ITASCA MEDICAL CARE (IMCare)
POLICY AND PROCEDURE

Title: Pharmacy Management	**Index:** Utilization Management
NCQA Standard #: UM11: Procedures for Pharmaceutical Management	
Statute/CFR#: MN Statutes, Section 62Q.527, 256B.0625, Subdivision 13	
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Written by: IMCare QI/UM Staff	**Reviewed/Revised Date:** 04/03/2018

POLICY

Itasca Medical Care (IMCare) will maintain a formulary for products offered to its membership that is based on sound clinical evidence.

The clinical criterion that IMCare utilizes to adopt pharmaceutical management procedure includes, but is not limited to:

- Pharmaceutical classes
- Classes preferred or covered at any level
- Lists of preferred pharmaceuticals or formularies
- 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
    - The criteria for prior authorization of any pharmaceutical
    - An exceptions process available to enrollees
    - 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.

IMCare uses clinical evidence to adopt pharmaceutical management procedures, including the following:

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

IMCare will collaborate with pharmacists, practitioners, and its delegated Pharmacy Benefit Management (PBM) vendor on the development of the formulary and management procedures. This includes clinical pharmacists and appropriate practitioners.

Pharmaceutical Restrictions/Preferences
IMCare will annually and as needed communicate pharmaceutical management procedures to providers via direct mail, web site, and/or formulary booklet. Annually and as updated, IMCare communicates to enrollees and prescribing practitioners:

1. A list of pharmaceuticals, including restrictions and preferences.
2. How to use the pharmaceutical management procedures.
3. An explanation of limits or quotas.
4. How prescribing practitioners must provide information to support an exception request.
5. IMCare's process for generic substitution, therapeutic interchange and step-therapy protocols.
6. Copayment information, including tiers
7. Limits on refills, doses or prescriptions
8. Pharmaceuticals that require prior authorization

How formulary updates are communicated, and how often, for scheduled formulary updates.

Pharmaceutical Patient Safety Issues
A Class I recall is a situation in which there is a reasonable probability that use of or exposure to a product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of or exposure to a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A market withdrawal is the removal or correction of a marketed product that the FDA considers to be in violation of the law it administers and against which initiate legal action.

IMCare will identify and notify enrollees and prescribing practitioners affected by a Class I or Class II recall, or voluntary drug withdrawals from the market for safety reasons within thirty (30) calendar days of the Food & Drug Administration (FDA) notification. IMCare will promptly identify and notify enrollees and prescribing practitioners affected by Class I recalls. IMCare will promptly identify and notify enrollees and prescribing practitioners of any market withdrawals.

Reviewing and Updating Procedures
Annually, IMCare, with participation of physicians and pharmacists:

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

Considering Exceptions
IMCare's Policy & Procedure 2.07.16 Pharmacy Exceptions describes the process for:

1. Making an exception request based on medical necessity
2. Obtaining medical necessity information from prescribing practitioners
3. Using appropriate pharmacists and practitioners when considering exception requests
4. Timely handling of requests
5. Communication the reason for a denial and an explanation of the appeal process when IMCare does not approve an exception request

Non-Formulary Antipsychotic Drugs
IMCare will provide coverage for an antipsychotic drug prescribed to treat emotional disturbance or mental illness, regardless of whether the drug is on IMCare's formulary, if the healthcare provider prescribing the drug:

1. Indicates to the dispensing pharmacist, orally or in writing, that the prescription must be dispensed as communicated;
2. Certifies in writing to IMCare that the health care provider has considered all equivalent drugs in IMCare's formulary and has determined that the drug prescribed will best treat the enrollee's condition.

IMCare is not required to provide coverage for a drug if the drug was removed from IMCare's formulary for safety reasons.

When IMCare has received a certification from the health care provider, IMCare may not:

1. Impose a special deductible, co-payment, coinsurance, or other special payment requirement that IMCare does not apply to drugs that are in the IMCare formulary; or
2. Require written certification from the prescribing provider each time a prescription is refilled or renewed that the drug prescribed will best treat the enrollee's condition.

Continuing Care
Enrollees receiving a prescribed drug to treat a diagnosed mental illness or emotional disturbance may continue to receive the prescribed drug for up to one (1) year without the imposition of a special deductible, co-payment, coinsurance, or other special payment requirements, when IMCare's formulary changes or an enrollee changes health plans and the medication has been shown to effectively treat the enrollee's condition. In order to be eligible for this continuing care benefit:

1. The enrollee must have been treated with the drug for ninety (90) days prior to change in a health plan's drug formulary or a change in the enrollee's health plan;
2. The health care provider prescribing the drug indicates to the dispensing pharmacist, orally or in writing, that the prescription must be dispensed as communicated; and
3. The health care provider prescribing the drug certifies in writing to IMCare that the drug prescribed will best treat the enrollee's condition.

The continuing care benefit shall be extended annually when the health care provider prescribing the drug:

1. Indicates to the dispensing pharmacist, orally or in writing, that the prescription must be dispensed as communicated; and
2. Certifies in writing to IMCare that the drug prescribed will best treat the enrollee's condition.

