug Use for Oncologic Indications

II. Purpose/Objective:
To provide a policy of coverage regarding Off-label Drug Use for Oncologic Indications

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit 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:
Off-label use of a drug or biologic may be determined to be medically necessary and medically accepted for an oncologic indication not included in the FDA approved labeling if it is supported in one or more drug compendia; is not specifically contraindicated, unsupported, or not recommended; and is supported by published clinical research data.

Off-label drug use: Use of a drug that has been approved by the Food and Drug Administration (FDA) for other indications, treatment regimens or in patient populations that are not specifically included in the approved labeling.

Orphan-drug: a designation granted by the FDA under the Orphan Drug Act of 1983. This designation is granted to a drug or biologic agent intended to treat or prevent a rare disease or condition, defined in the Rare Diseases Act of 2002 as one which affects less that 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing the drug would be recovered from the sale of the drug in the United States

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

Off-label drug use for an oncologic indication is considered to be medically necessary when **all** of the following criteria are met:

1. The drug has been approved by the FDA for at least one indication; **AND**
2. The drug is being prescribed to treat a condition not listed in the product labeling, but for which treatment is medically necessary; **AND**
3. Conventional therapies have been tried and failed, are contraindicated, or do not exist; **AND**
4. The proposed drug use is supported by any one or more of the following:
    - The National Comprehensive Cancer Network Practice Guidelines™ in Oncology category 1, 2A, or 2B recommendation; **OR**
    - The National Comprehensive Cancer Network Drug & Biologics Compendium™ category of Evidence and consensus 1, 2A, or 2B; **OR**
    - The American Hospital Formulary Service – Drug Information; **OR**
    - Thompson Micromedix DrugDEx Compendium (DrugDex®) class I or IIa indication; or
    - Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology®)

If a medical policy exists for a specific drug, reference should be made to that document for information regarding the FDA approved use(s) of that drug.

When a clinical trial is open for accrual that provides the drug under consideration for the indication requested, and when the insured individual meets the eligibility requirements of that trial, providers are encouraged to consider that option.

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.

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

Devised: 9/19/11

Revised: 12/1/15 (format), 5/16 (removed limitation), 1/21/22 (added NCCN category 2B)

Reviewed: 12/13, 12/1/15, 3/16, 3/30/17, 3/29/18, 2/28/19, 1/1/20, 1/1/21, 12/21/21