Children's Hospital and Health System
Chorus Community Health Plans
Policy and Procedure

This policy applies to the following entity(s):

☐ CHW – Milwaukee	☐ CHW - Fox Valley
☐ CHHS Foundation	☐ CHW - Surgicenter
☐ CHW – Community Services Division	☒ Chorus Community Health Plans
☐ Children's Medical Group - Primary Care	☐ Children's Specialty Group
☐ Children's Medical Group - Urgent Care	☐ CHHS Corporate Departments

Medical Utilization Management Policy

SUBJECT: EXPERIMENTAL, INVESTIGATIONAL, OR UNPROVEN MEDICAL INTERVENTIONS

INCLUDED PRODUCT(S):

Medicaid	**Individual and Family**
☒ BadgerCare Plus	☒ Commercial
☒ Care4Kids Program	☒ Marketplace

PURPOSE OR DESCRIPTION:

This policy explains 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 the clinical benefits of any completed studies are inconclusive.

POLICY:

1. Background: CCHP considers the experimental, investigational or unproven use of an intervention to be not medically necessary, and therefore not 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
Last reviewed: 10/23
Q:\CCHP Leadership\Utilization Management Medical Policies\APPROVED MEDICAL UM POLICIES\Experimental, Investigational, or Unproven Medical Interventions UM Policy
Developed by: CCHP Medical Directors

2. An intervention's use for an indication **is considered** experimental, investigational or unproven by CCHP when **ALL** the following criteria are met:
    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 met:
    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 non-affiliated, authoritative sources with measurable results, backed up by the positive endorsements from 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 of investigational settings within the medical community.