Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 33.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Medical Benefit Pharmaceutical Administrative Policy

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Medical Benefit Pharmaceutical Administrative Policy

II. Purpose/Objective:
1. To define the processes and procedures followed by Geisinger Health Plan for coverage determinations.
2. To provide a policy of coverage regarding medical benefit drugs without specific coverage criteria.
3. To provide a policy of coverage regarding medical benefit drugs with quantity limits.
4. To provide reference to a policy of coverage regarding medical benefit drugs with site of care requirements.

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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
1. FDA – Food and Drug Administration.
2. Prescribing healthcare professional – a person who writes, gives or orders medical drugs and is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of

3. Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. Providing healthcare provider – a person or entity who administers and/or dispenses medications and is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
5. GHP – Geisinger Health Plan or "Plan"
6. 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
7. Coverage Determination – A decision of coverage for a medication (approval/denial)
8. Member – Individual who has enlisted in the benefit
9. CPhT – Certified pharmacy technician
10. LPN – Licensed practical nurse
11. MBP – Medical Benefit Policy
12. 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.
13. 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 than 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

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:
This policy explains how coverage decisions are determined for GHP members who have medical drug benefits, including Commercial, Affordable Care Act (ACA), GHP Kids, Self-Insured plans, Medicare and Medicaid, unless a specific limitation, exception, or exclusion exists. Coverage exceptions include decisions about the medical necessity of a specific drug, decisions about drugs exceeding quantity limits, and decisions whether a member has satisfied prior authorization requirements, or site of care requirements. The policy is utilized when a drug specific policy does not exist or the existing drug specific policy does not address the requested indication or process.

A. Coverage Determination Procedure
    1. For the Medicaid (GHP Family) line of business: Requests should be directed to the Department of Pharmacy Services. The procedure set forth by Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization will be adhered to with the following exceptions:
        i. If a Member's prescription for a medication is not filled when a prescription is presented to the pharmacist due to a Prior Authorization requirement, GHP will instruct the pharmacist to dispense either a fifteen (15) day supply if the prescription qualifies as an ongoing medication for a GHP Family member, or a five (5) day supply for a new medication by contacting the Plan directly to dispense a 5-day supply for a new medication or to dispense a 15-day supply for ongoing therapy. When a pharmacist determines that taking the prescribed medication may jeopardize the health or

ii. safety of the member this 15-day and 5-day rule will not apply. GHP Family will allow one emergency fill per medication per 180 days.

2. For non-Medicaid (GHP Family) lines of business, a request may be initiated for an exception in accordance with the following:
    i. Requests should be directed to the Department of Pharmacy Services
    ii. Information needed for a determination include, but is not limited to, the following:
        1. Caller's name and telephone number;
        2. Member's medical record number and insurance identification number;
        3. Prescribing and providing healthcare provider's name and telephone number;
        4. The product and exception requested;
        5. Clinical rationale including medical records, laboratory data, past treatment history and other documentation, as determined by the Plan to be relevant.
    iii. Requests for exception will be reviewed as follows:
        1. A Certified Pharmacy Technician (CPhT) or License Practical Nurse (LPN), under the supervision of a Health Plan Pharmacist, will perform an initial review of medical record documentation and treatment history to recommend approval or denial of requests where there are explicit utilization management criteria and no clinical judgement is required, utilizing drug specific MBP.
            a. If the request for exception is approved, no further action will be required on the part of the Health Plan Pharmacist or the Licensed Physician (dependent upon the exception requested).
            b. If the CPhT or LPN recommends denial upon initial review, the requests will be forwarded to a Health Plan Pharmacist for review.
        2. For all requests where clinical judgement is required, explicit utilization management criteria do not exist, or those which a CPhT or LPN recommends denial (or approval, dependent upon the determination requested), a Health Plan Pharmacist will perform an initial review of medical record documentation and treatment history to recommend approval or denial, utilizing drug specific MBP if applicable as well as the compendia references listed below. The request will be approved if, in the professional judgment of the pharmacist reviewer, the services are medically necessary to meet the medical needs of the member of the request.
            a. If the request for exception is approved, no further action will be required on the part of the Licensed Physician.
            b. If the Health Plan Pharmacist recommends denial upon initial review, the request will be forwarded to a Licensed Physician for review.
        3. A Licensed Physician shall make the final decision in all instances where a Health Plan Pharmacist recommends denial. The request will be approved if, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member of the request.
    iv. Documentation of the determination of coverage and the notifications will take place within GHP coverage determination decision making or customer service documentation tool(s).

B. Off-Label Requests
1. Off-label drug use for a medical drug is considered to be medically necessary when **all** of the following criteria are met:
    i. The drug has been approved by the FDA for at least one indication; **AND**
    ii. The drug is being prescribed to treat a condition not listed in the product labeling, but for which treatment is medically necessary; **AND**
    iii. Conventional therapies have been tried and failed, are contraindicated, or do not exist; **AND**
    iv. 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 Micromedex DrugDex Compendium (DrugDex®) class I, IIa, or IIb indication; or
        - Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology®)
        - Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"
2. If a medical policy exists for a specific drug and addresses the requested off-label indication, reference should be made to that document for information regarding the medical necessity of that drug for the requested indication. When a clinical trial is open for accrual that provides the drug under consideration for

3. the indication requested, and when the insured individual meets the eligibility requirements of that trial, providers are encouraged to consider that option.

C. Quantity Limit Exceptions
    1. A quantity limit exception may be made for members who meet the following criteria:
        i. Medical record documentation that requested dose cannot be achieved by using a formulary alternative (e.g. use of one 90mg syringe in place of two 45mg syringes) **AND**
        ii. Medical record documentation that prescribed dosage does not exceed those approved by the Food and Drug Administration (FDA) or accepted standards of care **AND**
        iii. If request is for dose that exceeds Food and Drug Administration (FDA) approved labeling, medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling **AND**
        iv. Medical record documentation that current quantity limit has been ineffective in management of member's condition or is likely to be ineffective or adversely affect the patient's compliance based on clinical evidence & the known physical and mental characteristics of the member.

D. Site of Care (Excluding Medicaid and Medicare lines of business)
    1. Medical benefit policy (MBP) 181.0 provides a policy of coverage regarding the use of hospital-based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection for participating lines of business. See MBP 181.0 for information regarding the medical necessity of site of care.

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: 8/25/22

Revised: 12/15/22 (per DHS), 8/22/23 (Medicaid business segment), 8/19/24 (LOB table, taglines)

Reviewed:

MA UM Committee approval: 12/31/23, 12/31/24