



Pharmacy and Therapeutics Committee Policies and Procedures

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Charter

Mission

The mission of HealthPartners Pharmacy and Therapeutics (P&T) Committee is to promote the appropriate use of high quality and cost-effective pharmaceuticals for HealthPartners members.

Goals & Objectives

- ◆ Promote the appropriate use of high quality and cost-effective pharmaceuticals for HealthPartners members.
- ◆ Ensure compliance with appropriate standards and state and federal regulations.

Functions

The Pharmacy and Therapeutics Committee is responsible for the following major functions:

- ◆ Maintain the Drug Formularies to promote safety, effectiveness, and affordability according to the Formulary Principles.
- ◆ Oversight consists of the Commercial Drug Formularies, the Medicare Formulary, and the State Programs Formulary (Minnesota Health Care Programs).
- ◆ Maintain pharmacy-related medical policies that promote the safety, effectiveness, and affordability of medications used in clinic settings.
- ◆ Maintain Formulary Principles that guide the management of the Drug Formularies.
- ◆ Review new drugs, drug classes, new clinical indications, therapeutic advantages, new chemical entities, and new safety information. Policies and formularies are updated as appropriate based on the new information.
- ◆ Review the Drug Formularies and therapeutic classes, and the pharmacy related medical policies, at least annually.
- ◆ Review and update Pharmaceutical Management Policies and Procedures at least annually and as new pharmaceutical information becomes available.
- ◆ Policies are shared with providers annually and after updates in a plan newsletter.
- ◆ Policies are shared with members through the annual member notice and on healthpartners.com, with any updates posted to the website throughout the year.
- ◆ Maintain a formulary that prevents selection bias or discrimination and facilitates appropriate access to affordable prescription drug choices. A non-discriminatory formulary design does not have cost or access barriers imposed by individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

Structure & Membership

The Pharmacy and Therapeutics Committee reports to the Pharmacy Quality and Utilization Committee, which reports to the Quality Council. Membership consists of broad primary care and specialty representation, a majority of which are practicing physicians and pharmacists from both HealthPartners Medical Group and from Contracted Care providers. Membership includes at least one practicing medical physician, one practicing behavioral health physician, one practicing physician who is an expert in the care of the elderly or disabled persons, one practicing pharmacist who is an expert in the care of the elderly or disabled persons, and one patient representative. At least one

practicing physician and pharmacist will be free of conflicts of interest from HealthPartners and from pharmaceutical manufacturers. Members and a Committee Chair are appointed annually by the P&T Committee Chairperson.

Members complete a "Conflict of Interest" disclosure form and a "Non-Disclosure" Agreement annually.

Meetings

The Pharmacy and Therapeutics Committee meets at least quarterly. Minutes reflect the members in attendance, items discussed, and decisions reached. A majority of membership is required for a quorum. Minutes are forwarded to the Pharmacy Quality and Utilization Committee, and are maintained for at least 10 years in Pharmacy Administration.

Formulary Principles

The HealthPartners Pharmacy and Therapeutics Committee develops and maintains its formulary based on these guiding principles. These principles are prioritized in descending order (i.e. effectiveness is weighted most heavily, followed by safety issues, and then by cost). Formulary decisions are made following a careful review of these often-competing principles.

1. Clinical Appropriateness

a. Relative effectiveness documented in the medical literature

The primary consideration will be the degree to which a medication produces clinically desirable effects. Beneficial effects are assessed on the strength of scientific evidence including peer-reviewed medical literature, pharmacoeconomic studies, and outcomes research, and standards of practice including treatment protocols and evidence-based practice guidelines. Randomized, controlled trials are weighted most heavily, followed by non-randomized trials, case reports, and medical opinion.

b. Maximizing safety and minimizing the potential for errors.

The safety risk / benefit of a product will be compared with other treatments.

2. Optimizing cost-effectiveness.

The overall value of a drug or therapy will be compared with existing treatments to assess pharmacy costs in relation to medical outcomes. We will consider direct and indirect pharmacy and medical costs. We will take into consideration and give preference to those agents that optimize the use of financial and service resources over the largest potential population.

