BILLING FOR RESEARCH-RELATED SERVICES

PURPOSE:

The purpose of this policy is to establish guidelines for Creighton University Medical Center (CUMC) and Creighton University (CU) to ensure an accurate, timely, uniform, and efficient process for developing research budgets for patient services in study protocols and proper billing of sponsors and third party payers for such services.

POLICY:

CU and CUMC foster a research environment that promotes the responsible conduct of research and compliant research billing. CU and CUMC shall assist researchers in a timely and accurate manner to complete research budgets and to bill accurately sponsors or third party payers, as applicable, for services provided to subjects including, but not limited to, inpatient care, radiology, laboratory, diagnostic testing, and other related professional services.

SCOPE:

This policy applies to faculty, staff, students, and agents of CU and CUMC engaged in research. This policy applies to all health care items and services/procedures provided to a research subject, including professional services (e.g., physician evaluation, and physician interpretation of x-rays and diagnostic tests), laboratory tests, radiology procedures, pulmonary tests, neurology tests, cardiology tests, and/or any other test or procedure within the realm of the protocol.

PROCEDURE:

Department Contacts: See Department specific services requested through CUMC and contact personnel:

Tests Requested	Name of Contact	Phone/email
CUMC Contracts Administrator Hospital based procedures (technical fees only) both inpatient and outpatient	Lisa Ciurej	Lisa.Ciurej@tenethealth.com Phone: 449-4536
Outpatient Pharmacy Services	Craig Kessler	CraigKessler@creighton.edu Phone: 449-4560
Inpatient Pharmacy Services	Tammy Burns	Tammy.burns@tenethealth.com Phone: 449-4571 Fax: 449-5538
Radiology Services (professional fees only)	Sharon McGuire	Sharonm@creighton.edu Phone: 280-5205

Cardiology (professional fees only) (EKGs and Echocardiograms both technical and professional; other cardiology services—cath, nuclear)	Stephanie Maciejewski Cardiac Center Research Director	smacieje@cardiac.creighton.edu Phone: 280-4292
Pulmonary (professional fees only)	Margie Galkowski	Margie@creighton.edu Phone: 449-4487 Fax: 280-5256
Surgery	Laura Mueller	LauraMueller@creighton.edu Phone:402-280-4211 Alt Phone:402-980-0521
Pediatrics	David Barnum	DavidBarnum@creighton.edu Phone: 280-4585 Fax: 280-4855
Anesthesiology	Lisa Whelan	LisaWhelan@creighton.edu Phone:402-345-8828
Psychiatry	James Rodenbiker	jrodenbi@creighton.edu Phone: 345-8828 Fax: 345-8815
Clinical Laboratory and Anatomic Pathology (technical and professional)	Cindy Farrell or Marjel Whitmore	clfarr@creighton.edu Phone: 280-4133 marjelwhitmore@creighton.edu Phone: 280-4134 Fax: 280-5247
Family Medicine	Terry Fidler	tfidler@creighton.edu Phone: 280-4548 FAX: 280-5165
Medicine	Lori Kage	lorikage@creighton.edu Phone: 280-4553
Neurology (including EEG and EMG)	Lori Kage	lorikage@creighton.edu Phone: 280-4553
OB/GYN	Beth Lafave	bethlafave@creighton,edu Phone: 280- 4437 FAX: 280- 4843

Questions on the implementation of this policy may be directed to:

Research Operation Coordinator	Lorie Volkmer	Lorie.volkmer@tenethealth.com Phone: 449-4934
Hospital Compliance Officer	Tiffany Thompson	tiffany.thompson@tenethealth.com Phone: 449-5037
CU Compliance Director	Debra Fiala	debrafiala@creighton.edu Phone: 280-2107
Director, Clinical Research Office	David Cloutier	cloutier@creighton.edu Phone: 280-5660
Cardiac Center Research Director	Stephanie Maciejewski	smacieje@cardiac.creighton.edu Phone: 280-4292

Budget Preparation

Identifying the Payers for Proper Billing

Detailed information regarding determining coverage for health care items and services provided to a subject in a clinical trial is attached hereto as Appendix A. (Note: Questions regarding acronyms or other clinical research terminology may be found on the Creighton University Institutional Review Board website in the Investigators' Manual for Use of Human Subjects in Research at:
http://www2.creighton.edu/researchcompliance/irb/manual/index.php

Identifying items and services in the protocol as paid for by the Sponsor or routine items and services that may be paid for by Medicare or other government or private payers is an integral part of developing the research budget and negotiating payment from the Sponsor. Failure to properly identify protocol items and services prior to finalizing the study contract can result in insufficient funding of protocol services, which must then be absorbed by the Principal Investigator and/or his or her Department. Correctly identifying services that can be billed to the patient's insurer will allow the Principal Investigator to better negotiate payment under the Sponsor Contract to cover those items and services not billable to the patient's insurer.

In addition, billing for health care items and services received by research subjects enrolled in a clinical trial must be undertaken carefully, in accordance with state and federal law, payer requirements and the terms of the approved research protocol. Failure to comply with applicable billing rules and requirements in connection with billing for research related health care items or services can constitute a knowing submission of a false claim and subject CUMC, CU and the researcher to criminal fines and penalties. Researchers must properly identify items and services that may be billed to a subject's payer and communicate with each institution's billing staff to ensure research related care is appropriately billed.

It is the responsibility of the Principal Investigator or his/her staff to properly identify which research related health care items/services provided to subjects are to be billed to the researcher/grant and not to the subject or his/her insurer and to communicate this appropriately to CUMC and/or CU billing staff as set forth in this Policy. While research staff can assist in identifying health care items and services that are routine care (and therefore medically necessary) from those that are protocol-driven, the ultimate responsibility for identifying these items and services rests with the Principal Investigator.

