Medicare Advantage    X Commercial

Experimental and Investigational Services Policy

I. Purpose
Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Experimental and Investigational Services.

II. Scope
All Utilization Management (UM) staff conducting physical and behavioral health UM review.

III. Exceptions

1. **Category A** devices will not be covered because they are considered experimental and investigational, and therefore not considered reasonable and necessary medical services.

2. **Category B** devices will not be covered if **any of the following** apply:
   1. When the services or technologies are in the developmental or testing stage
   2. When there is no final regulatory or governmental approval
   3. When IDEs are applied in the inpatient setting, where they will be included in the Diagnosis Related Group (DRG) payment.

3. 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):
   1. Current and published scientific evidence and technology literature
   2. Technology updates, news and summaries from Hayes, the Cochrane Collaborative or other nationally recognized organizations, such as medical experts or affected specialty societies
   3. Published medical literature in peer-reviewed journals
   4. Published opinions, actions and other relevant documents of independent external research organizations such as NIH, NCI, FDA and HHS

*In addition to the below 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.

IV. Definitions

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 have 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.

V. Policy Statements

A. IU Health Plans considers Experimental and Investigational (E&I) Services medically necessary for all of the following:

1. All of the following:
   a. The medical service or application is supported in peer-reviewed medical literature and accepted as safe and effective by the medical community. There must be documentation of improvement if the health outcome is referenced by evidence-based medicine standards.
   b. It must be approved by appropriate regulatory agencies (e.g., FDA) for the specific intended use or purpose;
   c. The scientific evidence and/or clinical outcomes for the medical service and/or application are peer-reviewed and must be attainable outside the experimental or investigational setting;
   d. Application of the medical service must be within accepted standards of good medical practice;
   e. The medical service and/or its application must be appropriate in the treatment of the diagnosis or condition specified in the request.

2. One of the following:
   a. Devices with Investigational Device Exemptions (IDE) may be considered medically necessary for one of the following:
      1) Category A devices may be covered for routine care costs of patients participating in clinical trials if allowed under the member’s specific benefit plan according to IU Health Plan Policy# UMPA 029.0 Clinical Trials - Coverage of Routine Care Costs upon determination that the device is intended for all of the following:
         a) The diagnosis
         b) The monitoring or treatment of an immediately life-threatening disease/condition
         Note: The device itself will not be covered
      2) Category B devices may be considered for coverage if allowed under member’s specific benefit plan and all of the following apply:
         a) The device must be used within the context of the FDA approved clinical trial
         b) The device must be used according to the clinical trial’s approved patient protocol
c) The medical necessity of the device must be established for the member and medical appropriateness established for the amount, duration, and frequency of use or applications of the service

d) The setting where the service is furnished must be appropriate according to the member’s medical needs, condition, and benefit plan

b. Devices with Humanitarian Device Exemptions (HDE) may be considered medically necessary if all of the following are met:

1) 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:

   a) 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
   b) IRB approval for use of the HUD must be current according to the IRB requirements (e.g., updated annually)
   c) The HUD must only be used for HDE approved indications specified in the product labeling

VI. 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 have 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 IU Health Plans UM staff routinely conduct evidence-based reviews of new and emerging medical services. This assessment includes:

1. 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;
2. Discussion among a multidisciplinary group of health care providers to achieve an adequate understanding of the medical science and its application;
3. 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 considered to be 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.

Codes:
1. **ICD-9 Code V70.7 or ICD-10 Code Z00.6** must be reported as the secondary diagnosis
2. Utilization of appropriate modifiers Q0 and/or Q1

**IU Health Plans Experimental and Investigational CPT Codes requiring prior authorization (PA)**
0009M, 0071T, 0072T, 0085T, 0198T, 0200T, 0201T, 0202T, 0205T, 0206T, 0207T, 0208T, 0209T, 0210T, 0211T, 0212T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0219T, 0220T, 0221T, 0222T, 0228T, 0229T, 0303T, 0313T, 0332T, 0333T, 0335T, 0338T, 0339T, 0341T, 0342T, 0345T, 0347T, 0348T, 0349T, 0350T, 0351T, 0352T, 0353T, 0354T, 0355T, 0356T, 0357T, 0358T, 0362T, 0373T, 0374T, 0375T, 0376T, 0377T, 0378T, 0379T, 0380T, 0381T, 0382T, 0383T, 0384T, 0385T, 0386T, 19105, 19499, 22510, 22512, 22526, 22527, 22611, 22864, 22867, 22868, 22869, 22870, 22899, 33340, 33368, 33369, 33477, 33548, 37250, 37251, 37252, 37253, 41512, 41530, 43210, 43257, 43647, 43648, 43881, 43882, 44705, 46601, 46607, 46999, 53860, 55706, 55899, 58674, 62287, 64999, 72159, 73225, 75571, 75945, 75946, 76499, 76936, 78350, 78351, 78499, 81313, 81430, 81431, 88749, 91111, 91299, 92978, 92979, 93050, 93279, 97153, 97154, 97155, 97156, 97157, 97158, 97610, 97799, 94305, 94306, A4555, A4575, A4639, A9155, A9272, C1821, C9250, C9360, C9361, C9362, C9363, C9364, E0221, E0446, E0675, E0740, E0745, E0762, E0764, E0765, E0766, E0769, E0770, E1801, E1802, E1805, E1806, E1810, E1811, E1812, E1815, E1816, E1818, E1821, E1825, E1830, E1831, E1840, L8604, L8605, M0075, M0076, M0100, M0300, P0020, Q0035, Q4103, Q4107, Q4111, Q4112, Q4113, Q4115, Q4117, Q4118, Q4122, Q4123, Q4124, Q4125, Q4126, Q4127, Q4128, Q4130, Q4132, Q4133, Q4134, Q4135, Q4136, Q4137, Q4138, Q4139, Q4140, Q4141, Q4142, Q4143, Q4145, Q4146, Q4147, Q4148, Q4149, Q4150, Q4151, Q4152, Q4153, Q4154, Q4155, Q4156, Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, Q4174, Q4175, Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4182, Q4183, Q4184, Q4185, Q4186, Q4187, Q4188, Q4189, Q4190, Q4191, Q4192, Q4193, Q4194, Q4195, Q4196, Q4197, Q4198, Q4200, Q4201, Q4202, Q4203, Q4204, S1034, S1035, S1036, S1037, S2102, S2118, S2348, S3650, S3652, S3722, S3800, 0273T, 0274T, 0275T, 0278T, 0289T, 0290T, 0293T, 0294T, 0329T, 0330T, 28446, 28899, 31626, 31627, 31660, 31661, 32994, 33274, 33275, 33289, 93288, 93740, 93799, 93998, 94799, 95980, 95999, E1841, E2120, G0276, G0416, G0428, G0455, G0460, G4131, L5973, Q4157, Q4158, Q4159, Q4160, Q4161, Q4162, Q4163, Q4164, Q4165, S3852, S8080, S8130, S8131, S8940, S9034, S9090

**VII. Procedures**

None

**VIII. References/Citations**

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   b) Studies. Updated 06/16/15. [https://www.cms.gov/Regulations-and-

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    quirements/QualitySystemsRegulations/default.htm]

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    [http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm]

IX. Forms/Appendices

None

X. Responsibility

Medical Director

This Policy is proprietary and confidential. No part of this Policy may be disclosed in any manner to a third party without the prior written consent of IU Health Plans, Inc.