Investigator Documentation of MEDICAL NECESSITY
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Agenda

- Monitor physicians who are involved in research
- Auditing and monitoring for process improvement
- Leverage expertise
MEDICAL NECESSITY

Medical necessity is the reason a given service is covered and payable by Medicare. If the service is deemed “not medically necessary” for any reason, then Medicare will not pay the provider.

MEDICAL NECESSITY Documentation is part of the clinical trial billing process
**THE PROCESSES**

**COVERAGE ANALYSIS, billable or not billable**

*The Investigator must APPROVE the Coverage Analysis* to provide assurance that the determinations as to who should pay for the protocol-required procedures have been confirmed.

**Myth**

Medicare will pay for any item/service designated as "Standard of Care".

**Reality**

"Standard of Care" is not a Medicare concept. Payments for clinical study related items/services are issued by Medicare in accordance with coverage rules and defined terms set by statutes, regulations and local Medicare contractors. To determine which items/services are billable to Medicare, **review the coverage analysis**.
COVERAGE ANALYSIS, billable or not billable

The Investigator must refer to the approved Coverage Analysis to confirm who should pay for the protocol-required procedure.

Medical documentation should verify and validate routine care because it is utilized to decide who should pay during clinical trial participation.

The Coverage Analysis answers the following:

1. Is the research study a qualifying clinical trial? If not, the protocol required item is not billable.
2. Is the protocol required item for research purposes only? It is not billable.
3. Is the protocol required item considered a ‘routine cost’? If so, is it billable with the appropriate codes and modifiers or not billable because it is paid for by the sponsor or promised free to the participant?

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COVERAGE ANALYSIS

Review it, modify it per site specifications, indicate approval with a dated signature

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## RESEARCH STUDY ABC

## SCHEDULE OF ASSESSMENTS

### Visit Schedule

<table>
<thead>
<tr>
<th>Comments</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>EOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical examination, may include vital signs, height and weight</td>
<td>D1</td>
<td>D1</td>
<td>D1</td>
<td>D1</td>
<td>D3</td>
</tr>
<tr>
<td>ECG, 12-lead (triplicate)</td>
<td>93000, 93005, 93010</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Venipuncture, local lab</td>
<td>36415</td>
<td>Q1</td>
<td>Q1</td>
<td>Q1</td>
<td>Q1</td>
</tr>
<tr>
<td>CBC with DW</td>
<td>85035</td>
<td>Q1</td>
<td>Q1</td>
<td>Q1</td>
<td>Q1</td>
</tr>
</tbody>
</table>

### PROTOCOL RELATED ITEMS AND SERVICES

- Physical examination, may include vital signs, height and weight: NCD 310.1 allows for the coverage of routine cost of conventional care. An E&M at these timepoints is reasonable and necessary to monitor the subject’s condition. Medical records must document level of E&M and medical necessity.


- Venipuncture, local lab: NCD 310.1 allows for the coverage of routine cost of conventional care. Performed for acquisition of conventional care blood sample. Medical records must document medical necessity.

- CBC with DW: NCD 310.1 allows for the coverage of routine cost of managing toxicities. Drug ABC is known to cause hematologic toxicities including lymphopenia and anemia (Lexicomp). Testing appears performed to establish baseline and monitor potential toxicities of study drug during and at end of therapy. NCD 190.15 generally supports use. Medical records must document medical necessity.

### COVERAGE ANALYSIS

**Coverage Determinations, Local and National**

Medicare determines medical necessity in the electronic claims processing world with claim edits.

- When coverage is restricted by an NCD or LCD, claims processing edits will deny an item or service because the diagnosis code is not listed in the “approved” or “covered” list of codes.

- These coverage determinations should be noted in the line item “Comments” section of the Coverage Analysis.
INVESTIGATOR
Coverage Analysis and Medical Documentation

**Coverage Analysis** approval prior to study start up followed by clear and complete **Medical Documentation** throughout the study can help with protocol adherence, can help avert provider denials and can help avoid:

- Billing for items or services not supported by:
  - Documentation of study participation, as required
  - Adequate documentation of medical necessity for the item or service
  - A proper, signed order
- Billing without proper codes, modifiers or NCT #
- Waiving/paying/reimbursing subject co-pay or deductible obligations
- Billing for services that were not rendered
- Billing for services that are already paid by the sponsor or promised free in the informed consent
- Billing for services that are for research-purposes only or are part of a non-qualifying clinical trial
- Billing Medicare for device trials without CMS centralized review and approval
- Billing Medicare Advantage Plans (Part C) when claims should be directed to the Medicare Administrative Contractor

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If Billing to CMS – and Study Is Qualifying...

