Pharmacy Drug Policy Checklist

POLICY NAME	Illinois - Medical Exception Process	POLICY #	425

Criteria

Non-Formulary Drugs Coverage for drugs not listed on the formulary or drugs that will be removed from the formulary for reasons other than safety or market discontinuation is provided on an individual basis and may be approved if the following conditions are met:

- ☐ **1.1** The requested drug is not excluded from coverage based on criteria listed in the Excluded Drug List policy or benefit design, AND
- ☐ **1.2** The requested drug is prescribed for treatment of one of the following, AND:
  - An indication listed in the FDA-approved package insert.
  - An indication studied in a well-designed clinical trial published in peer-reviewed literature.
  - An indication listed in DRUGDEX with all of the following: –A Class IIb, or higher, Strength of Recommendation.
  - A Category B or higher Strength of Evidence –A Class IIa, or higher, Efficacy.
  - An indication listed in Lexicomp with all of the following: –A Level of Evidence of B, or higher.
- ☐ **1.3** One of the following applies:
  - Medication provides clinically superior outcomes compared to all currently available agents based upon review of the published literature.
  - Documentation of trial and failure to all currently available formulary agents in the same therapeutic class.
  - Documentation of allergic reactions or contraindication to all currently available formulary agents in the same therapeutic class.
- ☐ **1.4** Non-formulary approval durations are as follows:
  - Non-Urgent (Standard) – duration of the prescription, including refills.
  - Urgent (Expedited) – duration of the exigency.
- ☐ **1.5** An approved medical exception request for a non-covered drug will be covered at the non-preferred tier copay (Tier 3 for small molecules; Tier 6 for drugs that meet specialty drug criteria)
- ☐ **1.6** Non-formulary approval durations are as follows:
  - Non-Urgent (Standard) – duration of the prescription, including refills.
  - Urgent (Expedited) – duration of the exigency.
- ☐ **1.7** Drugs approved through the formulary exceptions process are not eligible for a tiering exception, see Medical Exception for Preferred Brand Copayment policy. Note: Quantity limits apply. See Section 3 for criteria.

Conditions for Bypassing Step Therapy Requirement A step therapy exception request shall be approved if documentation supports any one of the following:

☐ **2.1** The required prescription drug(s) is/are contraindicated.

☐ **2.2** The member has tried the required prescription drug and the prescribing provider submits evidence of failure or intolerance.

☐ **2.3** The member is stable on a prescription drug selected by healthcare provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. Prescribers are required to submit supporting documentation which shows the patient is stable. Stable is defined as:

- the patient is not likely to change or fail; firmly established. Required documentation may include, at a minimum, chart notes or a statement indicating the date the member started taking the drug, an analysis of compliance with the drug, and documentation showing the member's condition has not worsened since starting the drug. If treatment guidelines for the drug in question recommend lab monitoring to track disease improvement or progression, the prescriber may be required to submit laboratory test results showing that the member's condition has not worsened since starting the drug. Documentation must indicate that the patient is compliant with the drug requiring step therapy. Note: Quantity limits apply. See Section 3 for criteria.

Conditions for Approving Medical Exception of Formulary Quantity Limits Coverage for additional quantities of medication is provided on an individual basis and may be approved if one of the following conditions is met:

- ☐ **3.1** The daily dose and dosing frequency for the indication are supported in the FDA-approved package insert.
- ☐ **3.2** Additional quantities are required for titration to the FDA approved maximum daily dose and could not be otherwise achieved by using different strengths of the active moiety.
- ☐ **3.3** The dose and/or frequency of administration were shown to be safe and effective based on the results of one well-designed clinical trial published in peer-reviewed literature.
- ☐ **3.4** The requested dose listed in the FDA-approved package insert or well-designed clinical trial published in peer-reviewed literature, could not otherwise be achieved by using a higher strength dose of a pharmaceutical equivalent (i.e. one duloxetine 60mg capsule instead of two duloxetine 30mg capsules).
- ☐ **3.5** Additional doses are required to complete a course of therapy.
- ☐ **3.6** Supporting documentation indicates that the number of doses available under a quantity restriction for the prescription drug:
  - The number of doses available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition; AND/OR
  - Based on both sound clinical, medical, and scientific evidence, the known relevant physical and mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to: – Be ineffective; AND/OR
  - Adversely affect the drug’s effectiveness; AND/OR
  - Adversely affect the patient’s compliance.

Medical Exception Requests – General Information

- ☐ **4.1** Any request for approval of coverage made verbally or in writing at any time shall be reviewed by a pharmacist.
- ☐ **4.2** Urgent requests are reviewed and notification sent within 24 hours of receipt of the request.
- ☐ **4.3** Non-Urgent (Standard) requests are reviewed and notification sent within 72 hours of receipt of the request.
- ☐ **4.4** In the case of an approval, the prescribing provider's office will receive an electronic notification.
- ☐ **4.5** Approvals are honored for 12 months.
- ☐ **4.6** Drugs approved through the exceptions process are covered to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered.
- ☐ **4.7** In the case of a denial, the member or the member's authorized representative and the member's prescribing provider will receive notification including:
  - The reason for the denial,
  - An alternative covered medication, if applicable,
  - Information regarding the procedure for submitting an appeal to the denial.
- ☐ **4.8** If approved, Health Alliance shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered.

Exception for Continued Coverage Following Midyear Negative Formulary Change Following a midyear negative formulary change, the plan shall authorize continued coverage of the drug, at the same coverage level prior to the formulary change, if documentation indicates the following:

- ☐ **5.1** The prescriber submits any signed document, either in writing or electronically, indicating that continuation of the negatively affected drug is "medically necessary."
- ☐ **5.2** Exclusion: This does not apply to health plans as defined in the State Employees Group Insurance Act of 1971 or Self-Funded groups.

Appeals Process

- ☐ **6.1** Procedure for appeals to denied request for coverage of a non-covered drug can be found in the following policies:
  - Appeals Process Based on Medically Necessary Denials Pre-Service, Post-Service, Urgent/Expedited, Concurrent Reviews (Except MA/SF/Fed)
  - Appeals Process Based on Medically Necessary Denials Pre-Service, Post-Service, Urgent/Expedited, Concurrent (Fed) References