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ARTICLE FOR INVESTIGATIONAL DEVICE EXEMPTION REQUESTS – MEDICAL POLICY ARTICLE (A45910)

Contractor Information

Contractor Name

National Government Services, Inc.

Contractor Number

Number	Type	State(s)
06101	MAC– Part A	IL
06201	MAC– Part A	MN
06301	MAC– Part A	WI
13101	MAC– Part A	CT
13102	MAC– Part B	CT
13201	MAC– Part A	NY
13202	MAC– Part B	NY
13282	MAC– Part B	NY
13292	MAC– Part B	NY

Contractor Type

MAC- Part A
MAC- Part B

Article Information

Article ID Number

A45910

Article Type

Article

Key Article

Yes

Article Title

Investigational Device Exemption Requests -- Medical Policy Article

AMA CPT / ADA CDT Copyright Statement

Primary Geographic Jurisdiction

Number	Type	State(s)
06101	MAC– Part A	IL
06201	MAC– Part A	MN
06301	MAC– Part A	WI
13101	MAC– Part A	CT
13102	MAC– Part B	CT
13201	MAC– Part A	NY
13202	MAC– Part B	NY
13282	MAC– Part B	NY
13292	MAC– Part B	NY

Original Article Effective Date

10/01/2007

Article Revision Effective Date

08/10/2013

Article Text

Clinical Study Request

Compliance with the instructions contained in the Medicare Claims Processing Manual (Publication 100-04, chapter 32, sections 68 and 69) is a requirement for both National Government Services and our providers. Providers are required to notify Medicare about clinical studies under four conditions.

- 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).
- 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.
- Providers participating in post-market approval studies or registries of carotid stents shall notify the Medicare contractor prior to billing for these services.
- Providers participating in studies for proximal embolic protection devices (EPDs) in carotid artery stenting (CAS) procedures.

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.

National Government Services reviews clinical study requests from hospitals in Illinois, Minnesota and Wisconsin; and from both hospitals and physicians in Connecticut and New York. Clinical coverage determinations are applied uniformly across these regions. If a study has been reviewed for another facility you may not be required to submit study specific information. To reduce the amount of information you are required to submit, please send the following inquiry to National Government Services electronically prior to submitting a request for authorization.

Send email to: NGS IDE-Request@wellpoint.com

Subject line should read: 'Clinical Study Submission Inquiry'

Message: _____ will be participating in Clinical Study _____ (IDE/PMA/EPD# _____) Protocol Version # _____. Is full study and site specific information required or only site specific?

Providers without email access may fax the same inquiry to: 717-565-3432

or submit their inquiry to:

National Government Services IDE Request
2400 Thea Dr., Suite 3B
Harrisburg, PA 17110

The "Request Form for Investigational Device Exemptions (IDE),Carotid Stent Clinical Studies (PMA)" or Proximal Embolic Protection Device Studies (EPD) detailing study and site specific information required is located under 'Article Attachments' below.

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.

Coding Information

No Coding Information has been entered in this section of the article.

Other Information

Other Comments

Not applicable

Revision History Explanation

08/10/2013 - This article was revised to add the Jurisdiction 6 Minnesota Part A Contract Number 06201.

Minnesota has been added to the Clinical Study Request section.

07/13/2013 - This article was revised to add the Jurisdiction 6 Illinois Part A Contract Number 06101 and Wisconsin MAC Part A Contract Number 06301.

08/20/2012 - In accordance with Section 911 of the Medicare Modernization Act of 2003, carrier number 00630 is removed from this Article. Effective on this date, claims processing for Indiana Part B is performed by Wisconsin Physician Services, the Part A/Part B MAC contractor for this state.

References to IDE submissions for Indiana and Michigan have been deleted.

07/23/2012 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary numbers 00130 and 00452 are removed from this Article. Effective on this date, claims processing for Indiana and Michigan is performed by Wisconsin Physician Services, the Part A/Part B MAC contractor for these states.

10/17/2011 - In accordance with Section 911 of the Medicare Modernization Act of 2003, intermediary numbers 00160 and 00332 are removed from this article. Effective on this date, claims processing for Kentucky – Part A and Ohio –Part A is performed by CGS Administrators, LLC, the Part A/Part B MAC contractor for these states.

10/17/2011 - Removed Ohio and Kentucky from the Clinical Study Request secion. This is in accordance with Section 911 of the Medicare Modernization Act of 2003. Effective on 10/17/2011, claims processing for Kentucky – Part A and Ohio – Part A is performed by CGS Administrators, LLC, the Part A/Part B MAC contractor for these states.

Removed Virginia and West Virginia from the Clinical Study Request section in accordance with Section 911 of the Medicare Modernization Act of 2003. Effective on 05/16/2011, claims processing for Virginia - Part A and West Virginia - Part A is performed by Palmetto Government Benefits Administration, the Part A/Part B MAC contractor for these states. No comment and notice periods required and none given.

05/16/2011 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00453 is removed from this Article. Effective on this date, claims processing for Virginia and West Virginia is performed by Palmetto Government Benefits Administration, the Part A/Part B MAC contractor for these states.

04/30/2011 - In accordance with Section 911 of the Medicare Modernization Act of 2003, carrier number 00660 is removed from this Article. Effective on this date, claims processing for Kentucky is performed by Cigna Government Services, the Part A/Part B MAC contractor for this state.

03/24/2011 – Updated the Fax Number and address for submission of inquiry. Added Proximal Embolic Protection Devices (EPDs).

06/05/2009 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00270 was removed from this article as the claims processing for New Hampshire and Vermont was transitioned to NHIC, the Part A/Part B MAC contractor in these states.

05/15/2009 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary numbers 00180 and 00181 were removed from this Article as the claims processing for Maine and Massachusetts was transitioned to NHIC, the Part A/Part B MAC contractor in these states.

Third Revision: 01/01/2009 Format revised to add form as attachment.

Second Revision: 12/01/2007 Mailing address and fax number were updated.

First Revision: 10/01/2007 The following added for clarification: IDE request determinations (approval or denial) will be retroactive to the date the request is received by NGS. Any questions related to the IDE process may be submitted by email, fax, or mail to the addresses listed above.

In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy/article was retired due to the transition from Part B National Government Services (NGS) (Contract #00803) to the Part B MAC National Government Services (NGS) (Contract #13202).

11/14/2008 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00308 is removed from this article. Effective on this date, claims processing for Delaware is performed by Highmark Medicare Services, the Part A/Part B MAC contractor for this state, and the claims processing for New York and Connecticut is performed by National Government Services under the J-13 MAC contract; carrier number 00805 is removed, and claims processing for New Jersey is performed by Highmark Medicare Services, the Part A/Part B MAC contractor for this state.

Article Attachments

IDE - PMA Request Form PDF

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Last Modified: 8/10/13