CLINICAL POLICY AND PROCEDURE MANUAL

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PA.079.CC Experimental and Investigational Services

Summary

This clinical policy is intended to provide guidance when reviewing medical services that are considered experimental or investigational.

Definitions

Investigational/Experimental Procedures are defined as a procedure, device or pharmaceutical agent that is still undergoing pre-clinical or clinical evaluation, and/or has not yet received regulatory approval. It is the use of a service, procedure or supply that is not recognized by the Plan as standard medical care for the condition, disease, illness, or injury being treated. A service, procedure or supply includes but is not limited to the diagnostic service, treatment, facility, equipment, drug, or device. When basic safety and efficacy have been demonstrated by the experimental scientific process, the investigational phase begins.

Clinical Criteria

CountyCare considers review and approval of experimental services when the following apply:

a) In determining whether services are experimental or investigational, the plan will consider whether the services are in general use in the medical community, whether the services are under continued scientific testing and research, whether the services show a demonstrable benefit for a particular illness or disease, and whether they are proven to be safe and efficacious.
b) In determining whether services are experimental or investigational, the plan will consider whether the services result in greater benefits for a particular illness or disease than other generally available services, and do not pose a significant risk to health or safety of the patient.
c) The supporting documentation upon which the criteria are established must be made available for review upon written request in all instances

CountyCare considers services as Experimental and Investigational (E&I) if the following apply:

- The intervention does not have Food and Drug Administration (FDA) approval to be marketed for the specific relevant indication(s); or other regulatory agencies or
- Available scientific evidence does not permit conclusions concerning the effect of the intervention on health outcomes; or
- The intervention is not proven to be as safe or effective in achieving an outcome equal to or exceeding the outcome of alternative therapies; or
- The intervention does not improve health outcomes; or
- The intervention is not proven to be applicable outside the research setting.

For devices with Investigational Device Exemptions (IDE):

- **Category A** (Experimental) devices will not be covered because they are considered experimental and investigational, and therefore not considered reasonable and necessary medical services. Routine care costs of patients participating in clinical trials may be covered if allowed under the member's specific benefit plan according to PA.078 Clinical Trials - Coverage of Routine Care Costs upon determination that the device is intended for the diagnosis, monitoring or treatment of an immediately life-threatening disease/condition, but the device itself will not be covered.
- **Category B** (Nonexperimental/investigational) devices may be considered for coverage if allowed under member's specific benefit plan and all of the following apply:

    1. The device must be used within the context of the FDA approved clinical trial.
    2. The device must be used according to the clinical trial's approved patient protocol.
    3. The medical necessity of the device must be established for the particular member and medical appropriateness established for the amount, duration, and frequency of use or applications of the service.
    4. The setting where the service is furnished must be appropriate according to the member's medical needs, condition, and benefit plan.

For devices with Humanitarian Device Exemptions (HDE):

If appropriate under the member's specific plan, all of the following must apply for consideration of coverage for a Humanitarian Use Device (HUD) on the basis of an HDE:

1. A HUD may only be used in facilities that have an established local Institutional Review Board (IRB) to supervise the clinical testing of the device or service);
2. IRB approval for use of the HUD must be current according to the IRB requirements (e.g., updated annually);

3. The HUD must only be used for HDE approved indications specified in the product labeling.

Limitations

Category B devices will not be covered if any of the following apply:

- When the services or technologies are in the developmental or testing stage;
- When there is no final regulatory or governmental approval;
- When IDEs are applied in the inpatient setting, where they will be included in the Diagnosis Related Group (DRG) payment.

The service or procedure will be considered not medically necessary if the available scientific proof does not indicate that the treatment is safe and effective for treating or diagnosing the relevant medical condition or illness or the intervention has not been shown to improve health outcomes. Information may be accessed from the following sources (not limited to):

- Current and published scientific evidence and technology literature
- Technology updates, news and summaries from Hayes, the Cochrane Collaborative, or other nationally recognized organizations, such as medical experts or affected specialty societies
- Published medical literature in peer-reviewed journals
- Published opinions, actions, and other relevant documents of independent external research organizations such as NIH, NCI, FDA and HHS

In addition to the above criteria, the Medical Policy Committee (MPC) will consider recommendations of national physician specialty societies, nationally recognized professional healthcare organizations and public health agencies, and in its sole discretion, may consider other relevant factors, including information from the practicing community.

See Also

PA.078 – Clinical Trials

Background

Category A (Experimental) device refers to a device for which “absolute risk” of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Non-experimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type has been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type

The Medical Policy Committee (MPC) and UM staff routinely conduct evidence-based reviews of new and emerging medical services. This assessment includes:

- A thorough review of available scientific information, which may include peer-reviewed literature, results of clinical trials, outcomes data, regulatory requirements, and input from professionals in the field of the medical service under review.
- Discussion among a multidisciplinary group of health care providers to achieve an adequate understanding of the medical science and its application.
- An appropriate coverage recommendation based on the sum of the evidence.
- Identification of medical services as “experimental and investigational” according to the definition provided in this Policy.

Services determined to be experimental and investigational are listed, and experimental and investigational services which demonstrate a significant body of scientific evidence supporting safety and effectiveness are removed from the list. If there is no documentation that the experimental and investigational service does not provide benefit, or there is not any benefit that is equal or better than the standard of care, it is experimental and investigational. Due to the frequency at which new medical services are developed and researched, this list of services should not be considered all-inclusive as it has the potential to change frequently due to the body of evidence available.

Diagnosis Codes

- **ICD- 10 Code Z00.6** must be reported as the secondary diagnosis
- Utilization of appropriate modifiers Q0 and/or Q1

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Revision History

Revision	Date
Policy created	July, 2023

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.