Missouri Care

WellCare (Nebraska)

Experimental Technologies:
Policy Number: CP.MP.36

Last Review Date: 06/20

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

This policy outlines general guidelines to use in determining coverage of experimental or investigational, or potentially experimental or investigational medical and behavioral health technologies. These guidelines are to be used only when there is no other policy, criteria, or coverage statement available.

Note: For clinical trials, please refer to CP.MP.94 Clinical Trials.

POSITION STATEMENT

All coverage determinations regarding technologies (i.e., drugs, procedures, devices, services, or supplies) that are or may be considered experimental or investigational must be considered on a case-by-case basis by a physician or ad hoc committee and must be made in accordance with the Benefit Plan Contract provisions and applicable state and federal requirements.

A technology is considered experimental or investigational if it meets any of the following criteria:

A. It is currently the subject of active and credible evaluation (e.g., clinical trials or research) to determine:
1. Clinical efficacy, *or*
2. Therapeutic value or beneficial effects on health outcomes, *or*
3. Benefits beyond any established medical based alternatives.

B. It does not have final clearance from applicable governmental regulatory bodies (such as the US Food and Drug Administration "FDA") and unrestricted market approval for use in the treatment of a specified medical condition or the condition for which authorization of the service is requested and is the subject of an active and credible evaluation.

C. The most recent peer-reviewed scientific studies published or accepted for publication by nationally recognized medical journals do not conclude, or are inconclusive in finding, that the service is safe and effective for the

treatment of the condition for which authorization of the service is requested.

Under no circumstances is this policy to be construed as an acknowledgement or acceptance by the Health Plans of any obligation to cover experimental or investigational technologies where such technologies are not included in the benefits set forth in the Benefit Plan Contract or by applicable state and federal requirements. The Plan reserves the right to refuse coverage of an experimental or investigational technology on the grounds that such coverage is not required under the member's benefit plan. Approval of an experimental technology with respect to a particular case does not guarantee coverage of the same technology with respect to any other cases.

Criteria
The criteria listed below should be weighed when evaluating the medical necessity of a technology that is or may be experimental or investigational. Where medical necessity of a technology is confirmed under this policy, steps should be taken to ensure that the technology is furnished by a participating or in-state provider to the extent possible.

A. The technology should have final approval from appropriate governmental regulatory bodies. Regulatory bodies include the U.S. Food and Drug Administration (FDA) or any other governmental body with authority to regulate the technology. The indication for the technology under review does not need to be the same indication for which the technology has been approved.

If a request is for coverage of routine costs as part of a clinical trial, see CP.MP.94 Clinical Trials.

B. At least two studies published in peer-reviewed medical literature should be available that would support conclusions regarding the effect of the technology and its likely net health impact. Such studies must, by the standards of accepted medical research, be well-designed and well-conducted investigations yielding quality and consistent results, and the results of such studies should demonstrate the effect the technology will have on the disease, injury, illness, or condition in question.

The opinions and evaluations of national medical associations, consensus panels, and other technology evaluation bodies, or other specialists or professionals, who are subject matter experts with respect to the technology, may be taken into consideration according to the scientific quality of the supporting evidence and rationale for such opinions and evaluations.

C. The technology should be used to improve net health outcome of a severely disabling or life-threatening condition. The health benefits of the technology must outweigh any harmful effects or risks to the member.

D. Other established treatment alternatives to the technology should have been exhausted and failed or no established treatment exists.

E. The improvement to be gained by employing the technology should be attainable outside the control setting (i.e., in practice).

F. In the case of diagnostic procedures, it is anticipated that the results of the procedure will help determine the best plan of care. There must be some potential intervention or alteration to the current plan of care based on the diagnostic results.

G. The member fully understands the risks and benefits regarding the requested technology or treatment and has given informed consent.

REFERENCES

1. Bischel, MD. Medical review criteria guidelines for managing care. Apollo Managed Care Consultants. 12th edition, 2013.
2. Centers for Medicare and Medicaid. National coverage determination for routine costs in clinical trials (301.1). 2007 Oct 9. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA& .
3. Centers for Medicare and Medicaid Services. Medicare Local Coverage Determination for Category III CPT Codes; (ID#L35490). Effective 10/01/15.
4. Steinberg, EP, Tunis, S, Shapiro, D. Insurance coverage for experimental technologies. Health Affairs, 1995 Vol. 14:4.

REVIEWS, REVISIONS, AND APPROVALS

	Date	Approval Date
Initial effective date.		06/09
Moved information from Authorization Protocols to Policy section. Added reference to CP.MP.94 Clinical Trials	10/14	10/14
Removed "To the extent coverage….administrative reasons" sentence from 1st paragraph under criteria Converted into new template	10/15	10/15
Redefined experimental/investigational per Health Net definition.	09/16	09/16
References reviewed and updated.	09/17	09/17
References reviewed.	06/18	06/18
References reviewed	05/19	06/19
References reviewed. Added note: For clinical trials, refer to CP.MP. 94 Clinical Trials.	06/20	06/20