Application for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for Calendar Year (CY) 2024

The following technical instructions provide guidance to interested parties on how to apply for the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) under the ESRD PPS for CY 2024.

DEADLINE

Applicants must submit via email, a complete application no later than February 1, 2023. An application is considered complete when each item listed in the Required Information section has been addressed and the application has been submitted by the deadline.

WHERE TO SEND APPLICATIONS

The electronic version of the application must be emailed to ESRDApplications@cms.hhs.gov by the specified deadline. Emailed versions of the materials must be compatible with standard CMS software such as Adobe Acrobat DC for 2015 or Microsoft Word 2010. The subject line of the email must say "ESRD PPS TPNIES Application". Total attachments in one email must not exceed 20 megabytes. If necessary, multiple emails with attachments less than 20 megabytes may be sent. Questions pertaining to the TPNIES application process may also be sent to the electronic mailbox noted above. We will respond to questions as expeditiously as possible; however, any delay in responding to a question should not be construed as an extension of the deadline.

Please note: In order to meet the February 1, 2023 deadline, an applicant must submit the complete electronic version of the application via email prior to or on February 1, 2023.

DISCLAIMER

All content submitted as part of this application may be made public unless otherwise noted below. Throughout this application, "made public" refers to including information from a TPNIES application in our discussion of the application in proposed and final ESRD PPS rules published in the **Federal Register**, consistent with the process established in 42 C.F.R. § 413.236(c).

CMS generally only considers information that is made public when determining whether an equipment or supply meets the TPNIES eligibility criteria. If you would like to include information that should not be made public as part of your application, please refer to the "Additional Application Information - CONFIDENTIAL" section at the end of the application.

REQUIRED INFORMATION

Applications must address each item below. CMS may request additional information to evaluate specific requests for the TPNIES. A separate application is required for each distinct equipment or supply included in the TPNIES request.

1. Contact information.

- Name, address, telephone number, and email address for the 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. Equipment or supply name.

- Trade/brand name of the equipment or supply.

3. Description of the equipment or supply (using general terminology).

- What is it?
- What does it do?
- How is it used?
- Submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles relevant to the new equipment or supply.

4. Applications for other Medicare add-on payment pathways.

- Have you applied for pass-through payments under the Medicare Outpatient PPS or new technology add-on payments under the Medicare Inpatient PPS for the same equipment or supply that is the subject of this application for the TPNIES?
- If so, please provide the tracking number(s) or, if it was approved, please provide the date of approval.
- If you intend to apply for any other Medicare add-on payment pathway but have not done so, please identify the pathway and the date by which you intend to apply.

5. FDA marketing authorization.

Per 42 CFR § 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by the HCPCS Level II Code Application Deadline for Biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance prior to the particular calendar year. The HCPCS Level II coding guidance is available at: https://www.cms.gov/medicare/coding/medhcpcsgeninfo

- Have you already received FDA marketing approval for the equipment or supply for which you are applying for a TPNIES under ESRD PPS? If so, you must include with this application, a copy of the FDA marketing authorization.
- If you are seeking FDA marketing authorization, provide information on the pathway you applied for, the application date, and the date you anticipate receiving FDA marketing authorization.
- If marketing authorization has not yet been granted, you must provide a copy of the authorization to CMS immediately after it becomes available.

6. Contact at the FDA.

- List the name and telephone number or email address of a contact at FDA who is knowledgeable about the submission for marketing authorization for the new equipment or supply listed above.

7. Information on commercial availability.

- Did the equipment or supply become available on the market immediately after FDA marketing authorization?
- If not, provide the date that the equipment or supply came on the market (that is, first sales or availability) and an explanation and documentation of any delay in commercial availability (for example, manufacturing issues or other reasons).
- If commercial availability has not yet occurred, provide proof of commercial availability to CMS immediately after it becomes available, for example, a manufacturer's bill of sale. Note that the manufacturer must inform CMS by September 1, 2023 if the equipment or supply will not be available by January 1, 2024.

