Process and Information Required for a New Technology Ambulatory Payment Classification (APC) Assignment Under the Hospital Outpatient Prospective Payment System (OPPS)

Please note: For process and information required to apply for transitional pass-through payment status for **drugs and biologicals**, or for assignment and payment for **new pass-through device categories**, go to the main OPPS web page, currently at http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp to see the latest instructions. (NOTE: Due to the continuing development of the new cms.hhs.gov web site, this link may change.)

This guidance describes in detail the process and information required for applications requesting a New Technology APC assignment under the Medicare hospital outpatient prospective payment system (OPPS).

Refer to the final rule in the November 30, 2001 *Federal Register* (66 FR 59897) for a full discussion of the criteria and information needed for a new technology APC assignment.

Because CMS intends to make information used in the ratesetting process under the OPPS available to the public for analysis, applicants are advised that any information submitted, including commercial or financial data, is subject to disclosure for this purpose.

We will accept New Technology APC applications on an ongoing basis. However, we must receive applications sufficiently in advance of the first calendar quarter in which New Technology APC payment is sought to allow time for analysis, decision-making, and systems changes. The table below indicates the earliest date that New Technology APC status could be implemented once a completed application and all additional information are received.

CMS Must Have Complete Application and All Necessary Information by the First Business Date in:	**Earliest Possible Date For a New Technology APC Assignment to be Effective:**
March	July 1
June	October 1
September	January 1
December	April 1

PLEASE NOTE: New technology APC status may or may not be effective on the earliest possible effective date as described above. A longer evaluation period may be required if an application is incomplete, if further information is required, if a more extensive evaluation is required in order to determine eligibility, or due to other factors.

An application is not considered complete until—

- All required information has been submitted, AND
- All questions related to such information have been answered.

What kinds of services are appropriate for a "New Technology" APC?

- New Technology APCs are reserved for comprehensive services or procedures that are truly new and significant enough to warrant having a unique code under the Healthcare Common Procedure Coding System (HCPCS).

- New Technology APCs are intended to provide payment under the OPPS for complete services or procedures that cannot: 1) be appropriately reported by an existing HCPCS code assigned to a clinical APC or, 2) be appropriately reported by a new HCPCS code that could be appropriately assigned to a clinical APC. The most important criterion in determining whether a technology is "truly new" is the inability to describe appropriately the complete service with a current individual HCPCS code or combination of codes.

- A service that qualifies for a New Technology APC may be a complete, separate, stand-alone service (for example, water-induced thermotherapy of the prostate), or it may be a service that would always be billed in combination with other services (for example, coronary artery brachytherapy). Eligibility for assignment to a New Technology APC is not contingent on hospitals billing other HCPCS codes in conjunction with a proposed new technology procedure.

- A new technology service or procedure, even though billed in combination with other, previously existing procedures, describes a distinct new procedure with a beginning, middle, and end.

What kinds of services are NOT appropriate for a "New Technology" APC?

- A device, drug, biologic, radiopharmaceutical, or other product that qualifies for transitional pass-through payment under section 1833(t)(6) of the Social Security Act is not appropriate for assignment to a New Technology APC.

- Items, devices, materials, supplies, apparatuses, instruments, implements, or equipment whose costs are appropriately packaged into existing APC groups and that are used to accomplish more comprehensive services or procedures that are appropriately described by existing HCPCS codes are not eligible for payment under a New Technology APC.

- Drugs, supplies, devices, and equipment do not describe a distinct procedure with a beginning, middle, and end, and therefore are not be eligible for assignment to New Technology APCs.

- Items, devices, supplies or equipment used as a tool or that serve as an aid in performing a variety of procedures, such as a scalpel, are not appropriate for assignment to a New Technology APC.

- Integral components of procedures described by HCPCS codes, such as preparing a patient for surgery or the preparation and application of a wound dressing for wound care, are not eligible for assignment to a New Technology APC.