The formulary will serve as a guideline for the vast majority of patients.

- a. Utilization management programs such as prior authorization, step-edits, quantity limits, and age limits will be applied to promote appropriate utilization.
- b. A "Formulary Exception" process will be readily available, easy to use, and timely.
- c. A "Transition of Care" policy will be available to assist members transitioning to HealthPartners.

These principles apply to pharmaceuticals managed by the organization, whether they are covered under an organization's medical benefit or under its pharmacy benefit, including, but not limited to:

- All pharmaceuticals, whether or not they are listed in the organization's formularies.
- Pharmaceuticals administered or dispensed in all settings (e.g., inpatient, outpatient, at the pharmacy, at home).
- Customized pharmaceutical management procedures for a distinct set or class of pharmaceuticals, including injectables.

Drug Review Process

When are medications reviewed?

HealthPartners monitors for FDA New Drug Approvals and new clinical indications. HealthPartners also monitors guidelines, clinical studies, and safety information, and initiates reviews as needed.

Providers and members can also request reviews of new drugs and changes in current coverage criteria.

Requests should include advantages over existing formulary options, references to supporting literature, and a conflict-of-interest disclosure statement.

A request form is available at: www.healthpartners.com.

A reasonable effort is made to review new FDA approvals and new indications within 180 days of their availability, and to review classes of concern within 90 days.

The Pharmacy and Therapeutics Committee evaluates, analyzes and recommends treatment protocols and procedures for the timely use of and access to both formulary and non-formulary drug products at least annually.

How are medications reviewed?

New medications and revisions are first reviewed by Clinical Pharmacists within HealthPartners Pharmacy Services. The following clinical evidence is used as appropriate:

- Government agencies
- Medical associations
- National commissions
- Peer-reviewed journals
- Authoritative compendia

Preparation also includes a comparison with current alternatives, a pharmaco-economic comparison, and a competitor scan.

Medications may then be reviewed by a therapeutic-specific advisory group that includes specialists and primary care providers. This advisory group forwards recommendations to the P&T Committee.

The P&T Committee considers the clinical evidence and the advisory group recommendation for each medication and determines the coverage status and utilization management criteria. Coverage status determinations are based on the factors above and include must-cover and may-cover.

Utilization Management criteria may be added to the coverage status determination and are approved by the P&T Committee. Utilization management includes: PA (Prior Authorization), ST (Step-Therapy), QL (Quantity Limit), and Age (Age-limit). Decisions to add UM criteria are based on:

1. Clinical appropriateness
2. Cost Effectiveness
3. Competitor scans

Utilization Management criteria may be removed by the VAC Committee based on a business review.

Decisions are followed for all lines-of-business including Medicare Part D and State Programs, and updated per regulatory requirements.

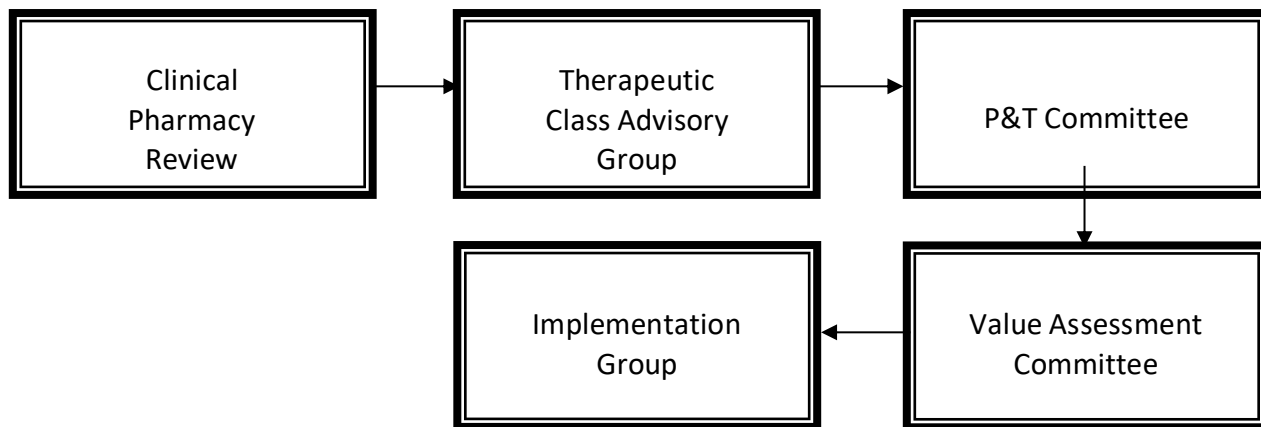
The P&T Committee can also recommend specific educational programs regarding appropriate use and request specific monitoring of utilization.

