CLINICAL TRIALS

Policy Number: ADMINISTRATIVE 152.14 T2
Effective Date: October 1, 2015

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<td>General benefits package</td>
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<tr>
<td>Referral Required</td>
<td>No</td>
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<td>Authorization Required</td>
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<td>Precertification with Medical Director Review Required</td>
<td>Yes†</td>
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<td>Applicable Site(s) of Service</td>
<td>Inpatient, Outpatient, Office</td>
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<tr>
<td>Special Considerations</td>
<td>1) Precertification with review by a Medical Director or their designee is required for all clinical trials. This policy must be reviewed in conjunction with Oxford's policy on Experimental/Investigational Treatment. 2) Requests for coverage must be submitted prior to initiation of trial.</td>
</tr>
</tbody>
</table>

The services described in Oxford policies are subject to the terms, conditions and limitations of the Member's contract or certificate. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage enrollees. Oxford reserves the right, in its sole discretion, to modify policies as necessary without prior written notice unless otherwise required by Oxford's administrative procedures or applicable state law. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

Certain policies may not be applicable to Self-Funded Members and certain insured products. Refer to the Member's plan of benefits or Certificate of Coverage to determine whether coverage is provided or if there are any exclusions or benefit limitations applicable to any of these policies. If there is a difference between any policy and the Member's plan of benefits or Certificate of Coverage, the plan of benefits or Certificate of Coverage will govern.

**CONDITIONS OF COVERAGE**

- Experimental/Investigational Treatment
- Experimental / Investigational Treatment for NJ Plans
This policy creates a limited exception to the total exclusion of benefits for Experimental/Investigational treatments. Payment of benefits under this policy is limited to participating providers within Oxford's network contracted specifically to provide these services, unless the Member is covered under a PPO or a contract with in-network and out-of-network benefits. In-network and out-of-network benefits are subject to all applicable cost sharing requirements.

A Member seeking approval for coverage of the routine costs associated with an in-network clinical trial will receive coverage subject to the Member's in-network cost-share. Out-of-network benefits are available to PPO and Members with in and out-of-network benefits only. Out-of-network benefits will be paid based upon the UCR, subject to the Member's out-of-network cost-share.

Note:
- Certain self-insured groups may be excluded from participation in clinical trials. Consult with the individual Group Benefits Administrator for specific coverage limitations.
- Routine patient costs of clinical trials are approved pursuant to this policy:
  - Members with in-network benefits only (HMO Members):
    - In-network clinical trials are subject to the applicable cost-share.
    - Out-of-Network clinical trials may only be covered as an in-network exception. (See Treatment Application Guidelines for in-network exception)
  - Members with in-network and out-of-network benefits:
    - In-network clinical trials are subject to the applicable cost-share
    - Out-of-Network clinical trials:
      - Routine costs for clinical trials are subject to UCR, deductible and co-insurance.
      - In-network exception may be requested. (See Treatment Application Guidelines for in-network exception)

In-Network Exceptions for Clinical Trials
All requests for in-network exceptions must be made prior to the treatment being rendered, in order to afford Oxford's medical directors the opportunity to identify the same or similar trial in network, and to conform to the Member's health benefit plan. Such exceptions will be made only pursuant to a treatment plan approved by the health plan in consultation with the primary care provider, the non-participating provider and the Member or Member's designee.

Oxford is not obligated to identify an in-network clinical trial using the same agent, modality, or treatment that the Member is requesting or prefers. Oxford's obligation does not extend to the agent or dosage used in the trial. Oxford's obligation in identifying a suitable clinical trial is based on the:
- Diagnosis,
- Stage of disease,
- Prior treatment history, (if applicable), and
- Phase of the trial.