To be considered for a New Technology APC, does a service or procedure have to have its own CPT code (Level I HCPCS code) or have received prior approval for an alphanumeric code (Level II HCPCS code)?

No. Lacking an appropriate CPT code or alphanumeric Level II HCPCS code, a service or procedure might be described by using a combination of several existing codes. Such a coding combination may not fully and accurately define the service and fail to take into account all the resources required to deliver the comprehensive service. If, upon review, we find that the service meets the criteria for assignment to a New Technology APC, we would consider creating a Level II HCPCS code to describe the procedure comprehensively. Hospitals would use the new Level II HCPCS code to bill under the OPPS for the new technology service, rather than relying on a combination of existing codes in an attempt to approximate a description of the service. The Level II HCPCS code would be assigned to the New Technology APC whose payment level most closely represents, in the aggregate, all of the resources needed to furnish the service.

Does having a HCPCS code mean that Medicare will pay for a service under the OPPS?

No. Neither assignment of a HCPCS code nor approval of a service for assignment to a New Technology APC assures coverage of the specific item or service in a given case. To receive payment, a new technology service must be considered reasonable and necessary; and each use of a new technology service is subject to medical review for determination of whether its use was reasonable and necessary.

If CMS assigns an alphanumeric HCPCS code to a service in order to allow payment for the service under the OPPS in a New Technology APC, does that mean the service will subsequently be approved for a national Level I or Level II HCPCS code?

No. The American Medical Association is solely responsible for the creation of codes under the Current Procedural Terminology (CPT), also known as Level I HCPCS codes. National HCPCS codes (Level II alphanumeric codes) are established separately, in accordance with the annual HCPCS cycle that is described at http://www.cms.gov/MedHCPCSGenInfo/ . The code that CMS assigns to facilitate billing and payment through a New Technology APC is independent of the other two coding systems and intended solely for hospitals to use when billing under the OPPS.

If a new national HCPCS code, either Level I or Level II, is created explicitly for a service during the AMA or CMS annual coding update process, does that mean the service automatically qualifies for payment under a New Technology APC?

No. In order to be paid for under a New Technology APC, a service or procedure has to meet the definition of services eligible for assignment to a New Technology APC and all of the applicable criteria for assignment to a New Technology APC. Those criteria are listed below.

How are New Technology APCs different from other APC groups?

- New Technology APCs are defined solely on the basis of cost and not the clinical characteristics of the service.
- The payment rate for each New Technology APC is based on the midpoint of a range of costs, not on a relative payment weight.

Which APC groups are New Technology APCs?

The current series of New Technology APC groups are numbered from 1491 through 1574. Services assigned to APCs 1491 through 1495 and APCs 1502 through 1537 are not subject to the multiple procedure payment reduction (status indicator of "S"). Services assigned to APCs 1539 through 1574 and APCs 1496 through 1500 are discounted when furnished with other procedures or services that are also subject to discounting (status indicator of "T"). (See the most recent OPPS/ASC final rule, Addendum A for the current list of New Technology APCs and their payment amounts (e.g., 75 FR 72275 - 72277)). These series of APCs may be changed from time to time, so readers are advised to refer to the most recently published OPPS update at https://www.cms.gov/HospitalOutpatientPPS/01_overview.asp, Addendum A, to see the most recent New Technology APCs in any given calendar year.

Who may apply? Device manufacturers, hospitals, or any interested party may apply to have a new service assigned to a New Technology APC.

What are the criteria that a service must meet to be eligible for assignment to a New Technology APC?