**Compliant billing requirements**

1. **Modifier Q1**
   - Medically necessary routine patient care
   - Treatment of complications arising from a Medicare beneficiary's participation in a Medicare-covered clinical trial.

2. **Modifier Q0**
   - Items and services that are being investigated as an objective within the study.

3. **Diagnosis code Z00.6**
   - Appended to every bill that includes a Q1 or Q0, in a secondary diagnosis-code position for all participants being treated for a diagnosed disorder; if the participant is a healthy volunteer enrolled in a control group of a diagnostic study, the Z00.6 must be placed in the primary diagnosis-code position

4. **Condition Code 30**
   - Appended to every hospital provider bill (typically, Medicare Part A, if participant is Medicare-insured) whenever a Q1 or Q0 and Z00.6 is required, note that Condition Code 30 is not required for professional billing (e.g. Medicare Part B billing)

5. **National Clinical Trial Number (NCT)**
   - When there is a Z00.6 and a condition code 30
   - For items and services provided in clinical trials or under CED

Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed.
MEDICARE  Research Codes and Modifiers

1. Hospital Inpatient Claims  
   Research modifiers not currently required

2. Hospital Outpatient Claims  
   Research modifiers required

3. Physician Claims  
   Research modifiers required

4. All Government Claims  
   Clinical Trial Number, 8 digit number

5. All Claims  
   Z00.6 diagnosis code as secondary diagnosis  
   ("examination of participant in clinical trial")

Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed.

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Before any Study Visit Occurs

A variety of information must be coordinated in order to manage compliance throughout systems and communicate to all stakeholders.

- The Principal Investigator (PI) should review the Coverage Analysis (CA) for accuracy and show approval with a dated signature.
- The CA should be shared as appropriate; it will communicate the determinations to the coordinator, billing department and other stakeholders.
- Processes must be in place for electronic medical record and billing systems to identify patients as research subjects with an ability to segregate and track. These processes must be communicated to appropriate departments.
- Prior to the study start up, each appropriate ancillary department must be aware of the method to identify study participants and the study requirements.

Why does it matter?

VISITS in which research events occur

Documentation of Study Participation

The billing provider must include in the beneficiary’s medical record the following information:

- Trial name,
- Sponsor, and
- Sponsor-assigned protocol number.

This information does not need to be submitted with the claim but must be provided if requested for medical review.

Medicare Claims Processing Manual, Chapter 32, §69.3 - Medical Records Documentation Requirements
VISITS in which research events occur

• **Mixed visit** - Documentation that occurs on the day of a research required visit that also includes conventional care must include a primary diagnosis other than participation in clinical research and supporting language. Medical documentation should not include language that indicates that the purpose of the visit is to screen or follow the patient for a research study.

• **Research only visit** - If the visit would not be performed per conventional care, no standard billing can occur. Clearly document that the visit is for research purposes only.

VISITS in which research events occur

**PHYSICIAN’S ORDERS**

• Physician’s orders establish medical necessity for the services provided which in turn supports the payment.

• It is the ordering provider’s responsibility to order services that are reasonable and necessary according to the patient’s clinical condition or signs and symptoms. Provider’s documentation in the medical record should support the basis of all orders requested.
VISITS in which research events occur

Study Visit Occurs

• Is the patient registered as a research subject?
• Is the person conducting the visit aware that research related events will occur?
• Is it clearly understood which procedures are protocol required and who is to pay? Are the Coverage Analysis determinations available for review?
• Does the medical record document study participation?
• Does the medical record clearly indicate that the visit and ordered procedures are medically necessary (and billable) or that one or more items is for research purposes only (sponsor to pay)?
• Does the medical record match the billing and coding of events?
• Is Z00.6 used as a secondary or later diagnosis code?

Why does it matter?

MEDICAL NECESSITY, Documentation

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CPT codes</th>
<th>Screen / Baseline</th>
<th>1 Month</th>
<th>EOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-lead ECG</td>
<td>93005 &amp; 93010 OR 93000</td>
<td>Q1</td>
<td>S</td>
<td>Q1</td>
</tr>
<tr>
<td>CXR</td>
<td>71020, 71020-26</td>
<td>Q1</td>
<td>Q1</td>
<td>S</td>
</tr>
<tr>
<td>CBC with Diff</td>
<td>85025</td>
<td>Q1</td>
<td>Q1</td>
<td>Q1</td>
</tr>
</tbody>
</table>

What is the “REASON FOR EXAM”?