In evaluating an in-network request for coverage of an out-of-network trial, Oxford will:
- Consider the diagnosis of the Member, the Member's prior treatment and stage of disease to identify other suitable clinical trials offered within Oxford's network.
- Compare the designated Phase (I-IV) of any in-network trials for which the Member might qualify, to the Phase of the out-of-network clinical trial.
Note: The Phase of a trial is an indication of the likelihood of ultimate licensure and acceptance of the trial agent or modality as an effective treatment; and a higher Phase denotes previous work that has been done, and an increasing likelihood of benefit.

If Oxford:

- **Cannot provide** a clinical trial of equal or higher Phase compared to the out-of-network trial that the Member is requesting, then an in-network exception **will be certified**. This will apply to both Members with in-network only benefits and Members with in and out-of-network benefits.
- **Can provide** the Member with the same clinical trial in-network, the in-network exception **will not be certified**, and will be subject to the Member's grievance rights under applicable State Statute.
- **Can identify** an in-network clinical trial of equal or higher Phase to that which the Member is requesting, the in-network exception **will not be certified**.

Note:

- The above means that a Member with:
  - **In-network benefits only**, this determination will mean that the Member will have no coverage for the out-of-network trial.
  - **In-network and out-of-network benefits**, an out-of-network clinical trial that otherwise meets our criteria for clinical trials will be covered pursuant to the Member's out-of-network benefit.

- In this type of case only (i.e. Oxford can identify an in-network clinical trial), Oxford's decision not to certify an out-of-network clinical trial for in-network coverage will be considered a utilization review decision. Therefore, Oxford's decision to deny certification of an out-of-network clinical trial for in-network coverage will be subject to external review under applicable State Statute.

**Product Specific Guidelines for Members Enrolled on CT Products**

The following information is specific to members enrolled on CT Products

- **Self-Funded products**: Certain Self Insured Groups may be excluded from participation in Clinical Trials.

- **For POS/PPO products**: Routine costs for out of network services are subject to deductible and co-insurance regardless of their availability within the service area. However, coverage for out of network hospitalization as part of the routine patient care costs associated with a clinical trial will be covered subject to the In network cost sharing if it is not available at an in-network facility and not paid for by the clinical trial sponsor. In network Clinical Trials are subject to applicable cost sharing.

- **For HMO products**: Routine patient care costs will be made available out of network if appropriate care is not available in network, and the services are approved by a medical director. Coverage for out of network hospitalization as part of the routine patient care costs associated with a clinical trial will be covered subject to the In network cost sharing if it is not available at an in-network facility and not paid for by the clinical trial sponsor. Out of network providers shall be paid according to the Member's in-network benefits, pursuant to the provider billing restrictions described in this policy. In network Clinical Trials are subject to applicable cost sharing.

- **Criteria For Approved Clinical Trials**: In addition to the criteria outlined in the **Coverage Rationale** section below, Oxford may, at any time, request documentation about the trial to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approvals.

- **Criteria for Qualified Individuals**: To be a qualified individual Members enrolled on CT products must be:
Covered under the health plan, and
Eligible to participate in an approved clinical trial according to the trial protocol based upon:
  - The individual was referred to the clinical trial by a health care professional who has concluded that the individual’s participation would be appropriate because the individual is eligible for the trial according to its protocol, or
  - The individual provides the plan with medical and scientific information that establishes that participation would be appropriate because the individual is eligible for the trial according to its protocol.

- **Official Request Form**: All requests for coverage of a Clinical Trial must be submitted to Oxford on a specific form developed by the Connecticut Department of Insurance.

- **Member Cost Share**: Routine patient costs of Clinical Trials approved pursuant to this policy are subject to all applicable cost sharing (co-payments, deductible or co-insurance) per Member certificate requirements.

- **Provider Selection and Provider Billing Restrictions**: Whenever possible, the routine tests and services (that are Routine Patient Costs) must be provided by a Network Provider.
  - All providers are prohibited from billing Oxford or a Member for the costs of any patient care services or products that are paid by the entity sponsoring or funding the Clinical Trial.
  - If the provider providing the Routine Patient Costs is a non-Network Provider, Oxford will allow the non-Network Provider the lesser of the:
    1. Lowest per diem, fee schedule rate or case rate as paid to any Network Provider in the State of Connecticut (that provides similar In-Network services); or
    2. Billed charges.
  - Participating and Non-Participating Connecticut providers must accept payment as payment in full, and may not balance bill the Member.
  - Members are subject to balance billing by Non-Participating, out of state providers.

