1 PURPOSE

1.1 This guidance describes the National Coverage Determination (NCD) for routine costs in a qualifying clinic trial.

1.2 The guidance begins when the Medicare Coverage Analysis (MCA) is determined applicable and is applied by the principal investigator or designee.

1.3 The guidance ends when the Medicare Coverage Analysis is performed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY STATEMENT

3.1 Appropriate steps are outlined to ensure that routine costs associated with Medicare Eligible recipient clinical trials are covered under Medicare guidelines.

3.2 Medicare coverage for items and services are established according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions found in 42 CFR 405.201-405.215, 411.15, and 411.406.

3.2.1 For information about Local Medical Review Policies (LMRPs), refer to www.lmrp.net, a searchable database of Medicare Administrative Contractor local policies.

3.3 For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare limits coverage to the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Publication 100-03 National Coverage Determination (NCD) Manual, and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

3.4 Criteria and requirements for covered services are listed in procedure 5.2 below.

3.5 These criteria will be easily verifiable, and where possible, dichotomous.

3.6 Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs.

3.7 A multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to the Centers for Medicare & Medicaid Services (CMS).

3.8 Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's principal investigator (PI) certifies that the trial meets the criteria.

3.9 This process will require the principal investigator and or clinical trial sponsor to enroll the trial in a Medicare clinical trials registry, currently under development.

3.10 The principal investigator of automatically qualified trials does not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

3.11 Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

3.11.1 Trials funded by National Institutes of Health (NIH), the Center for Disease Control (CDC), The Agency for Healthcare Research and Quality (AHRQ), CMS, the Department of Defense (DOD), and the Veterans Administration (VA).

3.11.2 Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;

3.11.3 Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration (FDA) and

3.11.4 Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

3.12 The CMS, through the NCD process, through an individualized assessment of benefits, risks, and research potential, may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a "reasonable and necessary" determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

3.13 Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

3.14 Should CMS find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act.

3.15 In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j)(4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

3.16 Medicare regulations require Medicare + Choice (M+C) organizations to follow CMS NCDs.

3.17 The following services are deemed to meet CMS's NCD, pending the clinical trial itself, meets the NCD requirements outlined above. This list is not all inclusive any may vary based on changing guideline.

- Ambulance Services
- Ambulatory Surgical Center Facility Services
- Antigens
- Artificial Legs, Arms, and eyes
- Audiology services
- Blood clotting factors for hemophilia patients
- Bone mass measurement
- Certified nurse-midwife services
- Certified registered nurse anesthetist services
- Chiropractor services
- Clinical nurse specialist services
- Clinical social worker specialist services
- Colorectal cancer screening tests
- Comprehensive outpatient rehab facility services
- Critical access hospital services
- Dental services
- Diabetes outpatient self-management training
- Diagnostic laboratory testing
- Diagnostic services in outpatient hospital
- Diagnostic tests (other)
- Diagnostic X-Rays tests
- Drugs and biologicals
- Institutional Dialysis services and supplies
- Leg, arm, back, and neck braces
- Medical nutrition therapy services
- Nurse practitioner services
- Optometrist services
- Oral anticancer drugs
- Aral antiemetic drugs
- Orthotics and prosthetics
- Osteoporosis drug
- Outpatient hospital services incident to a physician's service
- Outpatient occupational therapy services
- Outpatient speech language pathology services
- Partial hospitalization services
- Physician assistant services
- Physicians' services
- Pneumococcal vaccine and administration
- Podiatrist services
- Post hospital extended care services
- Post-institutional home health care services
- Prostate cancer screening test
- Prosthetic devices
- Qualified Psychologist services

- Durable medical equipment
- Erythropoietin for dialysis patients
- Extended care services
- Eyeglasses after cataract surgery
- Federally qualified health center services
- Hepatitis B vaccine and administration
- Home dialysis supplies and equipment
- Home health services
- Hospice care
- Immunosuppressive drugs
- Incident to a physician's professional service
- Influenza vaccine and administration
- Inpatients hospital services
- Inpatient psychiatric hospital services
- Religious non-medical healthcare institution
- Rural health clinic services
- Screening for glaucoma
- Screening for mammography
- Screening for pap smear
- Screening for pelvic exam
- Self-care home dialysis support services
- Shoes for patients with diabetes
- Skilled nursing facility
- Splints, casts. Other devices used for reduction of fractures and dislocations
- Transplantation services for ESRD-entitled beneficiaries
- X-ray, radium, and radioactive isotope therapy

4 RESPONSIBILITIES

4.1 The principal investigator or designee is responsible for ensuring that all Medicare eligible beneficiaries are screened using the National Coverage Determination for routine costs that are incurred throughout the study.

5 PROCEDURE

5.1 Indications and limitations of coverage:

5.1.1 Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

5.1.1.1 The investigational item or service, itself unless otherwise covered outside of the clinical trial;

5.1.1.2 Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

5.1.1.3 Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

5.1.2 Routine costs of clinical trials include:

5.1.2.1 Items or services that are typically provided absent a clinical trial (e.g., conventional care);

5.1.2.2 Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

5.1.2.3 Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications

5.2 Requirements for Medicare Coverage of Routine Costs:

5.2.1 Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

5.2.1.1 The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians'

service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

5.2.1.2 The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

5.2.1.3 Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

5.2.2 The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

5.2.2.1 The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

5.2.2.2 The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

5.2.2.3 The trial does not unjustifiably duplicate existing studies;

5.2.2.4 The trial design is appropriate to answer the research question being asked in the trial;

5.2.2.5 The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;

5.2.2.6 The trial is in compliance with Federal regulations relating to the protection of human subjects; and

5.2.2.7 All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

5.3 PIs or their designees are to follow *PROCESS MAP: General Clinical Trials Billing Process Map (HRP-720)*, *PROCESS MAP: Sharp System Oncology-Specific Clinical Trials Billing Process Map (HRP-721)* or *PROCESS MAP: Sharp Mesa Vista Research Center-Specific Clinical Trials Billing Process Map (HRP-722)* as appropriate.

5.3.1 PIs or their designees are to complete *WORKSHEET: Medicare Coverage Analysis (HRP-349)* and submit with *FORM: Initial IRB Submission (HRP-211).*

6 MATERIALS

6.1 FORM: Initial IRB Submission (HRP-211)

6.2 WORKSHEET: Medicare Coverage Analysis (HRP-349)

6.3 PROCESS MAP: General Clinical Trials Billing Process (HRP-720)

6.4 PROCESS MAP: Sharp System Oncology-Specific Clinical Trials Billing Process Map (HRP-721)

6.5 PROCESS MAP: Sharp Mesa Vista Research Center-Specific Clinical Trials Billing Process Map (HRP-722)

7 REFERENCES

7.1 National Coverage Determination (NCD) for Routine Costs in Clinical Trials (www.cms.gov/medicare-coverage-database/details/ncd)

This document is available on www.sharp.com/research , IRBANA or by contacting research@sharp.com.