8. Investigational device exemption (IDE).

- Is there an IDE number from the FDA assigned to the equipment or supply?
- If yes, please provide this code. Refer to FDA's IDE webpage for more details: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide

9. Assigned FDA class.

- What class (I, II, or III) was/is assigned to the equipment or supply? Refer to FDA's Overview of Device Regulation webpage for more details: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation

10. HCPCS application.

Submission of the HCPCS application is required by the HCPCS Level II Code Application Deadline for Biannual Coding Cycle 2 for DMEPOS items and services (as specified in the HCPCS Level II coding guidance on the CMS website at: https://www.cms.gov/medicare/coding/medhcpcsgeninfo).

- Has an application for an HCPCS code been submitted?

11. Cost.

- What is the anticipated cost of the equipment or supply to the ESRD facility, per treatment? Provide a breakdown of how the cost of the new equipment or supply is calculated.
- For a capital-related asset that is a home dialysis machine, what is the anticipated unit cost (excluding financing, sales tax, freight, installation and testing, excise taxes, legal or accounting fees, and maintenance)?

Disclaimer: For applications that are approved for the TPNIES, information related to cost will be made public in the ESRD PPS final rule for purposes of estimating impacts to the Medicare program, but we will not use it in connection with our assessment of TPNIES eligibility.

12. Volume.

- What is the anticipated Medicare ESRD PPS volume of this equipment or supply for CY 2024?
- What is the anticipated Medicare ESRD PPS volume of this equipment or supply for CY 2025?

Disclaimer: For applications that are approved for the TPNIES, information related to volume will be made public in the ESRD PPS final rule for purposes of estimating impacts to the Medicare program, but we will not use it in connection with our assessment of TPNIES eligibility.

13. Substantial clinical improvement.

The substantial clinical improvement (SCI) criteria under 42 C.F.R. § 413.236(b)(5) are specified at § 412.87(b)(1) and are also summarized at: www.cms.gov/files/document/cy-2021-tpnies-substantial-clinical-improvement-criterion.pdf. Additional information on the TPNIES eligibility criteria, including the SCI criteria can be found in the CY 2020 ESRD PPS final rule (84 FR 60684 through 60692) and the CY 2021 ESRD PPS final rule (85 FR 71410 through 71414). Additionally, the annual ESRD PPS final rule includes CMS' decision-making processes for each application.

Overview of the SCI Criteria

CMS uses the following criteria in its evaluation of the SCI for the purposes of the TPNIES:

1. The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
2. The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient.
3. The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the outcomes described below.

The equipment or supply must demonstrate that it meets at least one of these three SCI criteria in order to be eligible for the TPNIES.

Substantial Clinical Improvement Criterion 1:

- Does the new renal dialysis equipment or supply offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments? If No, skip to SCI Criterion 2 below. If Yes:
- Please provide a reason this equipment or supply meets this criterion using supporting data. Identify each reason for meeting this criterion as a separate claim.
    - Title of claim (include as many claims as desired)
    - Provide a full explanation as to why this equipment or supply meets SCI Criterion 1
    - Provide Supporting Evidence, if applicable. (Provide as many as desired for each claim). Attach file and answer the following questions related to each attachment:
        - Title of the supporting evidence
        - Data Source category (choose one)
            - Published, peer, reviewed studies using equipment or supply
            - Unpublished studies, abstracts, or presentations using equipment or supply
            - Other data submissions using equipment or supply
            - Data submissions as backgrounds (does not directly assess the equipment or supply)
        - Evidence Type (eg meta-analysis, case report, RCT)
        - Attached File
            - Page Number(s)
            - Citation
            - Reason for inclusion/relevance to the claim
            - Study summary: Please clearly summarize the study in full, to include (at minimum) the purpose of the study, number of patients treated, study arms, demographics, inclusion/exclusion criteria, endpoints tested, and outcomes (specify if statistically significant).
            - Results from the study that support this claim: Please provide the specific statistic(s)/outcome(s) from the study and the page/paragraph within the study where it can be found.

