Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-00-89 **Date: SEPTEMBER 19, 2000**

CHANGE REQUEST 1241

This Program Memorandum (PM) supersedes prior PM AB-00-89, Change Request 1241 released September 20, 2000. The corrections are redlined.

SUBJECT: Claims Processing Instructions for Carriers, DMERCS, Intermediaries and Regional Home Health Intermediaries (RHHIs) for Claims Submitted for Medicare Beneficiaries Participating in Medicare Qualifying Clinical Trials

The purpose of this Program Memorandum (PM) is to instruct carriers, DMERCs, intermediaries and RHHIs on the processing of claims and education of providers for services covered under Medicare qualifying clinical trials. This PM contains interim instructions on the identification and handling of these claims and for making adjustments to inadvertently denied clinical trial claims/services that are brought to your attention. HCFA is taking these interim steps to ensure that effective September 19, 2000, there is a process in place whereby these services may be identified and paid when covered. Another PM will subsequently be issued once a permanent process for handling clinical trial claims is formulated.

Background

President Clinton issued an executive memorandum on June 7, 2000, directing the Secretary to "explicitly authorize (Medicare) payment for routine patient care costs…and costs due to medical complications associated with participation in clinical trials".

HCFA has developed a National Coverage Determination (NCD) which can be accessed and downloaded from the HCFA webpage at www.hcfa.gov/quality/8d.htm. This NCD states that Medicare covers: 1) the routine costs of qualifying clinical trials as well as, 2) reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. This instruction addresses routine costs of qualifying clinical trials including complications resulting from qualifying clinical trials. Instructions regarding complications from non-qualifying clinical trials can be found at Medicare Carriers Manual §2300.1 and the Medicare Intermediary Manual §3100. All other Medicare rules apply.

Clinical Trial Services That Qualify for Coverage

Clinical trial services covered by Medicare must meet both the following requirements:

1. **Qualifying Trial.** In order to be covered, the service must be part of a trial that meets all of the following criteria to be considered a qualifying trial:

a) **Evaluates a Medicare Benefit.** 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).

b) **Has a Therapeutic Intent.** The trial must have a therapeutic intent (i.e., is not designed exclusively to test toxicity or disease pathophysiology).

c) **Enrolls Diagnosed Beneficiaries.** 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.

d) **Has Desirable Characteristics.** The desirable characteristics are listed in the NCD.

o **Deemed Trials.** Some trials are considered automatically deemed as having desirable characteristics. They include:

Effective September 19, 2000

- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Resesarch and Quality (AHRQ), HCFA, Department of Defense (DOD), and Department of Veterans Affairs (VA);

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

- Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drugs Administration (FDA).

- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) are deemed 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.

Until the Medicare clinical trials registry is established, the sponsors of both IND trials and IND exempt trials must identify themselves by e-mail to clinicaltrials@hcfa.gov for administration, payment and program integrity purposes.

Self-Certified Trials. In the future, a multi-agency Federal panel (see NCD for further details) will develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics as stated in the NCD. ***No trials are covered based upon self-certification at this time.***

2. **Routine Costs.** Routine costs of a clinical trial include all items and services that are provided in either the experimental or the control arms of a trial except those listed below as not covered. Services provided to Medicare beneficiaries in both the experimental group and the control group are eligible for coverage provided that all other criteria in this instruction are met.

Routine costs do NOT include (and are therefore not covered):

o The investigational item or service, itself;

o Items and services:

- For which there is no Medicare benefit category, or
- Which are statutorily excluded, or
- That fall under a national noncoverage policy;

o Items and services furnished solely to satisfy data collection and analysis needs 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);

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

- Items and services provided solely to determine trial eligibility.

Routine costs DO include (and are therefore covered):

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

- Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);

- Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

- Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

INTERIM PROCEDURES TO ENABLE PAYMENT FOR CLINICAL TRIAL ITEMS AND SERVICES

There may be clinical trial claims submitted for dates of service on or after September 19, 2000, that are inappropriately denied due to existing LMRPs or utilization edits. HCFA is releasing these interim instructions to all carriers, DMERCS, intermediaries and RHHIs to ensure that eligible services inadvertently denied are adjusted and paid when brought to your attention.

