CLINICAL COVERAGE POLICY

Clinical Coverage Policy:	Experimental and Investigational Services				
CCP#:	CCP-100	**Last Review Date:**	N/A	**Effective Date:**	04/19/2024
Prior Authorization Needed?	☒ Yes (always required) ☐ Yes (only in certain situations See this CCP for details) ☐ No				

DESCRIPTION

This Clinical Coverage Policy outlines general principles that Alliance Health will use to make coverage determinations for Experimental or Investigational Services (EIS). To ensure that coverage of EIS is consistent, Alliance will follow North Carolina Department of Health and Human Services (NCDHHS) Clinical Coverage Policy 1A-39: "Routine Patient Cost Furnished in Connection with Participation in Qualified Clinical Trials".

EIS are generally not covered by Alliance Health in accordance with 10A NCAC 25A.0201.

This Clinical Coverage Policy is to be used when there is no other policy, criteria, or coverage statement available.

DEFINITIONS AND ACRONYMS

Investigational services are drugs, biological products, or devices that have successfully completed phase one of a clinical investigation approved by the US Food and Drug Administration (FDA) but have not been approved for general use by the FDA and remain under investigation in an FDA approved clinical investigation. In general, the FDA must approve a new drug for general use. Clinical trials are scientific investigations of treatment alternatives designed to help compare the safety and efficacy of new, untested, or non-standard treatments to standard currently accepted treatments. Clinical trials are intended to improve clinicians' knowledge about a treatment and to improve clinical outcomes for future patients. Clinical trials are often conducted in four phases. The trials at each phase have a different purpose and help scientists answer different questions. Prior to approving a new drug for general use, the FDA may authorize its use in a clinical investigation. A clinical investigation is an experiment in which a drug is administered to one or more human subjects. A new drug under clinical investigation is an "investigational drug".

Experimental services are drugs, equipment, procedures, or services that are in a testing phase undergoing laboratory and/or animal studies prior to testing in humans. Experimental services are not undergoing clinical investigation.

Generally Accepted Standards of Medical Practice: Standards that are based on credible scientific data, are published in peer-reviewed medical/scientific literature, are recognized by the relevant medical community, and align with physician specialty society recommendations and views of physicians practicing in the relevant clinical areas.

CRITERIA

All coverage determinations for EIS must be considered on a case-by-case basis by a physician (MD, DO), and must be made in accordance with the Benefit Plan Contract provisions and applicable state and federal requirements using the criteria described in this section.

1. Eligibility criteria
    a. An eligible beneficiary shall be enrolled in Alliance Health Tailored Plan.
    b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
    c. Special provisions
        i. Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) beneficiaries are exempt from policy limitations if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition (health problem) identified through a screening examination including any evaluations by a physician or other licensed practitioner.
        ii. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed clinician.
        iii. EPSDT will not cover any service, product or procedure that is:
            1. Unsafe, ineffective, experimental, or investigational;
            2. Not medical in nature or not generally recognized as an accepted method of medical practice or treatment.
2. Clinical Coverage Criteria
    a. Alliance *will cover* procedures, products or services related to this policy when it is medically necessary AND when they meet ALL of the following:
        i. The procedure, product or service is individualized, specific and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
        ii. The procedure, product or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available;
        iii. The procedure, product or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider;
        iv. The health benefits of the EIS requested must outweigh any harmful effects or risks to the member AND the member, or legally responsible person if the member is incompetent, has been fully informed of the risks and benefits of the EIS;
        v. The beneficiary meets all the eligibility criteria of the qualified clinical trial;
        vi. The beneficiary is enrolled in the qualified clinical trial;
        vii. The beneficiary, or legally responsible person if the member is incompetent, has provided informed consent;
        viii. The beneficiary is treated according to the protocols of the qualified clinical trial;
        ix. The health care provider and the principal investigator completes the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial.

Approval of an EIS with respect to a particular case does not guarantee coverage of the same EIS with respect to any other requests however similar.

    b. Alliance *will not* cover procedure, products or services related to this policy if:
        i. The beneficiary does not meet the eligibility criteria described above;

ii. The procedure, product or service duplicates another provider's procedure, product, or service;
iii. The procedure, product or service is not a health care one;
iv. Any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project;
v. Any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project;
vi. Investigational drugs that do not have unrestricted market approval from the FDA for any diagnosis or treatment;
vii. After the clinical trial ends, coverage is not provided for non-FDA approved drugs that were provided or made available to an enrollee during a qualifying clinical trial;
viii. Travel, lodging, and meals

LIMITATIONS AND EXCLUSIONS

N/A

REFERENCES

- 10A NCAC 25A.0201 Pursuant to the State Plan, all medical services performed shall be medically necessary and may not be experimental in nature. Medical necessity shall be determined by generally accepted North Carolina community practice standards as verified by independent Medicaid consultants.
- 21 C.F.R. § 312.3(b) Drugs for Human Use: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.3 (Accessed 12/04/2023)
- NC DHHS Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials Clinical Coverage Policy 1A-39: https://medicaid.ncdhhs.gov/1a-39-routine-patient-costs-furnished-connection-participation-qualifying-clinical-trials/download?attachment (Accessed 12/04/2023)

REVISION LOG

Review/ Revision Date	Status	Change
2/13/2024	Original Approval	N/A