University of Michigan Health Plan

DRUG DETERMINATION POLICY

Title: DDP-02 Formulary Alternatives and Exclusions

Effective Date: 2/26/25

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by University of Michigan Health Plan and may not be covered by all University of Michigan Health plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials, including coverage policies.
4. The specific facts of the particular situation.

Contact University of Michigan Health Plan Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the process for coverage of formulary alternative drugs and excluded drugs.

This policy does not guarantee or approve Benefits. Coverage depends on the specific Benefit plan. Pharmacy Benefit Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

The Health Plan covers medications requiring prior approval, including specialty and high-cost agents, through the medical or outpatient Prescription Drug benefits using the following determination guidelines, which are developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. General Considerations

A. Medication trial [must meet all listed below]:

1. No pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

2. Trial timeline [must meet all listed below]:

a. Duration: continuous use of a medication for four months at therapeutic doses (exceptions can be made for fast-onset medications).

b. Timeframe: within an acceptable time, range (e.g., how long ago) relevant to disease state.

3. Medical condition: specifically prescribed and monitored for the treatment of the same medical condition.

B. Diagnosis: meets standard diagnostic criteria that designate signs, symptoms, and test results to support the specific diagnosis.

C. Single medication authorization/approval: only one medication is prior authorized/approved for the same medical condition in the same timeframe (to assess single product trial outcome).

D. Contraindications and black box warnings determination [must meet both listed below]

1. Published in the Food and Drug Administration-approved product Package Insert (PI).

2. Verifies a documented "contraindication" to a preferred product.

E. Site of care: preferred site of care determined by the Health Plan (see DDP-08 Site of Care for Administration of Parenteral Specialty Medications).

F. Dose Rounding: Medication requests may be automatically rounded up or down by 10% of the requested dose in order to fit the nearest manufacturer package size for patients weighing more than 10 Kg (see DDP-21 Dose Rounding and Wastage).

II. Formulary Designation.

A. Excluded drugs: determined not to be a covered benefit [must meet one below]

1. Traditional drugs as designated by Health Plan

a. Trials of all preferred products or standard treatments are required unless contraindicated. Trials must result in an inadequate response or severe adverse reaction.

2. Specialty drugs as designated by Health Plan: exceptions can be made to cover the excluded drug [must meet one listed below]:

a. Trials of all preferred products or standard treatments are required unless contraindicated. Trials must result in an inadequate response or severe adverse reaction.
b. Continuation of long-term stable therapy established for at least six months.

3. Compounded drugs (see Appendix I): individual review of cases.

4. OTC (over-the-counter) products OTC (over-the-counter) and related products: Products that are available OTC (over-the-counter), chemical equivalents are OTC, or other products in the same drug class are OTC.

5. New-to-market block: new medication introduced to the market that has not yet been reviewed and approved by ~~at~~ the Pharmacy and Therapeutics (P&T) Committee and, therefore, is blocked from coverage.

a. Trials of all preferred products or standard treatments are required unless contraindicated. Trials must result in an inadequate response or severe adverse reaction.

B. Utilization management edits [must meet preferred alternative/step therapy AND therapeutic edits listed below]

1. Preferred alternative: contraindicated, inadequate response or significant adverse effects to one listed below:

a. At least two preferred therapeutically equivalent alternative medication trials plus the generic if available.

b. At least two preferred medically appropriate medications if no preferred therapeutic equivalent exists.

2. Step therapy: designated preferred or generic formulary medication trial(s) [must meet one listed below]:

a. Trials of designated step therapy medications are required unless all are contraindicated. Trials must result in an inadequate response or severe adverse reaction.

3. Therapeutic edits:

a. Supply limits: within the supply limit (day's supply or quantity limit) established by the Plan or regulatory agencies.

b. Other edits (e.g., age, gender): meets the pertinent edits established by the Plan.

C. Appropriate medication use [must meet both listed below]:

1. FDA approval status [must meet one listed below]:

a. FDA approved: product, indication, and dosage regimen.

b. Non-FDA approved: compendium support (Lexicomp™) for the use of a drug for a non-FDA-approved indication or dosage regimen.

2. Place in therapy: sequence of therapy supported by national or internationally accepted guidelines and/or clinically relevant studies (e.g., oncologic, infectious conditions).

III. Specialty and High-Cost Agents

A. Specialty Agents

1. General definition: typically high-cost drugs, including but not limited to oral, topical, inhaled, inserted or implanted and injected routes of administration:

a. To treat and diagnose rare or complex diseases.

b. That requires close clinical monitoring and management.

c. That frequently requires special handling.

d. That may have limited access or distribution.