Edit clinical trial claims for beneficiary eligibility and provider enrollment, exact duplicates and services that are normally bundled (e.g., correct coding, global surgery). Also, continue to reject and/or return incomplete claims under existing procedures.

The coverage of routine care clinical trial items and services constitutes new coverage policy and the effective date precludes making necessary changes to Common Working File (CWF) and standard systems at this time. It may therefore be necessary for Medicare contractors to pay certain fee for service claims (fee for service enrollees and/or managed care enrollees) without CWF approval.

Clinical Trial Claims Submitted to Carriers and DMERCs

Effective for dates of service on or after September 19, 2000, providers submitting claims for services or items that meet the requirements as outlined in the NCD must identify these services with a newly created "QV" procedure code modifier and ICD-9-CM code V70.5 listed as a secondary diagnosis on the claim. The modifier definition is: "Item or service provided as routine care in a Medicare qualifying clinical trial". The ICD-9 code definition is "Health Examination of Defined Subpopulations".

The QV procedure code modifier plus the V70.5 diagnosis code will serve as the provider's attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

The modifier is line item specific. The modifier and ICD-9 code are used to identify clinical trial items and services that constitute routine patient care including the treatment of complications arising from a Medicare beneficiary's participation in a Medicare qualifying 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 using the QV modifier or ICD-9 code V70.5. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV modifier or

ICD-9 V70.5. Finally, items and services customarily provided by the research sponsors free of charge for any enrollee in the trial may not be billed to Medicare.

Payment Requirements for Carriers and DMERCs.--For dates of service on or after September 19, 2000, pay for Medicare covered services furnished to beneficiaries participating in Medicare qualifying clinical trials. Payment is based on the payment methodology applicable for the service that was furnished (e.g., physician fee schedule, lab fee schedule, DME fee schedule, reasonable charge). With the exception of managed care enrollees, applicable deductibles and coinsurance rules apply to clinical trial items and services. The Part A and Part B deductibles are assumed to be met for covered clinical trial services billed on a fee service basis for managed care enrollees.

Billing Requirements.--Clinical trial related services are billed on the standard claims forms (HCFA-1500) or electronic claim record format. The clinical trial modifier is entered in the blocks/fields designated for procedure code modifiers and the V70.5 ICD-9 code is reported as a secondary diagnosis in the diagnosis block or electronic equivalent. Instruct providers to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. For services that require a Certificate of Medical Necessity (CMN), continue to require CMNs.

Medical Records Documentation Requirements.--When submitting claims with the QV procedure code modifier and V70.5 diagnosis code, the billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information should not be submitted with the claim but must be provided if requested for medical review. A copy of the signed informed consent document must also be made readily available if requested for medical review activities.

Clinical Trial Claims Submitted to Intermediaries and RHHIs

For claims with dates of service on or after September 19, 2000, institutional providers submitting claims for services that meet the requirements as outlined in the final NCD should identify these services by reporting the ICD-9-CM diagnosis code of V70.5 (Health Examination of Defined Subpopulations). This code should be reported as the second or subsequent diagnosis code, (generally, the third or subsequent for HHAs) on the claim, not as the principal diagnosis code. All institutional providers should continue to code the principal diagnosis code chiefly responsible for the service.

The ICD-9 code is used to identify services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare qualifying clinical trial. 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. Services furnished without charge may not be billed with the V70.5 diagnosis code. In addition, services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using this ICD-9 code. Finally, items and services furnished by the research sponsor to the beneficiary may not be billed to Medicare. This ICD-9 code will serve as the provider's attestation that the service was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with trial participation.

Instruct providers to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim.

Payment Requirements for Intermediaries.--For claims with dates of service on or after September 19, 2000, pay for services under current payment methodologies specific to the provider that provides the service(s) and the type of service provided. Applicable deductibles and coinsurance rules apply to clinical trial items and services with one exception. For managed care enrollees, Part A and Part B deductibles are assumed to be met for covered clinical trial services billed on a fee for service basis.