The PI or his/her staff shall prepare a written list of ALL health care items/services under the research protocol, placing one or more of the following "payment" codes after each item/service:

- R – Items Billed to Research study: Protocol related items/services required by the study protocol that would not otherwise be provided to study enrollees outside the research study and/or the investigational item. (Reviewed for payment by the study; not billable to Medicare, Tricare or other payers).

- P – Items Billed to Study Participant: Routine items/services provided as part of a Medicare qualifying trial or Category A or B IDE accepted by the Medicare Administrative Contractor, but would be provided to the patient regardless of participation in the research (Billable to Medicare, and may be billable to other 3rd party payers. If not covered by other third party payers or the Sponsor, the items/services must be billed to the patient. Please note that even though some payers may cover these items, TriCare currently does not cover any of these items.)

- CL—Clinical laboratory tests that will be sent to a central laboratory facility. The Principal Investigator may identify these items/services in any manner, including use or the protocol grid or table of services. Alternatively, the form attached hereto as Appendix B may be used. The Principal Investigator or a member of his/her staff shall notify the Billing Manager of the Department prior to the commencement of the study and shall provide the Billing Manager with a copy of the list of health care items and services and the related payment information compiled above.

The CUMC Research Operations Coordinator will hold a standing meeting for study coordinators. The purpose of this standing meeting will be to review Appendix B or other Coverage Analysis tools, the prepared order sets, the cost sheet, and the IRB approved informed consent and to answer any questions that the study coordinator may have prior to the first patient presenting to CUMC for services. In addition to the Coverage Analysis tools, order sheets and cost sheet for a Protocol, the study coordinator will bring a redacted copy (i.e., dollar amounts for line items will be obscured) of the study budget to the meeting with the CUMC Research Operations Coordinator.

Completing the Cost Sheet

The Principal Investigator or his/her staff shall complete the cost sheet with procedures being requested by the protocol. A form of the cost sheet is attached hereto as Appendix C. The cost sheet will include all procedures being done locally for which research pricing is needed (i.e., procedures not billed to subject or subject's insurer). The Principal Investigator or his/her staff will send list to each Department that will be involved with the specific protocol testing. The professional component request can be sent simultaneously. When the Principal Investigator receives all of the different components from the Departments, this list should be combined into one sheet and the cumulative list should be sent to CUMC contracts administrator for insertion of technical portion of the procedures and insertion of the CPT codes. Rates charged for CUMC services will be established by agreement between CU and CUMC. Rates established on the cost sheet will be valid through the completion of the study if the study is commenced prior to December 31 of the year in which the cost sheet is completed. If the study is not commenced prior to December 31 of the year in which the cost sheet is completed, new price quotes must be obtained.

The section of the protocol that describes the specific procedure (include the portions of the protocol that contains the purpose, the procedure description and the specific handling specified by protocol) must be submitted to each Department. Departments prefer electronic submission, but if the protocol is not available in an electronic version, a paper version may be sent with the cost sheet. When completed, the cost sheet will serve as a basis for budget completion. Cost of the researcher's time should be included as per departmental standards.

Pharmacy Process for Investigational Studies: When Pharmacy receives the cost sheet, a protocol must be included. Pharmacy will review the protocol to estimate time required for training of staff, ordering/receiving drug shipments, documentation, preparation of drug, and storage requirements. From this, a start-up fee based on the attached charge listing will be determined (See Appendix D). A per subject fee based on type of drug product and preparation time required is also determined. The Principal Investigator may choose to pay one lump sum with the start-up fee and per subject fees rolled into one if number of subjects is known. Otherwise a start-up fee is charged and a per subject fee is determined and charged at the time of enrollment. The cost estimate is sent to the Principal Investigator as an attachment to the cost sheet.

Process after Decision to Conduct the Study (Approval of Budget Cost)

After the decision is made by the Principal Investigator to conduct the study; the completed cost sheet with all components, cost of all procedures that are paid for by the Sponsor (procedures to be billed to the patient/third party payer do not require the charges to be listed on the cost sheet) and CPT codes must be submitted to the CUMC Contracts Administrator. The CUMC Contracts Administrator will have the required CUMC officials sign the cost sheet. The final signature will be completed only after the study has been fully approved by the IRB. The Cost Sheet will be returned with required signatures within one week of final IRB approval. Required signatures for this form are the following:

1. Principal Investigator
2. CUMC Hospital Compliance Officer (Tiffany Thompson)
3. CUMC Hospital Vice President for Medical Affairs (Wesley Grigsby, M.D.)
4. CUMC Hospital Chief Financial Officer (Andrea Heffelfinger)

For each subject receiving outpatient services, the Principal Investigator or a member of his/her staff is responsible for notifying the service provider when services are scheduled that the individual receiving services is a subject in a research study and coordinating appropriate billing of services with the Billing Manager(s) of the affected Departments. The Principal Investigator or a member of his/her staff is responsible for notifying the Research Operations Coordinator at CUMC of any individual who is enrolled as a subject in a research study while an inpatient at CUMC or who is a research subject admitted to CUMC and coordinating appropriate billing of services.

Note: If a Protocol does not require services from CUMC (e.g., the only study procedures in the Protocol are EKG, echocardiogram and/or laboratory tests that will be performed on research subjects in the clinic setting), the cost sheet must still be completed as set forth above, but will it need not be submitted to CUMC for signature.

Note: If a protocol does not require services from CUMC but will recruit and conduct studies while a patient is hospitalized, the cost sheet must be completed and submitted to the Research Operations Coordinator as a notification that the study will be conducted on hospitalized patients (i.e., social behavioral studies).

