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CY 2021 ESRD PPS Final Rule Includes Policy Changes to Promote In-Home Dialysis

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The Calendar Year (CY) 2021 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule, CMS-1732-F (Final Rule) was published in the Federal Register on November 9, 2020. The Final Rule includes payment updates and policies for renal dialysis services furnished to beneficiaries enrolled in Medicare on or after January 1, 2021. The policies CMS finalized related to the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) are particularly noteworthy in the context of ongoing efforts to encourage increased provision of dialysis in the home.

Following the directives of an Executive Order issued on July 10, 2019, CMS previously issued new payment models designed to identify, incentivize and treat at-risk populations at earlier stages of kidney disease, and to increase in-home dialysis and kidney transplants. Most recently, CMS finalized a new mandatory payment model, known as the ESRD Treatment Choices (ETC) Model, which provides new incentives to encourage the provision of dialysis in the home and encourage kidney transplants for ESRD beneficiaries. In further support of home dialysis, CMS has also acknowledged that that ESRD patients who receive in-center dialysis are particularly vulnerable during the COVID-19 PHE and other disasters.

In keeping with this recent trend, the Final Rule includes policies to incentivize dialysis at home. Specifically, CMS finalized changes to the eligibility criteria and determination process for the TPNIES to include new and innovative capital-related assets that are home dialysis machines.

Changes to the Eligibility Criteria and Determination Process for the TPNIES

The add-on payment for TPNIES was established in the CY 2020 ESRD PPS final rule to help ESRD facilities incorporate new and innovative equipment and supplies into their businesses and to support ESRD facilities testing or incorporating these products when they are still new to the market.

Starting with dates of service occurring on or after January 1, 2020, CMS provides the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item satisfies the eligibility criteria in 42 C.F.R. § 413.236(b).

CMS revised the definition of "new" in these eligibility criteria for the TPNIES payment adjustment to mean: within three years beginning on the date of FDA marketing authorization (instead of the prior definition under which items were considered new if they were granted a marketing authorization by the FDA on or after January 1, 2020).

CMS expanded eligibility for the TPNIES to now cover certain capital-related assets that are home dialysis machines when used in the home for a single patient. This is a policy change because capital-related assets were excluded from eligibility when the TPNIES add-on payment was created.

Under the Final Rule, "capital-related asset" is redefined to mean an asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets.

CMS will evaluate applications to determine whether the home dialysis machine represents an advance that substantially improves the diagnosis and treatment of Medicare beneficiaries compared to renal dialysis services previously available, and meets the other requirements set forth in 42 C.F.R. § 413.236(b). For purposes of determining whether the home dialysis machine is new under § 413.236(b)(2), CMS would look at the date the machine is granted marketing authorization by FDA for home use.

The reasoning behind this policy is that CMS wants to ensure it does not pay the TPNIES for new home dialysis machines that are substantially similar to existing machines and not truly innovative. CMS will only consider an application for a capital-related asset that is a home dialysis machine that is received by February 1 prior to the particular calendar year in order to determine whether it qualifies for additional payment using TPNIES. If an application is not received by CMS by February 1, it will be denied, and the applicant needs to reapply within three years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES.

The Final Rule includes additional steps that MACs must follow to establish the basis of payment for TPNIES for these capital-related assets that are home dialysis machines used at home. This will include an offset to the pre-adjusted per treatment amount to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate.

CMS requires MACs to establish a price, using verifiable information from the following sources of information, if available:

1. the invoice amount, facility charges for the item, discounts, allowances, and rebates;
2. the price established for the item by other MACs and the sources of information used to establish that price;
3. payment amounts determined by other payers and the information used to establish those payment amounts; and
4. charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

CMS will pay 65 percent of the MAC determined pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines for two calendar years. After this two-year period, the home dialysis machines will not become outlier services and no change will be made to the ESRD base rate.

For more information, please contact Allison Cohen or anyone in the Baker Donelson Reimbursement Team.