



**Application for New Medical Services and Technologies Seeking to Qualify for
Add-On Payments Under the Hospital Inpatient Prospective Payment System
for Federal Fiscal Year (FY) 2021**

Section 1886(d)(5)(K) authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. To qualify for additional payments under this provision; a new technology must represent a substantial clinical improvement; data reflecting the cost of new technology must not yet be available in the data used to recalibrate the Medicare severity diagnosis-related groups (MS-DRGs); and the MS-DRG payment rate otherwise applicable to the new technology would be inadequate (see 42 CFR 412.87(b)).

DEADLINE

Submit an application with a response to each question (see required information below) – **No later than October 11, 2019**. Deadline for supplemental information to be included in the annual IPPS Proposed Rule – **No later than December 20, 2019**

Note: *An application is considered complete when all of the information requested above and below has been submitted by the dates specified and when questions related to such information have been answered by the applicant.*

WHERE TO SEND APPLICATIONS

Mail **four (4)** copies of each completed application to the following address:

Inpatient PPS New Medical Services and Technologies
Division of Acute Care
Mailstop C4-08-06
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Additionally, email an electronic version of the application, tracking form and all relevant material and supporting documentation to NewTech@cms.hhs.gov. Total attachments in one email must not exceed 20 megabytes. If necessary, send multiple emails with attachments less than 20 megabytes. Applicants can also include a complete application package (application, tracking form and all relevant material and supporting documentation) on a USB Drive with the hardcopy.

ANNUAL NEW TECHNOLOGY TOWN HALL MEETING

Section 1886(d)(5)(K)(viii) of the Act provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies, CMS holds an annual public town hall meeting at CMS Headquarters. Typically,

applicants present at the meeting (to the public and to the clinical staff of CMS) regarding whether their technology represents a substantial clinical improvement.

The annual town hall meeting has historically been held in February of each year. However, for FY 2020, this annual meeting was held in an earlier month, December 2018. For FY 2021 applications, we expect this annual meeting may also be held in an earlier month similar to last year. Applicants should monitor the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html> for further information and possible schedule changes.

REQUIRED INFORMATION

Applications must include a response to each question below. Information must be entered directly onto this form. Do not copy and paste questions and answers into a different document. CMS may request other information in order to evaluate specific requests.

Note: A separate application is required for each distinct technology or service included in a request. For example, if an applicant requests add-on payments for two unique technologies or services, a separate application is required for each technology or service. A completed tracking form. (A tracking form may be downloaded at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>.)

1. Name, address, telephone and email address **of primary and backup** contact for the application. If using a consultant, provide a contact from the manufacturer in addition to the consultant's contact information.
2. Trade/brand name of the new technology.
3. Describe the technology in general terminology.
 - What is it? What does it do? How is it used?
 - Also, submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles relevant to the new medical services and technologies.)
4. Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. Refer to <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html> for more information.

Alternative New Technology Pathway for Transformative New Devices

5. Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? **If yes, skip questions 6 through 21 (newness) and 34-36 (substantial clinical improvement) and proceed to question 22 - 33 (cost criterion). For additional details on the Alternative Pathway we refer applicants to 84 FR xxxxx – xxxxx for additional details.**

Newness Criterion

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the Medicare-Severity Diagnosis Related Groups (MS-DRGs). As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 5 through 20 (newness criterion).

6. If applicable, briefly describe current and/or alternative treatments for the disease or condition that your technology treats or diagnoses.
7. CMS has established a substantial similarity criteria to determine if a technology is similar to an existing technology. (Refer to 70 FR 47351 through 47352 and 74 FR 43813 through 43814 for additional details.)

A technology is not “new”, if it meets **all** three of the criteria below:

- a. If a product uses the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome; and
- b. If a product is assigned to the same DRG when compared to an existing technology; and
- c. If the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology.

Applicants must explain why they do not meet the criteria above.

8. Date of Food and Drug Administration (FDA) (or expected) approval for the technology, service or drug. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available.

Note: Include all types of approvals (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. CMS recommends a timeline if the technology, service or drug has received multiple types of approvals from the FDA.