Where the payment is bundled (e.g., DRG payments), Medicare will adjust amounts paid for non-covered investigational items and services for which payment should not have been included as part of the bundled payment. Further instructions on medical review (finding claims and making appropriate adjustments) will be forthcoming.

Billing Requirements for Intermediaries.--Follow the general review instructions in §3604 of the Medicare Intermediary Manual, Part 3. The provider bills you on Form HCFA-1450 or electronic equivalent.

Applicable Bill Types.--All bill types (inpatient and outpatient) are applicable.

Providers utilizing the UB-92 flat file use record type 40 to report bill type. Record type (Field No. 1), sequence number (Field No. 2), patient control number (Field No. 3) and type of bill (Field No. 4) are required.

Providers utilizing the hard copy UB-92 (Form HCFA-1450) report the applicable bill type in Form Locator (FL) 4 "Type of Bill."

Providers utilizing the Medicare A 837 Health Care Claim version 3051 implementations 3A.01 and 1A.C1, report the applicable bill type in 2-130-CLM01, CLM05-01, and CLM05-03.

Medical Records Documentation Requirements.--When submitting claims with the V70.5 diagnosis code the billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information should not be submitted with the claim but must be provided if requested for medical review. A copy of the signed informed consent document must also be made readily available if requested for medical review activities.

ICD-9-CM Reporting.--For claims with dates of service on or after September 19, 2000, providers report ICD-9 diagnosis code V70.5 (Health Examination of Defined Subpopulations) as the second or subsequent diagnosis code (generally, the third or subsequent for HHAs) when reporting a routine care clinical trial service. V70.5 cannot be reported as the Principal Diagnosis.

Providers utilizing the UB-92 flat file use record type 70, Other Diagnoses Code (Field No. 5-12) to report the ICD-9 code.

Providers utilizing the hard copy UB-92 report the ICD-9 code in Form Locators (FLs) 68-75 (Other Diagnoses Codes).

Providers utilizing the Medicare A 837 Health Care Claim version 3051 implementations 3A.01 and 1A.C1, report the ICD-9 in 2-225.A-HI03-02 through HI10-02.

Providers utilizing the Health Care Claim: Institutional 837 version 4010, report ICD-9 in OTHER DIAGNOSIS INFORMATION.

Interim Procedures for Handling Inadvertent Denials of Clinical Trial Services Brought to Your Attention

It is recognized that claims for clinical trial services will be processed under existing systems editing routines and claim examination procedures (i.e., contractors may not be aware that a service is related to a clinical trial). Under this scenario it is anticipated that many claims for these services will be paid but some may be inadvertently denied. When inadvertently denied covered clinical trial services are brought to your attention, you will need to adjust the claim.

Carrier and DMERC Claim Adjustments

When it is brought your attention that a Medicare qualifying clinical trial service was denied for a date of service on or after September 19, 2000, the action you take to adjust the claim and pay for the service will depend on whether the service was initially submitted with the QV modifier and V70.5 ICD-9 code.

Denied Service Was Not Billed With the QV Modifier and ICD-9 code V70.5

When services on an initial claim are denied and were not coded as routine care clinical trial services (i.e., the clinical trial modifier and ICD-9 code was not included), instruct the provider to resubmit the services on a new claim with the QV modifier and ICD-9 code for the routine care including medical complications arising from a Medicare qualifying clinical trial. When the service has the clinical trial modifier and ICD-9 code but is inadvertently denied and brought to your attention, take the action described below.

Inadvertently Denied Service Was Billed With The QV Modifier and ICD-9 code V70.5

If a service Medicare covers that is billed with the QV modifier and ICD-9 code V70.5 is inadvertently denied (e.g., for medical necessity or utilization) and subsequently brought to your attention, adjust the claim and approve Medicare covered services for payment.

Intermediary and RHHI Claim Adjustments

When it is brought to your attention that a Medicare qualifying clinical trial service was denied for a date of service on or after September 19, 2000, the action you take to approve and pay the claim depends on whether the claim was initially submitted with the clinical trial diagnosis code.

