Group Health Cooperative of South Central Wisconsin

Policy and Procedure

Title: Pharmacy: Pharmaceutical Management Program
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PURPOSE:

The purpose of this policy is to articulate the Pharmaceutical Management Program for Group Health Cooperative of South Central Wisconsin (GHC-SCW).

POLICY:

The GHC-SCW Pharmacy promotes and supports rational and cost-effective use of pharmaceuticals in compliance with NCQA guidelines for pharmaceutical management. This policy applies to pharmaceuticals covered under the GHC-SCW Pharmacy Benefit and is applied in the same manner to GHC-SCW's Commercial HMO product line and the Exchange HMO product line.

PROCEDURE:

1) Adoption of Policies and Procedures

a) Criteria used to adopt pharmaceutical management procedures.

i) The pharmaceuticals covered will include multiple options for most drug classes that are not excluded by the insurance contract.

ii) Evaluation of pharmaceuticals will take safety, effectiveness, and value into consideration. Other factors that may be considered in the evaluation include FDA approval, anticipated demand, addressing a medical need and quality of published studies.

iii) When coverage limits exist for specific pharmaceuticals on the Formulary, they will be noted within the Formulary list.

iv) An exceptions process for obtaining non-covered pharmaceuticals will conform to NCQA standards.

v) Criteria for prior authorization will be developed by pharmacists and approved by a Medical Director.

b) Evaluations will use clinical evidence from appropriate external organizations.

i) Evaluations from our contracted P&T resource will be reviewed for approval by GHC-SCW's internal utilization management committee: The Pharmaceutical and Technology Assessment Committee (PTAC).

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	7/13	12/13	9/14	11/16	6/17	11/18	9/19	1/20	11/20
	10/21								

ii) Other external organizations used include medical and pharmacy literature, University of Wisconsin Center for Drug Policy, U. S. Food and Drug Administration and its advisory panels, pharmaceutical industry news, and consultant-specialist recommendations.

iii) As appropriate, practitioners within the University of Wisconsin Hospital and Clinics system or MRI of America with clinical expertise will be consulted for comment on the development of policies or the adoption of criteria developed exclusively by GHC-SCW.

c) Procedures will be developed and approved by the PTAC, a Medical Director, and appropriate oversight committees.

i) PTAC is composed of practitioners and pharmacists, including a Medical Director. Membership is by appointment of the Chief Medical Officer. The Associate Medical Director – Informatics & Care Management serves as chair of the committee.

ii) Specialist recommendations are sought and made available to committee members.

d) Availability of pharmaceutical management procedures.

i) PTAC will review and approve changes to the Drug Formulary list and Pharmaceutical Management Procedures at least annually and additionally as needed. The most current Procedures will be posted at https://www.ghcscw.com/plan-providers/provider-resource-manual. Annual communications via newsletters will inform practitioners and provide a link to on-line content.

ii) New drugs may be added to the drug formulary after each PTAC meeting. The most current formulary will be posted on the health plan website.

iii) Members' financial responsibility will be identified on Formulary documents by Tier category. Members' plan Benefits Summary information will specify the actual copayment or coinsurance for each Tier.

e) Review process for requests outside of GHC published Prior Authorization Criteria

i) When a drug is requested for a use outside of GHC published Prior Authorization criteria, which may include labeled and unlabeled indications, it is subject to a review conforming to Medicare Benefit Policy Manual Ch. 15 standards per Section 50.4.2 – Unlabeled Use of Drug.

(1) An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

(2) A labeled use of a drug that is outside of GHC published Prior Authorization criteria may be covered if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

2) GHC-SCW maintains a list of pharmaceuticals covered under the drug benefit, which includes restrictions and preferences, and makes this information available to members and practitioners.

a) Current drug formularies are available on the health plan website and will reflect all approved updates and changes as of the effective date.

b) An additional link entitled "Recent Formulary Changes" is provided to direct members to a document listing recent and upcoming formulary changes within the past three months or planned within the next three months. The document associated with this link will be updated at a minimum following each PTAC meeting.

c) The website (https://www.ghcscw.com) includes information on how to use the GHC-SCW Formulary.

d) The Formulary includes information on restrictions or limits that may apply.

e) Practitioners must provide information to support an exceptions request, establishing that:

i) A reasonable number of similar drugs that are on the formulary have been tried and that the formulary drugs were tried with an adequate dose and duration of therapy;

ii) The formulary drugs were not tolerated or were not effective; and

iii) The requested drug therapy is evidence-based and generally accepted medical practice.

f) Related processes: generic substitution, therapeutic interchange, and step therapy.

i) Generic substitution is addressed in the Insurance Certificate, which may provide for a cost penalty when choosing a brand where an approved generic is available or identify a copayment tier for branded versions of generic pharmaceuticals.

ii) Therapeutic interchange is not part of the GHC-SCW pharmaceutical management program.

iii) Pharmaceuticals on Formulary subject to step-therapy will be identified on Formulary documents.