Preparation (Requisitions) and Billing

Laboratory: See Appendix E for laboratory procedure.

Pharmacy: When a research patient is hospitalized at CUMC, the pharmacy requires a written order for the investigational product with appropriate instructions for administration (a complete med order with drug, dose (if applicable), route, and frequency). The pharmacy will always build the study drug into the order entry system with no charge code attached in order to generate a label and charting action for nursing.

The pharmacy bills at the end of each month by sending a spreadsheet to the CUMC financial office for them in turn to bill each investigator.

Outpatient Tests: When ordering an outpatient procedure at CUMC on a research subject (other than an EKG or echocardiogram), the ordering investigator/coordinator must order the protocol specific test by calling the PAC office (449-5446). The PAC office will complete its intake form. The PAC office must be told that this is a research subject having a research procedure. The PAC office must also be told if the procedure will be billed to the research project/sponsor or the patient/patient's insurer. If the research project/sponsor will be billed, the reference number for the billing should be the IRB number assigned to the project. If the outpatient procedure will be billed to the patient/patient's insurer, the ordering investigator/coordinator must indicate on the order for the procedure that the patient is a research subject and include the IRB number assigned to the project.

When the test is ordered through the PAC office, the bill for the technical (hospital) portion of the procedure will be sent directly to the researcher/coordinator listed on the cost sheet for payment.

The CMA professional component will be done via a journal entry by the departmental billing administrators. The research team will receive a monthly report from each department for activities billed for that month.

Cardiology: For cardiology diagnostic tests required under a Protocol, send the Protocol and ECHO binder (if applicable) to the Cardiac Center Research Director (see contact list above). The research coordinator will need to provide the following information to the Cardiac Center Research Director with regard to the tests to be ordered:

For EKGs

- Where will the EKG be performed and will cardiology be performing the EKG?
- Will a cardiologist be an investigator?

For ECHOs

- Does the protocol call for an Echo with Doppler?
- Does the protocol call for an Echo with color flow?
- Will the recording of the Echo need to be burned to CD?
- Will the CD need to be shipped?
- Will the sponsor be covering the CD shipping costs?

Cardiology will send a requisition for EKGs and ECHOs to the research coordinator to order and schedule the test. The research coordinator will contact the phone number on the requisition to

order the EKG or Echocardiogram. If additional requisitions are needed contact Melina at 280-4032.

For all other cardiology services (e.g., catheterizations, nuclear studies), please contact the Cardiac Center Research Director.

Subject admitted to CUMC: The Principal Investigator will complete pre-printed orders containing all protocol-required procedures to be done while the subject is hospitalized. The orders will be placed on the subject's chart on the day the procedures are to be done. (e.g., Initial orders, Day 1, Day 2, etc) The CUMC Forms Committee (See Appendix G) must approve these pre-printed orders. Laboratory requisitions and EKG/Echocardiogram requisitions will be given to the departments by the coordinators with instructions on when to perform needed procedures. If there are additional tests (other than laboratory procedures and EKG/Echocardiogram), the research coordinator will need to call Admissions to register the subject with an outpatient (O/P) account. When registering the subject with the O/P account, the coordinator must make sure that the registrar uses the assigned IRB # as the third party payer on this O/P account. This account will be used when ordering additional procedures (such as x-ray, ultrasound, etc). These tests will be entered into Care Manager by the Hospital Unit Coordinators and must be ordered on the outpatient account. This O/P account will be used throughout the hospital admission when ordering specific research tests. The coordinator will receive separate labels and these labels must be affixed to all study specific orders and requisitions. If separate labels are not received (no procedures required to initiate the O/P account), inpatient labels may be used with the account number crossed out (this will avoid double billing). Note: No standard of care orders are to be included on the research procedure order sheet; standard of care orders must be written on the subject's standard medical record order sheet that contains the identifying information for the subject's hospital account (not the research O/P account). Physicians must authenticate standing orders related to research protocols in the same manner as other orders issued by the physician for services delivered at CUMC.

When a hospitalized patient is enrolled in a project, the CUMC Research Operations Coordinator must be notified regardless of study procedures. If study requires specific procedures, a copy of the pre-printed orders must also be sent to the CUMC Billing Office as a double check to avoid the improper research billing. In addition, in the event an investigator and/or study coordinator is aware that a research subject is presently admitted to CUMC for any reason (research-related service, potential adverse event, other reason such as routine care), the study coordinator must notify the CUMC Research Operations Coordinator of the admission.

NOTE: Patients who are registered at CUMC and will undergo research activities documentation of participation must be in the chart by either a copy of the informed consent or by documentation of procedures completed for research in the progress notes.

Adverse Events and Unscheduled Tests/Procedures

Adverse Events. In the event an investigator and/or study coordinator learns that a study subject has been admitted to any hospital or received medical care other than from the investigator on some past date (e.g., the subject reports a past hospitalization at a scheduled study visit) and the investigator and/or study coordinator determines that this hospitalization must be reviewed to

determine whether the subject had an adverse event related to the study (drug, device, procedure required under the Protocol, other), the investigator and study coordinator shall follow their normal procedures for reviewing that hospitalization (e.g., obtain medical records). If it is determined that the hospitalization was an adverse event, the study coordinator shall 1) if the subject received care at CUMC, notify the CUMC Research Operations Coordinator; or 2) if the subject received care from a Creighton Medical Associates physician or at a non-Creighton hospital, notify the Creighton University Compliance Director. The study coordinator shall review the contract for the study and determine whether the sponsor has agreed to pay for medical care provided to a subject in treatment of an adverse event. The study coordinator shall inform the CUMC Research Operations Coordinator or Compliance Director, as applicable, of this information. The CUMC Research Operations Coordinator or Compliance Director, as applicable, and the study coordinator will work together to determine whether any corrections need to be made to charges submitted for medical care the subject received.

