

Children's Hospital and Health System Children's Community Health Plan Policy and Procedure

This policy applies to the following entity(s):

- | | |
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| <input type="checkbox"/> CHW – Milwaukee | <input type="checkbox"/> CHW - Fox Valley |
| <input type="checkbox"/> CHHS Foundation | <input type="checkbox"/> CHW - Surgicenter |
| <input type="checkbox"/> CHW – Community Services Division | <input checked="" type="checkbox"/> Children's Community Health Plan |
| <input type="checkbox"/> Children's Medical Group - Primary Care | <input type="checkbox"/> Children's Specialty Group |
| <input type="checkbox"/> Children's Medical Group - Urgent Care | <input type="checkbox"/> CHHS Corporate Departments |

Medical Utilization Management Policy

SUBJECT: Experimental, Investigational, or Unproven Medical Interventions

INCLUDED PRODUCT(S):

Medicaid

BadgerCare Plus

Care4Kids Program

Commercial

Together with CCHP

Marketplace

Together with CCHP

PURPOSE OR DESCRIPTION:

Explain how CCHP determines when a healthcare treatment, test, device, technology, or procedure (collectively defined as healthcare "interventions") are considered experimental, investigational, or unproven ("E/I/U").

1. **Definition:** A healthcare intervention is considered experimental or investigational when it is the subject of ongoing medical studies, and any already completed studies are inconclusive regarding clinical benefits.

POLICY:

1. Background: CCHP considers the experimental, investigational or unproven use of an intervention not medically necessary, and therefore it will not be authorized.
 - a. An exception to this policy may exist when coverage and/or authorization of the use of an intervention is mandated by a federal/state statute or by contract, regardless of whether or not it meets this policy's definition of E/I/U.

Effective: 2/20

Revised:

Reviewed: 10/21

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Developed by: CCHP Medical Directors and Executive Director Health Plan Clinical Services

2. An intervention's use for an indication **is considered** experimental, investigational or unproven by CCHP when the following criteria exist:
 - a. It has **not** been approved by the FDA for the indication, **AND**
 - b. It is **not** considered a standard accepted treatment option for the intervention by the medical community ("off-label use").
3. An intervention's use for an indication **is considered NOT** experimental, investigational or unproven by CCHP when **ALL** the following criteria are fulfilled:
 - a. The intervention must have received final approval from the appropriate regulatory agency (e.g., FDA). Any other approval granted as an interim step in the FDA regulatory process (e.g., an Investigational Device Exemption or an Investigational New Drug Exemption) is not sufficient, **AND**
 - b. Evidence from published peer-reviewed literature must demonstrate the proven beneficial impact of the intervention on health outcomes for the given indication. The evidence must include reports of well-designed investigations that have been reproduced by nonaffiliated, authoritative sources with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale, **AND**
 - c. Published peer-reviewed literature must demonstrate that the intervention must be at least as effective as established interventions for the given indication, **AND**
 - d. Published peer-reviewed literature must demonstrate evidence that the intervention improves health outcomes over time for the given indication, **AND**
 - e. The outcomes for the given indication must be obtainable outside investigational settings within the medical community.

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