

Application for TRICARE new medical services and technologies seeking to qualify for add-on payments under the TRICARE Hospital Inpatient Prospective Payment System (HIPPS)

General information:

Name of new technology (list both trade name and generic, if applicable): _____

Name of manufacturer/applicant: _____

Note: An application is considered complete when all of the information requested and all of the questions on this form have been provided and submitted by the deadline specified. A complete packet includes:

- Completed application
- Completed tracking form
- List of attachments/documents

Deadline (mm/dd/yyyy): _____

Where to send applications:

Applicants should email an electronic version of the application, tracking form and all relevant material and supporting documentation to HMHSPrisingMailbox@humana.com with the subject line "TDNTAP FY20xx: insert technology name". Total attachments in one email must not exceed 20 megabytes. If necessary, send multiple emails with attachments less than 20 megabytes.

Application information:

Applications must include a response to each question below unless otherwise specified. Information must be entered directly onto this form. Do not copy and paste questions and answers into a different document. TRICARE 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 must also be submitted. (A tracking form may be downloaded at Health.mil/ntap.)

Note: Data provided in this application or in the tracking form may become subject to disclosure. If you are providing data or information that is proprietary or otherwise protected from disclosure, please mark this information as such. DHA will attempt, to the extent allowed by Federal Law, to keep this information protected from public view.

Contacts

1. Please provide the 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.

Primary contact

Name: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Email: _____

Backup contact

Name: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Email: _____

Consultant contact

Name: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Email: _____

Manufacturer contact

Name: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Email: _____

New technology

- 2. Please provide the name of the new technology being used (List both trade/brand name and generic if applicable):

Name of technology: _____

Trade/Brand or generic name: _____

- 3. Please describe the technology in general terminology.

What is it?: _____

What does it do?: _____

How is it used?: _____

Please submit relevant descriptive booklets, brochures, package insert or other supporting materials to HMHSPrisingMailbox@humana.com

Alternative new technology pathway for transformative new devices and for certain antimicrobial products

4. Alternative pathways:

- a. Is the technology a device that has received, or expects to receive, a Breakthrough Device designation from the Food and Drug Administration (FDA)?

- Yes
 No

If yes, what is the indication of the Breakthrough Device designation?

Note: The marketing authorization indication in question 6b must be the same as Breakthrough Device designation indication.

Please provide a copy of the Breakthrough Device designation letter and mail to HMHSPricingMailbox@humana.com

- b. Is the technology a product that has received, or expects to receive, a Qualified Infectious Disease Product (QIDP) designation or approval under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)?

- Yes
 No

If yes, what is the indication of the QIDP or product approved under the LPAD pathway?

Note: The marketing authorization indication in question 6b must be the same as the QIDP and/or LPAD indication.

Please provide a copy of the QIDP/LPAD letter.

If the answer is yes to either question 4a or 4b, skip questions 22-23 (newness criterion) and 35-37 (substantial clinical improvement criterion). You must still complete the FDA Information (Newness Period) and Cost sections in full. 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 CMS FY 2021 IPPS final rule.

5. FDA information (Newness Period) and coding (this section must be completed for all technologies)

A technology, service or drug is only eligible to receive a TRICARE-specific NTAP designation if it is within the two to three (2-3) year newness period, usually beginning from the date of FDA approval or clearance.

Note: an EUA is not considered FDA approval or clearance for the purposes of NTAP. For additional information on this discussion, we refer applicants to the FY 2022 IPPS final rule (86 FR 45160).

FDA marketing authorization:

a. Has the technology, service or drug received marketing authorization from the Food and Drug Administration (FDA) for the indication under which the applicant is applying for NTAP?

- Yes
- No

If yes, what is the date and type of approval/clearance received? (mm/dd/yyyy): _____

Type of approval/clearance received: _____

If no, what is the expected date of approval/clearance? (mm/dd/yyyy): _____

b. What is the indication for the technology, service or drug for which the applicant is submitting an NTAP application?

If it is not yet FDA approved or cleared, what is the proposed indication?

Please provide a copy of the FDA approval/clearance letter. If it is not yet FDA approved or cleared, please provide a copy of the approval notice to DHA immediately after it becomes available via: HMHSPrisingMailbox@Humana.com with the subject line “TDNTAP FY20xx: insert technology name”.