Unscheduled Tests/Procedures. In the event a study subject undergoes a test or procedure that is not ordered pursuant to the protocol schedule but may be used to fulfill protocol requirements (whether ordered by the investigator/physician or by another treating physician), the investigator and/or study coordinator shall review the study agreement and the clinical situation in which the test/procedure was performed to determine whether the test/procedure is properly billed to the subject's insurance or to the study sponsor. The investigator and/or study coordinator will notify the CUMC Research Operations Coordinator (if the test/procedure was performed at CUMC) and the Creighton University Compliance Director of any such test/procedure in order to ensure the test/procedure is billed properly and to correct any charges in the event the sponsor has agreed to pay for the test/procedure but the test/procedure has been billed to the subject's insurance. As an example: A study subject in an oncology trial is scheduled to have MRIs at intervals specified in the protocol. The subject has a change in clinical condition and the investigator/treating physician determines the subject requires a diagnostic MRI. The diagnostic MRI is not performed at the scheduled interval required by the protocol. The diagnostic MRI does not reveal an adverse event (see paragraph above for billing in the context of adverse events). However, the investigator/treating physician determines that the sponsor will accept the off-schedule MRI for data purposes and pay for the MRI. In this event, the investigator/treating physician or the study coordinator must notify the CUMC Research Operations Coordinator and the Creighton University Compliance Officer to ensure the MRI is not billed to the subject's insurer.

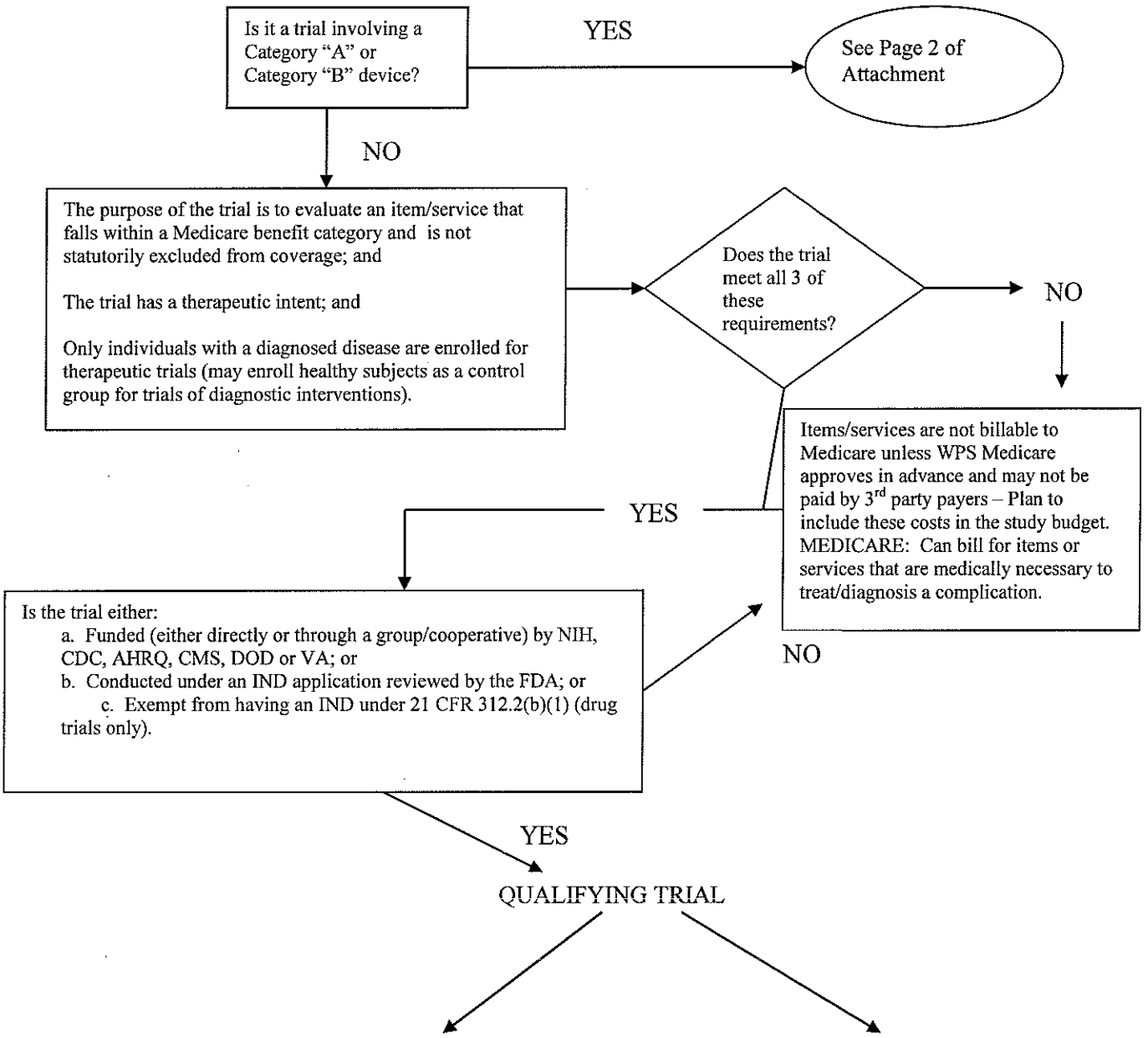
Review of and Amendments to Policy

This policy will be reviewed by the CUMC Hospital Compliance Officer and CU Compliance Director annually. This Policy may be amended by mutual agreement of CU and CUMC.

APPENDIX A

MEDICARE COVERAGE INFORMATION

MEDICARE DECISION TREE
WHAT KIND OF TRIAL IS IT?