3) Clinical and Patient Safety Programs

a) GHC-SCW will utilize a prescription claims system that identifies and classifies potential drug interactions. It will utilize a generally recognized reference source (e.g., Medispan) to identify and classify interactions and utilize prescriptions in the prescription claims database, i.e., written by any prescriber and dispensed by any practitioner the plan is aware of due to on-line prescription claim submissions.

b) GHC-SCW will notify the dispensing practitioner of potential interactions at the point of dispensing by using a prescription claims system that responds in real-time when a prescription claim is submitted on-line.

c) GHC-SCW will identify patients and prescribers affected by a Class II recall or a voluntary withdrawal from the market for safety reasons, by query of the central prescriptions claims database. Prescribers will be supplied the identity of the patients affected by this before communication goes to the patients. This process will be completed within thirty (30) calendar days of the FDA notification.

d) GHC-SCW will identify members and prescribers affected by a Class I drug recall by query of the central prescription dataset. Notification will be sent to affected patients and prescribers as quickly as possible, but no later than seven (7) calendar days from the FDA notification date.

e) Items 3.c and 3.d, above, do not apply if the recall is issued at the wholesale-level only or if the recall was not due to a safety issue OR for recalled or withdrawn pharmaceuticals for which GHC-SCW is unable to identify affected members from batch or lot numbers.

4) Review and Update of Pharmaceutical Management Procedures.

a) PTAC will review and approve changes to the GHC-SCW Drug Formulary and pharmaceutical management procedures at least annually and more often if needed to respond to practitioner, member, or pharmacist requests, or to address new drug approvals or information.

b) PTAC will review the list of covered pharmaceuticals no less often than quarterly at scheduled meetings. Revisions and updates to the list will occur subsequent to each meeting.

5) Exceptions Process

a) Requests for formulary exceptions may be made by the practitioner or the member by contacting GHC-SCW Pharmacy Services by telephone or fax. Practitioners who use GHC-SCW's electronic prescribing system may also submit a request by choosing the class of "Prior Auth" when electronically ordering a medication. Members may use the secure GHC-SCW MyChart website "Ask the Pharmacy" function to submit a request.

b) Formulary exceptions must be based on medical necessity. Any member-generated request will be forwarded to the member's practitioner to obtain documentation of medical necessity before evaluation of the request occurs.

c) (See also Section 2e: "Practitioner provides information supporting the request".) When the information submitted to support an exception request is insufficient to establish medical necessity, Pharmacy Services will contact the practitioner to obtain additional information.

d) The request is initially reviewed by Pharmacy Services. If the drug requested has specific written criteria established and the request includes information supporting that the criteria are met, the request may be approved. If support is unclear (or for any drugs without specific written criteria), the request is referred to a pharmacist for review. The pharmacist may consult, as appropriate, with a specialist, Medical Director or other practitioner before making a decision.

e) Exception requests will be handled in a timely manner. The timelines indicated are measured from the date when the request is received from the member or member's representative

i) The timelines will apply even if there is insufficient information to make the decision, subject to the specific exceptions noted.

ii) Urgent concurrent requests (member is in process of receiving the requested pharmaceutical services, even if the organization did not previously approve the earlier care) will be reviewed within 24 hours (1 calendar day) of receiving the request.

(1) Urgent Requests are defined as a request for pharmaceutical services where application of the time frame for making routine or non-life threatening care determinations could:

(a) seriously jeopardize the life or health of the member or of the member's ability to regain

maximum function, based on a prudent layperson's judgement,

(b) seriously jeopardized the life, health or safety of the member or others due to the member's psychological state,

(c) in the opinion of a practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

(2) Extension: If the request to approve additional days for urgent concurrent care is related to care not approved previously, and at least one documented attempt to obtain the necessary information within 24 hours of the request was made, but not received, then up to 72 hours is allowed to make a decision.

iii) Urgent pre-service requests will be decided and responded to within 72 hours (3 calendar days) of receipt.