Per § 412.87(c) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA approval or clearance for its new medical service or technology by July 1 prior to the beginning of the fiscal year (FY) for which the NTAP would be effective (for FY 2021, not later than July 1, 2020).

9. List the name and phone number of a contact at the FDA who is knowledgeable about the pre-market approval request for the new technology listed above.
10. Please describe the (most recent, if applicable) type of application and approval the technology, service or drug has received or is seeking from the FDA (i.e. Pre-Market Approval, HDE or HUD approval, expanded access approval, New Drug Approval).
11. Was the technology, service or drug available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation and documentation of any delay (i.e. manufacturing issues, shelf life concerns, or other reasons).

Drugs:

12. If the technology is a drug, was/is your FDA application considered under Fast Track, Breakthrough Therapy, Accelerated Approval, or Priority Review? Refer to <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccessstoimportantnewtherapies/ucm128291.htm> for more details.
13. If the technology is a drug, is this a drug that can only be administered orally?
14. If the technology is a drug, provide complete dosage information.

Devices:

15. If the technology is a device, is there an investigational device exemption (IDE) number from the FDA assigned to the device? If yes, please provide this code. Refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051480.htm> for more details.
16. If the technology is a device, what class (I, II, or III) was/is assigned to the device? Refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm> for more details.

Coding:

Note: *If the technology, device or drug (administered via procedure) were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-10-CM/PCS diagnosis and/or procedure code(s) on the claim in order to receive the add-on payment. The ICD-10 Coordination and Maintenance (C&M) Committee is responsible for approving coding changes, developing errata, addenda and other modifications. Requests for coding changes are submitted to the committee for discussion at either the Spring or Fall C&M meeting. If any coding changes are necessary to distinctly identify your technology by ICD-10-CM/PCS diagnosis and or procedure code(s), you **MUST** separately contact the ICD-10 C&M Committee **to submit a code request**. Refer to <https://www.cms.gov/Medicare/Coding/ICD10/newrevisedcodes.html> for more details including deadline to submit code request.*

17. List the diagnosis and/or procedure codes that are currently or will be used to identify your technology under the ICD-10-CM/PCS coding system.
18. Do the codes listed in question 17 distinctly identify your technology under the ICD-10-CM/PCS coding system? If not, please see the note above.
19. List any other technologies coded using the code(s) listed in question 17. For example, if you listed a single procedure code, what procedures use the code listed in question 17 aside from the procedure used for your technology? Similarly, if you listed a combination or multiple codes in question 17, what other procedures or technologies use the same combination of codes listed in question 17 aside from your technology?
20. Does the service or technology have an existing request pending with the ICD-10 C&M Committee?
21. Has the service or technology received a Healthcare Common Procedure Coding System (HCPCS) code? If yes, when was it approved? What is the code? Refer to <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html> for more information.

Cost Criterion

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the thresholds established for the FY (lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRGs to which the new technology is assigned) of the annual IPPS final rule. The most recent version of the thresholds can be downloaded at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>

Cost Information:

22. What is the (current and/or anticipated) cost of the technology to the hospital, per patient?

23. Provide a breakdown of how the cost of the technology is calculated:

(e.g. For drugs, the average dosage or number of units per patient (ml/kg/hr); For devices, a breakdown of the cost of all of the components used per patient, clearly showing which components are the “new” ones).

Charge Information: (You must answer the questions below whether the technology has FDA approval or is still pending FDA approval)

24. Under the MS-DRG grouper for FY 2020, list the MS-DRGs that the technology currently maps to?

25. Has the applicant made a request for the new technology to map to a new or different MS-DRG(s) for the upcoming fiscal year (2021) other than the ones listed in question 24?

26. Using the table as demonstrated in the spreadsheet as a template, show how the standardized charge per case (if applicable, case weighted) exceeds the threshold for the cost criterion.

Note: Refer to Appendix A for an explanation of how to standardize charges. Refer to the spreadsheet in the application packet how to case weight the average standardized charge per case if multiple MS-DRGs are affected by the technology.

27. With regard to the spreadsheet in question 26, provide all supporting data used to calculate charges and standardized charges per case involving the new technology (in electronic format).

