Investigator Documentation of **MEDICAL NECESSITY**

Kelly Willenberg, MBA, BSN, CHC, CHRC

Kelly Willenberg, DBA, RN, CHC, CHRC, CCRP

KELLY WILLENBERG
& ASSOCIATES
RESEARCH. COMPLIANCE. CONSULTING.

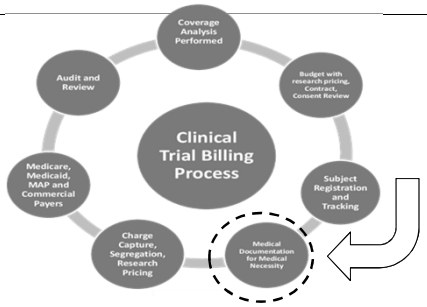
Agenda

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

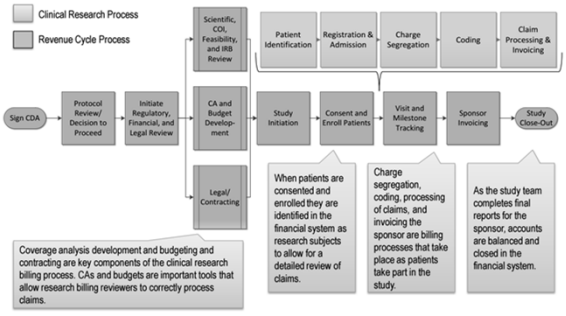
MEDICAL NECESSITY

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?

COVERAGE ANALYSIS

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

RESEARCH STUDY ABC								
SCHEDULE OF ASSESSMENTS		Visit	Visit Schedule:					Comments
			V1	V2	V3	V4	EOS	
PROTOCOL RELATED ITEMS AND SERVICES								
Physical examination, may include vital signs, height and weight	99201-99205, 99211-99215, 99221-99223, 99331-99333, 99241-99244, G0463		Q1	Q1	Q1	Q1	Q1	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.
ECG, 12-lead (triplicate)	93000, 93005, 93010		S		S		S	Per study budget, sponsor to pay. Protocol p 69, A triplicate 12-Lead ECG is performed.
Venipuncture, local lab	36415		S	S	S	S	S	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 diff	85025		S		S		S	NCD 310.1 allows for the coverage of routine cost of managing toxicities. Drug ABC is known to cause Hematologic toxicities including lymphocytopenia 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.
Pregnancy Test (WOCBP)	84702, 84703 (serum) 81025 (urine)							Pregnancy testing prior to administration of chemotherapy is the institutional standard. While Medicare may not reimburse for pregnancy testing under NCD 190.27 some other payers will reimburse. Per OPDIVO 3/2015 package insert, drug can cause fetal harm when administered to a pregnant woman. Medical records must document medical necessity.
CT, Chest	71250, 71260, 71270 Q9965, Q9966, Q9967		Q1					NCD 310.1 allows for routine cost to monitor disease and manage progression of disease. NCCN NSLCL Guidelines (v.4.2016) support Chest imaging at workup (NSCL-1) CTs are generally supported by NCD 220.1 Medical records must document medical necessity
Administration of study drug, IV	96413, 96415, 96365, 96367 96360, 96409, 96411, 96374-96376, 96360, 96361, 36591, 36592, J7030, J7040, J7050, 94760, 94761, J1642		Q1	Q1	Q1	Q1		NCD 310.1 allows for routine cost of Items or services required solely for the provision of the investigational item or service.
Study Drug: EC1456	IND # 119525		S	S	S	S		Per study budget and ICF, sponsor to pay.
S = Sponsor or Other Funding Source is responsible for coverage and payment of this item or service which generates a claim								
Q1 = Routine clinical service provided in a clinical research study that is in an approved clinical research study; Billable item or service to third party payer								
Q0 = Item under investigation in the trial/study when billed to a third party payer								
M = Billable to Medicare under standard Medicare Rules (conventional care)								
Signature, Principal Investigator		Date						

