group health Cooperative of eau claire **KMTSJ, Inc.**	DEPARTMENT:	Utilization Management
	SUBJECT:	Pharmaceutical Management Procedures
	PRODUCT LINE:	All
	POLICY NUMBER:	UM126
	ORIGINAL POLICY EFFECTIVE DATE:	5/1/2024
	LAST REVISED DATE:	5/1/2024
	LAST REVIEWED DATE:	5/1/2025

SCOPE:

To ensure procedures for pharmaceutical management promote the clinically appropriate use of pharmaceuticals.

POLICY:

GHC develops, regularly reviews and updates policies and procedures for pharmaceutical management based on sound clinical evidence.

PHARMACEUTICAL MANAGEMENT PROCEDURES:

Criteria Used to Adopt Pharmaceutical Management Procedures

The criteria used when adopting the pharmaceutical management procedures, includes:

- Pharmaceutical classes.
- Classes preferred or covered at any level.
- Lists of preferred pharmaceuticals or formularies.
- Considerations for limiting access to drugs in certain classes.
- Prior authorization criteria.
- Generic substitution, therapeutic interchange, step therapy or other management methods to which the practitioner's prescribing decisions are subject.
- Within each class of pharmaceuticals:
  - Pharmaceuticals preferred or covered at any level.
  - An exceptions process available to members.
  - Substitutions made automatically or with permission of the prescribing practitioner.
  - Evidence that preferred-status pharmaceuticals can produce similar or better results for a majority of the population than other pharmaceuticals in the same class.
  - Other requirements, restrictions, limitations or incentives that apply to the use of certain pharmaceuticals.

Use of Clinical Evidence from Appropriate External Organizations

Clinical evidence from the following external sources is used to make pharmaceutical decisions covered under both the medical and pharmacy benefit:

- Government agencies
- Medical associations
- National commissions
- Peer-reviewed journals.

- Authoritative compendia

Pharmaceutical Restrictions/Preferences and Communication of Management Processes

GHC, annually and after updates, communicates pharmaceutical policies to members and prescribing practitioners to ensure their understanding of pharmaceutical processes as noted below:

- Covered pharmaceuticals
- Copayment information, including tiers
- Pharmaceuticals that require prior authorization
- Limits on refills, doses or prescriptions
- Use of generic substitution, therapeutic interchange or step-therapy protocols.
- How formulary updates are communicated, and how often, if the organization has scheduled formulary updates.

GHC distributes pharmaceutical management procedures and updates to providers annually through the provider manual. The provider manual directs providers to the GHC website where detailed pharmacy processes are outlined. Providers are also sent an email annually directing them to the list of pharmaceuticals that require prior authorization. Any updates to providers would be sent via email.

Members receive information about pharmaceutical policies annually through the mail which directs them to the GHC website where detailed pharmacy processes are outlined. Any updates to members would be sent via email or mail.

Exception requests are not applicable for the pharmaceuticals that are covered under the medical benefit because there is not a closed formulary.

We do not use generic substitution or therapeutic interchange in our process for management of pharmaceuticals covered under the medical benefit. Step therapy protocols do apply and are outlined in our policies for the respective pharmaceutical, which are available on the website.

There may be limits on refills, doses, or prescriptions in our process for management of pharmaceuticals covered under the medical benefit,

Pharmaceutical Patient Safety Issues

To ensure patient safety related to pharmaceuticals, GHC has processes in place to address recalls and withdrawals related to pharmaceuticals that are covered under the medical benefit. Our PBM vendor has processes in place to address recalls and withdrawals related to pharmaceuticals covered under the pharmacy benefit.

Class II recall: Removal of a distributed product where use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious, adverse health consequences is remote.

Class I recall: Removal of a distributed product due to reasonable probability that use of or exposure to the product will cause serious, adverse health consequences or death.

Market withdrawal: Removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA.

Pharmaceutical procedures related to recalls and withdrawals include:

1. Identifying and notifying members and prescribing practitioners affected by a Class II recall or voluntary drug withdrawals from the market for safety reasons within 30 calendar days of the FDA notification. GHC receives FDA email notifications on drug recalls and withdrawals from. Prescribing practitioners and members are notified by letter within the above timeframe for Class II recalls and voluntary drug withdrawals.
2. An expedited process for prompt identification and notification of members and prescribing practitioners affected by a Class I recall. Members and prescribing practitioners are notified by letter within 5 calendar days of the FDA notification.
3. Content of notification
   a. Communication to affected members regarding recalled or withdrawn pharmaceuticals may include:
      - The name of the drug/pharmaceutical
      - The date of the withdrawal/recall
      - The reason for the withdrawal/recall
      - Instructions such as:
        - Return the pharmaceutical to the pharmacy
        - See the prescribing practitioner for directions or a new prescription

   b. Communication to affected practitioners may include:
      - The name of the pharmaceutical
      - The date of the withdrawal/recall
      - Patients affected (if known)

Reviewing and Updating Procedures

The GHC QI committee helps develop, reviews, and makes periodic updates to the pharmaceutical management policies and procedures for pharmaceuticals that are managed under the medical benefit. To ensure pharmacy management procedures promote the clinically appropriate use of pharmaceuticals, this committee includes:

- Clinical pharmacists
- Appropriate physicians

With the participation of physicians and pharmacists, the QI committee annually:

1. Reviews the pharmacy management procedures
2. Reviews the list of pharmaceuticals
3. Updates the procedures as appropriate
4. Updates the list of pharmaceuticals as appropriate

Our PBM vendor has a national P & T Committee that reviews and updates pharmaceutical procedures for pharmaceuticals covered under the pharmacy benefit.

Formulary Exceptions

Formulary exceptions are requests by members or their authorized representatives to obtain a pharmaceutical that is not included as part of the organization's closed formulary. GHC does not administer a closed formulary for pharmaceuticals covered under the medical benefit, therefore this element is not applicable. Formulary exceptions for pharmaceuticals covered under the pharmacy benefit for our commercial line of business are handled by our PBM vendor.

APPROVED: _____ DATE: 5/1/2025

REVISION HISTORY:

Rev. Date	Revised By/Title	Summary of Revision
5/1/2025	Michele Bauer, MD, CMO	Reviewed. No changes.