



*'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona*

*WellCare (Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Louisiana, Maine, Michigan, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, South Carolina, Tennessee, Texas, Washington)*

*WellCare Prescription Drug Plan (PDP)*

*WellCare TexanPlus (Medicare – Dallas & Houston markets)*

## Clinical Trials Coverage of Investigational Devices (Medicare)

Policy Number: HS-144

Original Effective Date: 11/19/2009

Revised Date(s): 11/12/2010; 10/6/2011;  
11/1/2012; 11/7/2013; 11/6/2014; 10/1/2015;  
10/6/2016; 7/6/2017; 7/5/2018; 6/6/2019

### APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on [www.wellcare.com](http://www.wellcare.com). Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

### BACKGROUND

The Food and Drug Administration (FDA) defines a medical device as:

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; **OR**
  - Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment; **OR**
  - prevention of disease, in man or other animals, **OR**
  - Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

For dates of service on or after November 1, 1995, Medicare may cover certain FDA-approved and Institutional Review Board (IRB) approved investigational devices and services incident to, provided the investigational device Clinical Coverage Guideline

page 1

meets the following conditions:

- Appears on the listing of devices eligible for coverage/payment on CMS' master file of IDE devices;
- Is reasonable and necessary for the individual patient;
- The device or services associated with the use of a device were provided to the beneficiary within the start and end dates contained in the master file; and,
- There is no national coverage policy that would otherwise prohibit Medicare coverage.

Devices that may be covered under Medicare include the following categories:

- Devices approved by the FDA through the Pre-Market Approval (PMA) process;
- Devices cleared by the FDA through the 510(k) process;
- FDA-approved IDE Category B devices; and
- Hospital Institutional Review Board (IRB) approved IDE devices

### **FDA Approval Investigational Device Exemptions (IDEs)**

The FDA assigns a special identifier number that corresponds to each device granted an investigational device exemption (IDE). Under the Food, Drug, and Cosmetic Act, devices are categorized into three classes. Class I devices are the least regulated. These are devices that the FDA has determined need to be subject only to general controls, such as good manufacturing practice regulations. Class II devices are those which, in addition to general controls, require special controls such as performance standards or post-market surveillance, to assure safety and effectiveness. Class III devices are those which cannot be classified into class I or class II because insufficient information exists to determine that either special or general controls, would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

For purposes of assisting CMS in determining Medicare coverage, the FDA will place all approved IDEs in one of two categories.

**Category A Experimental** - Innovative devices believed to be in class III for which absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type is safe and effective).

**Category B Nonexperimental** and/or investigational devices believed to be in classes I or II or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying 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 approval for that device type.

### **Payment of IDE Category B Devices**

Payment for a Category B IDE device or an IRB approved device (provided to a non-hospital patient) and the related services may not exceed what Medicare would have paid for a comparable approved device and related services.

## **POSITION STATEMENT**

### **Applicable To:**

- Medicare – excluding KY

**NOTE:** See clinical coverage guideline *HS-090, Clinical Trials, Coverage of Routine Patient Care Costs*, for more information on clinical trial-related coverage policy.

Investigational Device Exemption (IDE) Category B devices **are considered medically necessary** if the following criteria are met (CMS, 2012):

- The device must be within the context of an FDA and IRB-approved study; the approved study protocol limits the use of the device to a predetermined limited number of sites and predetermined limited number of patients; **AND,**

- The device must be used according to the clinical trial's approved patient protocols including the assignment of an IDE number which allows the Medicare contractor to establish the special claims procedures associated with the study; **AND**,
- There is an established national or local policy, or policy/position papers or recommendations made by pertinent
- specialty societies; **AND**,
- The device must be appropriate for the particular member, and the amount, duration, and frequency of use or application of service must be medically appropriate; **AND**,
- The device must be furnished in a setting appropriate to the member's medical needs and condition; **AND**
- The device must meet all Medicare coverage requirements.

Investigational Device Exemption (IDE) Category A devices **are considered NOT medically necessary and are NOT covered** because they do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary.

## CODING

**There are currently no applicable CPT, ICD-9-CM Procedure Codes for Category A and Category B IDE devices. HCPCS level II codes for Category B IDE, if applicable, are multiple and varied.**

**Category A:** Investigational Device Exemption (IDE) Category A devices are considered NOT Medically Necessary and are NOT COVERED because they do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary.

**Category B:** Investigational Device Exemption (IDE) Category B devices are considered medically necessary if the criteria above have been met.

### **Billing Criteria for IDE Category B:**

**Q0** - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.

**Q1** - Routine clinical service provided in a clinical research study that is in an approved clinical research study.

NOTE: Investigational clinical services are defined as items and services being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.

### **Institutional Inpatient Billing for Category B IDE devices**

- Providers must bill the IDE number on a 0624 Revenue Code line

### **Institutional Outpatient Billing for Category B IDE devices**

On a 0624 Revenue Code line institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable
- Appropriate HCPCS modifier:
  - **Q0** (numeral 0 versus the letter o) modifier for claims with dates of service on or after January 1, 2008
- The Category B IDE number
- Charges for the device billed as covered charges

### **Practitioner Billing for Category B IDE devices**

- **Q0 Modifier** For dates of service on or after January 1, 2008, must bill with a Q0 modifier (numeral 0 versus letter o) along with the IDE number

### **Covered ICD-10-CM Diagnosis Codes**

**Z00.6** Encounter for examination for normal comparison and control in clinical research program

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/ state laws.

## REFERENCES

1. Local coverage article for investigational device exemptions (A52841). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published February 2012. Accessed May 28, 2019.
2. New HCPCS modifiers when billing for patient care in clinical research studies. Centers for Medicare and Medicaid Services Web site. <https://www.cms.gov/Transmittals/downloads/R1418CP.pdf>. Published 2008. Accessed May 28, 2019.
3. Medicare benefit policy manual: chapter 14 medical devices. Centers for Medicare and Medicaid Services Web site. <https://www.cms.gov/manuals/downloads/bp102c14.pdf>. Revised November 6, 2014. Accessed May 28, 2019.

## MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
6/6/2019, 7/5/2018, 7/6/2017, 10/6/2016, 10/1/2015, 11/6/2014, 11/7/2013, 11/1/2012, 12/1/2011, 10/6/2011	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> <li>• Approved by MPC. Incorporated CMS (2012) updates to criteria (does not impact coverage).</li> <li>• New template design approved by MPC.</li> <li>• Approved by MPC.</li> </ul>