- **Decisions on Requests for Coverage**: Decisions for properly submitted requests will be made within; five business days of receiving the form and any other reasonable supporting materials necessary to determine eligibility as described herein. If independent experts are needed to review such requests, the response time is ten business days. Requests for coverage of Phase III Clinical Trials will be made within 14 business days of the receipt of the form and materials.

- **Appeals**:
  - A denial based on Medical Necessity may be appealed by the Member or the provider (with the Member’s written consent) to external review.
  - If a denial is issued because the trial does not meet the definition of Clinical Trial as described herein, or the Member does not meet the eligibility requirements, no external review is available. If an item of coverage does not meet the definition of Routine Patient Costs, no external review is available.

**Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such,
when using this guideline, it is important to refer to the member specific benefit document to determine benefit coverage.

**COVERAGE RATIONALE**

Effective for plan years starting on or after January 1, 2014, the Patient Protection and Affordable Care Act (“PPACA”) requires non-grandfathered health plans to cover “Routine Patient Costs” incurred by a “Qualifying Individual” who is participating in an “Approved Clinical Trial”.

Benefits include the reasonable and necessary items and services used to prevent, diagnose and treat complications arising from participation in a qualifying clinical trial.

Benefits are available only when the Member is clinically eligible for participation in the qualifying clinical trial as defined by the researcher.

I. APPROVED CLINICAL TRIAL

A. An “Approved Clinical Trial” is defined as:
   - Phase I, Phase II, Phase III, or Phase IV clinical trial,
   - Being conducted in relation to the prevention, detection or treatment for Cancer or other life threatening disease or condition, and
   - That meets the requirements under Section II below.

For purposes of this benefit, a “life-threatening disease or condition” is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

B. Additional Clinical Trials

The following clinical trials are not currently required by PPACA. However, these clinical trials are covered under Oxford’s clinical trial benefit.

   - Phase I, Phase II or Phase III clinical trial,
   - Being conducted in relation to the detection or treatment of non-life-threatening:
     - Cardiovascular disease (cardiac/stroke),
     - Surgical musculoskeletal disorders of the spine, hip and knees, and/or
     - Other Clinical Trials: Certain plans may allow clinical trials relating to other diseases or disorders which are not life-threatening. Please refer to the enrollee’s plan-specific SPD for coverage

That meets the requirements under Section II below.

II. CRITERIA FOR APPROVED CLINICAL TRIALS

A. The clinical trial must be described in paragraph 1, 2 or 3 below.

   1. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:
      - National Institutes of Health (NIH). (Includes National Cancer Institute (NCI).)
      - Centers for Disease Control and Prevention (CDC).
      - Agency for Healthcare Research and Quality (AHRQ).
      - Centers for Medicare and Medicaid Services (CMS).
      - A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the Veterans Administration (VA).
      - A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
1. The Department of Veterans Affairs, the Department of Defense or the Department of Energy as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following criteria:
   - Comparable to the system of peer review of studies and investigations used by the National Institutes of Health.
   - Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

or

2. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration; or

3. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

B. Additional Requirements

1. The 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 in the trial. We may, at any time, request documentation about the trial.

2. The subject or purpose of the trial must be the evaluation of an item or service that meets the definition of a Covered Health Service and is not otherwise excluded under the Policy.

III. QUALIFIED INDIVIDUAL

A. To be a qualified individual an individual must be:

1. Covered under the health plan, and

2. Eligible to participate in an approved clinical trial according to the trial protocol based upon:
   - The individual was referred to the clinical trial by an in-network health care professional who has concluded that the individual’s participation would be appropriate because the individual is eligible for the trial according to its protocol, or
   - The individual provides the plan with medical and scientific information that establishes that participation would be appropriate because the individual is eligible for the trial according to its protocol.