To be assigned to a New Technology APC, the following criteria have to be met:

- The service is one that could not have been adequately represented in the claims data being used for the most current annual OPPS payment update.
- The service does not qualify for an additional payment under the transitional pass-through provisions established under section 1833(t)(6) of the Social Security Act and in Subpart G, Transitional Pass-through Payments in the regulations at 42 CFR 419.
- The service cannot reasonably be placed in an existing clinical APC group that is appropriate in terms of clinical characteristics and resource costs.
- The service falls within the scope of Medicare benefits under section 1832(a) of the Act.
- The service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Social Security Act. However, the application process does not result in a coverage determination. Neither assignment of a HCPCS code nor approval of a service for assignment to a New Technology APC assures coverage of the specific item or service. Furthermore, each use of a qualified service is subject to medical review for determination of whether its use was reasonable and necessary in that particular case.

How long is a service eligible for payment within a New Technology APC?

A service is paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. We expect this to occur within two to three years from the time a new HCPCS code becomes effective. However, if we are able to collect sufficient claims data in less than two years, we would consider reassigning the service to an appropriate APC. Or, if we do not have sufficient data at the end of three years upon which to base its reassignment to an appropriate clinical APC, we would keep the service in a New Technology APC until adequate data become available.

What has to be included in an application for assignment to a New Technology APC?

To enable CMS to make an appropriate determination that the criteria for a New Technology APC assignment are met, applications for services to be assigned to a New Technology APC **must** include all of the information listed below. A separate application is required for each distinct New Technology APC assignment that is being requested. An application that does not include all of the following information is considered incomplete and will not be acted upon:

1. The name by which the service is most commonly known.
2. A clinical vignette, including patient diagnoses that the service is intended to treat, the typical patient, and a description of what resources are used to furnish the service by both the facility and the physician. For example, for a surgical procedure this would include staff, operating room, and recovery room services, as well as equipment, supplies, and devices, etc.
3. A list of any drugs or devices used as part of the service that require approval from the Food and Drug Administration (FDA) and information to document receipt of FDA approval/clearances and the date obtained, including a copy of the FDA approval or clearance letter. ***NOTE: Applicants are advised not to apply for a New Technology APC assignment until any required FDA approvals or clearances are received. An application is not complete without the required FDA information.***
4. A description of where the service is currently being performed (by location) and the approximate number of patients receiving the service in each location.
5. An estimate of the number of physicians who are furnishing the service nationally and the specialties they represent.
6. Information about the clinical use and efficacy of the service, such as peer-reviewed articles.
7. The CPT or HCPCS Level II code(s) that are currently being used to report the service and an explanation of why use of these HCPCS codes is inadequate to report the service under the OPPS.
8. A list of the CPT or HCPCS Level II codes for all items and procedures that are an integral part of the service. This list should include codes for all procedures and services that, if coded in addition to the code for the service under consideration for new technology status, would represent unbundling.
9. A list of all CPT and HCPCS Level II codes that would typically be reported in addition to the service.

10. A proposal for a new HCPCS code, including a descriptor and rationale for why the descriptor is appropriate. The proposal should include the reason why the service does not have a CPT or HCPCS Level II code, and why the CPT or HCPCS Level II code or codes currently used to describe the service are inadequate.
11. An itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc.
12. Name(s), address(es), e-mail addresses and telephone number(s) of the party or parties making the request and responsible for the information contained in the application. If different from the requester, give the name, address, e-mail address, and telephone number of the person that CMS should contact for any additional information that may be needed to evaluate the application.
13. Other information as CMS may require to evaluate specific requests or that the applicant believes CMS may need to evaluate the application.

WHERE TO SEND APPLICATIONS

Mail **five** copies of each completed application to the following address:

OPPS New Tech APC
Division of Outpatient Care
Mailstop C4-05-17
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Electronic copy requirement: Send the entire application, including all attachments and appendices, via email to NewTechAPCapplications@cms.hhs.gov. Email versions of the application must be compatible with standard CMS software such as Adobe Acrobat 9.0 or Microsoft Word 2007.

Questions pertaining to the pass-through payment application process may be sent via e-mail to the Division of Outpatient Care mailbox, OutpatientPPS@cms.hhs.gov or by phone to 410-786-0378.

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