Note: For a device that has received a Breakthrough Device designation from the FDA, the marketing authorization indication in question 6b must be the same as the 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 6b 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. DHA 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 CMS regulations, an applicant for the TRICARE-specific 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 example, for FY 2023, not later than July 1, 2022).

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, 2022 for FY 2023 applications), may be conditionally approved for the new technology add-on payment for a

particular FY, 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 FY for which the applicant applied for new technology add-on payments. See the CMS FY 2021 IPPS Final Rule for complete details.

- 6. 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.

Name: _____

Phone: _____

- 7. 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).

- 8. 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. was available to be sold) and an explanation and documentation of any delay (i.e. manufacturing issues, shelf life concerns, or other reasons).

- 9. Please describe any previous approvals/clearances for this technology, service or drug.

Drugs:

- 10. If the technology is a drug, was/is your FDA application considered under Fast Track, Breakthrough Therapy, Accelerated Approval or Priority Review?

- Yes
- No

- 11. If the technology is a drug, is this a drug that can only be administered orally?

- Yes
- No

12. If the technology is a drug, provide complete dosage information.

Dosage information: _____

Devices:

13. If the technology is a device, is there an Investigational Device Exemption (IDE) number from the FDA assigned to the device?

Yes

No

If yes, please provide the IDE number: _____

Refer to FDA.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051480.htm for more details.

14. Is the technology is a device?

Yes

No

If yes, what class (I, II, or III) was/is assigned to the device? _____

Refer to FDA.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm for more details.

15. If the technology is a device with a 510(k) clearance, please list the predicate device(s) and describe any differences between the devices.

Yes

No

Predicate device: _____

Device difference: _____

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, or the treatment would have to be authorized for the additional payment by the regional contractor. If there is no specific ICD-10-CM/PCS diagnosis and/or procedure code available for the technology, the provider will be responsible to submit documentation to the regional contractor which indicates that the technology was used to treat the TRICARE patient. The regional contractor will then track the claim in order to process the claim appropriately with the add-on payment.

16. If the technology is a drug and has received FDA approval for the indication that is the subject of this application, please list the National Drug Code (NDC):

NDC: _____

17. ICD-10-CM/PCS diagnosis and procedure codes

a. List the procedure codes that may currently be used to identify your technology under the ICD-10-PCS coding system:

Procedure codes: _____

b. Do these codes distinctly identify your technology under the ICD-10-PCS coding system? If not, please see the note above.

- Yes
- No

c. List the diagnosis codes that may currently be used to identify your technology under the ICD-10-CM coding system:

Diagnosis codes: _____

d. If the technology is a drug, is there an ICD-10-CM that is specific to the indication that is the subject of this application? If not, please see the note above.

e. If the technology is a Breakthrough Device, is there an ICD-10-CM diagnosis code that is specific to the indication listed under the Breakthrough Device designation? If not, please see the note above.

- Yes
- No

If yes, what is the ICD-10CM diagnosis code? _____

18. List any other technologies coded using the code(s) listed in question 18. For example, if you listed a single procedure code, what procedures use the code listed in question 18 aside from the procedure used for your technology? Similarly, if you listed a combination or multiple codes in question 18, what other procedures or technologies use the same combination of codes listed in question 18 aside from your technology?

Technologies coded using procedure codes listed in question 18: _____

19. Does the service or technology have an existing request pending with the ICD-10 C&M Committee?

- Yes
- No

20. Has the service or technology received a Healthcare Common Procedure Coding System (HCPCS) code?

- Yes
- No

If yes, when was it approved? What is the code?

Date approved (mm/dd/yyyy): _____ Code: _____

Refer to <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html> for more information.

Newness criterion (skip this section for alternative pathway technologies)

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 TRICARE Diagnosis Related Groups (DRG). CMS has established three substantial similarity criteria to determine if a technology is similar to an existing technology. DHA will be following the CMS guidance on these criteria. A technology is not “new” if it meets all three criteria listed below. (Refer to CMS 70 FR 47351 through 47352 and 74 FR 43813 through 43814 for additional details.)

21. If applicable, briefly describe current and/or alternative treatments for the disease or condition that your technology treats or diagnoses:

Applicants must explain why they do or do not meet each of the following criteria. A technology can be considered “new” as long as one of these criteria are NOT met.

