• Phonocardiogram with ECG lead, with indirect carotid artery and/or jugular vein tracing, and/or apex cardiogram; with interpretation and report,

• Phonocardiogram; without interpretation and report,

• Phonocardiogram; interpretation and report only,

• Intracardiac,

• Vectorcardiogram (VCG), with or without ECG; with interpretation and report,

• Vectorcardiogram; tracing only, without interpretation and report, and

• Vectorcardiogram; interpretation and report only.

310 - Clinical Trials
(Rev. 1, 10-03-03)

310.1 - Routine Costs in Clinical Trials (Effective July 9, 2007)
(Rev. 74, Issued: 09-07-07, Effective: 07-09-07, Implementation: 10-09-07)

Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

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:

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

- 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

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

Routine costs in clinical trials include:

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

o 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.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies (LMRP's) or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare contractors' local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers 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 Pub. 100-03, 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.

A. Requirements for Medicare Coverage of Routine Costs

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

- 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).

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

- 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.

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

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;

3. The trial does not unjustifiably duplicate existing studies;

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

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

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

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

B. Qualification Process for Clinical Trials

Using the authority found in §1142 of the Act (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to CMS.

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do 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.

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

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
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.

The CMS, through the national coverage determination (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.

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.

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. 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.

Medicare regulations require Medicare+Choice (M+C) organizations to follow CMS's national coverage decisions. This NCD raises special issues that require some
modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

(This NCD last reviewed July 2007.)
Effective April 1, 2006, two new condition codes were created for institutional use: 49 and 50 (Table 1). These new codes are used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due to warranty for a malfunction or recall.

<table>
<thead>
<tr>
<th>Table 1: New Condition Codes and Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condition Code</strong></td>
</tr>
<tr>
<td>49</td>
</tr>
<tr>
<td>50</td>
</tr>
</tbody>
</table>

- Providers must use these condition codes to identify medical devices that are provided by a manufacturer at no cost or with full credit due to warranty or recall. These condition codes will be used to track no cost/full credit devices replaced due to recall or warranty.

- Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no cost/full credit replacement device when conditions of warranty or recall are met.

**NOTE:** OPPS hospitals billing no cost/full credit devices must append modifier –FB to the procedure code for implanting the no cost/full credit device, along with the appropriate condition code if applicable (in Table 1 above), in instances when claims processing edits require that certain devices be billed with their associated procedures. The modifier identifies the procedure code line for the no cost/full credit device, while the condition code explains if the device was provided free of cost due to warranty or recall.

**68 – Investigational Device Exemption (IDE)**

*(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)*

**68.1 – General**

*(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)*

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

**NOTE:** For purposes of these instructions, IDEs will be referred to as “studies” instead of “trials” to help distinguish clinical trial instructions from IDE study instructions.

**Category A Devices**
Category A IDE devices are considered experimental and, therefore, are not eligible for payment. Institutional providers should not bill for Category A IDE devices, while practitioners are required to report the Category A IDE number on the claim as specified in §68.3 of this chapter (although they will not receive payment). Practitioners must report the Category A IDE number on the claim because the contractor must validate that the IDE number is part of a current clinical trial by reviewing a monthly file provided by CMS.

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. Both institutional providers and practitioners are required to bill for the routine costs of clinical trials involving Category A devices as specified in §68.3 of this chapter.

**Category B Devices**

Unlike Category A 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 in section 68.2 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 (Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

More information regarding these two categories of IDEs can be located in The Benefit Policy Manual, Chapter 14.

Future updates will be issued in a Recurring Update Notification.

**68.2 – Notifying Contractors of an IDE Device Trial**
(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Providers that participate in an IDE trial and anticipate filing Medicare claims must notify the Medicare contractor. The following information must be furnished prior to submission of a claim for payment:

- 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;
- The name of the device (both trade, common or usual, and classification name);
- Any action taken to conform to any applicable IDE special controls;
- A narrative description of the device sufficient to make a payment determination;
A statement indicating how the device is similar to and/or different from other comparable products;

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

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

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 of approval, all payment will cease. Providers must notify their contractor within 30 days of any change in status for an IDE. By billing for an IDE, whether it is for a Category B IDE device or for the routine costs of clinical trials involving a Category A IDE device, the provider attests that the device was approved at the time the services were rendered.

68.3 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE
(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Providers shall notify their contractor of the Category A IDE device trial before billing routine costs of the Category A IDE device trial, as listed in section 68.2 above. Upon receiving the required information for the trial, the contractor will determine if the Category A IDE device, as used in the trial, is intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease/condition. If the 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 IDE device.

Institutional Inpatient Billing

Routine Costs

Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.

Institutional Outpatient Billing

Routine Costs

Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.
instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.

**Practitioner Billing**

**Routine Costs**

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

**Category A Device**

Effective for dates of service on or before December 31, 2007, practitioners must place a QV modifier (Item or service provided as routine care in a Medicare qualifying clinical trial) on the line for the device along with the IDE number.

Effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QV modifier to identify the device. Instead, practitioners will bill a Q0 (numeral 0 versus the letter o) modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category A IDE number on practitioner claims:

<table>
<thead>
<tr>
<th>Data</th>
<th>CMS-1500</th>
<th>837i and 837p</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDE #</td>
<td>Item 23</td>
<td>Segment 2300, REF02 (REF01=LX)</td>
</tr>
</tbody>
</table>

Contractors will validate the IDE number for the Category A device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider. Remark code MA50 is used.

(Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services), along with Reason Code 16 (Claim/service lacks information which is needed for adjudication).

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

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

As noted above in section 68.2, of this chapter, providers shall first notify their contractor of the IDE device trial before submitting claims for Category B IDE devices and the routine costs of clinical trials involving Category B IDE devices. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill Category B IDE claims.
When billing for Category B IDEs, providers shall bill for the device and all related procedures. The Category B IDE device and the routine costs associated with its use are eligible for payment under Medicare. (payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

**Institutional Inpatient Billing**

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free of charge.

**Institutional Outpatient Billing**

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable.
- The appropriate HCPCS modifier:
  - Q0 (numeral 0 versus the letter o) modifier for claims with dates of service on or after January 1, 2008; or
  - QA modifier for claims with dates of service prior to January 1, 2008.
- The Category B IDE number.
- Charges for the device billed as covered charges.
NOTE: If the Category B IDE device is provided at no cost, OPPS providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing no cost items under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Practitioner Billing

Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter o) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category B IDE number on institutional and practitioner claims:

<table>
<thead>
<tr>
<th>Data</th>
<th>CMS-1450</th>
<th>CMS-1500</th>
<th>837i and 837p</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDE #</td>
<td>FL 43</td>
<td>Item 23</td>
<td>Segment 2300, REF02(REF01=LX)</td>
</tr>
</tbody>
</table>

Contractors will validate the IDE number for the Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider. (Remark code MA50 is used (Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services), along with Reason Code 16 (Claim/service lacks information which is needed for adjudication).

68.5 – Contractor Review of Category B IDEs
(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

When reviewing Category B IDE claims, Medicare contractors determine payment on a case-by-case basis. That is, contractors make local coverage determinations based on
whether or not certain criteria are met. In addition to other national and local coverage policies, the following criteria are used by Medicare contractors to determine Medicare payment for Category B IDE trials:

- The use of the device must be part of an FDA-approved clinical trial;
- The device must be assigned to Category B as described by FDA regulations;
- The use of the device must be medically necessary for the patient for whom coverage is sought;
- The amount, duration, and frequency of the use of the device must be medically appropriate;

The device must be used in a setting appropriate for the patient’s medical needs and condition.

**69 - Qualifying Clinical Trials**
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

**69.1 – General**
(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

The CMS has issued a National Coverage Determination (NCD) which allows Medicare coverage for the routine costs of qualifying clinical trial services as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. The coverage requirements for routine costs of qualifying clinical trial services are contained in *The National Coverage Determinations Manual, Section 310.1.*

**69.2 - Payment for Qualifying Clinical Trial Services**
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For dates of service on or after September 19, 2000, pay for covered services furnished to beneficiaries participating in 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, etc.). 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.

**69.3 - Medical Records Documentation Requirements**
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information
Appendix A (Clinical Trial Billing Documents)

does not need to be submitted with the claim but must be provided if requested for medical review.

69.4 - Local Medical Review Policy
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Do not develop new or revised LMRPs for clinical trial services. Clinical trial services that meet the requirements of the NCD are considered reasonable and necessary.

69.5 - Billing Requirements – General
(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Instruct practitioners and institutional 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. Items and services provided free of charge by research sponsors generally may not be billed to be paid by Medicare, and providers are not required to submit the charge to Medicare. If it is necessary for a provider to show the items and services that are provided free of charge in order to receive payment for the covered routine costs (e.g. administration of a non-covered chemotherapeutic agent), providers are instructed to submit such charges as non-covered at the time of entry, while also assuring that the beneficiary is not held liable. This instruction applies to all hospitals including hospitals located in Maryland under the jurisdiction of the Health Services Cost Review Commission (HSCRC).

For OPPS claims, providers must report a token charge for a no cost item in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service provided to furnish the no cost item, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing no cost items under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Future updates will be issued in a Recurring Update Notification.

69.6 - Requirements for Billing Routine Costs of Clinical Trials
(Rev. 2052, Issued: 09-17-10, Effective: 09-19-00, Implementation: 07-06-10)

Routine Costs Submitted by Practitioners/Suppliers

Claims with dates of service before January 1, 2008:

- HCPCS modifier ‘QV’
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

Claims with dates of service on or after January 1, 2008:
• HCPCS modifier ‘Q1’ (numeral 1 instead of the letter i) ; and
• Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

If the QV or Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service, presumably provided to a participant in the healthy volunteer group. CMS covers costs of healthy volunteers in a qualified clinical trial if it meets the following conditions:

• The trial is not designed exclusively to test toxicity or disease pathophysiology.
• The trial must have therapeutic intent.
• If the trial has therapeutic interventions, it must enroll patients with diagnosed disease rather than healthy volunteers.
• If the trial is studying diagnostic interventions, it may enroll healthy patients in order to have a proper control group.