28. List a step by step explanation of how the data and calculations in each column of the spreadsheet were determined. For example, within the explanation applicants must include the type of data used to calculate the average standardized charge (i.e. Medicare and/or non-Medicare, number of providers, time period from which data was collected) and/or the inflation factor used to inflate the charges etc... **An application is NOT complete without a complete step by step explanation of the applicant’s charge methodology.**

29. What is the (current and/or anticipated) charge of the technology by the hospital, per patient? Explain how this was determined.

Volume of Cases:

30. What is the anticipated Medicare volume of this technology for FY 2020 (October 1, 2019 – September 30, 2020)? Please describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your technology, not the total population eligible for the technology.
31. What is the anticipated Non-Medicare volume of this technology for FY 2020 (October 1, 2019 – September 30, 2020). Please describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your technology, not the total population eligible for the technology.
32. What is the anticipated Medicare volume of this technology for FY 2021 (October 1, 2020 – September 30, 2021). Please describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your technology, not the total population eligible for the technology.
33. What is the anticipated Non-Medicare volume of this technology for FY 2021 (October 1, 2020 – September 30, 2021). Please describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your technology, not the total population eligible for the technology.

Substantial Clinical Improvement Criterion

Note: A summary on the substantial clinical improvement criteria can be found in Appendix B. Complete information on the substantial clinical improvement criterion can be found in the September 7, 2001 Federal Register (66 FR 46913-14) and in the FY 2010 Final Rule (74 FR 43808-43823). Additionally, the annual final rule for prior years includes CMS's decision making process on each application. As noted above if the technology is a device has received a Breakthrough Device designation from the FDA, skip questions 33 through 35 (substantial clinical improvement criterion).

Convert posters to word documents or to provide a summary document of all posters.

34. Appendix B has descriptions of the substantial clinical improvement criteria, which are associated with treatments, diagnosis, and clinical outcomes. Using Appendix B, identify and describe how the technology meets the criteria for substantial clinical improvement over existing technologies.
35. Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology. In the annotation, please clearly summarize each article, describe the purpose of the article, and the relevance to the technology. Please indicate all literature that is referenced in question #35 above.

Note: Indicate if any peer-reviewed articles will be released after submission of this application.

36. For each claim of substantial clinical improvement over existing technologies, in table format (see Table 1 below), list the claim of substantial clinical improvement and summarize the supporting information to include relevant clinical trial(s) or data. See sample table below. (**Application is incomplete without this table**). Contact NewTech@cms.hhs.gov with questions concerning the table.

Table 1: Summary of Substantial Clinical Improvement highlights that support the asserted substantial clinical improvement claim(s).

Item number	Substantial Clinical Improvement Claim	Supporting evidence/ data Please provide reference	Study Type (e.g., case series, case-control, randomized clinical trial) and comparator(s) if applicable	Page number and paragraph of cited study	For each row, if necessary, provide a 500 character summary of the information cited in this row
1a1.	Reduced mortality rate in comparison to competitor drug/device	Doe, et al, "Reducing mortality in disease X population: - analysis," <i>JAMA</i> 2019, vol. 2(5), pp. 12-23.	RCT	Pg 12 methodology	RCT used to compare mortality rates between Drug 123 vs. 789 for disease X resulting in a 5% decrease in mortality rate for Drug 123 (p=0.02)
1a2.	Reduced mortality rate in comparison to competitor drug/device	Doe, et al, "Reducing mortality in disease X population: - analysis," <i>JAMA</i> 2019, vol. 2(5), pp. 12-23.	RCT	Pg 13 control and test arm description	Pertinent exclusion criteria were (only list exclusion criteria that is pertinent to supporting the reduced mortality rate) Controls were equally distributed among gender, race, Socioeconomic status. Both arms started drug 123 and 780 at baseline.
1a3.	Reduced mortality rate in comparison to competitor drug/device	Doe, et al, "Reducing mortality in disease X population: - analysis," <i>JAMA</i> 2019, vol. 2(5), pp. 12-23.	RCT	Pg 14 mortality rate results	3,6 and 9 months indicated statistically significant decreases in mortality rates for drug 123 w p- values 0.02, 0.05, 0.03 respectively.