Initial Claim Did Not Include the Clinical Trial Diagnosis Code.--When a claim or a line item on the claim is denied and the service was for a routine clinical trial service, instruct providers to submit an adjustment bill with the ICD-9 clinical trial diagnosis code. When the claim reflects the routine care clinical trial diagnosis code but is denied and brought to your attention, take the action described below.

Inadvertently Denied Claim Was Submitted With the Clinical Trial Diagnosis Code (As the Second or Subsequent Diagnosis, Generally the Third or Subsequent for HHAs).--If a claim or any item on the claim is inadvertently denied and the claim reflects the ICD-9 diagnosis code and subsequently brought to your attention, adjust the claim and pay for Medicare covered routine clinical trial services.

Other Carrier, DMERC, Intermediary and RHHI Actions

Other actions such as those described below may also be instituted immediately if they can be implemented without making standard system changes and the potential alternate approach is administratively cost effect:

Expert Systems.--Carriers, DMERCs, intermediaries and RHHIs that have the capability may also install local workarounds to facilitate claims processing and payment for covered services furnished under a Medicare qualifying clinical trial.

Other Local Contractor Workarounds.--You may also employ user controlled actions that will enhance your ability to identify clinical trial services or clinical trial beneficiaries so as to mitigate the inadvertent denial of payable trial services.

By October 2, 2000, inform HCFA via e-mail (clinicaltrials@hcfa.gov) of any internal workarounds you institute (or plan to institute) to enhance your ability to identify and pay for Medicare covered clinical trial services.

Local Medical Review Policy.--Carriers, DMERCs, intermediaries and RHHIs may not develop new or revised LMRPs for clinical trial services.

The criteria in the Program Integrity Manual (PIM) that contractors use to make reasonable and necessary determinations will be revised to clarify that routine clinical trial services which meet the requirements of the national coverage decision (NCD) (www.hcfa.gov/quality/8d.htm) are considered reasonable and necessary.

Informational Remittance Message (Carriers and DMERCs).--As soon as possible, include the following message in the informational section of the provider remittance: "For information on Medicare coverage of clinical trial services go to www.hcfa.gov/quality/8d.htm." This message may be discontinued March 31, 2001.

In addition, you must create a link from your website to the HCFA website indicated above for individuals who want more information about clinical trials.

Instructions for Processing Claims for Clinical Trial Services for M+C Enrollees

Until Medicare capitation rates are adjusted to account for clinical trials. Medicare contractors will pay providers directly on a fee for service basis for covered clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans. The standard system maintainers will not be making systems changes to accommodate this process at this time. If individual carriers or intermediaries need to make changes to implement these instructions, they should submit their request to clinicaltrials@hcfa.gov.

Providers serving managed care enrollees receiving clinical trial services must be enrolled with Medicare in order to bill on a fee-for-service basis. Providers that wish to bill but that have not yet enrolled with Medicare should contact their local carrier, intermediary, RHHI or National Supplier Clearinghouse, as appropriate, to obtain an enrollment application.

Payment for clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans should be determined according to the applicable fee for service rules, except that beneficiaries are not responsible for the Part A or Part B deductibles (i.e., assume the Part A or Part B deductible has been met). Managed care enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules.

In order for these fee for service bills to be paid, providers must include ICD-9 code V70.5 as the second or subsequent diagnosis code (generally, the third or subsequent for HHAs) on the UB-92 submitted to intermediaries. For claims submitted to carriers, providers must include the "QV" procedure code modifier and ICD-9 code on the claim. Claims that are not coded accordingly will not be paid, however providers may resubmit the claims with the clinical trials codes if they were inadvertently omitted.

Send fee for service clinical trial claims for managed care beneficiaries to CWF for payment authorization. CWF will reject fee for service claims for beneficiaries enrolled in managed care plans with an UR 5232 error code for carrier and DMERC processed claims and an UR 5233 error code for intermediary processed claims. When the UR 5232/5233 error code is received and you have the systems capability to do so, suspend the claim if it has the V70.5 diagnosis code (intermediaries) or the QV modifier and V70.5 diagnosis code (carriers and DMERCs) used to identify Medicare qualifying clinical trial services. If these codes are present, contractors will pay the services outside of CWF. If the V70.5 diagnosis code or QV procedure code modifier and ICD-9, as applicable, is not present, deny the claim following normal procedures.