22. Does the product use the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome?

- Yes
 No

- a. Does the product use the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome?

- Yes
 No

Please explain why they do or do not meet the required criteria: _____

- b. Is the product assigned to the same DRG when compared to an existing technology?

- Yes
 No

Please explain why they do or do not meet the required criteria: _____

c. Does the new use of the technology involve the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology?

- Yes
- No

Please explain why they do or do not meet the required criteria: _____

Cost information

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

24. Provide a breakdown of how the cost of the technology is calculated. Please identify if any components are capital costs.

(e.g. For drugs, include the average dosage and number of vials (whole vials if single-use) and/or units per patient (ml/kg/hr); For devices, include a breakdown of the cost of all of the components used per patient, clearly showing which components are the “new” ones; For technologies sold on a subscription basis, include an explanation of how the cost per case)

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

25. Under the TRICARE PPS DRG grouper for the current Calendar Year (CY), list the TRICARE DRG(s) that the technology currently maps to:

26. Has the applicant made a request for the new technology to map to a new or different TRICARE DRG(s) for the upcoming FY other than the ones listed in question 26?

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

Current and/or anticipated) charge of the technology by the hospital, per patient

Explain how this was determined

Volume of cases:

31. What is the anticipated inpatient TRICARE volume of this technology for the current FY? 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.

Anticipated inpatient TRICARE volume for current FY:

Please describe how you arrived at this estimate:

32. What is the anticipated inpatient TRICARE volume of this technology for the **next** FY? 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.

Anticipated inpatient Non-TRICARE volume for current FY:

Please describe how you arrived at this estimate:

Substantial clinical improvement criterion *(Skip this section for alternative pathway technologies)*

Note: A summary on the substantial clinical improvement criteria (as used by CMS for standard NTAPs) 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 CMS FY 2010 IPPS Final Rule (74 FR 43808-43823) and the CMS FY 2020 IPPS Final Rule (84 FR 42288-42292). Additionally, the annual CMS IPPS final rule includes CMS's decision making process for each application, which will also be followed by DHA for TRICARE-specific NTAPs.

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

33. Please explain why the technology does or does not meet each criterion using supporting data.

a. Does the new medical service or technology offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments?

- Yes
- No

Please provide an explanation: _____

b. Does the new medical service or technology offer 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? If so, describe how use of the new medical service or technology to make a diagnosis affects the management of the patient using evidence.

- Yes
- No

Please provide an explanation: _____

c. Does the use of the new medical service or technology significantly improve clinical outcomes relative to services or technologies previously available? See Appendix B for examples of outcomes.

- Yes
- No

Please provide an explanation: _____

34. Provide an annotated list and copies of published peer-reviewed articles relevant to the new service or technology for all literature that is referenced in question #36 above. In the annotation, please clearly summarize each article, describe the purpose of the article, and the relevance to the technology. Please also list the number of submissions for each data source category in the following table:

Number of published, peer-reviewed studies submitted using the technology	Summary of article	Purpose of article	Relevance to technology	Indicate if any peer-reviewed articles will be released after submission of this application
Number of unpublished studies, abstracts, or presentations submitted using the technology	Summary of article	Purpose of article	Relevance to technology	Indicate if any peer-reviewed articles will be released after submission of this application
Number of other data submissions using the technology	Summary of article	Purpose of article	Relevance to technology	Indicate if any peer-reviewed articles will be released after submission of this application
Number of data submissions as background	Summary of article	Purpose of article	Relevance to technology	Indicate if any peer-reviewed articles will be released after submission of this application

35. For each claim of substantial clinical improvement over existing technologies stated in question 35, in table format (see Table 1 below for example and template), 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).

Item number	Clinical Improvement (SCI) 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	Provide a summary of the information cited in each row. Please include the specific sample size detailing the number of treated vs. controls as well as the specific statistic that demonstrates the SCI claim, if applicable.
1a1					
1a2					
1a3					

See table 1 sample:

Item number	Clinical Improvement (SCI) 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	Provide a summary of the information cited in each row. Please include the specific sample size detailing the number of treated vs. controls as well as the specific statistic that demonstrates the SCI claim, if applicable.
1a1	Reduced mortality rate in comparison to competitor drug/device	Doe, et al, "Reducing mortality in disease X population:- analysis," JAMA 2019, vol. 2(5) pp. 12-23	RCT	Pg 12 methodology	RCT used to compare mortality rates between Drug 123 vs. 789 fpr 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," JAMA 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 morality 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," JAMA 2019, vol. 2(5) pp. 12-23	RCT	Pg 14 mortality rate results	Three, six and nine months indicated statistically significant decreases in morality rates for drug 123 w p- values 0.02, 0.05, 0.03 respectively.