Effective for claims processed after September 28, 2009, with dates of service on or after January 1, 2008, claims submitted with either the modifier QV or the modifier Q1 shall be returned as unprocessable if the diagnosis code V70.7 is not submitted on the claim.

Contractors shall return the following messages:

Claims adjustment Reason Code 16 – Claim/service lacks information which is needed for adjudication. As least one Remark Code must be provided (may be comprised of either the Remittance Advice Code or NCPDP Reject Reason Code.)

Remittance Advice Remark Code: M76, Missing/incomplete/invalid diagnosis or condition.

Effective for claim processed after September 28, 2009, with dates of service on or after January 1, 2008, contractors shall disable any edits that pertain to clinical trial services being considered diagnostic versus therapeutic based on whether the diagnosis code V70.7 is submitted as the primary or secondary diagnosis.

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is voluntary at this time. Refer to change request (CR) 5790 for more information regarding the 8-digit number. Below are the claim locators that providers should use to bill the 8-digit number:

• CMS-1500 paper form-place in Field 19 (preceded by ‘CT’); and
Routine Costs Submitted by Institutional Providers

All Institutional Clinical Trial Claims

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is voluntary at this time. Refer to CR 5790 for more information regarding the 8-digit number. To bill the 8-digit clinical trial number, institutional providers shall code value code ‘D4’—where the value code amount equals the 8-digit clinical trial number. Below are the claim locators in which to bill the 8-digit number:

- CMS-1450—Form Locator 39-41
- 837I-Loop 2300 HI – VALUE INFORMATION segment (qualifier BE)

NOTE: The QV/Q1 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/Q1 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/Q1 modifier. When billed in conjunction with the V70.7 diagnosis code, the QV/Q1 modifier 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).

Inpatient Clinical Trial Claims

Institutional providers billing clinical trial service(s) must report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer) and a condition code 30 regardless of whether all services are related to the clinical trial or not.

NOTE: HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., QV or Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

Outpatient Clinical Trial Claims

On all outpatient clinical trial claims, providers need to do the following:

- Report condition code 30,
• Report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer); and

• Identify all lines that contain an investigational item/service with a HCPCS modifier of:
  • QA/QR for dates of service before 1/1/08; or
  • Q0 for dates of service on or after 1/1/08.

• Identify all lines that contain a routine service with a HCPCS modifier of:
  • QV for dates of service before 1/1/08; or
  • Q1 for dates of service on or after 1/1/08.

For clinical trial billing requirements for patients enrolled in a managed care plan, please refer to Section 69.9 of this chapter.

69.7 - Reserved for Future Use
(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)

69.8 - Handling Erroneous Denials of Qualifying Clinical Trial Services
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If a service Medicare covers was billed with the appropriate clinical trial coding but was inadvertently denied (e.g., for medical necessity or utilization) and is subsequently brought to your attention, adjust the denied claim. If the denied services weren’t properly coded as clinical trial services, instruct the provider to resubmit the service on a new claim with appropriate clinical trial coding.

69.9 - Billing and Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees
(Rev. 1723, Issued: 05-01-09, Effective: 10-01-09, Implementation: 10-05-09)

For dates of service on or after September 19, 2000, and until notified otherwise by CMS, Medicare contractors will pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans. Providers who furnish covered clinical trial services to managed care beneficiaries must be enrolled with Medicare in order to bill on a fee-for-service basis. Providers that wish to bill fee for service but have not enrolled with Medicare must contact their local carrier, intermediary, regional home health intermediary or National Supplier Clearinghouse, as appropriate, to obtain an enrollment application.

Determine payment for covered clinical trial services furnished to beneficiaries enrolled in managed care plans in accordance with 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.
The clinical trial coding requirements for managed care enrollee claims are the same as those for regular Medicare fee for service claims. However, for beneficiaries enrolled in a managed care plan, institutional providers must not bill outpatient clinical trial services and non-clinical trial services on the same claim. If covered outpatient services unrelated to the clinical trial are rendered during the same day/stay, the provider must split-bill so that ONLY the clinical trial services are contained on a single claim and billed as fee-for-service (this allows the Medicare claims processing system to not apply deductible when the patient is found to be in a managed care plan). Any outpatient services unrelated to the clinical trial should be billed to the managed care plan.

69.10 - CWF Editing Of Clinical Trial Claims For Managed Care Enrollees
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Submit clinical trial services for managed care enrollees to CWF for payment approval. CWF will not reject clinical trial claims for managed care enrollees when all services on the claim transaction record are coded as clinical trial services and the date(s) of service is (are) on or after September 19, 2000. In addition, CWF will not apply Part B deductible to clinical trial claims for managed care enrollees (i.e., CWF will process clinical trial services for managed care enrollees as if the Part B deductible has already been met).

69.11 - Resolution of CWF UR 5232 Rejects
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If you send a claim transaction to CWF that includes both clinical and non-clinical trial services for a managed care enrollee, the entire claim will be rejected with the UR 5232 error code. When you receive a UR 5232 error code split the claim and resubmit the clinical trial portion to CWF. Process the non-clinical trial portion of the rejected claims in the same manner that other non-clinical trial fee for service claims for managed care enrollees are handled.

