

### Clinical Pharmacy Program Guidelines for Non-Solid Dosage Forms

Program	Prior Authorization
Medication	Non-Solid Dosage Forms
Issue Date	3/2014
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

**1. Background:**

Many medically necessary drugs are specially formulated for convenience of use in the pediatric population. Formulations include but are not limited to oral suspensions, oral solutions, patches, chewable, orally disintegrating, sprinkle capsules, etc. The formularies/PDLs of the health plans administered by UnitedHealthcare Community Plan are intended to provide the highest quality care while containing cost. UnitedHealthcare Community Plan will limit certain pediatric intended special drug formulations with an age limitation (e.g., use limited to patients less than 8 years old). Patients whose age exceeds the age limitation will require transition to a preferred product or a prior authorization to continue use of the age limited product.

UnitedHealthcare Community Plan requires age limitations for the drug therapies that are typically intended for pediatric convenience of use in order to promote high quality cost effective care, and to monitor utilization. This procedure enhances formulary/PDL compliance and appropriate prescribing. Eligibility for reimbursement is based upon a clinical review protocol established by the UnitedHealthcare Community Plan Pharmacy and Therapeutics Committee.

**2. Coverage Criteria:**

<p><b>A. <u>Approval Criteria</u></b></p> <p>1. <b><u>One</u></b> of the following:</p> <p style="padding-left: 40px;">a. Requested drug must be used for an FDA-approved indication</p> <p style="text-align: center;"><b>-OR-</b></p> <p style="padding-left: 40px;">b. <b><u>Both</u></b> of the following:</p> <p style="padding-left: 80px;">(1) The use of this drug is supported by information from the appropriate compendia of current literature†</p>
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**-AND-**

(2) The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

**-AND-**

2. The drug is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in the compendia of current literature†

**-AND-**

3. **One** of the following:

a. If the request is for a preferred product, the patient must have **one** of the following:

(1) **Both** of the following:

(a) The patient is able to swallow

**-AND-**

(b) **One** of the following:

- History of failure, contraindication, or intolerance to at least **three** preferred solid oral dosage forms. Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. **NOTE:** In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to **all** of the preferred products.
- There are no preferred formulary alternatives for the requested drug.

**-OR-**

(2) Patient is unable to swallow a solid dosage form

**-OR-**

(3) Patient utilizes a feeding tube for medication administration

**-OR-**

b. If the request is for a non-preferred product, the patient must have **one** of the following:

(1) **Both** of the following:

(a) The patient is able to swallow

**-AND-**

(b) **One** of the following:

- Patient has a history of failure, contraindication, or intolerance to at least **three** preferred alternatives. Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. **NOTE:** In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to **all** of the preferred products.

**-OR-**

- There are no preferred formulary alternatives for the requested drug

**-OR-**

(2) **Both** of the following:

(a) Patient is unable to swallow a solid dosage form or utilizes a feeding tube for medication administration

**-AND-**

(b) **One** of the following:

- Patient has a history of failure, contraindication, or intolerance to at least **three** preferred non-solid dosage form alternatives. Prior trials of formulary/PDL

alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. **NOTE:** In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to **all** of the preferred products.

**-OR-**

- There are no preferred formulary alternatives for the requested drug

**Authorization will be issued for 12 months.**

†Compendia of current literature: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology

Program	Prior Authorization
<b>Change Control</b>	
Date	Change
3/2014	New policy
11/2016	Annual review, updated policy template and changed name of policy from Special Formulations with Age Limitations to Non-Solid Dosage Forms
1/2017	Annual review. No changes to clinical criteria.
11/2017	Updated non-preferred language to ensure that non-preferred non-solid oral dosage formulations step through preferred non-solid oral dosage formulations.
3/2018	Updated Community Plan language in the background. Rearranged indication(s) and dosing criteria. Separated criteria into preferred and non-preferred products and updated trial/fail language.