

GENERAL INFORMATION

- a. Name of new technology (list both trade name and generic, if applicable):
- b. Name of manufacturer/applicant:

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

- Completed application
- List of attachments/documents

Deadline:

Providers should submit applications to Health Net Federal Services, LLC (HNFS) by July 8 of the preceding fiscal year (FY) for which the TRICARE-specific New Technology Ad-on Payment (NTAP) is to be considered (for example, for FY 2025, not later than **July 8, 2024**). **Note:** Please refer to the “FDA Information (Newness Period) and Coding” section of this application for additional due date/timeline information.

Where to send applications:

Applicants should email an electronic version of the application and all relevant material and supporting documentation to HNFS at HNFS_TRICARE_NTAPS@hnfs.com with the subject line “TDNTAP FY20xx: insert technology name.”

APPLICATION INFORMATION

Applications must include a response to each question below unless otherwise specified. Information must be entered directly into this application. 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.

1. Name, address, telephone and email address of **primary and secondary** contact for the application. If using a consultant, provide a contact from the manufacturer in addition to the consultant’s contact information.

Primary

Name:
Address:
Email:

Secondary

Name:
Address:
Email:

2. Name of the new technology (List both trade/brand name and generic if applicable):
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 insert, or other supporting materials.

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.

- 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 21-23 (Newness Criteria) and 35-37 (Substantial Clinical Improvement Criteria). 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 Centers for Medicare & Medicaid Services (CMS) FY 2021 Inpatient Prospective Payment System (IPPS) final rule.

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 2-3 year newness period, usually beginning from the date of FDA approval or clearance. *Note: an Emergency Use Authorization (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).*

5. FDA Marketing Authorization:

- a. Has the technology, service or drug received marketing authorization from the FDA for the indication under which the applicant is applying for NTAP?

- i. If **yes**, what is the date and type of approval/clearance received?

Date:

Approval/Clearance Type:

- ii. If **no**, what is the expected date of approval/clearance?

Expected Date:

Expected Approval/Clearance Type:

- 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: HNFS_TRICARE_NTAPS@hnfs.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 (that is, Pre-Market Approval, Humanitarian Device Exemption [HDE] or Humanitarian Use Device [HUD] approval, expanded access approval) the technology, service or drug received prior to submission of this application and/or is currently seeking. The Defense Health Agency (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 Title 42, Code of Federal Regulations, Part 412, § 412.87(e)(2), 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 FY for which the NTAP would be effective (for example, for FY 2025, not later than **July 1, 2024**).

Per § 412.87(f)(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 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 [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 (that is, 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?

Yes

No

If no, please provide the date that the medical service or technology came on the market (that is, was available to be sold) and an explanation and documentation of any delay (that is, manufacturing issues, shelf life concerns, or other reasons).

Date on Market:

Delay Explanation (enter N/A if not applicable):

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:

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 this code:

Refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051480.htm> for more details.

14. If the technology is a device, what class (I, II, or III) was/is assigned to the device?

- I
- II
- III

Refer to <http://www.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.

Predicate Device(s):

Differences:

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 TRICARE 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 TRICARE regional contractor that indicates that the technology was used to treat the TRICARE patient. The TRICARE 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):

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:

Do these codes distinctly identify your technology under the ICD-10-PCS coding system?

- Yes
- No (If no, please see the note above.)

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

i. 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?

- Yes
- No (If no, please see the note above.)

ii. 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?

- Yes
- No (If no, please see the note above.)

18. 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?

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?

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 an NTAP, the technology or service must result in average charges for cases using the technology to be in excess of TRICARE-specific thresholds which are calculated by TRICARE DRG. The TRICARE-specific NTAP DRG thresholds are calculated to be the lesser of: 75% of the TRICARE national standardized charge for each TRICARE DRG, or the most recent Medicare threshold amount for the Medicare Severity-DRG (MS-DRG). A description of the calculation used to determine the TRICARE-specific NTAP thresholds by DRG can be found in Appendix C.

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

22. 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 is NOT met.

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 provide an explanation:

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

- Yes
- No

Please provide an explanation:

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 provide an explanation:

Cost Criterion *(This section must be completed for all technologies)*

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology to be in excess of TRICARE-specific thresholds which are calculated by TRICARE DRG. The TRICARE-specific NTAP DRG thresholds are calculated to be the lesser of: 75% of the TRICARE national standardized charge for each TRICARE DRG, or the most recent Medicare threshold amount for the Medicare Severity-DRG (MS-DRG). A description of the calculation used to determine the TRICARE-specific NTAP thresholds by DRG can be found in Appendix C.

For this application, you must use the most recent TRICARE-specific NTAP thresholds found on the TRICARE health.mil/NTAP website. These thresholds are updated annually in accordance with the release of the TRICARE DRGs.

