

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.

Experimental and Investigational Procedures and Devices

Guideline Number: HS-136

Original Effective Date: 10/7/2009

Revision Date: n/a

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

A medical procedure or device is considered experimental or investigational and a non-covered benefit if ANY of the following criteria are met:

- 1) An approval from federal or other governmental body is required and that approval has not been granted, or does not have unrestricted market approval from the Food and Drug Administration (FDA), or final approval from any governmental regulatory body for use in treatment of a specified condition is not granted; **OR,**
- 2) The procedure or device is under investigation in a properly-controlled Phase I-III clinical trial; **OR,**
- 3) There is insufficient or inconclusive medical and scientific evidence to permit evaluation of therapeutic value and benefit to the member; **OR,**
- 4) There is inconclusive medical and scientific evidence in peer-reviewed medical literature that there is a beneficial effect on health outcomes; **OR,**
- 5) Evidence suggests the procedure or device under consideration is not as beneficial as any established alternatives; **OR,**
- 6) Reliable evidence shows that the prevailing opinion among experts regarding the procedure or device requires further study or clinical trials to determine the safety and efficacy as compared with standard means of treatment.

NOTE: Please see Clinical Coverage Guideline HS-090, "Clinical Trials, Coverage of Routine Patient Care Costs" for details on coverage of routine costs in clinical trials.

Scientific evidence regarding experimental and investigational procedures and devices is under a constant state of review. As supporting scientific evidence mandates, a change in status from experimental and investigational to medically necessary will occur. The following references are examples of the evidence sources used to make changes in coverage determinations:

- Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations
- State Medicaid coverage determinations
- Peer-reviewed scientific journal articles available via PubMed and other databases

- Hayes, Inc technology assessments
- Professional academy and society statements (example: American College of Cardiology, American Academy of Pediatrics, National Comprehensive Cancer Network)

CODING

n/a

REFERENCES

n/a