DO NOT ENTER
- “Baseline for PROSTATE Study” as the reason for exam in the order
- ICD-10 Code 200.6 primary (and only code)

DO ENTER the clinically indicated reason for exam
- Encounter for antineoplastic chemotherapy Z51.11
- Carcinoma in situ of prostate D07.5
- Participant in a clinical trial Z00.6
HAZARD AHEAD!
DEXA SCANS IN PROSTATE CANCER WITH ADT
(BONE MASS MEASUREMENT)

 HAZARD AHEAD!
DEXA SCANS IN PROSTATE CANCER WITH ADT
(BONE MASS MEASUREMENT)

Drug, long-term (current) use of gonadotropin-releasing hormone agonist:
Z79.818

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Modifier</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>V49.81</td>
<td>Asymptomatic postmenopausal status (age-related) (natural)</td>
<td>278.0</td>
<td>Asymptomatic menopausal state</td>
</tr>
<tr>
<td>V56.65</td>
<td>Long-term (current) use of steroids</td>
<td>279.51</td>
<td>Long term (current) use of inhaled steroids</td>
</tr>
<tr>
<td>V56.65</td>
<td>Long-term (current) use of steroids</td>
<td>279.52</td>
<td>Long term (current) use of systemic steroids</td>
</tr>
<tr>
<td>V56.68</td>
<td>Long-term (current) use of bisphosphonates</td>
<td>279.83</td>
<td>Long term (current) use of bisphosphonates</td>
</tr>
<tr>
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<tr>
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<td>Long term (current) use of inhaled steroids</td>
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<tr>
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<td>Long-term (current) use of bisphosphonates</td>
<td>279.83</td>
<td>Long term (current) use of bisphosphonates</td>
</tr>
<tr>
<td>V13.51</td>
<td>Personal history of pathologic fracture</td>
<td>287.310</td>
<td>Personal history of (healed) osteoporosis fracture</td>
</tr>
</tbody>
</table>


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HAZARD AHEAD!
DEXA SCANS
(BONE MASS MEASUREMENT)

Medicare Benefit Policy Manual Chapter 15, 80.5.6

80.5.6 - Beneficiaries Who May Be Covered
(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

To be covered, a beneficiary must meet at least one of the five conditions listed below:

1. A woman who has been determined by the physician or qualified nonphysician practitioner treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.
   
   NOTE: Since not every woman who has been prescribed estrogen replacement therapy (ERT) may be receiving an “adequate” dose of the therapy, the fact that a woman is receiving ERT should not preclude her treating physician or other qualified treating nonphysician practitioner from ordering a bone mass measurement for her. If a BMM is ordered for a woman following a careful evaluation of her medical need, however, it is expected that the ordering treating physician (or other qualified treating nonphysician practitioner) will document in her medical record why he or she believes that the woman is estrogen-deficient and at clinical risk for osteoporosis.

2. An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

3. An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average of 5.0 mg of prednisone, or greater, per day, for more than 3 months.

4. An individual with primary hyperparathyroidism.

5. An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

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### HELPFUL TOOLS TO KEEP YOU ON TRACK

#### Before Chemo | During Chemo | After Tx Complete
---|---|---
201.818  
- Encounter for other preprocedural examination  
- Encounter for examinations prior to antineoplastic chemotherapy  | 279.899  
Other long term (current) drug therapy  | 208  
Encounter for f/u exam after completed treatment for malignant neoplasm  

Additional codes should be used to describe the cancer that they have.

- Z51.0  
Encounter for antineoplastic radiation therapy  
- Z51.11  
Encounter for antineoplastic chemo  
- Z51.12  
Encounter for antineoplastic immunotherapy  

- Use additional code to identify any acquired absence of organs (Z90)  
- Use additional code to identify the personal history of malignant neoplasm (Z85)

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*This is an informal guide and does not in any way describe coverage. Code by what is documented in the medical record.*

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### HELPFUL TOOLS TO KEEP YOU ON TRACK

#### Pre-Operative for CV Procedure | Post CV Procedure | Monitoring Drug (Example- Coumadin)
---|---|---
201.810: Encounter for preprocedural cardiovascular examination  
201.811: Encounter for preprocedural respiratory examination  
201.812: Encounter for preprocedural lab examination  
201.818: Encounter for other preprocedural examination  
Include the condition requiring the procedure: (Example: Aortic Stenosis: I55.2 Non-rheumatic aortic (valve) stenosis with insufficiency)  | 209: Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm  
- Code to identify any applicable history of disease code (286.-, 287.-)  
Example: Z86.79 Personal history of other diseases of the circulatory system  
Example: Z95.2 Presence of prosthetic heart valve  | 251.81: Encounter for therapeutic drug level monitoring  
279.01: Long term (current) use of anticoagulants