(1) Extension: The time frame may be extended once, for 48 hours due to a lack of information if within 24 hours of receipt a request is made for the information necessary to make the decision.

(2) At least 48 hours will be extended to the member/member's representative to provide the information.

(3) The extension then begins either on the date which the requested information is received (even if insufficient) OR at the end of the 48 hour time period provided to the member/member's representative if no response is received.

iv) Non-urgent pre-service requests will be responded to within 15 calendar days of receipt.

(1) Extension: The time frame may be extended by up to 45 days if additional information is requested of the member/member's representative within the original decision time frame of 15 days.

(2) At least 45 days will be extended to the member/member's representative to provide the information.

(3) The extension then begins when the response is received (even if insufficient) OR at the end of the 45 day time period provided to the member/member's representative if no response is received.

v) Post-service requests will be responded to within 30 calendar days of receipt. Note: Requests for coverage of medications dispensed at a pharmacy may only be classified as urgent concurrent, urgent preservice or nonurgent preservice, depending on whether the request meets the definition of urgent. Medications dispensed at the pharmacy may not be classified as post-service requests.

(1) Extension: Same as for 5(e)(iv)(1) immediately above.

vi) Lack of response to a request for or inability to obtain additional information may result in a denial of that request. If, and when, additional supporting information is provided, it will be treated as a new exception request.

f) Pharmacy Services is responsible for notifying the member and requesting practitioner of the decision. Denials will further include the reason for the denial and an explanation of the plan's formal appeals process.

Approval notification may be made verbally, electronically or in writing. Denial notifications to members will be made in writing. Practitioners will be notified electronically, via fax, or in writing.

i) If information on the attending or treating practitioner is not provided with the request, GHC-SCW will attempt to identify the practitioner and document such efforts.

g) Pharmacy services allows practitioners to discuss a denial with a pharmacist reviewer via telephone or fax. Practitioners are given a chance to appeal a denial. This appeal must be done in writing, is designated as a "Provider Appeal," and is carried out via the following process:

i) Written notification of a request to appeal the decision is received by the Claims Department or Pharmacy Department via mail or fax.

ii) If additional information regarding the appeal is needed for review, a form titled "Provider Appeal Form" will be sent to the provider via fax.

iii) The original decision maker will compile the new information and, together with the original exception request, will review this information and present the case to a committee that meets on a weekly basis. In addition to the information received by the provider, a literature search is recommended so that all current medical evidence may be considered.

iv) The Provider Appeal will be discussed amongst a group of pharmacist reviewers. If a consensus decision to uphold or reverse the denial cannot be made, the original reviewer may seek the assistance of the Medical Director or acting party.

v) If the denial is ultimately upheld, the Pharmacy Department will notify the Claims Department. The Claims Department will notify the prescriber.

vi) If the denial is overturned, the requesting provider and member will be notified in the same manner as if the original request had been approved.

6) GHC-SCW has system controls in place to manage pharmacy Utilization Management (UM) Prior Authorization decisions in the scope of NCQA's health plan guidelines for Timeliness of UM Decisions. These controls protect UM denial data from being altered outside of prescribed protocols. GHC-SCW Pharmacy department utilizes a SharePoint based platform as our UM system for pharmacy decisions, hereinafter referred to as the Prior Authorization database.

a) The date of receipt is consistent with NCQA requirements

i) The date of receipt is defined as the initial date a Prior Authorization request is received by GHC-SCW from a patient or provider.

ii) Prior Authorization requests received via e-fax are dated by the requesting party. When the date GHC-SCW receives the e-faxed request is different than the date written on the fax by the requesting party, a screen shot of the electronic time stamp will be transposed onto the e-fax to ensure data integrity.

iii) Prior Authorizations entered electronically by providers via EpicCare are time and date stamped within EpicCare and cannot be altered.

b) The date of written decision notification is consistent with NCQA requirements

i) The date of written notification is defined as the date on which the decision letter is generated to the practitioner and member by GHC-SCW or if electronic notification is used, the date posted in the electronic system.

ii) Letters generated within EpicCare are time and date stamped and cannot be altered once accepted.

iii) Letters generated each business day are mailed or faxed within 24 hours. If faxed, the dated fax cover sheet is retained as documentation of the date of notification by fax.