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 (for example, 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 is calculated, including the list price of the technology and utilization across subscribers):

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

25. Under the TRICARE Prospective Payment System (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 fiscal year other than the ones listed in question 25?
- Yes
No
27. Using the table demonstrated in the “Cost Criterion Spreadsheet Example” available at www.health.mil/ntap as a template, show how the standardized charge per case (if applicable, case weighted) exceeds the TRICARE-specific NTAP threshold for the cost criterion:

Note: Refer to Appendix A in this document for an explanation of how to standardize charges for this TRICARE-specific NTAP application. Refer to the TRICARE-specific NTAP application example spreadsheet in the application packet for an explanation of how-to case weight the average standardize charge per case if multiple DRGs are affected by the technology. Please take note of the footnotes in the spreadsheet.

28. With regard to the spreadsheet in question 27, provide all supporting data used to calculate charges and standardized charges per case involving the new technology (in electronic format). Examples include claims data, the ICD-10-CM/PCS codes used to identify cases, the provider-specific factors used to standardize charges, and assumptions behind removing charges for prior technology:
29. 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 (that is, TRICARE and/or non-TRICARE, 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.**
30. What is the (current and/or anticipated) charge of the technology by the hospital, per patient?

Explain how this was determined:

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.

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.

32. What is the anticipated **inpatient** non-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.

33. 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.

34. What is the anticipated **inpatient** non-TRICARE volume of this technology 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.

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 criteria 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' decision making process for each application, which will also be followed by DHA for TRICARE-specific NTAPs.

35. 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:

36. 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 #35 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	Number of unpublished studies, abstracts, or presentations submitted using the technology	Number of other data submissions using the technology	Number of data submissions as background
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Note: Indicate if any peer-reviewed articles will be released after submission of this application.

37. For each claim of substantial clinical improvement over existing technologies stated in question 35, in table format (see Table 1 on page 9 for example and complete fillable table on page 7), list the claim of substantial clinical improvement and summarize the supporting information to include relevant clinical trial(s) or data. (**Application is incomplete without this table**).

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

Item number	Substantial Clinical Improvement (SCI) Claim	Supporting evidence/data Please provide reference	Study Type (for example, 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.
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Adverse Events/Recalls (This section must be completed for all technologies.)

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

Recall:

Yes

No

Adverse Event:

Yes

No

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

Yes

No

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

Item number	Substantial Clinical Improvement (SCI) Claim	Supporting evidence/ data Please provide reference	Study Type (for example, 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 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," 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 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," JAMA 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.
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," JAMA 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.

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.

40. The technology has been previously reviewed by CMS for an NTAP?

Yes

No

If yes, please attach the documentation from CMS, including the decision.

41. Did CMS reject the technology solely on the basis the technology was not being used to treat the Medicare beneficiary population?

Yes

No

If yes, please attach the documentation from CMS.

END OF APPLICATION. SEE P. 11 FOR APPENDICES.

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 most recent TRICARE-specific NTAP inflation factors can be found as part of the TRICARE-specific NTAP Supplemental Information workbook.

The "Supplemental Information workbook" refers to the most recent:

- TRICARE NTAP thresholds,
- TRICARE hospital CCRs,
- IDME factors, and
- CMS IPPS Final Impact file for wage index.

Hospital specific cost-to-charge ratio and IDME factors. The hospital specific operating CCR and IDME factors, can be requested from the TRICARE regional contractors. Each TRICARE regional contractor has a provider file that includes these pieces of information. The applicant can contact HNFS at the following:

Website: www.tricare-west.com

Phone: 1-844-866-WEST (1-844-866-9378)

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. For the FY24 IPPS final rule, see the following link:

<https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/fy-2024-wage-index-home-page>.

Note: If applying in CY24, use the most recent TRICARE NTAP thresholds, most recent TRICARE hospital CCRs and IDME factors, and the most recent CMS IPPS Final Impact file for wage index, which are part of the supplemental workbook. DHA will update the threshold values when the TRICARE DRG weights and Adjusted Standardized Amounts (ASA) are released.

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

If wage index greater than 1:

i) $\text{Operating Standardized Charge} = ((AOC * \text{Labor Share \% (Example} = 0.676 \text{ for FY23)}) / \text{wage index}) + ((AOC * \text{Non-Labor Share \% (Example} = .324 \text{ for FY23}))$

If wage index less than 1:

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

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 ASAs for all areas (visit <https://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/TRICARE-Health-Plan/Rates-and-Reimbursement/Diagnosis-Related-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 on the www.health.mil/NTAP website. 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. The current 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 CY24, the FY23 Medicare NTAP thresholds will be used for the comparison. The Medicare thresholds can be found in the FY2023 IPPS Final Rule files.

In the case that there is no equivalent MS-DRG threshold (that is, if the DRG is a TRICARE-specific pediatric DRG), then 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.