Adverse events/ Recalls (This section must be completed for all technologies):

36. Has the technology (drug/device) been the subject of a recall by the FDA and/or adverse event?

- Yes
- No

37. Has the technology been subject to any bulletins and or letters issued by the FDA regarding the safety of the technology?

- Yes
- No

Appendix A: Standardizing charges for TRICARE-specific NTAP application

This application uses standardized charges in order to compare charges equally amongst all hospitals. Standardized charges for TRICARE are charges per case after removing the wage index and Indirect Medical Education (IDME). In order to standardize charges, the applicant must obtain hospital specific operating Cost-to-charge Ratios (CCR), IDME factors, and hospital-specific Wage Index. The Children's Hospital differential (if applicable) and the TRICARE-specific NTAP inflation factors can be found as part of the TRICARE-specific NTAP example workbook.

Hospital specific CCR and IDME factors. The hospital specific operating CCR and IDME factors, can be requested from the regional contractors. Each contractor has a provider file which includes these pieces of information. The applicant can contact each regional contractor at the following:

Hospital specific wage index. The applicant is to use the same hospital-specific wage index as CMS uses from the applicable CMS IPPS Impact file located on the CMS IPPS Final Rule page (CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-ImpactFiles-for-FY-1994-through-Present.html).

Note: If applying in CY22, use the CY22 TRICARE NTAP thresholds, CY22 TRICARE hospital CCRs and IDME factors, and the most recent CMS IPPS Final Impact file for wage index.

Formula to standardize 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.

$$1. \text{ AOC} = [((\text{hospital-specific operating CCR}) * \text{Covered Charges}) / (1 + \text{Operating IDME})]$$

If wage index greater than 1:

$$i) \text{ Operating Standardized Charge} = ((\text{AOC} * \text{Labor Share \% (Example} = 0.676 \text{ for FY22)}) / \text{wage index}) + ((\text{AOC} * \text{Non-Labor Share \% (Example} = .324 \text{ for FY22)}))$$

If wage index less than 1:

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

To obtain the current labor and non-labor share values, please visit the TRICARE DRG page and go to the CY of interest. The labor and non-labor percentages can be calculated based on the Adjusted Standardized Amounts for all areas pages. (See <https://www.health.mil/Military-HealthTopics/Access-Cost-Quality-and-Safety/TRICARE-Health-Plan/Rates-and-Reimbursement/DiagnosisRelated-Group-Rates>)

Appendix B: Substantial clinical improvement

DHA uses the same process that CMS uses 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: TRICARE-Specific NTAP Threshold calculation

The most recent TRICARE-Specific NTAP Threshold amounts by TRICARE DRG can be found at [TRICARE.mil/NTAP](https://www.tricare.mil/NTAP). These thresholds can also be calculated manually using the following formula below.

The calculation is as follows for each TRICARE-DRG as the lesser of:

1. TRICARE specific NTAP Threshold = $[(\text{TRICARE-DRG weight} \times \text{TRICARE ASA (Same CY as Weights)}) / \text{TRICARE National Inpatient CCR (Same CY as Weights)}] \times .75$

Or

2. The Medicare Thresholds for the FY prior to the CY TRICARE update. For example, for calculation of the TRICARE-Specific NTAP thresholds in CY22, the FY22 Medicare thresholds will be used for the comparison. The Medicare thresholds can be found at [New Medical Services and New Technologies | CMS](#).

In the case that there is no equivalent Medicare MS-DRG threshold (i.e., if the DRG is a TRICARE-specific pediatric DRG), the threshold is calculated as the first calculation above. The applicant is directed to use the most-current thresholds available at the time of their application.

Note: Data provided in this application or in the tracking form may become subject to disclosure. If you are providing data or information that is proprietary or otherwise protected from disclosure, please mark this information as such. DHA will attempt, to the extent allowed by Federal law, to keep this information protected from public view.