

MEDICAL COVERAGE POLICY

SERVICE: Clinical Trials

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| Policy Number: | 296 |
| Effective Date: | 03/01/2023 |
| Last Review: | 02/23/2023 |
| Next Review Date: | 02/23/2024 |

Important note:

Unless otherwise indicated, this policy will apply to all lines of business.

Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

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PRIOR AUTHORIZATION: Not applicable.

POLICY: This policy is consistent with Centers for Medicare & Medicaid Services (CMS) policy and Patient Protection and Affordable Care Act (PPACA) requirements.

For **Medicare** plans, see NCD 310.1 for details regarding coverage during a clinical trial.

For **Medicaid** plans, per TMPPM (January 2023):

"While procedures and services that are experimental or investigational are not a benefit of Texas Medicaid, routine patient care costs for individuals enrolled in clinical trials may be covered as medically necessary when those services are current Texas Medicaid benefits. Texas Insurance Code Section 1379.051 defines "routine patient care costs" as "the costs of any medically necessary health care service for which benefits are provided under a health benefit plan, without regard to whether the enrollee is participating in a clinical trial." Refer to Texas Insurance Code Chapter 1379 for additional information."

For **all other plans**:

To qualify for the limited coverage outlined below, a clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards (IRBs) before participants are enrolled. Providers will not routinely be required to submit documentation about the trial to BSWHP, but BSWHP can, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approval(s).

BSWHP does NOT cover clinical trial costs including, but not limited to:

1. The experimental drug(s), procedure(s), imaging, laboratory testing, and all other services and interventions that are part of the Clinical Trial.
2. Other services related to the clinical trial and required by the trial, e.g., administrative Costs of data collection and record keeping that would not be required but for the clinical trial.
3. Services clearly inconsistent with widely accepted and established standards of care for a particular diagnosis

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4. Tests/services that determine clinical trial eligibility, when the test/service is otherwise considered experimental/investigational or not medically necessary
5. Items and services provided by the trial sponsor without charge.
6. Travel, lodging and meals.
7. Services/costs, inpatient stays required by the trial.

Baylor Scott & White Health Plan (BSWHP) does cover medically necessary routine patient care costs during clinical trials in the same way that it reimburses routine care for members not in clinical trials, according to the limitations outlined below:

1. All applicable plan limitations for coverage of out-of-network routine patient care will apply to routine patient care coverage and costs for members enrolled in a clinical trial.
2. Coverage policies that apply to routine care services for members not in clinical trials will also apply to routine patient care for members in clinical trials.
3. Members must meet all applicable plan prior authorization requirements for routine patient care.

In addition, BSWHP covers costs of medically necessary treatments for conditions that result as unexpected consequences (complications) of clinical trials.

Information Required for Review:

In order for medical necessity to be established, adequate information must be furnished by the treating physician. Necessary documentation includes, but is not limited to the following:

- Member's age and clinical history;
- Documentation of diagnosis and treatment history;
- Clinical Trial/research study name, trial/research study sponsor and numeric registry number;
- Clinical Trial protocol;
- Current IRB approval letter;
- Copy of the FDA approval with the scope of the indication that was approved (if applicable);
- Informed, signed consent to participate in the study.

SUPPORTING INFORMATION:

DEFINITIONS

Clinical Trial – a research study that assigns participants to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials generally proceed through four phases:

- Phase I - the study drug or treatment is given to a small group (6-100) of healthy volunteers for the first time to evaluate its safety, identify side effects, and determine a safe dosage range.

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- Phase II - the study drug or treatment is given to larger groups (100-300) of volunteers who have a particular disease to further evaluate its effectiveness, safety, and optimal dosage to achieve maximal benefit with the least side effects.
- Phase III - the study drug or treatment is given to large groups of volunteers (1000-3000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely.
- Phase IV - post marketing large-scale (10,000), long-term trials to delineate additional information about a treatment's risks, benefits, optimal use, and effects in various patient populations.

CMS: NCD 310.1: Routine Costs in Clinical Trials, effective date 7/9/2007

POLICY HISTORY:

| Status | Date | Action |
|----------|------------|----------------------------------------|
| New | 02/24/2022 | New policy |
| Reviewed | 02/23/23 | Clarified coverage by business segment |

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. National Coverage Determination (NCD) 310.1
2. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS). Decision Memorandum for the Clinical Trials Policy (CAG-00071R). Baltimore, MD: CMS; July 9, 2007.

Note: Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plans.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSA's. Individual HMO plans are offered through FirstCare in West Texas.