IOWA | Health and Human Services

INFORMATIONAL LETTER NO. 2587-MC-FFS

DATE: June 7, 2024

TO: All Iowa Medicaid Medical Providers

APPLIES TO: Managed Care (MC), Fee-for-Service (FFS)

FROM: Iowa Department of Health and Human Services (HHS), Iowa Medicaid

RE: Clinical Trials

EFFECTIVE: January 1, 2022

The purpose of this informational letter (IL) is to provide billing guidance for Food and Drug Administration (FDA) approved clinical trials. The Center for Medicaid and CHIP Services (CMCS) has issued a State Medicaid Director Letter[1] outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. This guidance applies to states and territories with respect to items and services furnished to Medicaid beneficiaries, including beneficiaries enrolled in Alternative Benefit Plans (ABPs), who are participating in a qualifying clinical trial.

This term is defined as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection or treatment of any serious or life-threatening disease or condition.

Reimbursable clinical trials generally proceed through three phases:

- Phase I clinical trials - the study drug or treatment is given to a small group of people for the first time to evaluate its safety, determine a safe dosage range and to identify side effects.
- Phase II clinical trials - the study drug or treatment is given to a large group of people to see if it is effective and to further evaluate its safety.
- Phase III clinical trials - the study drug or treatment is given usually to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the drug or treatment to be used safely.

[1] https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf

Coverage Determination Requirements

A prior authorization and attestation form will be required for a member to participate in a qualifying clinical trial. Coverage will be based on an attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator and be made using a streamlined uniform form developed for state use by the Secretary. The attestation form can be found on the Iowa Department of Health and Human Services (HHS) Prior Authorization webpage[2].

Criteria

A qualifying clinical trial must meet at least **ONE** of the following:

1. A study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by **ONE** or more of the following:
   a. The National Institutes of Health (NIH); **OR**
   b. The Centers for Disease Control and Prevention (CDC); **OR**
   c. The Agency for Health Care Research and Quality (AHRQ); **OR**
   d. The Centers for Medicare & Medicaid Services (CMS); **OR**
   e. A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs (VA); **OR**
   f. A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants; **OR**

2. A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review that the Secretary determines comparable to the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review by:
   a. The Department of Energy (DOE), **OR**
   b. The Department of Veterans Affairs (VA); **OR**
   c. The Department of Defense (DOD); **OR**

3. A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; **OR**

4. A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

[2] https://hhs.iowa.gov/programs/welcome-iowa-medicaid/policies-rules-and-regulations/covered-services-rates-and-payments/prior-authorization

Clinical Trial Codes

Procedure Code	Description
S9988	Services provided as part of a Phase I clinical trial
S9990	Services provided as part of a Phase II clinical trial
S9991	Services provided as part of a Phase III clinical trial
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Billing for Services Rendered as Part of the Clinical Trials

The applicable S code for the clinical trial should be submitted on the first claim line and billed at $0.00, while any subsequent claim lines containing the applicable specific procedure code(s) for actual services rendered will be billed at their usual and customary charge.

Please note, prior authorization is only required for the clinical trial (S9988, S9990 and S9991). Additional services rendered pertaining to a clinical trial will not require a prior authorization regardless of CPT or HCPCS code status with Iowa Medicaid.

If you have questions, please contact Iowa Medicaid Provider Services or the appropriate MCO:

Iowa Medicaid Provider Services:

- Phone: 1-800-338-7909
- Email: imeproviderservices@dhs.state.ia.us

Managed Care Organizations (MCOs):

Iowa Total Care:

- Phone: 1-833-404-1061
- Email: providerrelations@iowatotalcare.com
- Website: https://www.iowatotalcare.com

Molina Healthcare of Iowa:

- Phone: 1-844-236-1464
- Email: iaproviderrelations@molinahealthcare.com
- Website: https://www.molinahealthcare.com/providers/ia/medicaid/home.aspx
- Provider Portal: https://www.availity.com/molinahealthcare

Wellpoint Iowa, Inc. (formerly Amerigroup Iowa, Inc.):

- Phone: 1-833-731-2143
- Email: ProviderSolutionsIA@wellpoint.com
- Website: https://www.provider.wellpoint.com/iowa-provider/home