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?

<table>
<thead>
<tr>
<th>Procedure Description</th>
<th>M</th>
<th>Q0</th>
<th>Q1</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical examination, may include vital signs, height and weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Venipuncture, local lab</td>
<td>36415</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>CBC with diff</td>
<td>85025</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG, 12-lead (triplicate)</td>
<td>93000, 93005</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy Test (WOCBP)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT, Chest</td>
<td></td>
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</tbody>
</table>

Medical records must document medical necessity for acquisition of conventional care blood sample. NCD 310.1 allows for the coverage of routine cost of managing toxicities. Medical records must document medical necessity. Per OPDIVO 3/2015 package insert, drug can cause fetal harm when administered to a pregnant woman. NCD 190.15 generally supports use of therapy. Medical records must document medical necessity. Testing appears performed to establish baseline and monitor potential toxicities of study drug during and at end of therapy. NCD 310.1 allows for the coverage of routine cost of managing toxicities. Medical records must document medical necessity. Drug ABC is known to cause Hematologic toxicities including lymphocytopenia and anemia (Lexicomp). NCCN NSCLC Guidelines (v.4.2016) support Chest imaging at workup (NSCLC-1). NCD 310.1 allows for routine cost to monitor disease and manage progression of disease. Medical records must document medical necessity. Drug ABC is known to cause Hematologic toxicities including lymphocytopenia and anemia (Lexicomp). NCD 310.1 allows for the coverage of routine cost of managing toxicities. Medical records must document medical necessity. Drug ABC is known to cause Hematologic toxicities including lymphocytopenia and anemia (Lexicomp).
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/measuring 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

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

Compliant billing requirements

1. Modifier Q1
   - Medically necessary routine patient care
   - Medicare-covered 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 or in a cohort of a diagnostic group, if the participant is a healthy volunteer enrolled in a control group of a diagnostic study.

4. Condition Code 30
   - Appended to every hospital provider bill, typically Medicare Part A, if participant is Medicare insured and whenever a Q1 or Q0 is required.

5. National Clinical Trial Number (NCT)
   - 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.

**CODES & MODIFIERS**

- Condition Code 32 in Box 19
- Value Code 52 and 6-digit NCT identifier number in Box 36
- Modifier Q1 or Q2 in Box 44
- K00 code 208.6 in the secondary position in Box 48
- Skil code 208.6 in the secondary position in Box 21

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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 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 the 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, ¶61.3: Medical Records Documentation Requirements
### VISITS in which research events occur

**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.

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### 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.

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### 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>Screens / Baseline</th>
<th>1 Month</th>
<th>60s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinalysis</td>
<td>85209, 85280-26</td>
<td>00</td>
<td>00</td>
<td>00</td>
</tr>
<tr>
<td>CBC</td>
<td>85005, 85020-26</td>
<td>00</td>
<td>00</td>
<td>00</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 Z00.6 primary (and only code)

**DO ENTER** the clinically indicated reason for exam
- Encounter for antineoplastic chemotherapy 251.11
- Carcinoma in situ of prostate 807.5
- Participant in a clinical trial 293.6

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>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77080</td>
<td>DXA Scan (Bone Mass Measurement)</td>
</tr>
</tbody>
</table>

HAZARD AHEAD!
DEXA SCANS
(BONE MASS MEASUREMENT)

Medicare Benefit Policy Manual Chapter 15, 80.5.6

80.5.6 - Beneficiaries Who May Be Covered
(Denials: 01/2007, Effective: 04/01/07, Implementation: 07/02/07)

To be covered, a beneficiary must meet at least one of the two conditions listed below:
1. A woman who has been determined by the physician or a gynecologic oncologist to be estrogen deficient and/or is at clinical risk for osteoporosis, based on her medical history and other findings.
2. An individual with vertebral abnormalities as determined by a way to be indicative of changes by age, estrogen, or other factors.

- An individual whose bone density is indicative of osteopenia, osteoporosis, or vertebral fractures.
- An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.
- An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.
- An individual with a personal history of pathologic fracture.

NOTE: Since not every woman who has been prescribed estrogen replacement therapy (ERT) may be receiving an “adequate” dose, the physician or gynecologic oncologist must set the dose to be adequate for the woman's needs. The physician or gynecologic oncologist must also note in the medical record why he or she believes that the woman is estrogen-deficient and at clinical risk for osteoporosis.

In the event of a fracture, the doctor must document evidence of a clinical fracture, such as a radiograph showing bone density measurements. The doctor must also note in the chart that the woman is estrogen-deficient and at clinical risk for osteoporosis.

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HELPFUL TOOLS TO KEEP YOU ON TRACK

<table>
<thead>
<tr>
<th>Before Chemo</th>
<th>During Chemo</th>
<th>After Tx Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>983.818</td>
<td>983.819</td>
<td>Z01.818</td>
</tr>
<tr>
<td>+ Encounter for other preprocedural examination</td>
<td>+ Encounter for examinations prior to antineoplastic chemotherapy</td>
<td>+ Encounter for f/u exam after completed treatment for malignant neoplasm</td>
</tr>
</tbody>
</table>

Additional codes should be used to describe the cancers they have.

- 251.0 Encounter for antineoplastic radiation therapy
- 251.1 Encounter for antineoplastic therapy
- 251.12 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 (Z86)

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

HELPFUL TOOLS TO KEEP YOU ON TRACK

<table>
<thead>
<tr>
<th>Pre-Operative for CV Procedure</th>
<th>Post CV Procedure</th>
<th>Monitoring Drug (Example: Coumadin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>995.818 Encounter for preoperative cardiovascular examination</td>
<td>996.818 Encounter for follow-up examination after completed treatment for malignant neoplasm</td>
<td>990.818 Encounter for therapeutic drug level monitoring</td>
</tr>
<tr>
<td>Pre-Operative for preoperative respiratory examination</td>
<td>+ Use additional code to identify any acquired absence of organs (Z90)</td>
<td>276.9 Long term (current) use of anticoagulants</td>
</tr>
<tr>
<td>+ Use additional code to identify any applicable history of disease code (Z86-Z87)</td>
<td>Example: Z86.79 Personal history of other diseases of the circulatory system</td>
<td></td>
</tr>
<tr>
<td>Example: Z95.2 Presence of prosthetic heart valve</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

DOCUMENTATION EXAMPLES

REASON FOR EXAM

<table>
<thead>
<tr>
<th>Good</th>
<th>Insufficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cough, fever (ICD-10: R05, R06.1)</td>
<td>• No pneumonia (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>• 1/o cardio toxicity on study drug (279.899)</td>
</tr>
</tbody>
</table>
DOCUMENTATION EXAMPLES

REASON FOR EXAM

<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 (D08, 285.3)</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>

DOCUMENTATION EXAMPLES

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) (if) 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!

Contact Information

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