2. Health Plan definition: the Specialty Medications List is determined and modified as needed by the Health Plan.

B. High-Cost Agent: requires cost override per Health Plan specified threshold.

C. Supply limits.

1. Dispense and authorize up to one month's supply for retail and mail-order claims.

2. Exceptions: more than one month supply dependent on drug package size and dosing frequency.

D. Copay:

1. Subject to a one-month copay.

    a. Exceptions: if more than a one-month supply is dispensed depending on drug package size and dosing frequency, then the copay will be one month copay times the number of months covered.

2. Proration of copay only applies based on the member's outpatient prescription drug plan.

IV. Medication Trial Outcome.

A. Inadequate response [must meet both listed below]:

1. Fill history [must meet both listed below]:

    a. Consistent fill history electronically or verbally from the pharmacy.

    b. Physician attestation of medication use if no fill history as above.

2. Documentation: chart note indicating inadequate response with objective data.

B. Clinically significant adverse drug effect or reaction [must meet all listed below]:

1. Fill history [must meet one listed below]:

    a. Fill history electronically or verbally from the pharmacy.

    b. Physician attestation of medication use if no fill history as above.

2. Documentation: chart note indicating clinically significant adverse drug effects with objective data.

3. Causality supported: consistent time course and literature support for adverse drug reaction.

V. Approval

A. Initial: six months or shorter, depending on the agent's typical duration of use

B. Re-approval: [must meet both listed below]

1. Adherence: consistent fill history electronically or verbally from the pharmacy.

2. Safety/Efficacy: sufficient information to determine if the agent was safe and effective.

4.0 Unique Configuration/Prior Approval/Coverage Details:

None.

5.0 References, Citations & Resources:

1. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology https://www.nccn.org/professionals/physician_gls/default.aspx accessed December 2020.
2. http://online.factsandcomparisons.com/MonoDisp.aspx?monoID=fandc-hcp15420&quick=430846%7c14&search=430846%7c14&isstemmed=true - #FDA "Compounded Menopausal Hormone therapy: Questions and Answers.
3. CVS Specialty Pharmacy Drug List accessed 3/20, https://www.caremark.com/portal/asset/Specialty_Drug_List.pdf.

6.0 Appendices:

See page 6.

7.0 Revision History:

Original Effective Date: June 24, 2014

Next Review Date: 03/01/2026

Revision Date	Reason for Revision
2/19	Transitioned to the new format
4/19	Modified I. General A-D and IIB1 Preferred alternative
9/19	Opened for off-cycle review; replaced abbreviations, reformatted med use by diagnosis to Appropriate Medication Usage added place in therapy, clarified step therapy; removed COC citation
4/20	Annual review; changed excluded drug /utilization management (UM) verbiage, clarified choice instructions, added generic to UM 1a; replaced abbreviations
12/20	Annual review, changed trial duration from 3 to 4 months, added NCCN category 2A to place in therapy, clarified instructions; added diagnosis statement under the general section, approved by P&T 2/24/21
5/21	Off-cycle review added compendium support for non-FDA approved indication
12/21	Annual review added quantity limit under appropriate use section, clarification or OTC exclusions
11/22	Ad Hoc review: added reg agencies to ql determiners; clarified FDA indication, dose, etc.
12/22	Annual review
1/23	Off-cycle review; clarify initial and re-approval criteria
4/23	Off-cycle review, integrated DDP-45 Specialty and High-Cost Agents. Corrected II.A.3. to Appendix I instead of II
12/23	Annual review; updated OTC language to include related products. Removed article requirement for new to market block section. Updated other therapies language.
12/24	Annual review, clarified other therapies and place in therapy

Appendix I: Risks associated with compounded drugs

A. Compounded drugs can pose direct and indirect health risks:
   - Direct health risks: poor quality compounding practices resulting in sub- or super-potent, contaminated, or otherwise adulterated unsafe products.
   - Indirect health risks: use of ineffective compounded drugs instead of FDA-approved drugs shown to be safe and effective.

B. Pharmacists may not be well-trained/well-equipped to compound certain medications safely:
   - Various levels of compounding skills and equipment; some drugs may be inappropriate for compounding.
   - Lack of sufficient controls (e.g., equipment, training, testing, or facilities) to ensure compounded product quality for complex drugs like sterile or extended-release drugs.
   - Unknown quality of compounded drugs can pose potential risks to the patients.

C. Pharmacy compounders with high-volume distribution increase the risk of patient harm.

   FDA warning examples:
   - December 2006: five firms were warned about their standardized compounded high-strength topical anesthetic creams. Two deaths connected to the anesthetics compounded by two pharmacies.
   - August 2006: three firms were warned to stop manufacturing & distributing thousands of doses of unapproved “compounded” inhalation drugs. Serious concerns sited included inadequate quality control, variable potency and compounding copies of FDA-approved drugs.
   - March 2006: Maryland firm was warned regarding contaminated compounded of cardioplegia solutions used in open-heart surgeries; 5 serious systemic infections in five hospitalized patients resulted in three deaths.