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All You Need and Want to Know about TDAPA

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Agenda

- Overview of the TDAPA
- The Fundamentals of the TDAPA
- Potential Implementation Challenges
- Current Guidance
- What to Expect Next

Overview of the TDAPA

Transitional Drug Add-on Payment Amount

- A temporary (2 year) payment for a new injectable or intravenous drug or biological used for the treatment of ESRD for which there is no current functional category

Community sought to mirror new drug policies used for hospital PPS

- Important to understand utilization patterns
- Pay at ASP+6% during transition period
- New money; not budget neutral

The Fundamentals of the TDAPA

Regulatory Policy
- 42 CFR § 413.234(c)

Purpose
- To facilitate beneficiary access to certain new products

Incentive
- Allows payment for these drugs and biologicals while CMS collects utilization data

Length
- At least two years

Bundle
- At the end of the transition, CMS will use the utilization and price data to incorporate the costs of these drugs into the ESRD PPS

Triggering the TDAPA

Criteria
- Approved by the FDA
- Commercially available
- Assigned a HCPCS code
- Identified as having an end action effect that treats or manages a condition or conditions associated with ESRD
- Identified as not fitting into an established ESRD PPS functional category
- Designated by CMS as a renal dialysis service under §413.171

The Transition Payment Policy

- CMS pays for drug or biological using a transitional drug add-on payment adjustment, using methodologies in SSA § 1847A
  - SSA § 1847A establishes separate methodologies for calculating WAC and ASP for single source and multisource drugs
- After 2 to 3 years, CMS engages in notice and comment rulemaking to include the drug or biological in the ESRD PPS

Under the ESRD PPS, there is no payment mechanism to pay for drugs and biologicals eligible for the TDAPA until guidance is issued by CMS

Potential Implementation Challenges for IV and Oral Calcimimetics

Guidance Timing

- Important that the transition period does not begin tolling until the drug is in use to ensure that there are no months included in the transition period when the drug is not being used

Part B versus Part D

- Need to clarify with the PDPs that the oral calcimimetic remains reimbursable under Part D for ESRD patients until the date CMS specifies in the Change Notice
- Part D data on the oral calcimimetic may not adequately reflect the utilization of the drug once it is part of the Part B program
- Need to address financial burden beneficiaries may experience in transitioning from Part D to Part B

Potential Implementation Challenges for IV and Oral Calcimimetics (Con't)

Pricing

- CMS should establish separate payment rates for the two drugs during the transition period

State Pharmacy Laws

- CMS should address the fact that dialysis facilities are rarely licensed as pharmacies

Submitting Amount Dispensed on Claims

- As it does with hospitals and SNFs, CMS should require facilities to include the amount dispensed on the claim, not the amount used

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- CMS should clarify in writing how it will address this issue so there is no confusion about the drug being excluded from the restriction

Unanswered Billing Questions

- Does CMS plan to establish a minimum and/or maximum number of days of medication that can be supplied?
- Who bears the risk if a patient receives a multi-day supply of the oral calcimimetic and the patient dies?
- How should changes in physician dosing requirements be implemented if a patient has a 30-day or greater supply of the drug?
- How should dialysis facilities bill if medication is sent to a beneficiary's home, the beneficiary indicates he/she never received it, and a new supply is sent? Can the facility bill for the second supply?

Current Guidance

CMS.gov
Centers for Medicare & Medicaid Services

- Medicare Benefit Policy Manual Chapter 11 - End Stage Renal Disease (ESRD) § 20.3.1
  - Reiterates basic policy, does not answer questions
- Website
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html
  - Confirms process, but not much more

What to Expect Next

- CMS will issue
  - HCPCS Code
  - Change Request
- Community seeks
  - Additional guidance to facilities
  - Guidance to Part D plans
- Data Collection
  - Utilization and pricing data will be crucial to providing for the integrity of the bundle