Medication Utilization Management Work Group
Executive Summary
December 8, 2015

Preamble
Medication utilization management (MUM) balances concerns for patient benefit, safety and cost. The process is a part of most, if not all, coverage products offered by health plans to individual and employer purchasers. These programs run in parallel to separate programs set up by state governments, the federal government and self-insured employers who, by law, have the ability to have medication utilization management programs of their own. Additionally, the community needs to balance the high costs of pharmaceuticals with the health plans’ need to control these costs through MUM in order to assure health care is affordable. This is in keeping with the goals of the Affordable Care Act.

Following is a summary of the work and recommendations from a group of key stakeholders convened by ICSI. This goal for this phase of the work was to understand the MUM process and offer recommendations to improve the process. A second phase could be an implementation phase. During the implementation phase, details under each action would be fleshed out. IT capabilities and implementation costs will be key considerations when determining the feasibility of implementing this model. Many of the actions rely on electronic solutions. The ability of individual health systems to achieve full electronic solutions is highly variable. It is estimated that the design and piloting of a model based on this document will take approximately 12 months.

Work Group Charge and Members

Purpose
As a neutral convener, ICSI was asked to bring together key stakeholders in response to concerns over prior authorization for medications. We learned that prior authorization is only one component of medication management. Therefore the charge was to include medications managed through processes involving step therapy, quantity limits, prior authorization and medical necessity. This included analyzing key issues and defining opportunities for improvement and creating recommendations and guiding principles for improving medication utilization management.

Goal(s)
To improve the medication utilization management process to create high value by improved efficiency, effectiveness to provide safe care, manage costs and improve the experience of everyone involved.

Responsibilities
This team was charged to:
1. Understand the current medication utilization management process and identify areas of concern for all stakeholders.
2. Identify opportunities for improvement and recommend improvements in the process.
3. Support implementation of recommendations to achieve the goals of this group.
Current State Key Learnings and Issues Identified

Prior authorization process is applied to all types of medication utilization – step therapy, quantity limits, medical necessity and prior authorization – therefore the focus of the work group was expanded to include Medication Utilization Management (MUM).

Rejections are different than denials. Rejections occur when the pharmacy verifies the patient’s health plan medication benefit and is notified the medication will require approval prior to dispensing. Rejection is the signal for the MUM process to begin. A denial is at the end of the MUM process and is a determination that the medication will not be covered by the patient’s benefit plan. A denial can be appealed. Rejections result in provider and patient frustration and cause much of the burden. Addressing the issues with MUM will require a collaborative approach between health plans, care delivery, Pharmacy Benefit Managers (PBMs) and retail pharmacies.

Health plans establish formulary and utilization management requirements, but medication utilization management is also established by CMS, DHS, employer benefit packages, the FDA, and PBMs.

No one person or provider group can remember and keep track of all these requirements. A computer/electronic-supported process is the only way to create an efficient, consistent process while navigating the many requirements and rules that must be communicated across tools and systems.

Minnesota law requires that, “Effective January 1, 2011, all providers, group purchasers, prescribers, and dispensers must establish, maintain, and use an electronic prescription drug program.” An update of the state of e-prescribing is available here:
Additionally, the Minnesota legislature passed a bill requiring electronic prior authorization by January 2016. There is great variability among the health plans, providers and pharmacies working to meet this deadline.

Short vs. long-term solutions: It is recommended that prior to implementation a set of priorities for implementation be developed. Some of these recommendations will take time and resources to implement.

Reflections on the current state process map:

1. There is no mechanism in place to prevent a rejection in the process. A rejection in the prescribing process is the start of the MUM process.
2. There are variable mechanisms to inform prescribers, at the time of prescribing, which medications require MUM, the type of MUM and what alternatives exist.
3. The person who is informed of the benefit rejection (pharmacist) has little information to deal with the issue.
4. The outcome value of the process is unclear to those involved.
5. There are multiple cycles of unclear handoffs between those involved across various systems and organizations.
Current State Map

Medication Utilization Management*

Current State Process Map

Day 1

Pharmacy contacts Provider
Provider informs Patient

Communication
- Prescriber
- Pharmacy

Provider reviews med or Refill
EMR may flag order
Dispensing
Pharmacy
Processes med
Medication is rejected for processing

