Bright HealthCare™

Medical Policy

Investigational or Experimental Services and Clinical Trials	
MEDICAL POLICY NUMBER	Med_Clin_Ops-023
CURRENT VERSION EFFECTIVE DATE	March 1, 2023
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All *Small Group*: All *Medicare Advantage:* All

Bright Health develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Bright Health Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Bright Health Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Bright Health Medical Policy may visit Bright Health's provider portal or brighthealthcare.com/provider. Bright Health policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Bright Health medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Bright Health medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Bright Health does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

The purpose of this policy is to:

- Define the criteria by which services are deemed investigational, experimental, or unproven and are therefore excluded from coverage
- Establish the clinical review criteria that support coverage of investigational, experimental, or unproven related services

POLICY

Bright HealthCare determines whether a medical or pharmaceutical service is investigational, experimental, unproven for treatment of a condition, disease, illness, or injury. Investigational, experimental, or unproven services may include diagnostic or therapeutic procedures, tests, treatments, facilities, equipment, supplies, drugs, and devices.

Bright HealthCare covers services, procedures, devices, biologic products, and drugs ("health services") when there is sufficient scientific evidence to support their use or when the treatment is required by federal or state laws, rules and regulation.

Bright HealthCare does not provide coverage for services that are determined to be investigational, experimental or of unproven efficacy, except as described below. Additionally, Bright HealthCare does not provide coverage for services related to or supporting the administration of services determined to be investigational, experimental, or unproven.

Investigational, Experimental, or Unproven Services

Investigational, experimental, or unproven services are not covered unless those services are:

1) Mandated by State or Federal rules or specified in the member's coverage policy.
2) Deemed to be covered routine care costs during the course of an approved Clinical Trial (see below for criteria).

A service is considered investigational/experimental/unproven if **any** of the following criteria are met:

1) The service does not have unrestricted market approval from the Food and Drug Administration, as applicable for use in treatment of the member's condition as described in FDA labelling. *Note: Certain medications that are routinely and broadly recommended for use off label by recognized specialty society treatment guidelines are considered proven even if not included the FDA approved labelling. This is commonly the case for medications tested in adults yet used in children*

2) There is insufficient or inconclusive evidence published in peer-reviewed medical literature to consider the service a standard of care and acceptable medical practice meaning it shows a demonstrable benefit for a particular illness or disease and is proven to be safe and efficacious.

3) There is insufficient or inconclusive evidence published in peer-reviewed medical literature to indicate that the service improves meaningful health outcomes. Supportive medical literature should include two or more large randomized and controlled trials published in leading clinical journals such as the New England Journal of Medicine, Journal of the American Medical Association, Journal of the American College of Surgeons etc.

Clinical Trial Criteria

Criteria for determining an approved Clinical Trial of investigational, experimental, or unproven services for which Bright HealthCare will provide covera**ge** of routine covered patient care services necessary for that Clinical Trial.

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Covered health services include routine patient care costs (refer to the background section below for more information) during a clinical trial that may be approved if **ALL** of the following are met:

1. The member must have a life threatening or disabling condition or disease.
2. The treating physician recommends participation in the clinical trial after determining that participation in the clinical trial has the potential to provide significant therapeutic health benefit to the member.
3. The proposed experimental or investigational treatment is likely to be more beneficial that any standard treatment(s) for the member's life-threatening or disabling condition or disease.
4. The treating physician or the member provides medical and scientific information establishing that the member's participation in such trial would be appropriate.
5. The member suffers from a condition that is life threatening.
6. Other established treatment alternatives to the trial treatment have been exhausted, contraindicated, failed, or no established treatment exists.
7. The clinical trial or study is approved under the September 19, 2000, Medicare national coverage decision regarding clinical trials, as amended, or is an approved Clinical trial as defined below.
8. The patient care is provided by a certified, registered, or licensed health care provider practicing within the scope of his or her practice, and the facility and personnel providing the treatment have the experience and training to provide the treatment in a competent manner.
9. Prior to participation in a clinical trial or study, the member has signed a statement of consent indicating that the member has been informed of the procedure to be undertaken, alternative methods of treatment, the general nature, and extent of the risks associated with participation in the clinical trial or study.