BILLABLE

BILL MEDICARE USING MODIFIER "Q1" and ICD-9 "V70.7"

Routine Items/Services typically provided absent a clinical trial if not customarily provided by the Sponsor.

Items/services required for the provision of the investigational item/service.

Items/services medically necessary for the diagnosis/treatment of complications arising from the provision of an investigation item or service.

Items/services required for the clinically appropriate monitoring of the effects of the item/service or prevention of complications.

NOT BILLABLE

FACTOR THESE INTO YOUR STUDY BUDGET

Items/Services customarily provided by the Sponsor or paid for by the Sponsor.

The investigational item/service (but see exception for Category B devices).

Items/services for which there is no Medicare benefit category; that are statutorily excluded or are excluded under a NCD/LCD.

Items/services furnished solely to satisfy data collection and analysis needs that are not used for clinical management of the patient.

Items/services provided solely to determine trial eligibility.

MAY NEED TO OBTAIN AN ABN (MEDICARE ONLY)

Items/Services Provided to TriCare beneficiaries

MEDICARE IDE COVERAGE

Medicare determines device coverage based on which category the FDA assigns the device. Devices are designated as either a Category A IDE or a Category B IDE.

Category A Devices

Category A devices are considered experimental. Therefore, the Category A device is not eligible for payment, and should not be billed to Medicare. Nonetheless, effective January 1, 2005, routine costs (as described in The National Coverage Determinations Manual, Section 310.1) of clinical trials involving a Category A IDE devices are covered when the Medicare contractors determine that the device is used in the trial for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

Category B Devices

Category B devices are newer generations of proven technologies that have had questions about its safety and effectiveness resolved. Category B devices may be covered under Medicare as long as it meets the billing requirements listed below. If the device is billed under a Category B IDE study, and it meets the billing requirements for IDEs, the device itself and the routine costs associated with its use are eligible for payment (Reimbursement for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

Providers that participate in an IDE trial and anticipate filing Medicare claims must notify the Medicare Contractor (i.e., WPS Medicare). The following information must be furnished prior to submission of a claim for payment:

1. A copy of the FDA-approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number must be on the letter

2. The name of the device (both trade, common or usual, and classification name)

3. Any action taken to conform to any applicable IDE special controls

4. A narrative description of the device sufficient to make a payment determination

5. A statement indicating how the device is similar to and/or different from other comparable products

6. Indication of whether the device will be billed on an inpatient or outpatient claim

7. A brief summary of the study design or a copy of the actual trial protocol

8. The provider's protocol for obtaining informed consents for beneficiaries participating in the clinical trial.

NOTE: Potential Medicare coverage of Category B IDE devices is predicated, in part, on the device's status with the FDA. If a sponsor loses its Category B status for the device or violates relevant IDE requirements necessitating the FDA's withdrawal approval, all payment will cease. Providers must notify the Medicare Contractor within 30 days of any change in status for an IDE. By billing for an IDE, whether it is for a Category B device or for the routine costs of clinical trials involving a Category A device, the provider attests that the device was approved at the time the services were rendered.

Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE

Providers shall notify the Medicare Contractor of the Category A IDE device trial before billing routine costs of clinical trials involving a Category A device. Upon receiving the required information for the trial, the Medicare Contractor will determine if the Category A device, as used in the trial, is intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease/condition. If the Medicare Contractor determines that the device does, in fact, meet the requirements of coverage, then the provider may begin billing the routine costs of a clinical trial involving a Category A device.

In addition to billing the routine costs, providers must identify the line for which the Category A IDE device is being billed.

Institutional Billing

Institutional providers must bill the device involved with the clinical trial by placing the Category A IDE Number on a 0624 (IDE) revenue code line, with the charges for the device placed in the "Non-covered" charges field. The 0624 revenue code and the Q0 modifier alert contractors that the Category A IDE is billed on that line.

Practitioner/Supplier Billing

Practitioner/suppliers will bill a Q0 modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE

Once the Medicare Contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill claims for the particular Category B IDE. When billing for Category B IDEs, providers shall bill for the device and all related procedures. The Category B IDE and the routine costs associated with its use are eligible for payment under Medicare. (Reimbursement for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA approved).

Institutional Billing

Institutional providers must bill the Category B IDE Number on a 0624 revenue code line with charges in the covered charges field (providers receiving the device free of charge must bill the IDE charges as non-covered).

Practitioner/Supplier Billing

Practitioners/suppliers will bill a Q0 modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

MEDICARE COVERAGE OF CERTAIN ANTI-CANCER DRUGS

On January 28, 2005, the Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD), No. CAG-00179N, covering the off-label use of certain anti-cancer drugs.

The NCD covers nine specific National Cancer Institute-sponsored clinical trials of colorectal cancer and other cancer types (see Table 2, below). The trials are investigating one or more of the following anti-cancer drugs: oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), or bevacizumab (Avastin™).

As of April 22, 2008, eight of the nine trials are open and enrolling patients; one of the trials is active but has closed to new accruals. See a list of all nine trials, including the trial description, eligibility criteria, and participating sites.

The 2005 Anti-Cancer Drugs NCD policy provides additional coverage for those Medicare beneficiaries who enroll in one of the nine specific clinical trials listed in Table 2 - for example, the costs of pretreatment and prerandomization tests (as defined by each study protocol).

Major differences between the two policies are described in Table 1.

Table1: Comparison of Medicare Policies

	2000 Clinical Trials Policy	2005 Anti-Cancer Drug NCD
What kinds of costs are covered?	Routine costs associated with the patients' medical care in the clinical trial.	Both routine and nonroutine costs associated with the patients' care in any of the nine trials. An example of a nonroutine cost would be an additional lab or imaging test required by the study protocol for data analysis.
Does the policy pay for off-label use of anti-cancer drugs?	Maybe. Coverage of off-label use varies depending on whether the trial in question meets the policy's requirements.	Yes, off-label use is covered for the anti-cancer drugs in all nine trials.