70 - Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial
(Rev. 986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

For services performed on or after October 1, 2004, Medicare will cover islet cell transplantation for patients with Type I diabetes who are participating in an NIH sponsored clinical trial. See Pub 100-04 (National Coverage Determinations Manual) section 260.3.1 for complete coverage policy.

The islet cell transplant may be done alone or in combination with a kidney transplant. Islet recipients will also need immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care will be necessary for each trial patient. See Pub 100-04, section 310 for further guidance relative to routine care. All other uses for islet cell services will remain non-covered.

ALERT: Clinical Trials & Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers’ Compensation

When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported. The appropriate Responsible Reporting Entity (RRE) should report the date that the injury/complication first arose as the Date of Incident (DOI). The situation should also be reported as one involving Ongoing Responsibility for Medicals (ORM).
Humanitarian Use Devices

A Humanitarian Use Device (HUD), as defined by the Food and Drug Administration (FDA), is a device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals per year in the United States. When the manufacturer submits a Humanitarian Device Exemption (HDE) application to the FDA, it must provide sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury to the patient and that the probable benefits to health outweigh the risk of injury or illness from its use. The manufacturer is not required to provide the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose prior to marketing (see FDA regulations (21 CFR 814.124)). This regulation was developed to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting limited populations. Such devices may only be used in institutions where a local Institutional Review Board (IRB) has approved the use of the device to treat or diagnose the specific rare disease. Absent IRB approval, the device cannot be used in humans.

Medicare has no specific rules, regulations or instructions with regard to HUDs. Medicare does not require nor is there any process for obtaining prior approval for HUDs. Furthermore, Medicare does not perform “prior authorizations” for insertion of these devices.

Additionally, coverage under general Medicare rules (see Social Security Act, Section 1862 (a)(1)(A) Medically Reasonable and Necessary) indicates most HUDs are not covered by Medicare. FDA approval does not speak to the effectiveness of the device, while coverage by Medicare requires a device be considered reasonable and necessary in the treatment of disease or illness and it must have been determined to be effective.
FDA-Approved Investigational Device Exemption (IDE) Pre-Approval Submission Checklist

The items listed below are required to process your request. Incomplete packets will be returned and delay the processing of your submission. Please submit the following **required** information.

**Note:** The verification and validity of all documentation remain the provider’s responsibility, as is the guarantee that Medicare is billed according to Medicare guidelines.

- The name of the device (both trade, common or usual and classification name).
- The Food and Drug Administration (FDA)-assigned Investigational Device Exemption (IDE) number (GXXXXXX or PXXXXXX).
- A narrative description of the device. Include a statement as to the device’s similarities and differences from other products if not explicitly and clearly indicated in submitted documents.
- Clinical trial identification number from ClinicalTrials.gov (NCTXXXXXXX).
- An **unredacted** copy of FDA approval letters sent to the provider and/or the sponsor or manufacturer of the device. The approved IDE number must be on the letter.
- A copy of the approval letter from the provider’s **Institutional Review Board (IRB)**. (A copy of the approval letter for any time extension or other update must also be submitted after the initial approval occurs.)
- Requests for post-approval extension studies for carotid artery stenting must also include a copy of the CMS approval letter (i.e., CAPTURE, CHOICE, SAPPHIRE).
- A description of the action(s) taken to conform to any applicable FDA and/or IRB special controls and/or other requirements.
- Total number of study subjects anticipated for the facility/provider.
- Indication if approval is being submitted for Part A or Part B (or both).
- A list of all providers and provider numbers participating in the study.
- The name of the facility and provider number where the study is being performed.
- A copy of the study protocol, or protocol summary, including patient inclusion criteria.
- A copy or description of the provider’s protocol for obtaining informed patient consent.
- A sample of the patient consent form. Form must clearly describe the patient’s financial responsibility. Form also must clearly indicate any financial or other interest of the participating provider(s) and others at the facility directly involved in conducting the study or directly affected by the outcome of the study.
- A description of the facility’s processes/procedures for ensuring Medicare is not billed for:
  - Non-routine care costs.
  - Sponsor or other reimbursed costs.
  - Services or devices provided without charge or reimbursed from other sources.

**You may submit the following optional information:**

- Copies of all agreements between the sponsor and the provider, especially, but not limited to, financial agreements. Note that any and all payments for each aspect of the study must be included.
- The Principal Investigator’s (PI’s) budget for the study, showing allocation of all funds from all sources. If not indicated on the protocol itself, the budget should specify the costs of the
services (including evaluations), tests and procedures that will be performed throughout the course of the study and which will be billed to Medicare. Submit the PI’s determination of which tests and procedures are necessary to the research and which tests and procedures are standard of care for the treatment of the underlying disease in the absence of the study intervention.

- The provider may elect to delineate the Medicare-billed services on a copy of the study protocol or follow the procedure described in the bullet above. On this protocol copy, for each service or procedure in the protocol, indicate next to the service or procedure either the word “study” to indicate the service or procedure is a cost and responsibility of the study (and will not be billed to Medicare) or the word “Medicare” for a service or procedure that: (a) is medically necessary for the patient’s care; (b) would have been incurred in the absence of the study; and (c) is a Medicare-covered benefit/service.

