Investigational Device Exemption (IDE) Request Form

Providers are required to notify Medicare about clinical studies under three conditions.

1. Providers that participate in an IDE clinical study and anticipate filing Medicare claims must notify the Medicare contractor. This applies to all IDEs assigned an identifying number beginning with a 'G' and a CMS category B (B1, B2, B3, or B4) by the Food and Drug Administration (FDA).
2. Providers shall notify their contractor of the Category A IDE device clinical study before billing routine costs of clinical studies involving a Category A device.
3. Providers participating in post-market approval studies or registries of carotid stents shall notify the Medicare contractor prior to billing for these services.

Notice is not required for humanitarian use devices, post-market approval studies or registries of devices other than carotid stents, or clinical studies other than those described above.

Electronic submission of documentation, by email or fax, is preferred and will substantially shorten the time required to review the information supplied. Information may be submitted to: NGS-IDE-Request@wellpoint.com ; NGS-IDE-Request per fax: (540) 853-3692; or National Government Services IDE Request, 602 S. Jefferson St., Roanoke, VA 24011

Compliance with the instructions contained in the *Medicare Claims Processing Manual* (Publication 100-4, chapter 32, sections 68 and 69) is a requirement for both National Government Services and our providers. IDE request determinations (approval or denial) will be retroactive to the date the complete request is received by National Government Services or the effective date of the IRB approval, which ever is later. Questions related to the IDE process may be submitted by email, fax, or mail to the addresses listed above. Use of any other National Government Services address will delay the response because of the need to re-direct your mail.

Inquiries submitted electronically should contain, in the subject line, the provider's name, the code assigned by the FDA (the alpha numeric code beginning with either a "G" or a "P"), and the name of the study or device.

NOTE: National Government Services is: the Medicare fiscal intermediary in California, Connecticut, Delaware, Hawaii, Illinois, Maine, Massachusetts, Michigan, New Hampshire, New York, Ohio, Vermont, Virginia, West Virginia, Wisconsin; the Medicare carrier in New Jersey; and both fiscal intermediary and carrier in Indiana, Kentucky, and down-state New York (except Queens County.)

The following form may be used when submitting the request to National Government Services.

Contact person for this request:

Name:

Address:

Phone number:

Email address:

Addressee (if different from contact person)

Name:

Request on behalf of (may be both categories):

[ ] Facility(ies) (Medicare Part A)

[ ] Individual practitioner(s) (Medicare Part B)

IDE number:

Study Name:

Trade name (device):

Common name of the device:

Please submit the following site specific information:

Facility(ies) where service will be provided:

Facility Name	Address	NPI (not UPIN)

Participating practitioner (s):

	Name	MD / DO	NPI (not UPIN)
PI			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			

Number of enrollees anticipated at the facility:

Anticipated bill type: (inpatient, outpatient, or both):

The following site specific documents are needed to process this request. They may be submitted in hard copy or electronic format.

1. A signed copy of the IRB approval letter.
2. A copy of the informed consent approved by the IRB.
3. A fully executed copy of the investigative agreement.
4. A list of any devices, supplies, drugs, or services for which the facility or physician will be reimbursed by the manufacturer.

The following documents specific to the study, trial, and/or registry are needed to process this request. They may be submitted by either the sponsor or the provider.

1. A non-redacted copy of the FDA-approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number and category designation must be on the letter.
2. A description of any action(s) taken to conform to any applicable IDE special controls.
3. A full copy of the applicable protocol.
4. A narrative description of the device sufficient to make a payment determination. (If this is part of the protocol, identify the page number(s).)
5. A statement indicating how the device is similar to and/or different from other comparable products. (If this is part of the protocol, identify the page number(s).)
6. At least two (2) supporting scientific articles (full texts) for the investigational device and its intended indication published in peer reviewed literature.

Providers requesting a continuation of coverage or an expansion of coverage for which National Government Services has already issued a letter of approval should submit the following documents:

1. A copy of the original letter(s) from National Government Services approving the study.
2. A current copy of the IRB approval letter.
3. A copy of any documents that have changed since the original approval was issued (eg: consent form, protocol, investigative agreement, FDA letter).
4. If the request is for an expansion of the anticipated number of patients, what is the new total anticipated?
5. If the request is for the addition of sub-investigators or a change in the chief investigator, submit a list of the new physician investigator team. Indicate appropriate professional designation (eg: M.D. or D.O) and include the NPI numbers.