IV. ROUTINE PATIENT COSTS DURING CLINICAL TRIALS INCLUDE:

A. Covered Health Services for which Benefits are typically provided absent a clinical trial.

B. Covered Health Services required solely for:

1. The provision of the Experimental or Investigational service(s) or item (e.g. the infusion administration services to deliver an investigational drug), and/or

2. The clinically appropriate monitoring of the effects of the service or item (e.g. lab tests and imaging done at a frequency consistent with signs and symptoms and other standards of care for that diagnosis or treatment type), and/or

3. The prevention of complications.

C. Covered Health Services needed for reasonable and necessary care arising from the provision of an Experimental or Investigational service(s) item.

Network Plans:
If one or more network providers are participating in a clinical trial, then Oxford may require that the Qualified Individual participate in the clinical trial using a network provider, as long as the network provider will accept the qualifying individual as a participant in the trial. However, if an Approved Clinical Trial is conducted outside of the Qualified Individual’s state of residence, then Oxford may not deny or otherwise limit payment for Routine Patient Services solely on the basis that the trial is conducted out-of-state.

**COVERAGE LIMITATIONS AND EXCLUSIONS:**

A. The Experimental or Investigational Service(s) or item that is used in the clinical trial is not covered, except for the following:
   1. Certain *Category B* devices (see definition below)
   2. Certain promising interventions for patients with terminal illnesses.
   3. Other items and services that, in our determination, meet specified criteria in accordance with our medical and drug policies.

B. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient. Examples include, but are not limited to:
   - Laboratory tests and imaging studies done at a frequency dictated by the study protocol and not consistent with signs and symptoms and other standards of care for that diagnosis or treatment type.

C. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

D. Items and services provided by the research sponsors free of charge for any person enrolled in the trial.

E. Travel and transportation expenses are excluded from coverage. These include, but are not limited to, the following examples:
   1. Fees for all types of transportation. Examples include, but are not limited to: personal vehicle, taxi, medical van, ambulance, commercial airline, and train.
   2. Rental car expenses.
   3. Mileage reimbursement for driving a personal vehicle.
   4. Lodging.
   5. Meals.

F. Routine patient costs obtained out-of-network where non-network benefits do not exist under the plan.

G. Clinical Trials that do not meet the requirements listed in the Indications for Coverage section above. An example includes, but is not limited to, Phase 0 drug clinical trials.

**DEFINITIONS**

**Category B Devices:** As determined by the FDA, non-experimental and/or investigational devices where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Only certain FDA-designated Category B devices are covered. In order to be covered, all of the following criteria must be met:

1) The device must be used within the context of an FDA-approved clinical trial.
2) The device must be used according to the clinical trial’s approved protocols.
3) Must fall under a covered benefit category and must not be excluded by law, regulation or current Medicare coverage guidelines.
4) The device is medically necessary for the member, and the amount, duration and frequency of use or application of the service is medically appropriate.
5) The device is furnished in a setting appropriate to the member’s medical needs and condition.
**Experimental or Investigational Service(s):** medical, surgical, diagnostic, psychiatric, mental health, substance related and addictive disorders or other health care services, technologies, supplies, treatments, procedures, drug therapies, medications or devices that, at the time we make a determination regarding coverage in a particular case, are determined to be any of the following:

- Not approved by the *U.S. Food and Drug Administration (FDA)* to be lawfully marketed for the proposed use and not identified in the *American Hospital Formulary Service* or the *United States Pharmacopoeia Dispensing Information* as appropriate for the proposed use.
- Subject to review and approval by any institutional review board for the proposed use. (Devices which are *FDA* approved under the *Humanitarian Use Device* exemption are not considered to be Experimental or Investigational.)
- The subject of an ongoing clinical trial that meets the definition of a Phase I, II or III clinical trial set forth in the *FDA* regulations, regardless of whether the trial is actually subject to *FDA* oversight.