Value Assessment Committee (VAC)

The Value Assessment Committee (VAC) reviews medications after the P&T Committee. VAC considers non-clinical business considerations (including costs and business requirements) to make final decisions.

Utilization Management criteria may be added by the VAC Committee for medications with a may-cover status. If the P&T Committee has determined a may-cover status, then the VAC Committee can add preferred alternative criteria.

This P&T review process is shown below



Availability of Coverage Policies

The HealthPartners internet site contains the Drug Formularies, our Pharmaceutical Management Policies and Procedures, and several commonly used forms (www.healthpartners.com/Provider, Pharmacy Services). This information is updated quarterly and is mailed upon request.

Formulary information is made available to new providers. Updates are provided at least annually.

Drug-related Medical Policies are available on our HealthPartners internet site.

Communication of Changes

The HealthPartners Quarterly Drug Formulary Update and policies are distributed as a Fast Facts provider newsletter.

The HealthPartners internet site contains recent Drug Formulary Updates (www.healthpartners.com). This information is updated quarterly and is mailed upon request.

HealthPartners generally provides notice to affected members at least 60 days prior to negative formulary changes.

Providers are notified at least 45 days prior to updates.

Changes may be made more quickly for significant safety issues.

New FDA approvals

New medications default to a non-formulary status until their review by the P&T Committee.

Coverage for new FDA-approvals and new indications is based on FDA-approved indications and dosing, clinical trial inclusion and exclusion criteria, available guidelines, product(s) previously tried, and medical contraindications to alternatives.

Line extensions

New formulations and strengths of drugs currently on formulary will be added to the Drug Formulary by Pharmacy Administration if they are cost-neutral.

New formulations and strengths with a significant cost or member impact are brought to the P&T Committee for consideration.

Classes of Concern

All classes of clinical concern are covered.

Classes of clinical concern are anticonvulsants, antipsychotics, antidepressants, chemotherapies and antineoplastic medications, HIV medications including antiretroviral medications, and immunosuppressants. Newly approved medications in these classes receive expedited reviews. These new medications are generally added administratively by HealthPartners Pharmacy Administration to the Part D formulary in order to meet CMS requirements, and then receive a clinical review at the following P&T Committee meeting. Coverage criteria may be updated following the clinical review by the P&T Committee.

Drug Utilization Management

Formulary Status

HealthPartners uses various tools to ensure cost-effective drug utilization and prevent over and underutilization.

Formulary (F)

These medications are on formulary.

Non-Formulary (NF)

Non-formulary medications are not on the formulary.

Excluded Formulary Status

These medications are excluded per standard contract language. These are administrative decisions. This includes products not approved by the FDA, cosmetic medications, and OTC medications.

Covered

The covered status is used for preferred diabetic supplies, infertility medications, and growth hormone products. These are covered as a unique benefit and are not considered a formulary product.

Not Covered (NC)

The not-covered status is used for non-preferred diabetic supplies, infertility medications, and growth hormone products.

Not covered medications are noted in the formulary.

Medical

These medications are available in-clinic.

Utilization Management

Utilization management edits are described below.

Prior Authorization (PA)

Prior authorization helps assure the appropriate use of medications. Prior authorization criteria are listed in the Drug Formulary.

A "Formulary Exception" process is available for unique situations not addressed in prior authorization criteria. The process for submitting and reviewing requests are described in the Prior Authorization Review Process.

Step-Therapy (ST)

Step-Therapy helps assure the appropriate use of medications and can simplify the request process. A specific medication must be tried prior to using step-therapy medications. The formulary lists specific step-therapy criteria.