“I certify the above is accurate and complete and understand that it is my responsibility to ensure that claims are submitted to Medicare in compliance with Medicare guidelines.”

(To be signed by IDE investigator or proxy)

Consideration for approval of the device will occur only after receipt of all required items listed above. Failure to submit each required item may result in disapproval of the device.

PLEASE COMPLETE THE FOLLOWING:

Provider name and Medicare provider number:

Date this information is being mailed:

Contact regarding submission of documents:

Contact phone number:

Contact regarding technical/clinical questions:

Return address for determination letter:

Note: Be sure to indicate whether this is a request for Medicare Part A and/or Medicare Part B coverage.

Send requests to: TrailBlazer Health Enterprises, LLC
Contractor Medical Director
Executive Center III
8330 LBJ Freeway
Dallas, TX 75243-1213
FDA-Approved IDE and Clinical Trial
Part A Billing Instructions

The CMS-1450 (UB-04) claim form contains Form Locators (FLs) that must be specifically coded for Investigational Device Exemption (IDE) and clinical trial claims according to CMS instructions. The following Medicare Part A billing instructions should be used when coding IDE and clinical trial items and services.

<table>
<thead>
<tr>
<th>Use the modifiers listed below for dates of service on or before December 31, 2007.</th>
<th>Use the modifiers listed below for dates of service on or after January 1, 2008.</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA – FDA investigational device exemption.</td>
<td>Q0 – Investigational clinical service provided in a clinical research study that is in an approved clinical research study.</td>
</tr>
<tr>
<td>QV – Item or service provided as routine care in a Medicare-qualifying clinical trial.</td>
<td>Q1 – Routine clinical service provided in a clinical research study that is in an approved clinical research study.</td>
</tr>
</tbody>
</table>

Category B IDEs

After receiving approval from TrailBlazerSM, providers should follow the billing instructions below:

- Bill with condition code 30 for all types of service.
- In FL 42 (Revenue Code), or the electronic equivalent, report all IDE devices and procedures under revenue code 0624. This code was specifically created by CMS to identify IDE devices and is only applicable to investigational devices and procedures with Food and Drug Administration (FDA)- and Institutional Review Board (IRB)-approved IDEs. (Refer to the Medicare Claims Processing Manual, Internet-Only Manual (IOM) Pub. 100-04, Chapter 32, Section 68.)
- In FL 43 (Description), or the electronic equivalent, report the IDE number (i.e., GXXXXXX or PXXXXXX). (Refer to the Medicare Claims Processing Manual, IOM Pub. 100-04, Chapter 32, Section 68.)
- In FL 44 (HCPCS/Rates), or the electronic equivalent, report the HCPCS code (or “C” code if applicable) opposite revenue code 0624. (Note: May be xxx99.) (Refer to the Medicare Claims Processing Manual, IOM Pub. 100-04, Chapter 32, Section 68.)
• The ICD-9-CM diagnosis codes listed on the claim must be consistent with IDE trial indications.
• The claim must include ICD-9-CM diagnosis code V70.7 (examination of participant in clinical trial) as the secondary diagnosis.
• Include the QV or Q1 modifier to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from participation in a study involving a Category B device (only for institutional outpatient claims).
• The QV or Q1 modifier may not be used for items and services provided solely for data collection and analysis for the clinical trial, and the information is not used in the clinical management of the patient (only for institutional outpatient claims).
• The QV or Q1 modifier may not be used for items and services not covered by Medicare due to statutory exclusion or lack of a benefit category (only for institutional outpatient claims).

Category A IDEs

After receiving approval from TrailBlazer, providers should follow the billing instructions below:
• The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.
• Bill with condition code 30 for all types of service.
• The ICD-9-CM diagnosis codes listed on the claim must be consistent with IDE trial indications.
• Coverage for routine services associated with Category A devices requires the patient have a primary diagnosis of an immediately life-threatening disease.
• The claim must include ICD-9-CM diagnosis code V70.7 (examination of participant in clinical trial) as a secondary diagnosis for all types of service.
• Include the QV or Q1 modifier to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from participation in a study involving a Category A device (only for institutional outpatient claims).
• The QV or Q1 modifier may not be used for items and services provided solely for data collection and analysis for the clinical trial, and the information is not used in the clinical management of the patient (only for institutional outpatient claims).
• The QV or Q1 modifier may not be used for items and services not covered by Medicare due to statutory exclusion or lack of a benefit category (only for institutional outpatient claims).
• Items and services provided free of charge by research sponsors may not be billed for Medicare payment. (If it is necessary for a provider to show the items and services that
are provided free of charge to receive payment for the covered routine costs, the provider is instructed to submit such charges as non-covered at the time of entry, while also ensuring the beneficiary is not held liable.)