**Exceptions:**

- Clinical trials for which Benefits are available as described under *Clinical Trials* in *Section 1: Covered Health Services*.
- If you are not a participant in a qualifying clinical trial, as described under *Clinical Trials in Section 1: Covered Health Services*, and have a Sickness or condition that is likely to cause death within one year of the request for treatment we may, in our discretion, consider an otherwise Experimental or Investigational Service to be a Covered Health Service for that Sickness or condition. Prior to such a consideration, we must first establish that there is sufficient evidence to conclude that, albeit unproven, the service has significant potential as an effective treatment for that Sickness or condition.

**Clinical Trials/Studies Involving Investigational New Drugs:** (National Institutes of Health [http://clinicaltrials.gov/ct2/about-studies/glossary#P](http://clinicaltrials.gov/ct2/about-studies/glossary#P))

- **Phase 0:** Exploratory study involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies).
- **Phase 1:** Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.
- **Phase 2:** Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.
- **Phase 3:** Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.
- **Phase 4:** Studies occurring after the US Food and Drug Administration (FDA) has approved a drug for marketing. These include post-market requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.

**Covered Health Service(s):** Those health services, including services, supplies, or Pharmaceutical Products, which we determine to be all of the following:

- Medically Necessary.
- Described as a Covered Health Service in this policy under *Section 1: Covered Health Services* and in the members Schedule of Benefits.
- Not otherwise excluded in this policy under *Section 2: Exclusions and Limitations*.
Connecticut Product Specific Definitions

- **Approved Clinical Trial:**
  - Phase I, Phase II, Phase III, or Phase IV clinical trial,
  - Being conducted in relation to the prevention, detection or treatment for Cancer or other disabling or life threatening disease or condition, and
  - That meets the requirements under Section II below.

  For purposes of this benefit, a “life-threatening disease or condition” is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

- **Experimental or Investigational Service(s):** Medical, surgical, diagnostic, psychiatric, mental health, substance use disorders or other health care services, technologies, supplies, treatments, procedures, drug therapies, medications or devices that, at the time we make a determination regarding coverage in a particular case, are determined to be any of the following:

  Not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use and not identified in the American Hospital Formulary Service or the United States Pharmacopeia Dispensing Information as appropriate for the proposed use, except that coverage is provided for a drug which has been prescribed for treatment of certain types of cancer for which the drug has not been approved by the FDA, provided the drug is recognized for the treatment of the specific type of cancer for which the drug has been prescribed in one of the following three established reference compendia: (1) The U.S. Pharmacopeia Drug Information Guide for the Health Care Professional (USPDI); (2) The American Medical Association's Drug Evaluations (AMADE); or (3) The American Society of Hospital's Pharmacist's American Hospital Formulary Service Drug Information (AHES-DI). However, there is no coverage for any drug which the FDA has determined to be contraindicated for the specific cancer for which the drug has been prescribed.

  - Subject to review and approval by any institutional review board for the proposed use. (Devices which are FDA approved under the Humanitarian Use Device exemption are not considered to be Experimental or Investigational.)
  - The subject of an ongoing clinical trial that meets the definition of a Phase I, II or III clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight, except that Benefits for a procedure, treatment or the use of any drug will not be denied as experimental if such procedure, treatment or drug, for the illness of condition being treated, or for the diagnosis for which it is being prescribed, has successfully completed a Phase 3 clinical trial.

**Exceptions:**

- Clinical trials for which Benefits are available as described under Clinical Trials in Section 1: Covered Health Services.
- If you are not a participant in a qualifying clinical trial, as described under Clinical Trials in Section 1: Covered Health Services, and have a Sickness or condition that is likely to cause death within one year of the request for treatment we may, in our discretion, consider an otherwise Experimental or Investigational Service to be a Covered Health Service for that Sickness or condition. Prior to such a consideration, we must first establish that there is sufficient evidence to conclude that, albeit unproven, the service has significant potential as an effective treatment for that Sickness or condition.