If a claim for the required medication is in our pharmacy database (a previous prescription claim from HealthPartners), then the step-therapy medication will be processed (there is no need for approval from HealthPartners Pharmacy Customer Service).

If a record of the required medication is not available, then the prior authorization process should be followed (a request form needs to be submitted to HealthPartners Pharmacy Services).

A "Formulary Exception" process is available for unique situations not meeting step-therapy criteria. All requests not meeting criteria are reviewed by a pharmacist or medical director.

Preferred drug rules for the Medicare Part B Step program are voted upon and approved by the P&T committee per CMS regulations (§ 422.136) and follow all policies and procedures set forth in this document.

Quantity Limits (QL)

Quantity limits help ensure the appropriate use of medications and are specified in the formulary. Quantity limits may be applied for safety reasons and/ or for cost reasons.

Quantity Limits that are set at FDA recommended maximum dosing are considered administrative updates, updated by HealthPartners Pharmacy Administration. All other quantity limits (such as dose optimization limits, and quantity limits that are more restrictive than the FDA label) are reviewed by the P&T Committee.

Quantity Limit recommendations are followed for all lines-of-business including Medicare Part D and State Programs and updated as needed per regulatory requirements.

A "Formulary Exception" process is available for unique situations requiring greater quantities.

Age-Edit (AGE)

Age-Edits help assure the appropriate use of medications and can simplify the request process for some medications. Age-edit medications are available without restrictions for patients within specific age groups. Age criteria are listed in the Drug Formulary. Patients outside of the specified age group need to meet specific criteria before the medication is approved, and need to use the prior authorization process to submit this information.

A "Formulary Exception" process is available for unique situations not meeting age-edit criteria. All requests not meeting criteria are reviewed by a pharmacist or medical director.

Excluded Drug List

The Excluded Drug List includes selected products that may be excluded from coverage. The Value Assessment Committee (VAC) can add this excluded drug list status when P&T determines may-cover and do-not-cover.

Trial Drug

The first several fills of these medications may be limited to less than a month supply. If tolerated and effective, members can receive the remainder of the supply and pay no more than one copay for each full month supply.

Specialty Drug (SP)

In order to provide our members with quality health care and use premium dollars responsibly, HealthPartners has made arrangements with select vendors for specialty medications.

This program applies only to specialty medications, and members can continue to obtain all other non-specialty prescription medications through retail or mail order pharmacy. This program doesn't apply to in-clinic administration of medications.

Specialty Medications are noted as SP in the Drug Formulary and in the Specialty Drug List.

Drugs are designated as specialty drugs by the HealthPartners Value Assessment Committee. New FDA approvals are reviewed weekly and identified as specialty by HealthPartners Pharmacy Administration. The list is confirmed and updated quarterly by the Value Assessment Committee.

A "Formulary Exception" process is available for unique situations that require dispensing from other pharmacy providers.

Affordable Care Act

HealthPartners offers certain preventive service benefits at no cost to you. This means you don't have to pay a copay or coinsurance. These medications are part of the Affordable Care Act (ACA).

The Patient Protection and Affordable Care Act (ACA) establishes coverage for essential health benefits without charging a copayment, coinsurance, or deductible. Essential health benefits include medications that are outlined by the United States Preventive Services Task Force (USPSTF) recommendations with an A or B rating, recommendations from the Advisory Committee on Immunization Practices (ACIP), and guidelines supported by the Health Resources and Services Administration (HRSA) for pediatrics and women.

Affordable Care Act with PA: These products are covered under the Affordable Care Act if prior authorization criteria are met.

HSA Preventive Drug

Preventive drugs are used to help avoid disease and maintain health. Some insurance plans have a benefit that allows preventive drugs at a copay.

Two HSA drug lists available. The Basic HSA Drug List provides lower-cost options to treat common conditions. The Enhanced HSA Drug List provides broader coverage than the Basic HSA Drug List.

Generic Substitution Policy

HealthPartners requires the use of a generic product when available, unless specifically noted.

Generics are considered clinically equivalent to reference products. Formulary preferences between Brands and their equivalent generics are made by the VAC Committee.

