



**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) 2022**

Section 1886(d)(5)(K) authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. In general, 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)). (Eligibility criteria for the alternative pathway for certain transformative new devices can be found in 42 CFR 412.87(c) and eligibility criteria for alternative pathway for certain antimicrobial products can be found in 42 CFR 412.87(d).)

DEADLINE

Submit an application with a response to each question (see required information below) – **No later than October 16, 2020**. Deadline for supplemental information to guarantee inclusion in the annual IPPS Proposed Rule – **No later than December 18, 2020**.

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 **two (2)** copies of each completed application to the following address:

Inpatient PPS New Medical Services and Technologies
Division of New Technology and Pricing
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.

For FY 2022 applications, we expect this annual meeting be held in December 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 and for Certain Antimicrobial Products.

5. a. Is the technology a device that has received a Breakthrough Device designation from the Food and Drug Administration (FDA)? If yes, please state the indication of Breakthrough Device designation by the FDA. Note: The marketing authorization indication in question 8A and 8B must be the same as Breakthrough Device designation indication.

b. Is the technology a product that has been designated by the FDA as a Qualified Infectious Disease Product (QIDP) or is the product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway? If yes, please state the indication of QIDP and/or LPAD by the FDA. Note: The marketing authorization indication in question 8A and 8B must be the same as the QIDP and/or LPAD indication.

If the answer is yes to either question 5a or 5b, skip questions 6 through 7 (newness) and 34-36 (substantial clinical improvement) and proceed to questions 8 - 32. For additional

details on the alternative pathway for transformative new devices and certain antimicrobial products, we refer applicants to 84 FR 42292 – 42297 and section III.F. of the FY 2021 IPPS final rule.

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 applying under the alternative pathway for certain transformative new devices or certain antimicrobial products, skip questions 6 through 7 (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.

FDA Information (Newness Period) and Coding

This section MUST be completed for ALL technologies, including a technology that is applying under the alternative pathway for certain transformative new devices or certain antimicrobial products.

8. FDA Marketing Authorization
 - a. Date of Food and Drug Administration (FDA) (or expected) marketing authorization for the technology, service or drug.
 - b. Provide a copy of the FDA approval/clearance letter. If marketing authorization has not yet been granted, please state the proposed pending indication that the technology will receive marketing authorization under review by the FDA. Please provide a copy of the approval notice to CMS immediately after it becomes available. Note: For a device that has received a Breakthrough Device designation from the FDA, the marketing authorization indication in question 8A and 8B must be the same as Breakthrough Device designation indication in question 5a. For a product that has been designated by the FDA as a QIDP and/or a product approved under FDA’s LPAD pathway, the marketing authorization indication in question 8A and 8B must be the same as the QIDP and/or LPAD indication in question 5b.

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.*

For applications NOT applying under an alternative pathway for certain antimicrobial products (QIDP and or LPAD), per § 412.87(e)(2) of the regulations, an applicant for new technology add-on payments (NTAP) must receive FDA marketing authorization 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 2022, not later than July 1, 2021).

Per § 412.87(e)(3) of the regulations, a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that does not receive FDA marketing authorization by the July 1 deadline specified in paragraph (e)(2) of the regulations (July 1, 2021 for FY 2022 applications), may be conditionally approved for the new technology add-on payment for a particular fiscal year, effective for discharges beginning in the first quarter after FDA marketing authorization is granted, provided that FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments. See the FY 2021 IPPS Final Rule for complete details.

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/speedingaccesstoimportantnewtherapies/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 (HCPSC) code? If yes, when was it approved? What is the code? Refer to <http://www.cms.gov/Medicare/Coding/MedHCPSCGenInfo/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 with the release of the most recent annual IPPS final rule (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). The most recent version of the thresholds can be downloaded at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>

*Note: If the technology is proposed to be assigned to a proposed new MS-DRG in the upcoming annual IPPS proposed rule, then per the policy CMS finalized in the FY 2021 IPPS final rule, CMS uses the proposed threshold for the upcoming fiscal year for any proposed new MS-DRG to evaluate the cost criterion. **For this application you must use the thresholds established with the release of the most recent annual IPPS final rule.***

This section MUST be completed for ALL technologies, including a technology that is applying under the alternative pathway for certain transformative new devices or certain antimicrobial products..

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 and number of vials (whole vials if single-use) and/or 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 2021, 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 (2022) 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 standardize 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 inpatient 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.
31. What is the anticipated inpatient 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.
32. What is the anticipated inpatient Medicare volume of this technology for FY 2022 (October 1, 2021 – September 30, 2022). 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 inpatient Non-Medicare volume of this technology for FY 2022 (October 1, 2021 – 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), the FY 2010 IPPS Final Rule (74 FR 43808-43823) and the [FY 2020 IPPS Final Rule \(84 FR 42288-42292\)](#). Additionally, the annual IPPS final rule includes CMS's decision making process for each application. **As noted above if the technology is applying under the alternative pathway for certain transformative new devices or certain antimicrobial products, skip questions 34 through 36 (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 #34 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.

Adverse Events/ Recalls

37. Has the technology (drug/ device) been the subject of a recall by the FDA and/or adverse event?
38. Has the technology been subject to any bulletins and or letters issued by the FDA regarding the safety of the technology?

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 = $\frac{(((\text{Capital CCR} / (\text{Capital CCR} + \text{Operating CCR})) * \text{Covered Charges}) / (1 + \text{Capital IME} + \text{Capital DSH})) / \text{GAF}}{(1 + (0.3152 * (\text{COLA} - 1)))}$

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) = $\frac{((\text{Operating CCR} / (\text{Capital CCR} + \text{Operating CCR})) * \text{Covered Charges})}{(1 + \text{Operating IME} + \text{Operating DSH})}$

If wage index greater than 1:

- i) Operating Standardized Charge = $\frac{((\text{AOC} * \text{Labor Share \%}) / \text{wage index}) + ((\text{AOC} * \text{Non Labor Share \%}) / \text{COLA})$

If wage index less than 1:

- ii) Operating Standardized Charge = $\frac{((\text{AOC} * .62) / \text{wage index}) + ((\text{AOC} * .38) / \text{COLA})$

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

CMS uses the following aspects to evaluate Substantial Clinical Improvement for purposes of the add-on payment for a new technology (see 42 CFR 412.87(b)):

1. The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
2. A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means:
 - The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
 - The new medical service or 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, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.
 - The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following:
 - A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
 - A decreased rate of at least one subsequent diagnostic or therapeutic intervention (for example, due to reduced rate of recurrence of the disease process);
 - A decreased number of future hospitalizations or physician visits;
 - A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time;
 - An improvement in one or more activities of daily living;
 - An improved quality of life;
 - A demonstrated greater medication adherence or compliance.
 - The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
3. Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
4. The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
5. The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

Appendix C

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