Clinical Trials

- Bill with condition code 30 for all types of service.
- The claim must include ICD-9-CM diagnosis code V70.7 (examination of participant in clinical trial) as the secondary diagnosis for all types of service.
- Include the QV or Q1 modifier to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from participation in a Medicare-covered clinical trial (only for institutional outpatient claims).
- The QV or Q1 modifier may not be used for items and services provided solely for data collection and analysis for the clinical trial, and the information is not used in the clinical management of the patient (only for institutional outpatient claims).
- The QV or Q1 modifier may not be used for items and services not covered by Medicare due to statutory exclusion or lack of a benefit category (only for institutional outpatient claims).
- Items and services provided free of charge by research sponsors may not be billed for payment by Medicare. (If it is necessary for a provider to show the items and services that are provided free of charge to receive payment for the covered routine costs, the provider is instructed to submit such charges as non-covered at the time of entry, while also ensuring that the beneficiary is not held liable.)

Additional Instructions

- Per Change Request (CR) 5790, providers are encouraged to report the eight-digit clinical trial number on their claims. For more information, refer to MLN Matters article MM 5790 at:
  

- Per CR 6185, institutions billing claims for implantation of an artificial heart (ICD-9-CM procedure code 37.52) should follow the clinical trial billing instructions listed above. **Note:** These claims require the eight-digit national clinical trial number (the trial number must match an approved artificial heart trial). For more information, refer to MM 6185 at:

Note: Services denied for incorrect coding should be resubmitted on a new claim with the appropriate IDE or clinical trial coding.

The verification and validity of all documentation remain the provider's responsibility, as is the guarantee that Medicare is billed according to Medicare guidelines.

References

- Medicare Claims Processing Manual, IOM Pub. 100-04:
  - Chapter 25.
  - Chapter 32, Sections 67–69.
FDA-Approved IDE and Clinical Trial
Part B Billing Instructions

The CMS-1500 claim form (or the electronic equivalent) must be specifically coded for Investigational Device Exemption (IDE) and clinical trial claims according to CMS instructions. The following Medicare Part B billing instructions should be used when coding IDE and clinical trial items and services.

<table>
<thead>
<tr>
<th>Use the modifiers listed below for dates of service on or before December 31, 2007.</th>
<th>Use the modifiers listed below for dates of service on or after January 1, 2008.</th>
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<tbody>
<tr>
<td>QA – FDA investigational device exemption.</td>
<td>Q0 – Investigational clinical service provided in a clinical research study that is in an approved clinical research study.</td>
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<tr>
<td>QV – Item or service provided as routine care in a Medicare qualifying clinical trial.</td>
<td>Q1 – Routine clinical service provided in a clinical research study that is in an approved clinical research study.</td>
</tr>
</tbody>
</table>

Category B IDEs

After receiving approval from TrailBlazerSM, providers should follow the billing instructions below.

- The ICD-9-CM diagnosis codes listed on the claim must be consistent with IDE trial indications.
- The claim must include ICD-9-CM diagnosis code V70.7 (examination of participant in clinical trial) as the secondary diagnosis.
- Report the IDE number in Item 23 of the claim form (or electronic equivalent) as outlined in the CMS instructions for billing of Part B IDEs. (Refer to the Medicare Claims Processing Manual, Chapter 32, Section 68.)
- Include the QA or Q0 modifier on the line item that identifies the investigational device.
- Include the QV or Q1 modifier on each line item on the claim, which identifies routine services associated with the study.
Category A IDEs

After receiving approval from TrailBlazer, providers should use the following billing instructions:

- The Category A IDE device shall not be reported on Part B claims since it is non-covered by Medicare.
- The ICD-9-CM diagnosis codes listed on the claim must be consistent with IDE trial indications.
- Coverage for routine services associated with Category A devices requires the patient have a primary diagnosis of an immediately life-threatening disease.
- The claim must include ICD-9-CM diagnosis code V70.7 (examination of participant in clinical trial) as a secondary diagnosis.
- Report the IDE number in Item 23 of the claim form (or electronic equivalent) as outlined in the CMS instructions for billing of Part B IDEs. (Refer to the Medicare Claims Processing Manual, Chapter 32, Section 68.)
- Include the QV or Q1 modifier on the line items on the claim to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from participation in a study involving a Category A device.
- The QV or Q1 modifier may not be used for items and services provided solely for data collection and analysis for the clinical trial, and the information is not used in the clinical management of the patient.
- The QV or Q1 modifier may not be used for items and services not covered by Medicare due to statutory exclusion or lack of a benefit category.
- Items and services provided free of charge by research sponsors may not be billed for Medicare payment and may not be billed to the beneficiary.

Clinical Trials

- The claim must include ICD-9-CM diagnosis code V70.7 (examination of participant in clinical trial) as the secondary diagnosis.
- Include the QV or Q1 modifier on the line items on the claim to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from participation in a Medicare-covered clinical trial.
- The QV or Q1 modifier may not be used for items and services provided solely for data collection and analysis for the clinical trial, and the information is not used in the clinical management of the patient.
- The QV or Q1 modifier may not be used for items and services not covered by Medicare due to statutory exclusion or lack of a benefit category.
• Items and services provided free of charge by research sponsors may not be billed for Medicare payment and may not be billed to the beneficiary.