Providers can request brand name products if medically necessary by submitting a prior authorization request and writing “Dispense as Written” on the prescription. The prior authorization request should include the medical contra-indication to the generic.

Biosimilar Policy

Biosimilars are reviewed administratively by HealthPartners Pharmacy Administration, with a preference for the lowest cost product.

Biosimilars are considered clinically equivalent to reference products, including indications unique to reference products only (e.g., orphan indications). Biosimilars with clinical concerns are brought to the P&T Committee for consideration.

Multi-Source Brand Policy

Multi-Source Brands are generally non-formulary.

When Multi-Source Brands become available, the equivalent generic replaces the Brand medication (taking the formulary status of the Brand medication), and the Brand moves to a non-formulary status.

OTC Medications

Over-the-counter products can be purchased without a prescription and are not covered under HealthPartners’ benefit plans or the benefit plans of its Related Organizations unless otherwise noted.

Herbal Medications

Herbal products can be purchased without a prescription and are not covered under HealthPartners’ benefit plans or the benefit plans of its Related Organizations unless otherwise noted.

Compounded Medications

Compounded prescriptions are a combination of a prescription medication with one or more other products, prepared by individual pharmacies, usually because a commercially-available product is not available.

Compounded prescriptions may be covered at the member’s in-network benefit when submitted on-line by a contracted network pharmacy.

High-cost compounded prescriptions (over \$150) will be reviewed for medical necessity. Required information includes the diagnosis, products previously tried, evidence of efficacy, and medical necessity.

This policy is available in medical coverage policies, https://www.healthpartners.com/public/coverage-criteria/policy.html?contentid=AENTRY_045857.

Prior Authorization Review Process

This review process is used for utilization management programs, including prior authorization, step-therapy exceptions, quantity limit exceptions, and non-formulary medication requests.

Prior Authorization (PA)

Requests are reviewed and responded in compliance with applicable regulations. Expedited requests will be reviewed within applicable regulation. All requests not meeting criteria are reviewed by a pharmacist or medical director.

Approval Process: If requests meet the prior authorization criteria, an authorization is entered into the pharmacy billing system to allow any contracted network pharmacy to process the prescription for the enrollee's appropriate benefit tier. Approvals will be entered for a sufficient time period to ensure continued therapy under the enrollee's appropriate benefit tier. The requesting individual is notified of this approval.

Re-authorizations: Re-authorization criteria are listed in the Drug Formulary. Requests are generally approved for patients stable on current therapy.

Denial Process: If denied, both the requesting provider and the enrollee are notified of the denial by mail or fax, the reason for the denial, and the process for appealing this decision.

A "Formulary Exception" process is available for unique situations not meeting prior authorization criteria.

Step-Therapy (ST)

Step-Therapy helps assure the appropriate use of medications and can simplify the request process. A specific medication must be tried prior to using step-therapy medications. The formulary lists specific step-therapy criteria.

If a claim for the required medication is in our pharmacy database (a previous prescription claim from HealthPartners), then the step-therapy medication will be processed (there is no need for approval from HealthPartners Pharmacy Customer Service).

If a record of the required medication is not available, then the prior authorization process should be followed (a request form needs to be submitted to HealthPartners Pharmacy Services).

A "Formulary Exception" process is available for unique situations not meeting step-therapy criteria. All requests not meeting criteria are reviewed by a pharmacist or medical director.

Quantity Limits (QL)

Quantity limits are specified in the formulary.

Quantity Limits that are set at FDA recommended maximum dosing are considered administrative updates, updated by HealthPartners Pharmacy Administration. All other quantity limits (such as dose optimization limits, and quantity limits that are more restrictive than the FDA label) are reviewed by the P&T Committee.

A "Formulary Exception" process is available for unique situations requiring greater quantities. All requests not meeting criteria are reviewed for medical necessity by a pharmacist or medical director.

Age-Edit (AGE)

Age-Edits help assure the appropriate use of medications and can simplify the request process for some medications. Age-edit medications are available without restrictions for patients within specific age groups. Age criteria are listed in the Drug Formulary. Patients outside of the specified age group need to meet specific criteria before the medication is approved, and need to use the prior authorization process to submit this information.

