



Easy Choice Health Plan

Missouri Care

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

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Experimental and Investigational Procedures and Devices

Policy Number: HS-136

Original Effective Date: 10/7/2009

Revised Date(s): 10/29/2010; 9/15/2011;
10/4/2012; 10/3/2013; 10/2/2014;
7/9/2015; 7/7/2016; 6/1/2017; 7/5/2018

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. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

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)

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets
- Medicare – All Markets

Exclusions

Experimental therapy is excluded from coverage by all Company policies. Requests for enrollment in clinical studies will be received and handled as a non-covered benefit.

A medical procedure, device, drug or pharmaceutical agent **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

CODING

Non-Covered CPT © Codes

All CPT codes designated as unlisted procedures when billed for experimental and investigational services.

Non-Covered CPT © Category III Codes

All Category III codes are temporary codes for emerging technology, services and procedures and are not covered.

Non-Covered HCPCS Level II© Codes

All HCPCS Level II Codes designated as unlisted or not otherwise classified are not covered.

Non-Covered Draft ICD-10-CM Diagnosis Codes

No diagnosis codes are covered for experimental and investigational procedures and devices.

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.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
7/5/2018, 6/1/2017, 7/7/2016, 7/9/2015, 10/2/2014, 10/3/2013, 10/4/2012	<ul style="list-style-type: none"> • Approved by MPC. No changes.
12/1/2011	<ul style="list-style-type: none"> • New template design approved by MPC.
9/15/2011	<ul style="list-style-type: none"> • Approved by MPC. No changes.