Additional Instructions

• Per Change Request (CR) 5790, providers are encouraged to report the eight-digit clinical trial number on their claims. For more information, refer to the MLN Matters article MM 5790 at:


• Per CR 6185, providers/suppliers billing claims for implantation of an artificial heart (procedure code 0051T) should follow the clinical trial billing instructions listed above. Note: These claims require the eight-digit national clinical trial number (the trial number must match an approved artificial heart trial). For more information, refer to MM 6185 at:


Note: Services denied for incorrect coding should be resubmitted on a new claim with the appropriate IDE or clinical trial coding.

The verification and validity of all documentation remain the provider's responsibility, as is the guarantee that Medicare is billed according to Medicare guidelines.

References


• *Medicare Claims Processing Manual*, IOM Pub. 100-04:
  o Chapter 26, Section 10.
  o Chapter 32, Sections 67–69.

Investigational Device Exemption

The Investigational Device Exemption (IDE) guidelines established by CMS on November 1, 1995, provide coverage for the use of some Category A and approved Category B devices with a Food and Drug Administration (FDA)-approved IDE. IDE coverage is contingent on approval by TrailBlazerSM of the IDE application for reimbursement.

Medicare may provide reimbursement for some investigational devices and related services. Related services may be furnished in preparation for device use, contemporaneously with and necessary to the use of the device, and as follow-up care after device use. Coverage is contingent on TrailBlazer's approval of the application for reimbursement.

Medicare covers the use of devices that are “reasonable and necessary for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body member” (Social Security Act, Section 1862.9(A)(1)(A)). By law, CMS may only pay for medical services considered reasonable and necessary. Consequently, Medicare denies coverage of experimental devices due to the absence of medical necessity, which cannot be established when the safety and effectiveness of a device are unknown. A device the FDA has categorized as investigational, including devices being studied under IDEs, is presumed to be experimental. Historically, this interpretation meant that a medical device required either clearance or FDA pre-marketing approval, based on evidence establishing the device’s safety and effectiveness, to qualify for payment.

Prior to submitting claims for Category B IDE devices and/or for services associated with Category A or B IDE investigations, providers must submit all required information for Medicare contractor review and approval.

Applying for Coverage

To apply for coverage of a Category B device and/or associated routine services or for routine services associated with Category A IDE investigations:

- Submit the information outlined on the Pre-Approval Submission Checklist. Applications will not be considered for review until all required information has been received.
- Mail submissions to the Medical Directors.
- Provider notification will occur, in writing, upon approval/disapproval. If an application is approved, the claim payment systems will be set to accept the provider’s claims.

Coverage Criteria

Coverage criteria for IDEs include:

- **The device must pose no significant risk to patients and must be potentially effective (i.e., produce or contribute to a therapeutic advantage).**
Implementation of this criterion required the FDA to refine its classification system to reflect differences in presumed safety. As a result, devices studied in clinical trials under IDEs fall into two categories: A and B. The new classification system distinguishes between “investigational” devices that may be considered for Medicare payment and devices that are truly “experimental” or breakthrough technologies that may not be considered for Medicare payment under the IDE coverage policy.

Category A devices are novel, first-of-a-kind technologies. These are innovative devices for which initial questions of safety and effectiveness have not been resolved, and the absolute risk of the device type has not been established. The FDA has insufficient evidence to determine whether these device types can be safe and effective. Category A devices remain non-covered, though coverage for routine services associated with approved Category A IDE investigations became effective January 1, 2005, when the approved device is used for the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.

Note: The Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003, Section 731(b) allows some coverage, in accordance with the Clinical Trials Policy (Internet-Only Manual (IOM) Pub. 100-03, Section 310.1) – not IDE coverage – of the routine patient care costs associated with specific studies that involve specific Category A devices (IOM Pub. 100-03, Chapter 1, Section 20.7; IOM Pub. 100-04, Chapter 32, Sections 69.0–69.11).

Category B devices are newer generation devices of already proven technologies. Initial questions of safety and effectiveness of these devices have been resolved. Devices in this category represent evolutionary changes in proven technologies and will be viewed as potentially reasonable and necessary by Medicare. These devices may be eligible for coverage and payment under the IDE coverage legislation.

Note: This legislation does not guarantee that all Category B devices undergoing clinical trials will be covered under Medicare. The contractor makes the final coverage decision based on the submission of the required documentation.

- **The device must be used in the context of an FDA- and Institutional Review Board-approved study.** The approved study protocol limits the use of the device to a predetermined limited number of sites and predetermined limited number of patients.
- **The device must have an assigned IDE number.** This identification number allows the Medicare contractor to establish special claims processing procedures associated with the study.
- **The device must meet all Medicare coverage requirements.** This policy change does not mean that all Category B devices undergoing clinical trials will be covered under Medicare.
SEC. 10102. AMENDMENTS TO SUBTITLE B.

(a) Section 1102(a)(2)(B) of this Act is amended—

(1) in the matter preceding clause (i), by striking “group health benefits plan” and inserting “group benefits plan providing health benefits”; and

(2) in clause (i)(I), by inserting “or any agency or instrumentality of any of the foregoing” before the closed parenthetical.