RESEARCH STUDY ABC							
SCHEDULE OF ASSESSMENTS		Visit Schedule					Comments
		V1	V2	V3	V4	EOS	
PROTOCOL RELATED ITEMS AND SERVICES							
Physical examination, may include vital signs, height and weight	99201-99205, 99211-99215,G0463	Q1	Q1	Q1	Q1	Q1	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.
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CBC with diff	85025	Q1	Q1	Q1	Q1	Q1	NCD 310.1 allows for the coverage of routine cost of managing toxicities. Drug ABC is known to cause Hematologic toxicities including lymphocytopenia 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.
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M = Billable ... edicare under standard Medicare Rules (conventional care)							
Signature, Principal Investigator	Date						

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

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

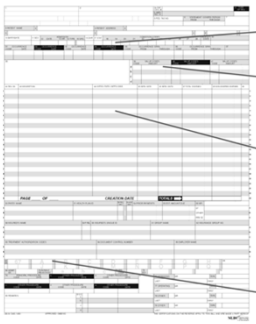
Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed.

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.

CODES & MODIFIERS



Condition Code '30' in Box 18

18	19	20	21	CONDITION CODES 22	23	24
30						

Value Code 'D4' and 8-digit NCT identifier number in Box 39

	CODE	VALUE AMOUNT
a	D4	12345678

Modifier Q1 or Q0 in Box 44

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE
1	300	LABORATORY	36415Q1
2	305	LAB/HEMATOLOGY	85025Q1
3	335	CHEMOTHERAP-IV	96413Q1
4	335	CHEMOTHERAP-IV	96415Q1
5	636	N46345039602	J9033Q1

36415 = Venipuncture
85025 = CBC
96413 = Chemotherapy Infusion, Up to 1 Hour
96415 = Chemotherapy Infusion, Each Additional Hour
J9033 = Bendamustine, 180 Mg (Drug)

ICD-10 code Z00.6 in the secondary position in Box 66

ABC	20410	Z00.6

204.10 = Chronic lymphoid leukemia

CODES & MODIFIERS

8-digit NCT identifier number in Box 19 with "CT" attached. Electronic version 837P does not require "CT"

19. RESERVED FOR LOCAL USE
CT12345678

ICD-10 code Z00.6 in the secondary position in Box 21

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY
1. L204 . 10
2. Z00 6

204.10 = Chronic lymphoid leukemia

Modifier Q1 or Q0 in Box 24.D

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
05	01	15	05	01	15			36415	Q1		1 2	30	00	1	
05	01	15	05	01	15			85025	Q1		1 2	50	00	1	

36415 = Venipuncture
85025 = CBC

CODES & MODIFIERS

Type of Study	Hospital Charges, Outpatient Claims CMS 1450 (UB-04)	Hospital Charges, Inpatient Claims CMS 1450 (UB-04)	Professional Charges, Outpatient Claims CMS-1500 (HCFA 1500)
Qualifying Clinical Trial **Medicare Clinical Trial Policy** • Instructions apply to conventional care, including treatment of complications • Billing provider must include in the medical record the following information: trial name, trial sponsor, and sponsor-assigned protocol number	• ICD-10 diagnosis code Z00.6 as the secondary diagnosis code for trial participation and comparison controls • ICD-10 diagnosis code Z00.6 as the primary diagnosis code for healthy controls only		
	• NCT#		• NCT# preceded by "CT"
	• Q0 Modifier- for each service identified as investigational		• Q0 Modifier- for each service identified as investigational
	• Q1 Modifier- for both participants and healthy controls- apply to each item or service identified as conventional care only on line items related to the clinical trial		• Q1 Modifier- for both participants and healthy controls- apply to each item or service identified as conventional care only on line items related to the clinical trial
	• IDE number assigned by the FDA • Reported in field 43 on a UB-04 • Value Code FD reported on claims when certain IDEs are provided free of charge as part of a device study • Condition Code 53 reported on outpatient claims for initial placement of a medical device when the device is furnished without cost and provided as part of a device study (effective July 1, 2015)	• IDE number assigned by the FDA • Reported in field 43 on a UB-04 • Value Code FD reported on claims when certain IDEs are provided free of charge as part of a device study	• IDE number assigned by the FDA • Reported in item 23 on a 1500 claim form • Value Code FD reported on claims when certain IDEs are provided free of charge as part of a device study • Condition Code 53 reported on outpatient claims for initial placement of a medical device when the device is furnished without cost and provided as part of a device study (effective July 1, 2015)
	• Revenue Code 0624 – FDA Investigational Devices • Reported on all outpatient claims even if the device is provided free of charge. If provided at no cost, must report a token charge (e.g. $1.00 or $00.01) in the non-covered charge field	• Revenue Code 0624 – FDA Investigational Devices • Reported only on inpatient claims if the device is not provided free of charge	
	• Condition Code 30 (qualifying clinical trial) reported at the claim level for both trial participants and healthy controls		
	• Include Z00.6, Condition Code 30 and NCT# regardless of whether all services on the claim are related to the clinical trial or not *Note: CMS will return claims as unable to process if the Z00.6 and NCT# are not on claim with the Condition Code 30*		

