meridianRx
A WellCare Company

POLICY AND PROCEDURE MANUAL

Policy Title: Request for Exceptions to the Formulary	Policy Number: M50.04
Primary Department: Pharmacy & Therapeutics	NCQA Standard: UM11
Affiliated Department(s): Executive Committee	URAC Standard: DrUM 1, DrUM 12, PTFD 3
Last Revision Date: 12/18 Revision Dates: 02/13, 10/13, 01/17,12/18 Effective Date: 01/11	Next Review Date: 12/19 Review Dates: 04/11, 01/12, 04/12, 08/12, 02/13, 10/13, 02/14, 02/15, 10/15, 01/16, 01/17, 01/18, 12/18

Special Instructions Alert

State/Program	MI	IL	Commercial		
Medicare:	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP		☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP
Medicaid:	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP		☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP
Commercial:	☐Exchange ☐Employer ☐Private	☐Exchange ☐Employer ☐Private	☐CMC	☐Exchange ☐Employer ☐Private	☐Exchange ☐Employer ☐Private
State/Program					
Medicare:	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP	☐SNP ☐MMAI ☐MA ☐PDP
Medicaid:	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP	☐TANF ☐SPD ☐SCHIP
Commercial:	☐Exchange ☐Employer ☐Private	☐Exchange ☐Employer ☐Private	☐Exchange ☐Employer ☐Private	☐Exchange ☐Employer ☐Private	☐Exchange ☐Employer ☐Private

Policy:

MeridianRx provides network practitioners a process for requesting exceptions to the client formulary. Exceptions to the formulary will only be considered in cases where medical necessity is the basis for the exception request. Medical necessity is defined as a medication that is required to prevent, manage, or treat conditions in a person that cause acute suffering, endanger the life of, result in an illness or interferes with the capacity for normal activity or growth in accordance with 42 CFR § 1395y.

Nothing in this section shall preclude the prescribing health care professional from prescribing another drug covered by the plan that is medically appropriate for the consumer, nor shall anything in this section be construed to prohibit generic drug substitutions.

Exceptions to the Formulary:

A. Prescribers who choose to prescribe a non-formulary drug must complete the Request for Formulary Exception Form and submit it to MeridianRx. This form is located on the client website or can be obtained by contacting the appropriate MeridianRx service line (Refer to MeridianRx website for the correct client customer service phone number). All information requested in the Request for Formulary Exception Form must be submitted to MeridianRx.

B. The Exception request is reviewed by a MeridianRx Clinical Pharmacist against the following criteria:
1. The request must be for an approved FDA indication.
2. The indication (diagnosis) must be supported by the clinical information submitted.
3. The request is not for convenience purposes.
4. Any request for a non-covered NDC will require a Med Watch form, when there is an adverse reaction indicated.
5. Pertinent clinical information including:
   a. Lab results and test results
   b. Current chart notes
   c. Disease history
   d. Must be prescribed by appropriate specialist
6. Documentation that there has been an adequate trial and failure of all formulary medications, carved out medications due to regulatory requirements, and trial and failure of medical therapies.
7. Clinical documentation showing compliance to previous therapy and office visits.
8. The consumer has a contraindication to all formulary alternatives or develops contraindications to, or an intolerance of, formulary alternatives.
9. No formulary alternatives exist to treat the consumer's condition.
10. The requested exception is considered the Standard of Care as evidenced by accepted Clinical Practice Guidelines developed by the appropriate medical specialty and supported by at least two peer-reviewed journal articles that are: randomized, prospective, double-blinded, against placebo and/or alternative therapy. All requirements, including Clinical literature must be submitted with Formulary Exception form for approval.
11. The CMO and/or COO may require review of consumer's case at an academic institution.
12. MeridianRx may also utilize an outside Independent Review Organization (IRO) when MeridianRx deems necessary.

C. MeridianRx notifies the practitioner when the exception request is approved or denied. This notification occurs within the established timeframes. (Refer to PP M50.02 and 50.08 for specific timeframes).

D. When MeridianRx denies the request, a denial letter is sent to the practitioner and the consumer, informing them of the specific reason for the denial, including reference to the information upon which the decision was based, and an explanation of their appeal rights (see attached denial letter template). The practitioner is also notified that he/she has the

option of discussing the decision further with a MeridianRx Pharmacist or designee and the phone number where they can be reached.

E. If the prescribing prescriber/consumer chooses to appeal the decision, the appeal is reviewed by a MeridianRx Physician or Pharmacist Reviewer. This reviewer is a physician or pharmacist who did not participate in the original decision, is of the same or similar specialty, and one who typically treats the medical condition. MeridianRx may elect to enlist the services of an IRO to review the request and make a recommendation. The consumer and practitioner are notified of the approval or denial within the specified timeframes (Refer to PP M50.02 and 50.08 for further information). If the appeal is denied, the consumer is notified of further appeal rights. (See P&P 50.25 Consumer Appeal Rights and Process, for further information.)

Initiating Oral Exceptions: Medicaid

A. In the event a Member, Provider, or Pharmacy requests a Formulary Exception orally or via website, MeridianRx initiates the process by sending the Formulary Exception form to the prescribing physician. This process is for Meridian Health Plan's Medicaid population only.

Tracking Approved Exceptions:

A. MeridianRx tracks approved exceptions through prior authorization status reports. The reports can be filtered by a specified date range and can be run at any time
B. MeridianRx uses designated contact codes to track and identify members with orally initiated Formulary Exceptions

Special Instructions:

State/Program: N/A

State/Program: N/A

References:

Medicare Managed Care Manual:	NA	NA	NA	NA
Medicaid CFR:	42 CFR §438.404	NA	NA	NA
State Administrative Codes:	NA	NA	NA	NA
Contract Requirements:	IL Medicaid 5.19.7	MI Medicaid XIII (G)(4,5,6)	NA	NA
Related Policies:	M50.02	M50.25	NA	NA
Related Desk Level Procedures/Job Aids/Template Letters:	NA	NA	NA	NA
Related Algorithms/Flowcharts /Attachments	NA	NA	NA	NA