

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline

WellCare Prescription Insurance, Inc.



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



WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

WellCare of Texas, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

HealthEase of Florida, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

Coverage of Investigational Device Exemptions in Clinical Trials

Guideline Number: HS-144

Original Effective Date: 11/19/2009

Revision Date: 11/12/2010

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. 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 Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. 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.

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DISCLAIMER

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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.

CLINICAL COVERAGE GUIDELINE

NOTE: The following criteria and informational set is applicable to Medicare only.

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:

- The device must be within the context of an FDA-approved clinical trial; **AND**,
- The device must be used according to the clinical trial's approved patient protocols; **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.

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.

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,
- 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 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 pre-market 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 nonhospital patient) and the related services may not exceed what Medicare would have paid for a comparable approved device and related services.

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:

Modifier for dates of service on or after January 1, 2008

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

Investigational clinical services are defined as those items and services that are 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
 - - **QA** modifier for claims with dates of service prior to January 1, 2008
- The Category B IDE number
- Charges for the device billed as covered charges

Practitioner Billing for Category B IDE devices

- **QA Modifier** For dates of service on or before December 31, 2007, must bill the Category B IDE device with a QA modifier along with the IDE number
- **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

ICD-9-CM Diagnosis Code

V70.7 Examination of participant in clinical trial should be listed as the secondary diagnosis code

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REFERENCES

1. Centers for Medicare and Medicaid (CMS) Medicare Benefit Policy Manual. Chapter 14- Medical Devices.