If your system is not able to suspend clinical trial claims for managed care enrollees for processing outside of CWF based on the receipt of CWF error code 5232 (for claims with the QV modifier and V70.5 ICD-9 code) or error code 5233 (for claims with the V70.5 diagnosis code) and the claim is denied, you must create a process to adjust and pay claims outside of CWF for covered clinical trial services brought to your attention.

When payment is made outside of CWF, contractors will still need to prepare and send payment determination notices to providers and beneficiaries (e.g., manually prepared notices, if necessary). You must also establish a process (either pre or postpay) for detecting duplicate payments made outside of CWF for covered clinical trial services for managed care enrollees.

The process for paying claims outside CWF, which includes keeping a record of paid claims and processing the claims through CWF once systems changes are made, is described in §3863 of the Intermediary Manual and §6009 of the Carriers Manual. Intermediaries, carriers, DMERCs and RHHIs do not need to obtain prior approval from regional offices for paying clinical trial claims for managed care enrollees outside of CWF. This HCFA directive serves as your authorization to pay these claims outside of CWF. Note that there are required monthly reports described in these Intermediary and Carriers Manual sections that include both the detail and summary information. Submit a separate report on clinical trial claims paid outside of CWF for both fee for service and managed care enrollees to the following address (as well as to the appropriate Consortia Contractor Management Officer):

Clinical Trials NCD
c/o Shana Olshan
HCFA/OCSQ/CAG
7500 Security Boulevard, Mail Stop: S3-02-01
Baltimore, MD 21244-1850

Carrier and DMERC Provider Notification

Publish Attachment 1 in your next regularly scheduled bulletin or newsletter.

In addition, post this article within 5 working days of receipt of this PM on any other provider communication links (e.g., electronic bulletin boards, websites) you maintain and share this article with medical societies who may wish to publish it as well.

Intermediary and RHHI Provider Notification

Publish Attachment 2 in your next regularly scheduled bulletin or newsletter.

In addition, post this article within 5 working days of receipt of this PM on any other provider communication links (e.g., electronic bulletin boards, websites) you maintain and share this article with associations who may wish to publish it as well.

If you have any operational or coverage questions regarding clinical trials, you must send them via e-mail to clinicaltrials@HCFA.GOV

The effective date for this Program Memorandum (PM) is September 19, 2000.

The implementation date for this PM is September 19, 2000.

Funding is available through the Supplemental Budget Request process for costs required for implementation.

This PM may be discarded after September 19, 2001.

Attachments

Attachment 1

Carrier and DMERC Provider Bulletin

"On June 7, 2000, the President of the United States issued an executive memorandum directing the Health Care Financing Administration (HCFA) to "explicitly authorize [Medicare] payment for routine patient care costs…and costs due to medical complications associated with participation in clinical trials." In keeping with the President's directive, this National Coverage Decision (NCD) serves to define the routine costs of clinical trials and identify the clinical trials for which payment for such routine costs should be made for eligible services furnished on or after September 19, 2000.

HCFA has developed a National Coverage Determination (NCD) which can be accessed and downloaded from the HCFA webpage at www.hcfa.gov/quality/8d.htm. This NCD states that Medicare covers: 1) the routine costs of qualifying clinical trials as well as, 2) reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. This instruction addresses routine costs of qualifying clinical trials including complications resulting from qualifying clinical trials. All other Medicare rules apply.

Clinical Trial Services That Qualify for Coverage

Clinical trial services covered by Medicare must meet both the following requirements:

1. **Qualifying Trial.** In order to be covered, the service must be part of a trial that meets all of the following criteria in order to be considered a qualifying trial:

a) **Evaluates a Medicare Benefit.** 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).

b) **Has a Therapeutic Intent.** The trial must have a therapeutic intent (i.e., is not designed exclusively to test toxicity or disease pathophysiology).

c) **Enrolls Diagnosed Beneficiaries.** 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.

d) **Has Desirable Characteristics.** The desirable characteristics are listed in the NCD.

o **Deemed Trials.** Some trials are considered automatically deemed as having desirable characteristics. They include:

Effective September 19, 2000

- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), HCFA, Department of Defense (DOD), and Department of Veterans Affairs (VA);

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

- Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drugs Administration (FDA); and

- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) are deemed until the qualifying criteria are developed and the certification process is in place. At 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.