What about billing procedures?

Billing instructions for the nine clinical trials covered under the 2005 Anti-Cancer Drugs NCD can be found via the links on the following Web page maintained by the National Cancer Institute's Cancer Trial Support Unit (CTSU): CTSU Menu Trials Included in Medicare Pilot.

Table 2: Clinical Trials Covered Under the 2005 Anti-Cancer Drugs NCD

Study #	Study Title	Study Status	Location
C80405	Cetuximab and/or Bevacizumab Combined With Combination Chemotherapy in Treating Patients With Metastatic Colorectal Cancer	Open	Nationwide
E2204	Bevacizumab or Cetuximab Given Together With Gemcitabine, Capecitabine, and Radiation Therapy in Treating Patients With Pancreatic Cancer That Has Been Completely Removed By Surgery	Closed to accrual	Nationwide
E4203	Bevacizumab and Oxaliplatin Combined With Irinotecan or Leucovorin and Fluorouracil in Treating Patients With Metastatic or Recurrent Colorectal Cancer	Open	Nationwide
E5202	Oxaliplatin, Leucovorin, and Fluorouracil With or Without Bevacizumab in Treating Patients Who Have Undergone Surgery for Stage II Colon Cancer	Open	Nationwide
E5204	Chemotherapy With or Without Bevacizumab in Treating Patients With Stage II or Stage III Rectal Cancer	Open	Nationwide
NSABP-R-04	Radiation Therapy and Either Capecitabine or Fluorouracil With or Without Oxaliplatin Before Surgery in Treating Patients With Resectable Rectal Cancer	Open	Nationwide
RTOG-0522	Radiation Therapy and Cisplatin With or Without Cetuximab in Treating Patients With Stage III or Stage IV Head and Neck Cancer	Open	Nationwide
S0502	Phase III Randomized Study of Imatinib, with or without Bevacizumab, in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors	Open	Nationwide
7325	Combination Chemotherapy With or Without Bevacizumab in Treating Patients With Metastatic or Locally Advanced Unresectable Colorectal Cancer or Other Solid Tumors	Open	Limited Regions

APPENDIX B

Coverage Analysis Form

Study Title: Sample Study
Study Sponsor: Sample Sponsor
Sponsor Protocol #: Sample 1234
Principal Investigator: Dr. Sample
Study Coordinator: Sample Coordinator

		Screening	Treatment								
Design:	**Code**	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**EOT**	**Billed to Research**	**Billed to Patient**
Informed Consent		R								1	0
Inclusion / Exclusion Criteria		R								1	0
Physical Exam	99213	P		P			P			0	3
Demographics		R								0	0
Vital Signs		R		R		R		R		3	0
12-lead ECG	93000	R								1	0
Comprehensive Metabolic Panel	80053	CL		CL		CL		CL		0	0
Complete Blood Count w/ differential	85025	P		P			P				
Dispense Study Meds		R	R	R	R	R	R			6	0
Record Outcome Events / SAE		R	R	R	R	R	R	R	R	8	0
Participant Stipend		R	R	R	R	R	R	R	R	8	0
Coordinator charges			R	R	R	R	R	R		6	0

P	Billable to Patient / Medicare / 3rd Party Payer
R	Paid for by Research Sponsor
CL	Central Lab

APPENDIX C

COST SHEET FORM

CREIGHTON UNIVERSITY MEDICAL CENTER
COST SHEET AND APPROVAL OF RESEARCH PROTOCOLS FORM
Attach a copy of the Entire Proposal including Informed Consent Form to this Cost Sheet

Project Name: _____
Principal Investigator: _____
Person responsible for completing this cost sheet and to whom questions should be directed for billing:

Print Name	Department	Telephone	E-mail
_____	_____	_____	_____

Has the Creighton University IRB approved this project? Yes ☐ IRB Number:_____
No ☐ If no, please indicate the anticipated date for submitting the project to the IRB:_____

Proposed Start Date:_____ Estimated Completion Date:_____

This Study will require the following services (multiple boxes may be selected):

☐ Lab Services
☐ Pharmacy Services
☐ Cardiology Services
☐ Pulmonary Services
☐ Radiology or Interventional Radiology Services
☐ Inpatient/Overnight Stay
☐ No Services Requested

Department to be charged for the requested services: _____ Fund/Org Numbers:_____

Are patients to be billed for the requested services?
Yes ☐ If yes, please indicate any restrictions (e.g., do not bill patient's insurance):_____
No ☐ If no and patient will be registered at CUMC then completion of this form is required

Will patients receive a series of the services? Yes ☐ No ☐
Yes, the Hospital's electronic medical records for these services will be stored in one folder. This will enable you to access the series with one file number and will require only one signed informed consent form to be submitted.

