MEDICAL COVERAGE POLICY	
SERVICE:	**Clinical Trials**
Policy Number:	**296**
Effective Date:	**03/01/2025**
Last Review:	**02/10/2025**
Next Review:	**02/10/2026**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Clinical Trials

PRIOR AUTHORIZATION: Not applicable.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details. This policy is consistent with Centers for Medicare & Medicaid Services (CMS) policy and Patient Protection and Affordable Care Act (PPACA) requirements.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). NCD 310.1 - Routine Costs in Clinical Trials. Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

> "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
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.

Clinical Trials Search Resources

1. Clinical Trials Search - https://clinicaltrials.gov/
2. FDA Clinical Trials Search for patients - https://www.fda.gov/patients/clinical-trials-what-patients-need-know
3. Approved Investigational Device Exemption Studies https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved

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.
- 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.

POLICY HISTORY:

Status	Date	Action
New	02/24/2022	New policy
Reviewed	02/23/2023	Clarified coverage by business segment
Reviewed	02/12/2024	Formatting changes and added hyperlinks to CMS and TMPPM resources, beginning and ending note sections updated to align with CMS requirements and business entity changes.
Reviewed	02/10/2025	No changes

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 Trial Policy (CAG-00071R). Baltimore, MD: CMS; July 9, 2007.
3. Clinical Trials.gov - https://clinicaltrials.gov/
4. FDA / Clinical Trials - https://www.fda.gov/patients/clinical-trials-what-patients-need-know
5. Approved Investigational Device Exemption Studies - https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved
6. Use of 8 Digit Registry Number on Clinical Trial Claims. MLN Matters Number: MM5790, Medicare Learning Network.

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5790.pdf

7. Clarification of Medicare Payment for Routine Costs in a Clinical Trial. MLN Matters Number: SE0822 Revised, Medicare Learning Network. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/se0822.pdf
8. Billing / Coding of Routine Costs. Investigational device exemption (IDE) studies. NOVITAS. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00080347

***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 Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.