Until the Medicare clinical trials registry is established, the sponsors of both IND trials and IND-exempt trials must identify themselves by e-mail to clinicaltrials@hcfa.gov for administration, payment and program integrity purposes.

o **Self-Certified Trials.** In the future, a multi-agency Federal panel (see NCD for further details) will develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics as stated in the NCD. ***No trials are covered based upon self-certification at this time.***

2. **Routine Costs.** Routine costs of a clinical trial include all items and services that are provided in either the experimental or the control arms of a trial except those listed below as not covered. Services provided to Medicare beneficiaries in both the experimental group and the control group are eligible for coverage provided that all other criteria in this instruction are met.

Routine costs do NOT include (and are therefore are not covered):

o The investigational item or service, itself;

o Items and services:

o For which there is no Medicare benefit category; or

- Which are statutorily excluded; or
- That fall under a national noncoverage policy;

o Items and services furnished solely to satisfy data collection and analysis needs 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);

o Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial; and

o Items and services provided solely to determine trial eligibility.

Routine costs DO include (and are therefore covered):

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

o Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);

o Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

o Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

This national coverage policy is based upon the authority found in §1862(a)(1)(E) of the Social Security Act (Act). It is binding on all Medicare carriers, intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, and Medicare+Choice organizations (§1852 (a)(1)(A) of the Act)."

Effective for dates of service on or after September 19, 2000, when submitting claims for services or items that meet the requirements as outlined in the final National Coverage Decision you must identify these services with the "QV" procedure code modifier. "QV" – "Item or service provided as routine care in an approved clinical trial" (The full coverage policy regarding clinical trials may be accessed at www.hcfa.gov/quality/8d.htm.)

The modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered 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 using the QV modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV modifier. Finally, items and services customarily provided by the research sponsor free of charge for any enrollee in the trial may not be billed.

In addition to the QV modifier, providers must also report diagnosis code V70.5 (Health Examination of Defined Subpopulations) as a secondary diagnosis for patients participating in Medicare covered clinical trials.

The QV modifier and V70.5 diagnosis code will serve as your attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation.)

Submit separate line items for clinical trial services when billing other covered services not directly related to a Medicare qualifying clinical trial on the same claim.

When submitting claims with the QV procedure code modifier and V70.5 diagnosis code, the billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information should not be submitted with the claim but must be provided if requested for medical review. A copy of the signed informed consent document must also be made readily available if requested for medical review

Payment for these qualifying clinical trial services furnished on or after September 19, 2000, will be made based on the payment methodology applicable for the service that was furnished (e.g., physician fee schedule, lab fee schedule, DME fee schedule, reasonable charge). All applicable deductible and coinsurance rules apply to these services with one exception. Managed care enrollees will not be responsible for the Part A and Part B deductibles for covered clinical trial services billed as fee for service.

If you have a claim for a Medicare qualifying clinical trial service that has been denied for a date of service on or after September 19, 2000, the action you take to get the claim paid will depend on whether the service was initially submitted with the QV modifier and ICD-9 code.

Initial Claim Did Not Include the QV Modifier and ICD-9 Code V70.5.--If clinical trial routine care services on a claim are denied and were not identified as clinical trial services (i.e., the clinical trial modifier and ICD-9 code was not included), resubmit the services on a new claim with the QV modifier and ICD-9 code V70.5 for the care or medical complications arising from a Medicare qualifying clinical trial.

Denied Service Included the QV Modifier and ICD-9 Code.--If a service Medicare covers is billed with the QV modifier and ICD-9 code and initially denied (e.g., for medical necessity or utilization) contact us (insert the phone number for providers) and request an adjustment to the claim. If appropriate, we will adjust and pay the claim."