Does this project involve use of an implantable device? Yes ☐ No ☐
If yes, (a) what is the name of the device: _____
(b) is the device FDA approved for this use? Yes ☐ No ☐
(c) the Chair of any involved Hospital Department having control of such devices must approve:

Name	Department/Section/Service	Date
_____	_____	_____

Does this project involve an invasive procedure (e.g. surgical, endoscopy, etc)? Yes ☐ No ☐
What procedure(s)? _____
What physician will be performing the procedure(s)? _____
Does the physician have Hospital medical staff privileges for the procedure? Yes ☐ No ☐
Medical Staff Services verification:

Name	Date
_____	_____

Does this project involve any drugs for inpatients or observation patients? Yes ☐ No ☐
If yes, the Inpatient Director of Pharmacy Services and the Chair of the Hospital P & T Committee must approve:

Director of Pharmacy Services	Date	Chair of P & T Committee	Date
_____	_____	_____	_____

CREIGHTON UNIVERSITY MEDICAL CENTER RESEARCH COST SHEET FOR PHYSICIAN SERVICES (INCLUDING DIAGNOSTIC PROFESSIONAL COMPONENT), LAB, HOSPITAL INPATIENT AND/OR OUTPATIENT SERVICES

Principal Investigator: _____ IRB #: _____

Study Coordinator: _____ Phone Number: _____ E-mail: _____

Study Name: _____

Number of Subjects to be enrolled: _____

Anticipated date to be submitted for IRB Review: _____

Services Requested (list professional components separately)	HCPCS/CPT or APC Code	Estimated times per subject	Bill Study (√)	Unit Price Quote
				$
				$
				$
				$
				$
				$
				$
				$
				$
				$
				$
				$
				$
				$
				$
				$

This Price Quote is based upon the research protocol submitted with this request and is valid until the end of the study if the study is commenced prior to December 31 of the year in which the cost sheet is completed. If the study is not commenced prior to December 31 of the year in which the cost sheet is completed, new price quotes must be obtained.

_____ _____
Principal Investigator Date

_____ _____
CUMC Hospital Compliance Office (Tiffany Thompson) Date

_____ _____
CUMC Hospital Vice President for Medical Affairs (Wesley Grigsby, M.D.) Date

_____ _____
CUMC Hospital Chief Financial Office (Andrea Heffelfinger) Date
IRB Final Approval Letter Date/Initials_____

Note: If the study does not involve any laboratory, diagnostic or other medical procedures to be performed on subjects in or by CUMC (e.g., study involves survey, observation), check the box: ☐

Appendix D

INVESTIGATIONAL DRUG SERVICE
Department of Pharmacy Services
Creighton University Medical Center
Price List for Pharmacy Services for 2007

		Cost for Study
Start-Up Charges	$500.00 and up	____
Includes but not limited to:		
Protocol Consultation,	$75.00/hour	____
Pharmacy and Nursing Medication Education Sheets	$75.00/hour	____
Preparation/Presentation of Nursing / Pharmacy in-services	$75.00/hour	____
Development of Dispensing Procedures:	$75.00 / hour	____
Record Keeping		
Ordering Drug Supply:	$75.00 / order	____
Receiving Drug Supply:	$75.00 / order	____
Maintaining Drug Accountability Records:	$75.00 / hour	____
Study Monitor Audit Visits:	$75.00 / hour	____
Blinding and randomization	$75.00/ hour	____
Storage of Medication and Study Supplies		
Room Temperature:	$25.00 / ft3 / month	____
Refrigerated:	$50.00 / ft3 / month	____
Controlled Substances:	$250.00 / ft3 / month	____
Dispensing Study Medication		
Inpatient Dispensing Fees:		
Unit Dose for Inpatient Use:	$50.00 / patient	____
Intravenous Dose (Cost of Supplies & Labor)	$100.00 & Up / dose	____
Patient Monitoring		
Written reports / memos-to-file:	$75.00 / hour	____
	Total	____

_____
Signature of Authorized Pharmacist/Designee

Prices Effective of as February 1, 2007.

For further information, contact:
Debra Lee, Pharm.D. Director of Pharmaceutical Services, at (402) 449-4565.

Note: If the study does not involve any laboratory, diagnostic or other medical procedures to be performed on subjects in or by CUMC (e.g., study involves survey, observation), check the box: ☐

Appendix E

Creighton Medical Laboratories
RESEARCH ACCOUNT ESTABLISHMENT and USAGE

Price Quotes

A preliminary price quote may be requested in email format from the principal investigator or study coordinator to the CML designee (see contact list below). An electronic copy of the protocol is required in assigning pricing and a copy of the laboratory portion must be sent to the CML designee for pricing. However, the Principal Investigator and/or Study Coordinator must also review the protocol to determine what laboratory tests are required and discuss with CML personnel.

Account Establishment

The principal investigator/study coordinator will send a Cost Sheet to the laboratory a minimum of one week prior to expected first patient enrollment date.

The CML designee will:

1. Quote prices from the current Medicare fee schedule.
   NOTE: Prices for testing performed at CML are valid until study completion. Prices for testing that is referred by CML to other laboratories are subject to change without notice.
2. Set up a dedicated account in the LIS and have Creighton Medical Laboratories (CML) requisitions printed and sent to the study coordinator.
3. Send an email to the Study Coordinator and/or Primary Investigator with account and pricing information indicating that the lab is ready to receive specimens.
4. Forward the documentation to the Study Coordinator.

Ordering Testing on Research Patients (non-CUMC patients)
Fill out a CML requisition and send it to the CML laboratory located in Criss I, Beirne Tower, Room 410 with the specimens that were drawn in the researcher's clinic.
NOTE: DO NOT write additional tests on the lab requisition unless there has been an addendum or amendment (see below) to the Cost Sheet and you are instructed to do so by the CML Designee.

Ordering Testing on Research Patients (CUMC inpatients)
Fill out a CML requisition and bring to the Central Deposit (CD) counter in the CUMC laboratory. Requisitions for multiple collections may be brought to CD at the same time. If the patient has any clinical draws scheduled for similar times, draws will be coordinated to avoid unnecessary phlebotomization of the patient. If the clinical draws will cover the testing requested by the research account requisition, the research test will be credited.

NOTE: DO NOT ask the Nursing staff to place research orders for laboratory testing in HIS (STAR or Care Manager). This will result in research testing being billed in error to the patient's clinical account.