iv) An Urgent or Concurrent decision may be communicated via telephone to the ordering provider.

c) Process for recording dates in the Prior Authorization database

i) Upon each entry, the Prior Authorization database assigns a log number to the data entered. If a duplicate entry is found, staff are instructed to change the data information to "DUPLICATE" and not delete the entry.

ii) Within the audit trail, the date and time the entry is originally created can not be modified or deleted.

iii) The Prior Authorization database will not allow manual entry of a log number. The log number cannot be duplicated. If an entry is deleted the log will be missing a number. Entries are not to be deleted for any reason.

d) Level of staff authorized to access the Prior Authorization database and modifications allowed

i) Access to the Prior Authorization database is limited to only select Pharmacy Administration employees who specifically work with Pharmacy Prior Authorization requests. These include Pharmacy Administrative Assistants and Administrative Pharmacists.

ii) Authorized staff are allowed to make modifications to a Prior Authorization database entry to document clinical information, upload documents, and/or record the decision information associated with the request, as required.

iii) Modifications to dates are only allowed in the event of a transcription error.

iv) Any modification to a Prior Authorization database entry field, including but not limited to a date, starting the day after the entry is finalized requires documentation of what change was made, the date and time of the change, and the initials of the staff who made the change. For a modification to a date, the reason the modification was made is required.

e) GHC-SCW Prior Authorization audit trail

i) Each entry within the Prior Authorization database is stamped with the date, time and name of the authorized personnel who made the entry. This information is viewable within the audit trail of the Prior Authorization data in SharePoint and this information cannot be edited.

ii) Each entry within the Prior Authorization database is stamped with the date, time and name of the authorized personnel who last modified the entry. This information is viewable within the audit trail of the Prior Authorization data in SharePoint and this information cannot be edited.

f) Processes in place that protect data from unauthorized access or modification

i) GHC-SCW has systems in place to prevent physical access to work areas. These practices include employee badge identification requirements to access the physical workspace located behind locked doors.

ii) GHC-SCW has systems preventing unauthorized access and changes to data. Software systems have password requirements with login ID's that are managed through the IT Security department.

iii) GHC-SCW has a secure identification system for password protection. We have two factor identification and password changes are required every 60 days and cannot be duplicated with any password used within the previous year.

iv) GHC-SCW practices the policy of disabling passwords of employees who leave their role or the organization. Managers submit an offboarding request to the IT Security Administrator and access is ended within 1-3 business days. HR Policy mandates that employees that are being let go have their access removed immediately.

g) How GHC-SCW audits the process and procedures in items 6 a) through 6 f) above.

i) Audits will be conducted by, or under the supervision of, the Manager of the Pharmacy Department, an Administrative Pharmacist, and/or the Pharmacy Administration Team Leader.

ii) Audits are tracked in the Audit File, which contains the date of the audit, a list of the items audited, the personnel conducting the audit, and the outcome of the audit.

iii) A random sampling of 10 prior authorizations per authorized employee per quarter will be reviewed.

iv) The Prior Authorization Database will be reviewed quarterly for data integrity, for missing log numbers and for out of sequence dates.

v) All changes made on or after the day after a database entry is finalized (per d(iv)) will be audited for compliance with policy. This includes modifications to dates.

vi) If any deficiencies with compliance are identified, a corrective action plan will be implemented as soon as possible to address any issues with the system or with the GHC-SCW associates involved with the prior authorizations reviewed.

(1) Modifications to dates occurring outside policy will be addressed with the associate who made the modification. A team reminder will be sent as needed.
(2) The event(s) will be documented in the Audit File.
(3) An audit of date modifications will be conducted in subsequent quarters by the Manager of the Pharmacy Department, an Administrative Pharmacist and/or the Pharmacy Administration Team Leader until an improvement is demonstrated over at least three consecutive quarters.

vii) GHC-SCW's Compliance Department also conducts random audits of employees accessing member records to ensure employees are only accessing records directly related to their work.

7) Delegation of UM

a) Group Health Cooperative of South Central Wisconsin delegates to Navitus Health Solutions the UM functions specific to pharmaceutical patient safety recall notifications. A formal written delegation agreement delineates which activities have been delegated and includes the responsibilities for both GHC-SCW and Navitus Health Solutions as defined under the NCQA standard for Delegation of UM.