A “Formulary Exception” process is available for unique situations not meeting age-edit criteria. All requests not meeting criteria are reviewed by a pharmacist or medical director.

Formulary Exceptions

A “Formulary Exception” process is available for non-formulary medications, continued coverage of drugs removed from formulary, exceptions to prior authorization criteria, exceptions to step therapy criteria, exceptions to quantity and age limitations, medications newly approved by the FDA, and for new enrollees transitioning from other prescription drug coverages.

Providers can submit information for formulary exceptions with the PA request form found below and additional clinical information for consideration can be included with the request.

Exception reviews are based on diagnosis, formulary product(s) previously tried, evidence of efficacy, and medical necessity. Requests are reviewed and responded in compliance with applicable regulations. Expedited requests will be reviewed within applicable regulation. All requests not meeting criteria are reviewed by a pharmacist or medical director.

Requests are generally approved if enrollees have tried and failed formulary products due to either an inadequate response or a medical contraindication to their use, and for enrollees who are previously stable on certain medications such as anticonvulsants, antipsychotics, antidepressants, chemotherapy, HIV medications, immunosuppressants, and medications determined to be medically necessary.

All requests are reviewed by HealthPartners Clinical Pharmacists, either directly or per protocol. Requests are reviewed and responded in compliance with applicable regulations. Expedited requests will be reviewed within applicable regulations. Required information includes diagnosis and the results of previous therapy.

Approval Process: If requests meet the prior authorization criteria, an authorization is entered into the pharmacy billing system to allow any contracted network pharmacy to process the prescription for the enrollee’s appropriate benefit tier. Approvals will be entered for a sufficient time period to ensure continued therapy under the enrollee’s appropriate benefit tier. The requesting individual is notified of this approval. Members are notified following regulatory protocol.

Denial Process: If denied, both the requesting provider and the enrollee are notified of the denial by mail or fax, the reason for the denial, and the process for appealing this decision.

Prior Authorization Request Form

Electronic Prior Authorization submissions are accepted and preferred.

The HealthPartners Prior Authorization form is available on our HealthPartners site (HealthPartners.com/provider, Admin tools, Pharmacy policies). Request forms can be faxed to HealthPartners Pharmacy Services at 952-853-8700 or 1-888-883-5434.

The Minnesota Uniform Form for Prescription Drug Prior Authorization (PA) is accepted.

This request form can be used by providers, for prior authorization requests, step-therapy exceptions, quantity limit exceptions, and non-formulary medication requests.

Requests by enrollees and enrollees' authorized representatives can be submitted to HealthPartners Member Services via phone, fax, or mail or initiated on-line at HealthPartners.com. In most cases, the prescriber will need to submit specific information to document whether criteria are met.

Hours of Operation

HealthPartners call center is available to providers (physicians, pharmacies, and pharmacists) 365 days per year and 24 hours per day.

Pharmacy Customer Service is available to providers (physicians and pharmacies) from 8AM - 6PM CST, Monday through Friday and 8AM – 4PM CST, on Saturday. After hours calls are answered by our Pharmacy Benefit Manager, available 365 days per year and 24 hours per day.

- Fax 952-853-8700 or 1-888-883-5434
- Telephone 952-883-5813 or 1-800-492-7259
- Mail - HealthPartners Pharmacy Services, 8170 33rd Avenue S, PO Box 1309, Minneapolis, MN 55440.

If a provider is calling with an urgent prior authorization or coverage determination request over the weekend or on holidays, they may press option 2 and leave a message for a staff member to return the call.

Pharmacy Customer Service answers inquiries regarding claims processing, benefit coverage, claims submission and payment, and prior authorization. This help line is staffed by trained Pharmacy Customer Service Assistants and clinical pharmacists.

Appeals Process

Appeals by enrollees and physicians should be directed to HealthPartners Member Services.

Decisions on Medicare Part D enrollee appeals will be communicated by Member Rights and Benefits pursuant to CMS policy and procedures.

Decisions on Non-Part D enrollee appeals will be communicated by Member Rights and Benefits pursuant to regulatory rules.