Substantial Clinical Improvement Criterion 2:

- Does the new renal dialysis equipment or supply 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 No, skip to SCI Criterion 3 below. If Yes:
- Please provide a reason this equipment or supply meets this criterion using supporting data. Identify each reason for meeting this criterion as a separate claim.
    - Title of claim (include as many claims as desired)
    - Provide a full explanation as to why this equipment or supply meets SCI Criterion 2
    - Provide Supporting Evidence, if applicable. (Provide as many as desired for each claim). Attach file and answer the following questions related to each attachment:
        - Title of the supporting evidence
        - Data Source category (choose one)
            - Published, peer, reviewed studies using equipment or supply
            - Unpublished studies, abstracts, or presentations using equipment or supply
            - Other data submissions using equipment or supply
            - Data submissions as backgrounds (does not directly assess the equipment or supply)
        - Evidence Type (eg meta-analysis, case report, RCT)
        - Attached File
            - Page Number(s)
            - Citation
            - Reason for inclusion/relevance to the claim
            - Study summary: Please clearly summarize the study in full, to include (at minimum) the purpose of the study, number of patients treated, study arms, demographics, inclusion/exclusion criteria, endpoints tested, and outcomes (specify if statistically significant).
            - Results from the study that support this claim: Please provide the specific statistic(s)/outcome(s) from the study and the page/paragraph within the study where it can be found.

Substantial Clinical Improvement Criterion 3:

- Does the use of the new renal dialysis equipment or supply significantly improve clinical outcomes relative to services or technologies previously available? If No, skip to the SCI Criterion Summary below. **NOTE: At least one of the 3 SCI Criteria must be a Yes selection.** If Yes:
- Please provide a reason this equipment or supply meets this criterion using supporting data. Identify each reason for meeting this criterion as a separate claim.
    - Title of claim (include as many claims as desired)
    - Provide a full explanation as to why this equipment or supply meets SCI Criterion 3
    - Provide Supporting Evidence, if applicable. (Provide as many as desired for each claim). Attach file and answer the following questions related to each attachment:
        - Title of the supporting evidence
        - Data Source category (choose one)
            - Published, peer, reviewed studies using equipment or supply
            - Unpublished studies, abstracts, or presentations using equipment or supply
            - Other data submissions using equipment or supply

        - Data submissions as backgrounds (does not directly assess the equipment or supply)
    - Evidence Type (eg meta-analysis, case report, RCT)
    - Attached File
        - Page Number(s)
        - Citation
        - Reason for inclusion/relevance to the claim
        - Study summary: Please clearly summarize the study in full, to include (at minimum) the purpose of the study, number of patients treated, study arms, demographics, inclusion/exclusion criteria, endpoints tested, and outcomes (specify if statistically significant).
        - Results from the study that support this claim: Please provide the specific statistic(s)/outcome(s) from the study and the page/paragraph within the study where it can be found.

SCI Source Summary

Based on the information provided for SCI Criteria 1 through 3 above, populate numerical totals below.

- Total number of claims
- Number of published, peer-reviewed studies submitted using the equipment or supply
- Number of unpublished studies, abstracts, or presentations submitted using the equipment or supply
- Number of data submissions using the equipment or supply
- Number of data submissions as background

SCI Criterion – Narrative Summary

- Briefly summarize how the renal dialysis equipment or supply meets the substantial clinical improvement criterion overall.

14. Additional Application Information – Confidential.

Applicants are not required to submit proprietary or confidential information as part of the TPNIES application, but may choose to provide such information. However, please note that the information identified as confidential in this section of the application will not be considered when determining whether an equipment or supply meets the TPNIES eligibility criteria and will not be made public in the annual update to the ESRD PPS.

- Do you have any information that you wish to provide as part of your application that should not be made public?
- If yes, identify the relevant application section(s) (i.e., item numbers 1 – 13 above). **Disclaimer:** Data provided in the application that is identified as confidential in this section may become subject to disclosure unless the required conditions are met that would circumvent disclosure that is required by law. CMS will attempt, to the extent allowed by law, to keep this information protected from public view.
- Attach any relevant files (optional).