SUBJECT: Experimental, Investigational, or Unproven Medical Interventions

INCLUDED PRODUCT(S):

- Medicaid
  - BadgerCare Plus
  - Care4Kids Program

- Individual and Family
  - Commercial
  - Marketplace

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.
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.