Note: In a randomized and controlled trial, the individual may be in the non-treatment control group. and this does not preclude coverage under this policy.

Medical and Drug coverage does not include:

- Any portion of the clinical trial or study that is paid for by a government or a biotechnical, pharmaceutical, or medical industry.
- Any drug or device that is paid for by the manufacturer, distributor, or provider of the drug or device.
- The cost of an investigational new drug or device that has not been approved for market for any indication by the FDA.
- Costs of services that (A) are inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis, or (B) are performed specifically to meet the requirements of the Clinical Trial.
- Extraneous expenses related to participation in the clinical trial or study including, but not limited to, travel, housing, and other expenses that the member or person accompanying the member may incur.
- An item or service that is provided solely to satisfy a need for data collection or analysis that

is not directly related to the clinical management of the member.
- Costs for the management of research relating to the clinical trial or study.
- Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the member's health plan.
- After the clinical trial ends, coverage is not provided for non-FDA approved drugs that were provided or made available to a member during a covered clinical trial.
- Items or services required solely for the provision of the investigational items or services, the clinically appropriate monitoring of the effects of the item of service, or the prevention of complications.
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

BACKGROUND

Federal Statute Section 10103(c) of PPACA (Patient Protection and Affordable Care Act of 2010) added a new provision to the federal Public Health Service Act which requires group health plans and health insurance issuers offering individual or group health insurance products to provide for coverage of routine patient costs associated with approved clinical trials.

A qualified individual under the Affordable Care Act and PHS Act section 2709(b) is generally a participant or beneficiary who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the treatment of cancer or another life-threatening disease or condition; and either: (1) the referring health care professional is a participating provider and has concluded that the individual's participation in such trial would be appropriate; or (2) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate.

DEFINITIONS

1. ***Clinical trial*** (approved clinical trial) as defined by Patient Protection and Affordable Care Act of 2010 (PPACA) means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other imminent life-threatening disease or condition and is described in any of the following subparagraphs:
    (A) Federally Funded Trials- The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:
        (i) The National Institutes of Health.
        (ii) The Centers for Disease Control and Prevention.
        (iii) The Agency for Health Care Research and Quality.
        (iv) The Centers for Medicare & Medicaid Services.
        (v) cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.

(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) A study or investigation has been conducted and approved through a system of peer review by one of the following:

a. The Department of Veterans Affairs.
b. The Department of Defense.
c. The Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

2. ***Disabling Condition*** - a disabling condition means that the member is unable to engage in any substantial gainful activities by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve months]

3. ***Life-threatening condition -*** any disease or condition from which death is likely unless the disease or condition is treated

4. ***Insufficient or inconclusive evidence*** means that there is insufficient scientific data published in two or more large randomized and controlled trials published in leading clinical journals (e.g. Journal of the American Medical Association or affiliated journals, New England Journal of Medicine or affiliated journals or references, British Medical Journal, The Lancet, Annals of Internal Medicine, etc.). In addition, there is insufficient information on the service(s) reviewed and published in credible knowledge bases e.g. Hayes, UpToDate, MCG, etc. or textbooks of medicine.

5. ***Routine patient care cost*** refers to items and services that are Covered Health Services for a member with a similar condition who is not enrolled in a clinical trial.

CODING

Codes identified as investigational or experimental are listed on Bright HealthCare's website: I/E Code List

Other applicable CPT/HCPCS codes will be determined on a case-by-case basis with individual patient records and notes that define the services requested and meet the definition of investigational or experimental above.

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POLICY HISTORY

This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Bright HealthCare's policies on clinical criteria and policy development.

Approval Body	Utilization Management Committee		
Version History	**Approval Date**	**Effective Date**	**Action**
V1	09-24-2020	09-24-2020	New Policy
V2	12-20-2020	12-20-2020	Updated to reflect new lines of business
V3	09-23-2021	09-23-2021	Annual review
V4	09-28-2022	10-1-2022	Annual review – clarified coverage of I/E services, incorporated elements of the now retired MED_Clin_Ops-016 Benefit Exceptions Policy
V5	09-28-2022	03-1-2023	Adopted by MA UM Committee (no policy revisions made)