Item number	Substantial Clinical Improvement Claim	Supporting evidence/ data Please provide reference	Study Type (e.g., case series, case-control, randomized clinical trial) and comparator(s) if applicable	Page number and paragraph of cited study	For each row, if necessary, provide a 500 character summary of the information cited in this row
1b.	Reduced mortality in comparison to competitor drug/device	Smith, J et al. "Mortality rate improvement using XXX in comparison to current therapy with YYY. Lancet 2019, vol. 15, pp 230-245	Case Control	Pg 234 methodology Pg 240 mortality rate	4 indicated statistically significant decreases in mortality rates for drug 123 w p- value 0.02
2.	Decreased rate of subsequent diagnostic or therapeutic interventions	Doe, et al, "Reducing mortality in disease X population: - analysis," <i>JAMA</i> 2019, vol. 2(5), pp. 14.	Meta-Analysis	Pg 14	Studies demonstrate lower length of stay which results in less interventions.
3.	Decreased number of future hospitalizations or physician visits	Case Study Data from Physicians	Collected by applicant and not published	Supplemental Document provided in application	Compared outcomes within 30 days which demonstrated lower readmission rate.

Appendix A

Standardizing Charges

We standardize charges in order to compare charges equally amongst all hospitals. Standardized charges are charges per case after removing the wage index, indirect medical education (IME) and disproportionate share hospital (DSH). The formula below explains how to calculate standardized charges per case.

In order to standardize charges you must obtain hospital specific operating cost-to-charge ratio (CCR), capital CCR, DSH (operating and capital), IME (operating and capital), Wage Index, GAF and COLA.

Note: Use all values (DSH, IME etc...) from the fiscal year that corresponds to the year that the claim(s) is/are being submitted from including the Labor and Non Labor share percentage. Also, different labor and non-labor percentages may apply for hospitals with a wage index over or under 1 depending on the fiscal year.

Formula to Standardize Charges:

Capital Charges

The formula to calculate the Capital Standardized Charge is below.

1. Capital Standardized Charge = (((Capital CCR/(Capital CCR + Operating CCR)) * Covered Charges) / (1 + Capital IME + Capital DSH)) / GAF) / (1 +(0.3152*(COLA-1)))

Operating Charges

The formula to calculate the operating standardized charge is a two-step process; first you must calculate the Adjusted Operating Charge (AOC) then use the calculated AOC to compute the Operating Standardized Charge.

2. Adjusted Operating Charge (AOC) = ((Operating CCR / (Capital CCR + Operating CCR)) * Covered Charges) / (1 + Operating IME + Operating DSH)

If wage index greater than 1:

- i) Operating Standardized Charge = ((AOC* Labor Share %) / wage index) + ((AOC * Non Labor Share %) / COLA)

If wage index less than 1:

- ii) Operating Standardized Charge = ((AOC * .62) / wage index) + ((AOC * .38) / COLA)

Total Standardized Charges

The formula to calculate Total Standardized Charges is below

- 3) Standardize Charges = Capital Standardize Charges + Operating Standardized Charges

Definition Key

-The Labor share percentages and Non Labor share percentages can be obtained from Table 1A of the annual IPPS final rule.

-COLA is always equal to 1, except for hospitals in Alaska and Hawaii.

-Operating CCR, capital CCR, DSH (operating and capital), IME (operating and capital), Wage Index, GAF and COLA values by provider can be obtained by downloading the Public Use Files at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> or

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html> or

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present.html>

Appendix B

For Substantial Clinical Improvement, CMS evaluates a request for add-on payment for a new technology against the following criteria:

1. The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
2. The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
3. Use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of technologies are the following:
 - Reduced mortality rate with use of the device.
 - Reduced rate of device-related complications.
 - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
 - Decreased number of future hospitalizations or physician visits.
 - More rapid beneficial resolution of the disease process treatment because of the use of the device.
 - Decreased pain, bleeding, or other quantifiable symptom.
 - Reduced recovery time.

Appendix C

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1. Completed application
2. Completed tracking form
3. List of attachments/ documents