Payment Of Clinical Trial Services For Managed Care Enrollees.-- Until Medicare capitation rates are adjusted to account for clinical trials, payment for clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans will be made on a fee for service basis by the Medicare contractors that process fee for service claims. Providers will need to submit fee for service bills for Medicare covered clinical trial services furnished to managed care enrollees. The payment amounts will be based on the applicable Medicare fee schedules for such services. In addition, the Part A and Part B deductibles are assumed to be met for covered clinical trial services billed as fee for service for managed care enrollees.

Attachment 2

Intermediary and RHHI Provider Bulletin

"On June 7, 2000, the President of the United States issued an executive memorandum directing the Health Care Financing Administration (HCFA) to "explicitly authorize [Medicare] payment for routine patient care costs…and costs due to medical complications associated with participation in clinical trials." In keeping with the President's directive, this National Coverage Decision (NCD) serves to define the routine costs of clinical trials and identify the clinical trials for which payment for such routine costs should be made for eligible services furnished on or after September 19, 2000.

HCFA has developed a National Coverage Determination (NCD) which can be accessed and downloaded from the HCFA webpage at www.hcfa.gov/quality/8d.htm. This NCD states that Medicare covers: 1) the routine costs of qualifying clinical trials as well as, 2) reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. This instruction addresses routine costs of qualifying clinical trials including complications resulting from qualifying clinical trials. All other Medicare rules apply.

Clinical Trial Services That Qualify for Coverage

Clinical trial services covered by Medicare must meet both the following requirements:

1. **Qualifying Trial.** In order to be covered, the service must be part of a trial that meets all of the following criteria in order to be considered a qualifying trial:

a) **Evaluates a Medicare Benefit.** 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).

b) **Has a Therapeutic Intent.** The trial must have a therapeutic intent (i.e., is not designed exclusively to test toxicity or disease pathophysiology).

c) **Enrolls Diagnosed Beneficiaries.** 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.

d) **Has Desirable Characteristics.** The desirable characteristics are listed in the NCD.

o **Deemed Trials.** Some trials are considered automatically deemed as having desirable characteristics. They include:

Effective September 19, 2000

-- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Resesarch and Quality (AHRQ), HCFA, Department of Defense (DOD), and Department of Veterans Affairs (VA);

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

-- Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drugs Administration (FDA); and

-- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) are deemed 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.

Until the Medicare clinical trials registry is established, the sponsors of both IND trials and IND-exempt trials must identify themselves by e-mail to clinicaltrials@hcfa.gov for administration, payment and program integrity purposes.

o **Self-Certified Trials.** In the future, a multi-agency Federal panel (see NCD for further details) will develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics as stated in the NCD. ***No trials are covered based upon self-certification at this time.***

1. **Routine Costs.** Routine costs of a clinical trial include all items and services that are provided in either the experimental or the control arms of a trial except those listed below as not covered. Services provided to Medicare beneficiaries in both the experimental group and the control group are eligible for coverage provided that all other criteria in this instruction are met.

Routine costs do NOT include (and are therefore not covered):

o The investigational item or service, itself;

o Items and services:

- For which there is no Medicare benefit category, or
- Which are statutorily excluded, or
- That fall under a national noncoverage policy.

o Items and services furnished solely to satisfy data collection and analysis needs 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);

o Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial; and

o Items and services provided solely to determine trial eligibility.

Routine costs DO include (and are therefore covered):

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

o Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);

o Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

o Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

This national coverage policy is based upon the authority found in §1862(a)(1)(E) of the Social Security Act (Act). It is binding on all Medicare carriers, intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, and Medicare+Choice organizations (§1852 (a)(1)(A) of the Act)."

For claims with dates of service on or after September 19, 2000, submit claims for services that meet the requirements as outlined in the final National Coverage Decision for Medicare qualifying clinical trial services by reporting the ICD-9-CM diagnosis code of V70.5 (Health Examination of Defined Subpopulations). Report this code as the second or subsequent diagnosis code (generally, the third or subsequent for HHAs) not as the principal diagnosis code on the claim. Continue to code the principal diagnosis code chiefly responsible for the service.

