Department of Health & Human Services
Centers for Medicare & Medicaid Services
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Center for Medicare

Substantial Clinical Improvement Criteria for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) under the ESRD PPS

CMS uses the following criteria to evaluate Substantial Clinical Improvement for purposes of the TPNIES (see 42 CFR 413.236(b)(5) and 412.87(b)(1)):

The criteria are:

(1) A new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

(i) The totality of the circumstances is considered when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

(ii) A determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

(A) The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(B) 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 and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient.

(C) 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.

(*1*) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

(*2*) A decreased rate of at least one subsequent diagnostic or therapeutic intervention.

(*3*) A decreased number of future hospitalizations or physician visits.

(*4*) A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time.

(*5*) An improvement in one or more activities of daily living.

(*6*) An improved quality of life.

(*7*) A demonstrated greater medication adherence or compliance.

(D) The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

(iii) Evidence from published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Information source may include the following:

(A) Clinical trials;
(B) Peer reviewed journal articles;
(C) Study results;
(D) Meta-analyses;
(E) Consensus statements;
(F) White papers;
(G) Patient surveys;
(H) Case studies;
(I) Reports;
(J) Systematic literature reviews;
(K) Letters from major healthcare associations;
(L) Editorials and letters to the editor; and,
(M) Public comments.
(N) Other appropriate information sources may be considered.

(iv) The medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

(v) The new renal dialysis equipment or supply may represent an advance that substantially improves, relative to renal dialysis services previously available, the

diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.