Before any Study Visit Occurs

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

- 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 stake holders.
- 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 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

Procedure	CPT codes	Screen / Baseline	1 Month	EOS
12-lead ECG	93005 & 93010 OR 93000	Q1	S	Q1
CXR	71020, 71020-26	Q1	Q1	S
CBC with Diff	85025	Q1	Q1	Q1

How would you document the one month visit?

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 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)

DXA Scan (bone mass measurement)	DXA NOT COVERED PER Medicare NCD 150.3 for bone mass measurement ABN required for Medicare patients.	CPT 77080 or 77081	Q0, (GA when Medicare ABN obt)

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

V49.81	Asymptomatic postmenopausal status (age-related) (natural)	Z78.0	Asymptomatic menopausal state
V58.65	Long-term (current) use of steroids	Z79.51	Long term (current) use of inhaled steroids
V58.65	Long-term (current) use of steroids	Z79.52	Long term (current) use of systemic steroids
V58.68	Long term (current) use of bisphosphonates	Z79.83	Long term (current) use of bisphosphonates
V49.81	Asymptomatic postmenopausal status (age-related) (natural)	Z78.0	Asymptomatic menopausal state
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V58.65	Long-term (current) use of steroids	Z79.52	Long term (current) use of systemic steroids
V58.68	Long term (current) use of bisphosphonates	Z79.83	Long term (current) use of bisphosphonates
V13.51	Personal history of pathologic fracture	Z87.310	Personal history of (healed) osteoporosis fracture

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R70BP.pdf

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.

HELPFUL TOOLS TO KEEP YOU ON TRACK

Before Chemo	During Chemo	After Tx Complete
Z01.818 • Encounter for other preprocedural examination • Encounter for examinations prior to antineoplastic chemotherapy	Z79.899 Other long term (current) drug therapy	Z08 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 hx of malignant neoplasm (Z85)

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

Pre-Operative for CV Procedure	Post CV Procedure	Monitoring Drug (Example- Coumadin)
Z01.810: Encounter for preprocedural cardiovascular examination Z01.811: Encounter for preprocedural respiratory examination Z01.812: Encounter for preprocedural lab examination Z01.818: Encounter for other pre-procedural examination Include the condition requiring the procedure: (Example: Aortic Stenosis, I35.2 Nonrheumatic aortic (valve) stenosis with insufficiency)	Z09 Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm → Code to identify any applicable history of disease code (Z86.-. Z87.-) Example: Z86.79 Personal history of other diseases of the circulatory system Example: Z95.2 Presence of prosthetic heart valve	Z51.81 Encounter for therapeutic drug level monitoring Z79.01 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.

DOCUMENTATION EXAMPLES

REASON FOR EXAM

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

DOCUMENTATION EXAMPLES

REASON FOR EXAM

Good	Insufficient
• 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.	• Brain tumor

DOCUMENTATION EXAMPLES

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

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) (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!

Contact Information

Kelly Willenberg
864-473-7209
www.kellywillenberg.com
kelly@kellywillenberg.com