The ICD-9 code is used to identify services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered clinical trial. 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. In addition, services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using this ICD-9 code. Finally, items and services customarily provided by the research sponsors free of charge for any enrollee in the trial may not be billed. ***This code will serve as your attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).***

When submitting claims with the V70.5 diagnosis code you must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information should not be submitted with the claim but must be provided if requested for medical review. A copy of the signed informed consent document must also be made readily available if requested for medical review activities.

Submit separate line items for clinical trial services when the claim includes other covered services not directly related to a Medicare qualifying clinical trial.

Payment Requirements

Payment for these Medicare qualifying clinical trial services furnished on or after September 19, 2000, will be made under current payment methodologies specific to your provider type and the service being provided. All applicable deductible and coinsurance rules apply to clinical trial services with one exception. Managed care enrollees will not be responsible for the Part A and Part B deductibles for covered clinical trials services billed as fee for service.

Where the payment is bundled (e.g., DRG payments), Medicare will later adjust amounts paid for non-covered investigational items and services for which payment should not have been included as part of the bundled payment.

Billing Requirements

Bill on HCFA Form HCFA-1450 or electronic equivalent.

Applicable Bill Types--All institutional provider bill types (inpatient and outpatient) are applicable.

When utilizing the UB-92 flat file use record type 40 to report bill type. Record type (Field No. 1), sequence number (Field No. 2), patient control number (Field No. 3), and type of bill (Field No. 4) are required.

When utilizing the hard copy UB-92 (Form HCFA-1450) report the applicable bill type in Form Locator (FL) 4 "Type of Bill."

When utilizing the Medicare A 837 Health Care Claim version 3051 implementations 3A.01 and 1A.C1, report the applicable bill type in 2-130-CLM01, CLM05-01, and CLM05-03.

ICD-9-CM Reporting.--For claims with dates of service on or after September 19, 2000, report ICD-9 diagnosis code V70.5 (Health Examination of Defined Subpopulation) as the second or subsequent diagnosis code (generally, the third or subsequent for HHAs) when billing for a Medicare qualifying clinical trial service. V70.5 cannot be reported as the principal diagnosis.

When utilizing the UB-92 flat file use record type 70, Other Diagnoses Code (Field No. 5-12) to report the ICD-9 code.

When utilizing the hard copy UB-92 report the ICD-9 code in Form Locators (FLs) 68-75 (Other Diagnoses Codes).

When utilizing the Medicare A 837 Health Care Claim version 3051 implementations 3A.01 and 1A.C1, report the ICD-9 in 2-225.A-HI03-02 through HI10-02.

When utilizing the Health Care Claim: Institutional 837 version 4010, report the ICD-9 in OTHER DIAGNOSIS INFORMATION.

If a claim for a Medicare covered clinical trial service was erroneously denied for a date of service on or after September 19, 2000. The action you take to receive payment for this service depends on whether the claim was initially submitted with the clinical trial diagnosis code.

Initial Claim Did Not Include the Clinical Trial Diagnosis Code.--Submit an adjustment bill with the clinical trial ICD-9 diagnosis code. If the claim or any line item on the claim is denied, notify us (insert the telephone number for providers) that the denied service(s) on the claim was related to a Medicare covered clinical trial and, if appropriate, payment will be made.

Inadvertently Denied Claim Was Submitted With the Clinical Trail Diagnosis Code (As the Second or Subsequent Diagnosis, Generally the Third or Subsequent for HHAs).--Notify us that a denied service(s) on the claim was related to a Medicare covered clinical trial service and, if appropriate, payment will be made.

Payment Of Clinical Trial Services For Managed Care Enrollees.--Until Medicare capitation rates are adjusted to account for clinical trials, payment for clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans will be made by the Medicare contractors that process fee for service claims. You will need to submit fee for service bills to those entities for covered clinical trial services furnished to Medicare managed care enrollees. Payment will be based on the current fee for service payment methodologies specific to your provider type and the service being provided. In addition, the Part A and Part B deductibles are assumed to be met for covered clinical trial services billed as fee for service for managed care enrollees.