IMCare must promptly grant an exception to the IMCare formulary for an enrollee when:

1. The health care provider prescribing the drug indicates to IMCare that: The formulary drug causes an adverse reaction in the enrollee,
2. The formulary drug is contraindicated for the enrollee, or

3. The IMCare provider demonstrates to IMCare that the prescription drug must be dispensed as written to provider maximum medical benefit to the enrollee.

PROCEDURE

Formulary

The Pharmacy Director and/or Medical Director is responsible for the following:

1. Maintaining IMCare's closed formularies based on sound clinical information.
    a. The formulary is developed and maintained by the Pharmacy and Therapeutics (P&T) Subcommittee whose membership includes actively practicing physicians and pharmacists.
    b. Quarterly, IMCare meets with its delegated Pharmacy Benefit Management (PBM) vendor to review formulary, policies, utilization data, and to recommend pharmaceuticals for formulary inclusion/exclusion.
    c. The PBM vendor presents clinical evidence for IMCare's consideration on:
        - Safety
        - Efficacy
        - Comparison studies
        - Approved indications
        - Adverse effects
        - Contraindications/warnings/precautions
        - Pharmacokinetics
        - Patient administration/compliance considerations
        - Medical outcomes and pharmacoeconomic studies
    d. The formulary is reviewed and revised with the Pharmacy and Therapeutics Subcommittee at least annually, to include:
        - Criteria used for pharmaceuticals requiring pre-service review,
        - Pharmacy management policies and procedures,
        - Formulary inclusions and exclusions by categories.

Pharmacists

The Pharmacists are responsible for the following:

Pharmacists dispense medications based on the following guidelines:

1. Generics: Brand names shown in the formulary are for reference only. A different brand or a generic version may be dispensed if both of the following factors are met:
    - The generic drug must contain the same active ingredients(s) and be the same strength and the same dosage form as the brand name product.
    - The FDA has given the generic an "A" rating compared to the branded product indicating bioequivalent and has determined the generic is therapeutically equivalent to the reference brand.
2. Drug Limitations: Managed drug limitations (MDL) provide for a maximum quantity of a drug product that IMCare's contracted pharmacies can dispense per prescription and over a period of time.
3. Step Therapy requires the use of one (1) or more prerequisite drugs that meet specific conditions prior to the use of another drug or drugs.
4. Over the Counter (OTC) products are included in the formulary. Providers must prescribe

the product for IMCare to cover under the enrollees benefits.

QI/UM Nurses/Medical Director/Physician Reviewers
The QI/UM Nurses/Medical Director/physician reviewers are responsible for the following:

1. Prior Authorization: Some pharmaceuticals require prior authorization approval as outlined in Policy and Procedure 2.07.22 - Pre-service Review.
    a. If the submitted clinical documentation meets the established criteria, the request is approved for drug coverage.
    b. If the submitted clinical documentation does not meet the established clinical criteria for coverage, the requesting provider, the pharmacy, and the enrollee are notified in writing as to this decision.
    c. The pharmacy, enrollee and the requesting provider receive phone calls.
2. Benefit Exceptions: Providers on behalf of enrollees can request an exception to benefit by providing patient name, ID number, provider name, address and telephone number, drug name, strength and directions, diagnosis, and medical history as outlined in Policy and Procedure 2.07.16 -Pharmacy Exception.
    d. If the clinical research meets the established criteria, the request is approved for drug coverage.
    e. If the clinical research does not meet the criteria, the requesting provider, the pharmacy, and the enrollee are notified verbally and in writing of this decision.
3. Enrollee Appeals: Adverse determinations can be appealed by an enrollee and/or their provider on behalf of the enrollee by initiating the appeal process within ninety (90) days of the denial, termination or reduction letter and as outlined in Policy and Procedure 2.05.01.
4. Pharmacy Management Exception: The provider can request exceptions to protocols for step therapy, quantity limitations, OTCs, and generic use.

Pharmacy Benefit Management (PBM) Vendor
The Pharmacy Benefit Management Team is responsible for the following:

1. IMCare's PBM maintains policies and procedures that include:
    - A system for point of dispensing communications to identify and classify drug-to-drug interactions by severity,
    - Notification to dispensing providers at the point of dispensing of specific interactions when they meet the organization's severity threshold,
    - When possible, identification and notification of enrollees and prescribing practitioners affected by a Class II recall or voluntary drug withdrawals from the market within thirty (30)calendar days of the FDA notification,
    - An expedited process for prompt identification and notification of enrollees to IMCare enrollees affected by a Class I recall.

QI/UM Nurses/Medical Director/Physician Reviewers
The QI/UM Nurses/Medical Director/physician reviewers are responsible for the following:

1. Notifies enrollees and providers affected by Class I recalls.
2. Disseminates updated formulary booklet(s) which include management procedures to all providers annually.

3. Communicates formulary updates quarterly via physician announcements, and website updates.
4. Performs oversight of the PBM and its performance of delegated functions.