**APPLICABLE CODES**

The Current Procedural Terminology (CPT®) codes and/or Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or
non-covered health service. Coverage is determined by the member specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

### Applicable Modifiers

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
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<tbody>
<tr>
<td>Q0</td>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study.</td>
</tr>
<tr>
<td>Q1</td>
<td>Routine clinical service provided in a clinical research study that is in an approved clinical research study.</td>
</tr>
</tbody>
</table>

### Applicable HCPCS Codes – Reimbursable (when above criteria is met)

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0276</td>
<td>Blinded procedure for lumbar stenosis. Percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial</td>
</tr>
<tr>
<td>G0293</td>
<td>Non-covered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a medicare qualifying clinical trial, per day</td>
</tr>
<tr>
<td>G0294</td>
<td>Non-covered procedure(s) using either no anesthesia or local anesthesia only, in a medicare qualifying clinical trial, per day</td>
</tr>
<tr>
<td>S9988</td>
<td>Services provided as part of a phase i clinical trial</td>
</tr>
<tr>
<td>S9990</td>
<td>Services provided as part of a phase ii clinical trial</td>
</tr>
<tr>
<td>S9991</td>
<td>Services provided as part of a phase iii clinical trial</td>
</tr>
</tbody>
</table>

### Applicable HCPCS Codes – Non-Reimbursable

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G9057</td>
<td>Oncology; practice guidelines; management differs from guidelines as a result of patient enrollment in an institutional review board approved clinical trial (for use in a medicare-approved demonstration project)</td>
</tr>
<tr>
<td>S9992</td>
<td>Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion</td>
</tr>
<tr>
<td>S9994</td>
<td>Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion</td>
</tr>
<tr>
<td>S9996</td>
<td>Meals for clinical trial participant and one caregiver/companion</td>
</tr>
</tbody>
</table>

### ICD-9 Diagnosis Codes (Discontinued 10/01/15)

The following list of codes is provided for reference purposes only. Effective October 1, 2015, the Centers for Medicare & Medicaid Services (CMS) implemented ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures), replacing the ICD-9-CM diagnosis and procedure code sets. **ICD-9 codes will not be accepted for services provided on or after October 1, 2015.**

<table>
<thead>
<tr>
<th>ICD-9 Diagnosis Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>V70.7</td>
<td>Examination of participant in clinical trial</td>
</tr>
</tbody>
</table>

### ICD-10 Codes (Effective 10/01/15)

ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures) must be used to report services provided on or after October 1, 2015. **ICD-10 codes will not be accepted for services provided prior to October 1, 2015.**
ICD-10 Diagnosis Code (Effective 10/01/2015) | Description
---|---
Z00.6 | Encounter for examination for normal comparison and control in clinical research program.

**DESCRIPTION OF SERVICES**

Clinical trials are the means by which new therapies and treatments for disease are produced in the medical sciences. These experimental and/or investigational therapies are tested in humans during clinical trials. These trials are carefully designed investigations of the effect of a drug, a medical treatment or a device on a group of patients. Clinical trials follow up on basic research and involve the use of scientific methods in specifically designed studies through a series of graduated steps or phases. All phases involve the use of human subjects and each phase has specific goals.

**REFERENCES**

The foregoing Oxford policy has been adapted, in part, from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee [CDG.006.04]

2. Connecticut Senate Bill 325.

**POLICY HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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| 10/01/2015| Updated lists of applicable codes; added language to indicate ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures) must be used to report services provided on or after 10/01/2015:  
  - ICD-9 codes will not be accepted for services provided on or after 10/01/2015  
  - ICD-10 codes will not be accepted for services provided prior to 10/01/2015  
  - Archived previous policy version ADMINISTRATIVE 152.13 T2 |