Day 1

CMS - 30 days

Risk Management

FDA - Employers - CSG - Insurers

CMS Rules +
Health Plan
PBM establishes Formulary + Rules

Rules may be loaded to EMR

Provider Prescribes Med or Refill

Approved

Denied
Appeal Process

* Quantity Limits
Step Therapy
Prior Authorization
Medical Necessity

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**Future State Map**

**Medication Utilization Management**

**Desired Future State Map**

**Step One**
Health plans/PMB/CMS/ DHS and others establish formulary and MUM rules

**Step Two**
Prescriber orders thru EMR. MUM requirements appear to inform prescriber and provide alternatives

**Step Three**
MUM forms are auto-populated by EMR. Prescriber completes needed information and sends for auto approval

**Step Four**
Auto approval received and e-prescription is sent to pharmacy

**Step Five**
Patient picks up medication in the Pharmacy

OR
Prescriber can select an alternative, non-MUM medication

OR
Order requires individualized review at health plan or PBM

MUM order is denied (order not sent to pharmacy)

Appeal process is implemented or alternative prescription is used
Recommendations/Guiding Principles

After reviewing the current issues and creating a future state map of the process, the work group generated recommendations and guiding principles for all stakeholders involved in the MUM process. These would be used to guide future implementation of the new model.

A recommendation is a course of action that needs to be taken to achieve the goal. The action may require further technical specifications.

Guiding principles establish the fundamental norms, rules, or ethics that represent what is desirable.

Work Group Recommendations outline a course of action that needs to be taken to achieve the goal of improving the medication utilization management process to create high value through improved efficiency and effectiveness to provide safe care, manage costs and improve the experience of everyone involved.

Each of these recommendations is based on the future state process map.

Step One: Health Plans/PBM/Others establish formulary and rules

• Individuals will have access to a preferred medication whenever possible. When a patient is on a maintenance therapy and their condition is stable on that therapy, a provider can appeal a suggested formulary change so the patient could stay on the preferred medication. Adequate notice and transition time would be built into this process. There may be benefit differences between the recommended and the preferred medications. No one whose chronic condition is controlled on a medication should be forced to change except when there is a safety, quality, significant cost impact or regulatory restriction.

• If there is a formulary change the health plan gives the patient and provider sufficient time and information for them to create an informed transition plan to a new medication or request continued coverage of the existing medication.

• Step therapy requirements are honored between plans so patient is not required to re-try first line requirements. Documentation of previous step therapy failure from the prescriber may be required.

Step Two: Prescriber orders through EMR and MUM requirements appear to inform prescriber of alternatives

• Everyone should comply with the legislative mandate for e-prescribing and e-prior authorization as soon as possible via computer systems integrated with an EMR.

• E-prior authorization and e-prescribing should be a blended electronic process, seamless to the prescriber.

• At the time of order the following are provided through the EMR and automatically appear when the prescriber selects a medication for e-prescribing:
o Medication requires MUM
o Type of MUM: step therapy, quantity limit, PA, or other
o Alternative drug options that do not require MUM
o For a future build of tools, include denial information so provider and patient would know the origination of rule (CMS, DHS, FDA or health plan) and identifying whether it can be appealed; technical denial; benefit exclusion, etc.
o Criteria for prescribing: form available and auto populated with patient’s information and information needed by health plan
o Cost indication: high, medium or low cost medication

• Interfaces between EMR, electronic prior authorization, and PBMs and formularies are real time or frequent so the clinician has specific, accurate and up-to-date information when prescribing.

• Shared decision-making is used with patient at the time MUM is recognized, and the patient is included in the choice of alternatives.

• Information is available to the patient regarding MUM.

**Step Three: MUM form is auto-populated by the EMR; prescriber completes needed information and sends for auto authorization**

• Once the MUM form is submitted to the health plan, the approval process is automated and is done in real time.

• Some complex requests may need an individualized review.

**Step Four: Medication is auto approved, or information is requested, or the benefit is denied**

• If additional information is required, the prescription is held in the EMR until the information is complete and the medication is approved or denied.

• Pharmacy does not receive an order until the MUM process is complete.

• Specific reasons for denial are given with preferred alternatives.