In addition, if enrollees would like to review the status or discuss the request with the decision maker, enrollees may contact HealthPartners. A temporary override will be extended to new enrollees processing through a grievance and appeal.

Pharmacy Programs

Transition of Care Policy

A transition process is available to new enrollees who are transitioning from other prescription drug coverages, enrollees whose current drug therapies may not be included in the HealthPartners formulary, and unplanned transitions as individuals change treatment settings due to changes in level of care.

Protected class medications are authorized to allow continued therapy. These medications include anticonvulsants, antipsychotics, antidepressants, antineoplastic medications, HIV medications, and immunosuppressants for prophylaxis of organ transplant rejection, and medications determined to be medically necessary. Patients who have been treated with a drug to treat a mental illness or emotional disturbance for 90 days may continue to receive the prescribed drug for up to one year without the imposition of special co-payment requirements.

HealthPartners offers temporary coverage for other medications for new and transitioning enrollees. This is designed to accommodate the immediate needs of enrollees for a limited period of time.

Long Term Care Exception Process

Enrollees residing in a LTC facility will receive special consideration based upon their enrollment and transition to a LTC facility. Overrides will be in place until an appropriate liaison between the facility, the attending physician, and the plan's LTC pharmacy can be achieved. The overrides will be effective for a minimum of 90 days to accomplish appropriate communication.

Therapeutic Interchange

Member-outreach programs are used to promote lower-cost alternatives.

Members receiving specific medications receive communications from HealthPartners, notifying them of a lower-cost alternative. This is a voluntary program. If members are interested, they are asked to review with their pharmacist or provider.

Member Cost Sharing

Member benefits are applied to all pharmaceuticals and are collected at the point of service. Member benefits vary with specific benefit designs.

Tiered cost-sharing is available to encourage cost-effective utilization. Member payments are usually lowest for generic formulary products, followed by formulary brands, and then non-formulary products (highest co-pay).

Pharmacy Network

The HealthPartners pharmacy network is maintained by our pharmacy benefit manager. The network is required to comply with standards for pharmacy practice as established by State Boards of Pharmacy.

Quality Assurance Programs

These quality assurance tools are used to help reduce medication errors and adverse drug reactions, and to improve appropriate medication use.

Concurrent Drug Utilization Reviews

Point-of-dispensing screening edits are routinely applied by our pharmacy benefit manager to each prescription claim.

These edits are designed to check the member's prescription history for possible conflicts. Edits applied before dispensing include screening for drug interactions, allergies (if data available), early refills, duplicate prescriptions, over utilization/ refill too soon, underutilization, pediatric warnings, geriatric warnings, acute/maintenance dosing, therapeutic duplication, drug-inferred health state, drugs exceeding maximum daily dosage and drugs below minimum daily dosage.

Drug interactions are screened based on the First Data Bank drug interaction severity rating system. There are four severity types:

- Major: Interactions have the potential of serious adverse outcomes (potentially life-threatening).
- Moderate: Interactions are less likely than major interactions to cause harm to the member.
- Minor: Interactions pose a limited or unclear risk to the member.
- None: No known interactions

When concurrent DUR warnings occur, pharmacists are expected to use their professional judgment in dispensing a product after consultation with the physician and/or patient as necessary.

Retrospective Drug Utilization Reviews

Retrospective drug reviews using claims data are performed to identify patterns of inappropriate or medically unnecessary care.

Review programs for Medicare include a drug management program for frequently abused drugs. This program includes case management for each potential at-risk beneficiary.

Medication Therapy Management

HealthPartners has developed a network of Medication Therapy Management (MTM) pharmacists. The goal of the program is to ensure optimum therapeutic outcomes through improved medication use.

Drug Recalls, Withdrawals, and Safety Advisories

Communications are sent to providers and members for significant drug recalls, product withdrawals, and safety advisories.

Follow-up by HealthPartners is determined by the Medical Director with input from Clinical Pharmacy and from practicing providers. Issues considered in determining follow-up by HealthPartners include the degree of health risk, the extent of distribution, the extent of media coverage, and recommendations by local providers.

Issues are identified using the FDA MedWatch e-list, the FDA Recall e-list, notifications by manufacturers, and press releases. Drug utilization reviews by HealthPartners are also used to identify issues.

