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Medical Policy

Clinical Trial Procedure – WEA Primary

Policy Number: 1031

Policy History			
Approve Date:	01/13/2015	Effective Date:	01/13/2015
Reviewed/Revised Date:	01/13/2016, 01/13/2017, 01/13/2018, 04/29/2019, 04/28/2020		

Preauthorization	
All Plans	Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details.

Policy

Indications of Coverage

This policy applies to members with WEA Primary insurance.

WEA Trust covers medically necessary routine patient care costs in cancer trials as mandated by Wisconsin statute 632.87 if all of the following five criteria are met:

I. The purpose of the trial is to test whether the intervention potentially improves the trial participant's health outcomes

II. The treatment provided as part of the trial is given with the intention of improving the trial participant's health outcomes

III. The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology

IV. The trial does one of the following:
   A. Tests how to administer a health care service, items, or drug for the treatment of cancer
   B. Tests responses to a health care service, item or drug for the treatment of cancer
   C. Compares the effectiveness of health care services, items or drugs for the treatment of cancer with that of other health care services, items or drugs for the treatment of cancer OR
   D. Studies new uses of health care services, items, or drugs for the treatment of cancer

V. The trial is approved by one of the following:
   A. A National Institute of Health or one of its cooperative groups or centers, under the federal department of health and human services
   B. The federal food and drug administration
   C. The federal department of defense
   D. The federal department of veterans affairs

Routine patient care includes all of the following that would be covered under the policy if the member were not enrolled in a clinical trial:

I. All health care services, items, and drugs for the treatment of cancer

II. All health care services, items, and drugs that are typically provided in health care including:
   A. Health care services, items, and drugs provided to a patient during the course of treatment in a cancer trial for a condition or any of its complications that are consistent with the usual and customary standard of care, including the type and frequency of any diagnostic modality

Routine patient care does NOT include:
I. The health care services, item or investigational drug that is the subject of the cancer clinical trial

II. Any health care service, item or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient; e.g., additional radiologic scans to tack disease progress more regularly

III. An investigational drug or device that has not been approved for market by the federal food and drug administration for the specific purpose for which it is being used

IV. Transportation, lodging, food or other expenses that are associated with traveling to or from the facility providing the clinical trial

V. Any services, items or drugs provided by the clinical trial sponsors free of charge for a patient and

VI. Any services, items or drugs that are eligible for reimbursement by a person or entity other than WEA Trust (e.g., the sponsor of the clinical trial, according to the clinical trial agreement)

Non-Cancer Clinical Trials
Non-cancer clinical trials are considered investigational and experimental and are not covered by WEA Trust.

Also see:
Clinical Trial Procedure – WEA Secondary Insurance

Background

Clinical trials are prospective biomedical or behavioral research studies on human subjects that are designed to answer specific questions about biomedical or behavioral interventions (novel vaccines, drugs, treatments, functional foods, dietary supplements, devices or new ways of using known interventions), generating safety and efficacy data.[1] They are conducted only after satisfactory information has been gathered that satisfies health authority/ethics committee approval in the country where approval of the therapy is sought.

Wisconsin State Mandate
Coverage of Certain Health Care Costs in Cancer Clinical Trials—Health care policies, plans, and contracts are prohibited from excluding coverage for certain health care services, items, or drugs administered to an insured in a cancer clinical trial in certain situations that would be covered under the policy, plan, or contract if the insured were not enrolled in a cancer clinical trial. The coverage is subject to all terms, conditions and restrictions that apply to other coverage under the policy, including the treatment and services performed by participating and nonparticipating providers. This includes policy requirements that the cancer clinical trial services be performed by a participating provider. This applies to all health insurance policies and self-insured health plans of the state or of

a county, city, village, town, or school district. However, if an insurance policy covers employees under a collective bargaining agreement containing provisions inconsistent with these changes, the changes first apply to a policy issued or renewed on the earlier of: (a) the date the collective bargaining agreement expires; or (b) the date the collective bargaining agreement is extended, modified, or renewed. If a self-insured plan covers employees under a collective bargaining agreement containing provisions inconsistent with the changes, the changes first apply to a plan established, extended, modified, or renewed on the earlier of: (a) the date the collective bargaining agreement expires; or (b) the date the collective bargaining agreement is extended, modified, or renewed. [ss. 40.51 (8), 66.0137 (4), 120.13 (2) (g), 185.981 (4t), 185.983 (1) (intro.), 632.855 (2) (intro.) 632.855 (3), and 632.855 (3) (bm), 632.87 (1), and 632.87 (6), Wis. Stat.]

References

The above policy is based on the following references:

1. Wisconsin Statute: 632.87
2. Centers for Medicare & Medicaid Services (CMS): National Coverage Determination for Routine Costs in Clinical Trials (310.1)