(b) Section 1103(a) of this Act is amended—

(1) in paragraph (1), by inserting “, or small business in,” after “residents of any”; and

(2) by striking paragraph (2) and inserting the following:

“(2) CONNECTING TO AFFORDABLE COVERAGE.—An Internet website established under paragraph (1) shall, to the extent practicable, provide ways for residents of, and small businesses in, any State to receive information on at least the following coverage options:

“(A) Health insurance coverage offered by health insurance issuers, other than coverage that provides reimbursement only for the treatment or mitigation of—

“(i) a single disease or condition; or

“(ii) an unreasonably limited set of diseases or conditions (as determined by the Secretary).

“(B) Medicaid coverage under title XIX of the Social Security Act.

“(C) Coverage under title XXI of the Social Security Act.

“(D) A State health benefits high risk pool, to the extent that such high risk pool is offered in such State; and

“(E) Coverage under a high risk pool under section 1101.

“(F) Coverage within the small group market for small businesses and their employees, including reinsurance for early retirees under section 1102, tax credits available under section 45R of the Internal Revenue Code of 1986 (as added by section 1421), and other information specifically for small businesses regarding affordable health care options.”.

SEC. 10103. AMENDMENTS TO SUBTITLE C.

(a) Section 2701(a)(5) of the Public Health Service Act, as added by section 1201(4) of this Act, is amended by inserting “(other than self-insured group health plans offered in such market)” after “such market”.

(b) Section 2708 of the Public Health Service Act, as added by section 1201(4) of this Act, is amended by inserting “other than self-insured group health plans offered in such market” after “such market”.

(c) Subpart I of part A of title XXVII of the Public Health Service Act, as added by section 1201(4) of this Act, is amended by inserting after section 2708, the following:

“SEC. 2708. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

“(a) COVERAGE.—

“(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—
(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);
(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
(C) may not discriminate against the individual on the basis of the individual’s participation in such trial.

(2) ROUTINE PATIENT COSTS.—
(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.
(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—
(i) the investigational item, device, or service, itself;
(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or
(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.
(2) Either—
(A) the referring health care professional is a participating health care provider and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or
(B) the participant or beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).
(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer
offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan’s (or coverage’s) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term ‘approved clinical trial’ means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

(i) The National Institutes of Health.

(ii) The Centers for Disease Control and Prevention.

(iii) The Agency for Health Care Research and Quality.

(iv) The Centers for Medicare & Medicaid Services.

(v) cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.

(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) Any of the following if the conditions described in paragraph (2) are met:

(I) The Department of Veterans Affairs.

(II) The Department of Defense.

(III) The Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) LIFE-THREATENING CONDITION DEFINED.—In this section, the term ‘life-threatening condition’ means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(f) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s or issuer’s coverage with respect to clinical trials.
(g) Application to FEHBP.—Notwithstanding any provision of chapter 89 of title 5, United States Code, this section shall apply to health plans offered under the program under such chapter.

(h) Preemption.—Notwithstanding any other provision of this Act, nothing in this section shall preempt State laws that require a clinical trials policy for State regulated health insurance plans that is in addition to the policy required under this section.

(d) Section 1251(a) of this Act is amended—

(1) in paragraph (2), by striking “With” and inserting “Except as provided in paragraph (3), with” ; and

(2) by adding at the end the following:

“(3) Application of Certain Provisions.—The provisions of sections 2715 and 2718 of the Public Health Service Act (as added by subtitle A) shall apply to grandfathered health plans for plan years beginning on or after the date of enactment of this Act.”.

e) Section 1253 of this Act is amended insert before the period the following: “, except that—

(1) section 1251 shall take effect on the date of enactment of this Act; and

(2) the provisions of section 2704 of the Public Health Service Act (as amended by section 1201), as they apply to enrollees who are under 19 years of age, shall become effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act.”.

f) Subtitle C of title I of this Act is amended—

(1) by redesignating section 1253 as section 1255; and

(2) by inserting after section 1252, the following:

“SEC. 1253. ANNUAL REPORT ON SELF-INSURED PLANS.

“Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Secretary of Labor shall prepare an aggregate annual report, using data collected from the Annual Return/Report of Employee Benefit Plan (Department of Labor Form 5500), that shall include general information on self-insured group health plans (including plan type, number of participants, benefits offered, funding arrangements, and benefit arrangements) as well as data from the financial filings of self-insured employers (including information on assets, liabilities, contributions, investments, and expenses). The Secretary shall submit such reports to the appropriate committees of Congress.

“SEC. 1254. STUDY OF LARGE GROUP MARKET.

“(a) In General.—The Secretary of Health and Human Services shall conduct a study of the fully-insured and self-insured group health plan markets to—

(1) compare the characteristics of employers (including industry, size, and other characteristics as determined appropriate by the Secretary), health plan benefits, financial solvency, capital reserve levels, and the risks of becoming insolvent; and

(2) determine the extent to which new insurance market reforms are likely to cause adverse selection in the large group market or to encourage small and midsize employers to self-insure.

(b) Collection of Information.—In conducting the study under subsection (a), the Secretary, in coordination with the Secretary of Labor, shall collect information and analyze—