*This is an informal guide and does not in any way describe coverage. Code by what is documented in the medical record.*

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# DOCUMENTATION EXAMPLES

## REASON FOR EXAM

<table>
<thead>
<tr>
<th>Good</th>
<th>Insufficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cough, fever</td>
<td>• r/o pneumonia</td>
</tr>
<tr>
<td>(ICD-10: R05, R50.81)</td>
<td>(no dx code)</td>
</tr>
<tr>
<td>• New onset SOB and chest pain on exertion; s/p 2 cycles doxorubicin for Hodgkin lymphoma (R06.02, R07.89, C81.90, Z79.899)</td>
<td>• r/o cardio toxicity on study drug (Z79.899)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Good</th>
<th>Insufficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Newly diagnosed primary CNS lymphoma. He has a dominant mass in the right thalamus/hypothalamus with 2 punctate satellite lesions. Need Chest/abdomen CT to determine whether there is a metastatic source.</td>
<td>• Brain tumor</td>
</tr>
</tbody>
</table>
### DOCUMENTATION EXAMPLES

<table>
<thead>
<tr>
<th>Good</th>
<th>Insufficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Anemia due to chemo regimen (D64.81)</td>
<td>• Anemia (D64.9 )</td>
</tr>
<tr>
<td>• 6-month post chemo surveillance for progression; breast cancer (Z08, Z85.3)</td>
<td>• Breast cancer (not clear as to whether this is a new dx or where the patient is on the treatment timeline.)</td>
</tr>
</tbody>
</table>

### NURSING NOTE:

Called Mrs. Smith and told her that, in order to be in the study, her hemoglobin needs to be above 10 and her hgb is 8.6. Dr. Jones says she will need a transfusion to get into the study. Patient agrees. Scheduled for a transfusion tomorrow.
DIAGNOSIS CODE Z01.818

Encounter for other pre-procedural examination

Applicable To:
- Encounter for pre-procedural examination NOS
- Encounter for examinations prior to antineoplastic chemotherapy

Examination (for) (following) (general) (of) (routine) Z00.00
- pre-chemotherapy (antineoplastic) Z01.818
- prior to chemotherapy (antineoplastic) Z01.818
- pre-procedural (pre-operative); specified NEC Z01.818
- medical (adult) (for) (of) Z00.00; pre-procedural specified NEC Z01.818

It’s All About the $$$$
Impact on Revenue Integrity

Denials not worked
Appeals – who understands the process for a trial
Pre-authorizations not performed when necessary
Write offs unknown to research team
Stop the bleed…..

Claim Denials

Reminders, this may cause a denial

- Inadequate process for identifying research studies and study participants
- Inadequate medical documentation or documentation that negates therapeutic intent
- Test ordered using an ICD-10 code with an LCD that prohibits payment
- Un-matching hospital and professional billing claims
- Government codes used on commercial payer claims
- Lack of NCT# when there is a Z00.6 and a condition code 30
- Z00.6 not in the secondary position, it is removed from claim
- Medicare Contractors march to the beat of a different drummer in each region, Sponsor must be willing to work with sites according to region to avoid denials
Leverage Expertise

Research Site Impact

- More scrutiny with more responsibilities
- Time intensive procedures
- Back end bill hold and review
- Auditing function necessary to ensure compliance

Understand Payer Issues When Monitoring Reimbursements

- Covered Medical Benefits
- Covered Drug Benefits
- Network Requirements
- Authorizations Requirements
- Payer Medical Management Policies
- Denials & Appeals
- Improve communication with payers to facilitate authorization and reimbursement
- Facilitate the appeals process if the payers deny coverage
Certificate Of Coverage and Evidence Of Coverage

A document given to an insured that describes the benefits, limitations and exclusions of coverage provided by an insurance company.

- **Benefits** - The health care items or services covered under a health insurance plan. Covered benefits and excluded services are defined in the health insurance plan’s coverage documents.

- **Medical Necessity** - Health care services or supplies needed to prevent, diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.

How Do You Train Your Physicians?

- Help them understand the coverage analysis process
- Ensure they document to medical necessity
- Be consistent – establish business rules
- When in doubt, don’t bill it and have sponsor cover the costs!
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