**Step Five: The appeal process is implemented or alternative prescription is used.**

• The appeal process is transparent to the patient and prescriber.
**Guiding Principles** to identify fundamental norms, rules or ethics that represent what is desirable within the process of medication utilization management.

**Step One: Health Plans/PBM/Others establish formulary and rules**

- **Extended approvals:** If a medication is approved, it should be for the length of time the patient is on that health plan’s product. This applies to commercial products and is subject to regulations. Public programs are not included. This is subject to change if there is new scientific evidence, patient safety issues or significant price increases including the average wholesale price.

- There is a clear and transparent process for review and removal of medications requiring MUM.

- Principles of safety, effectiveness and cost guide the decision-making regarding medications requiring MUM.

- For individual purchasers of health care coverage, members can be assured that if their medication was on the formulary for the future benefit year when they applied for membership, it remains on the formulary for the upcoming benefit year.

- With the implementation of the electronic approval process, the health plans standardize the process to retrieve information, making it clear what information is needed, and ensure that it automatically feeds from the EHR through the template.

- There is are in-person health plan resources available to prescribers who are knowledgeable about options, protocols, etc.

- Health plans inform prescribers about the goals of their MUM program and provide data on how the goals are being met, addressing all the Triple Aim components.

- The evidence basis for MUM is available upon request.

**Step Two: Prescriber orders through EMR; MUM requirements appear to inform prescriber of alternatives**

- Education will be provided to prescribers on MUM, including:
  - What comprises MUM: step therapy, quantity limits, medical necessity, prior authorization
  - The goals of the MUM program
  - How (and who) develops MUM formularies and rules
  - Today’s medication issues, such as the high price of generics

- An order will be held in the EMR until it is approved or denied. Order is not sent to pharmacy until approved.
Step Three: MUM form is auto populated by the EMR; prescriber completes needed information and sends for auto authorization

- Health plans create an auto approval process that does not require a person to review the MUM for approval when the correct information is provided.

Step Four: Medication is auto approved; information is requested or denied

- No guiding principles – see recommendations

Step Five: The appeal process is implemented or alternative prescription is used

- The patient and prescriber have a contact to verify the status of an appeal.
- Prescriber has access to information to verify whether patient picked up their medications.

Note: Even with a strong recommendation, there are situations that require exceptions to these recommendations and principles. These recommendations cannot cover every single person’s experience or needs.

Communication Plan

This executive summary report will be presented to the following stakeholders:

- ICSI Board
- ICSI member and sponsor community
- Minnesota Medical Association
- Minnesota Council of Health Plans
- Minnesota Hospital Association
- Board of Pharmacy
- Other stakeholders as determined by the Advisory Work Group

Recommendations for Implementation

Implementation options include:

- Recommendations and Guiding Principles are communicated broadly
- Independent implementation where each organization establishes their own work plan and implementation timeline

OR

- A collaborative implementation pilot where ICSI facilitates a common implementation design and work plan, and supports a pilot implementation and development of an implementation toolkit that can be used by organizations across Minnesota.
Phases of the collaborative implementation could include:

- **Communication**: ICSI coordinates and supports initial communication of recommendations and guiding principles to key stakeholders.

- **Assessment and Recruitment**: ICSI completes an assessment of organizational interest across stakeholder groups and recruits work group and implementation participants.

- **Project Planning and Oversight**: ICSI establishes/expands Advisory Group and establishes initial subgroups:
  - Technology/Specifications Subcommittee (vendors, PBMs/health plans, medical groups, IT, etc.) to understand technology capabilities, define specifications and integration timelines.
  - Measurement Subcommittee to define measures of success.

- **Contracting**: Stakeholders individually establish contracting or financial arrangements for electronic capacity and integration.

- **Implementation Pilot and Toolkit for Spread**: ICSI creates implementation timeline and work plan, facilitates implementation, and develops a toolkit that can be used by organizations to spread implementation.

- **Education/Communication**: ICSI would coordinate communication and education with key partners (MCHP, MMA, health plans, ICSI members, etc.).

  Staff Allocation - 12 months – 1.0 FTE (Project Manager and support team)

**Next Steps**

- The Executive Summary and report were shared with the ICSI Board, MMA, and MCHP. We are awaiting a determination as to which implementation approach has the required support.