Drug Safety Alerts are categorized into three classes, according to the level of hazard involved:

- Class I Recalls: Dangerous or defective products that predictably could cause serious health problems or death. Members and providers are notified in an expedited manner, within 14 days.
- Class II Recalls: Products that might cause a temporary health problem or pose only a slight threat of a serious nature. Members and providers are notified within 30 days for Class II recalls with the potential for significant negative effects.
- Class III Recalls, Unclassified Recalls, Product Withdrawals, and Safety Advisories: Members and providers are notified within 30 days for issues with the potential for significant negative effects.

Members are identified using a report of recent pharmacy and/or medical claims.

Communication options include notifications to providers and/ or patients by either HealthPartners or its business partners (e.g. our pharmacy benefit manager, our specialty pharmacy provider(s), and the pharmacy network). Communications may be sent via US mail, fax, and by e-mail.

A log of issues and follow-up is kept in Pharmacy Administration.

HealthPartners supports and promotes reporting serious medication-related adverse reactions to the MedWatch Reporting System.

Pharmacy Fraud, Waste, and Abuse Program

HealthPartners Pharmacy Fraud, Waste & Abuse Program employs retrospective claim review across all products to identify patterns of inappropriate and/or medically unnecessary medication use, prescribing, or distribution.

Multifaceted member-, provider, and pharmacy-level clinical assessments of claims are conducted quarterly by pharmacists in conjunction with a multidisciplinary team including physicians, nurses, and/or quality review professionals.

Clinical criteria are used to identify outlier members, providers, and pharmacies with high or duplicative utilization, prescribing, or distribution of controlled substances, costly medications, and/or medications of concern over a sustained period of time.

Formal communication between HealthPartners clinical staff and providers is used to ascertain medical necessity in concerning cases. Case review findings and results are documented by Pharmacy Administration. Formal communication is used to convey case review findings to providers as needed.

When necessary following clinical review, outlier members, providers, and/or pharmacies are referred to appropriate entities for further action. HealthPartners may also utilize beneficiary-level point-of-sale edits for Medicare Part D members; providers and beneficiaries are formally notified of edits prior to implementation.

Sampling Policy

A primary concern is patient safety. In addition, the use of samples leads to prescribing and use which may not be most effective or efficient for our members

Clinics should eliminate sampling of all prescription pharmaceutical products supplied by manufacturers and dispensed by clinic providers and staff directly to patients.

Clinics choosing to continue to stock and dispense sample medications must follow safe medication practices, consistent with those identified by JCAHO. These requirements include but are not limited to:

- Develop procedures for sample storage and disposal (e.g. must be locked and have controlled access and checked for outdates that are appropriately disposed of).
- Develop procedures for proper dispensing (labeling, patient education, documentation in the medical record, review for allergies and drug interactions).
- Keep a log of all samples dispensed which includes: date, patient, medication name, dose, expiration date and prescriber.
- Designate a person or persons to be responsible for the sampling program at the clinic and ensuring compliance with policies and procedures.
- Develop an approved list of samples with care taken to evaluate efficacy, safety and value compared to other alternatives.

Contact Information

HealthPartners Pharmacy Services may be contacted using the following:

HealthPartners Pharmacy Services

8170 33rd Ave S, P.O. Box 1309, Minneapolis, MN 55440

Fax 952-853-8700 or 1-888-883-5434

Telephone 952-883-5813 or 1-800-492-7259

HealthPartners call center is available to providers (physicians, pharmacies, and pharmacists) 365 days per year and 24 hours per day. HealthPartners Pharmacy Prior Authorization Provider help line at 952-883-5813 or 1-800-492-7259 is available from 8 AM - 6 PM Central Time, Monday through Friday, and 8 AM – 4 PM Saturday. After these hours, the telephone line is routed to our Pharmacy Benefit Manager. Our PBM is available 365 days per year and 24 hours per day. Pharmacy Customer Service answers inquiries regarding claims processing, benefit coverage, claims submission and payment, and prior authorization. This help line is staffed by trained Pharmacy Customer Service Assistants and clinical pharmacists.