

701 Pennsylvania Ave., NW, Suite 800
Washington, DC 20004-2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org



December 19, 2016

Via Electronic Mail Only

Tamara Syrek Jensen, Director
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Mail Stop S3-02-01
Baltimore, MD 21244

Re: Non-coverage of Codes Accompanying NTAP Procedures

Dear Ms. Syrek Jensen:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to raise an issue related to non-coverage of Category III CPT codes. AdvaMed has previously communicated with your division regarding the implications of blanket non-coverage of these codes by Medicare contractors who deem them to be experimental. We have recently learned of a situation where Category III codes that are essential to the completion of a procedure that has been granted New Technology Add-on Payment (NTAP) status by CMS are not being covered.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

Sections 1886(d)(5)(K) and (L) of the Social Security Act establish a process for identifying and ensuring adequate payment for new medical services and technologies under the Inpatient Prospective Payment System (IPPS) and form the basis for establishing NTAP status. Substantial criterion must be satisfied in order to receive this special payment status including that a new technology will be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, *the diagnosis or treatment of Medicare beneficiaries* (see 66 FR 46902).

NTAP status, once received, allows the treating facility to use the designated device to treat Medicare patients who could benefit from its use. Though there is no additional payment for the facility or for the physician under the NTAP program, the reasonable expectation is that both will

be compensated for rendering procedures and services associated with utilizing the device that has received NTAP status. This is typically achieved through a hospital billing the appropriate MS-DRG and a physician billing the appropriate procedure code for his or her services. Physician payment for a procedure performed in the hospital setting, even one utilizing an NTAP device, is dependent upon coverage of the applicable procedure code.

Coverage of the physician service/procedure code used in conjunction with an NTAP device is not automatic. In fact, in some instances these codes are Category III CPT codes that are only covered at the discretion of a local Medicare contractor. Consequently, as is the case with many Category III codes, a code used by the physician to perform the NTAP associated device procedure may not be covered--resulting in a situation where the device itself is covered in the inpatient setting and the hospital receives compensation **but** the actual provider of the service is unable to receive payment for his or her services.

AdvaMed does not believe that this outcome was anticipated by CMS when it designed its criteria for coverage and payment of NTAP devices and is concerned that coverage discrepancies like the one described may have the unintended consequence of impairing Medicare beneficiary access to NTAP technologies. As such we recommend that CMS require coverage of the physician procedure that is required to install the device that is subject to the additional NTAP payment whenever the associated procedure code is billed in conjunction with the NTAP device. This will ensure that the intent of the NTAP program is fulfilled and that coverage decisions are aligned to promote access to these innovative devices by the Medicare beneficiaries who need them.

Conclusion

AdvaMed appreciates the opportunity to bring this issue to your attention and looks forward to working with CMS to resolve our concern. We would be pleased to answer any questions regarding this letter. Please contact DeChane L. Dorsey, Esq. at (202) 434-7218 or Chandra Branham, Esq. at (202) 434-7219, if we can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "Donald May". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Donald May
Executive Vice President,
Payment and Health Care Delivery