Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 206.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Khapzory (Levoleucovorin)

I. Policy:
Khapzory (Levoleucovorin)

II. Purpose/Objective:
To provide a policy of coverage regarding Khapzory (Levoleucovorin)

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:
Khapzory (Levoleucovorin) is a chemotherapy modulating agent, folate analog. Levoleucovorin counteracts the toxic (and therapeutic) effects of folic acid antagonists (eg, methotrexate) which act by inhibiting dihydrofolate reductase. Levoleucovorin is the levo isomeric and pharmacologic active form of leucovorin (levoleucovorin does not require reduction by dihydrofolate reductase). A reduced derivative of folic acid, leucovorin supplies the necessary cofactor blocked by methotrexate. Leucovorin enhances the activity (and toxicity) of fluorouracil by stabilizing the binding of 5-fluoro-2'-deoxyuridine-5'-monophosphate (FdUMP; a fluorouracil metabolite) to thymidylate synthetase resulting in inhibition of this enzyme.

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

Khapzory (Levoleucovorin) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of intolerance to or contraindication to preferred levoleucovorin calcium products.

Preferred products: levoleucovorin calcium vial, powder for reconstitution, levoleucovorin calcium vial, solution

AUTHORIZATION DURATION: Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate 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.

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.

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

Devised: 12/20/19

Revised: 10/4/22 (Medicaid PARP statement)

Reviewed: 11/2/20, 10/4/21