NOTE: DO NOT write additional tests on the lab requisition unless there has been an addendum or amendment (see below) to the Cost Sheet and you are instructed to do so by the CML designee.

CUMC Laboratory will be responsible for communicating the inpatient laboratory draws to CML and coordinate the transfer of samples to CML within the required timeframe for specimen stability.

For laboratory specimens that are collected from inpatients that are scheduled to be drawn after 6 p. on Friday to 7 am on Monday or between midnight and 7 am Monday through Friday, study coordinators should contact the CML lab at 402-280-4382 to alert them of incoming specimens.

Addendums/Amendments to Protocols

If it is determined additional testing than was originally included on the Cost Sheet is necessary, the Study Coordinator will need to addend or amend the Cost Sheet and send to the laboratory:

1. Print UPDATED and the date at the top of the original Cost Sheet.
2. Make additions and deletions to the testing requested.
3. Send to the CML designee.

Additional Testing due to Adverse Events

If additional testing is necessary due to an adverse event (AE), a phone call to the CML Call Center at 280-4382 will help to get the testing performed in a timely manner. A copy of the Reporting Form for Unanticipated Problems Posing Risk to subjects and Others (Including Reportable adverse Events) that was sent to the IRB should be forwarded to the lab to prevent the charges from being billed to the patient within 3 business days. In the event laboratory tests have been performed and billed to a subject's insurance and it is later determined that the testing was related to the research, contact the CML Client Billing Coordinator to ensure charges are corrected as necessary.

Billing for Laboratory Testing

CML will journal entry debit the fund/org listed on the Cost Sheet for the testing performed on the research account established. If the fund or org needs to be changed during the project, be sure to notify the CML Client Billing Coordinator.

CML Contacts:
CML designee: Cindy Farrell clfarr@creighton.edu: Phone: 280-4133
Alternate: Marjel Whitmore marjelwhitmore@creighton.edu: Phone: 280-4134
CML Client Billing Coordinator: Victoria Scholtes; victoriascholtes@creighton.edu Phone: 280-4202

CUMC Laboratory Contact:
Laura Brook, CUMC Lab Director: laura.brock@tenethealth.com

Appendix F

Ordering Requisition for Inpatient and Outpatient EKGs and Echocardiograms

THE CARDIAC CENTER
of CREIGHTON UNIVERSITY MEDICAL CENTER
Quality Patient Care Through Education and Research

RESEARCH EKG REGISTRATION FORM

Location: _____

Place patient label
here if available

Date of Service: _____/_____/_____

Time performed: _____

IDX MRN: _____

Med Rec #: _____

Last Name: _____

First Name: _____

DOB: _____/_____/_____

Gender: M____ F ____

RSH Subject #: _____

IRB # : _____

Study Name: _____

Principal Investigator: _____

Research Coordinator: _____

Contact ph #: _____

FAX TO: EKG @ 280-4541

****

****

Reading Physician: _____

Reading Physician's #: _____

Technician Initials:_____

Please send completed forms to:

Patient Accounts / Attn: Karen Mruz

APPENDIX G

CUMC Form Approval Request

The PI/Study Coordinator will use the Physician Orders Form template provided by CUMC (see labeled form located with policy on specified websites). All applicable orders should be included on the Physician Orders Form. The CUMC Forms Committee must approve all Physician Order Forms in advance. The CUMC Forms Committee meets every Monday at 1PM in the CUMC Nursing Administrative Conference Room located on the Lobby level of the Hospital in Room 2128. The Study Coordinator will need to e-mail the Physician Order Forms and the Form Request and approval Checklist (attached on the following page) to the CUMC HIM Director at maryjo.fike@tenethealth.com by the Thursday prior to the Monday meeting to ensure the forms are included on the agenda. The CUMC Forms Committee will review the orders for consistency with existing CUMC order language. It is recommended that the Study Coordinator attend the meeting when the proposed physician orders are being discussed to expedite the approval process.

Form #_____
A)_____
B)

Creighton University Medical Center

Saint Joseph Hospital
Administrative Policy IM-20C

FORM REQUEST AND APPROVAL CHECKLIST

Date:	
Form Name:	
Submitted By:	
Department:	
Phone:	

Form Criteria:

1. **The attached two Physician order form templates are to be used for all orders. They are attached and labeled #1 and #2.**
2. **Acceptable formats that will be used with the templates are to use numbers on the form to indicate what will always be done or a □ (box) for choices.**
3. **Only one order per line.**
4. **No blank lines.**
5. **No abbreviations or symbols.**
6. **Medications are to be listed with generic and trade names and complete medication order (route, frequency, dose, indication if new or PRN).**
7. **Licensed Independent Practitioner signature line must be included on each page.**
8. **Orders for Lab Panels must include a list of the individual test part of the panel, exception for Comprehensive Metabolic Profile.**
9. **Form to be sent electronically to the Forms Committee.**

NEW FORM

Does this form need to be a permanent part of the patient record? If yes, explain.	_____
Were actual users consulted concerning the content?	☐Yes (List) _____ ☐ No (Explain): _____
Impact if form is not approved?	_____
Form Format:	☐ **Option** ☐ **Multipart** **Estimated Annual Usage:** _____
Justification for Multi-part Form:	_____
Other Committee Approvals:	☐ Pharmacy and Therapeutics ☐ Medical Executive Committee ☐ _____ ☐ _____

REVISED FORM

Justification: (attach old form and highlight changes. Identify the benefits of the revised form)	_____

FORM APPROVAL

Member	Signature	Date
#1 Health Information Director		
#2 Lab Representative		
#3 Nursing Representative		
#4 Clinical Informatics Representative		
#5 Pharmacy Representative		

See Separate Attached Form For Template Physician Order Sheet