Assessing payment adequacy and updating payments: Outpatient dialysis services

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MEDPAC

Overview of outpatient dialysis services, 2018

- Outpatient dialysis services used to treat individuals with end-stage renal disease (ESRD)
- FFS beneficiaries: About 395,000
- Providers: About 7,400 dialysis facilities
- Medicare FFS dialysis spending: $12.7 billion

Source: MedPAC analysis of 100 percent claims submitted to dialysis facilities to CMS and CMS's Dialysis Compare files. Data are preliminary and subject to change.

Follow-up from December meeting

- The 2019 ESRD Quality Incentive Program
  - 73% facilities experienced no payment reduction
  - 27% of facilities experienced reduced payments of 0.5 percent to 2 percent (the maximum payment reduction)*
- Differences in outcomes between home and in-center dialysis
  - Difficult to assess because of self-selection bias
  - Findings from observational studies show mixed results
  - Each dialysis method has advantages and disadvantages
- First two years of ESRD Seamless Care Organizations resulted in:
  - Lower Parts A and B spending
  - Fewer acute inpatient admissions
  - Lower catheter use

*Based on analysis of CMS's Dialysis Compare File for facilities with a quality score. Data are preliminary and subject to change.

Summary: Outpatient dialysis payment adequacy indicators generally positive

Beneficiaries' access to care	Quality of care	Access to capital	Medicare payments and providers' costs
• Growth in provider supply and capacity • Positive marginal profit (18%)	• Modest increase in home dialysis use • Mortality and readmission rates steady	• Continued entry of for-profits • Sector viewed favorably by investors	• 2018 Medicare margin: 2.1% • 2020 projected margin: 2.4%
Positive	Stable	Positive	Positive

Improving the ESRD PPS: Refining the transitional drug add-on payment adjustment (TDAPA)

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Overview of dialysis drugs in the ESRD PPS

- Prior to 2011, many commonly-used drugs were paid separately
- MIPPA established the ESRD bundle and required the inclusion of all ESRD-related drugs:*
  - Drugs already in the composite rate (a smaller bundle used before 2011)
  - ESAs used to treat ESRD (paid separately before 2011)
  - Other drugs and biologicals used to treat ESRD (paid separately before 2011)
  - *Oral-only drugs excluded until 2025, or until a non-oral form is available
- Since 2011, Medicare has paid dialysis facilities a per treatment amount that covers all items and services in the ESRD bundle
  - Including equipment, supplies, labor, labs, and drugs related to treating ESRD

Medicare Improvement for Patients and Providers Act of 2008 (MIPPA). Erythropoietin stimulating agents (ESAs).

Drugs in the ESRD bundle by functional category

- To implement the bundle, CMS categorized ESRD-related drugs in 11 functional categories
  - Identifying ESRD-related drugs by category would allow CMS to respond to changes in drug therapies over time
  - CMS implied that new drugs in an existing functional category would be included in the bundle when they became available
- How would the ESRD PPS address new ESRD-related drugs?
  - Depends on whether or not the new drug is in an existing functional category

TDAPA policy for new ESRD drugs depends on whether they are in an existing functional category

New ESRD-related drugs that:	Are *not* in an existing functional category	Are in an existing functional category
Initial policy year	2016	2020
How is payment set?	ASP	ASP
Length of add-on payment period	At least 2 years	2 calendar years
Is the ESRD PPS base rate updated at end of add-on payment period?	Yes	No

Transitional drug add-on payment adjustment (TDAPA). Average sales price (ASP). Prospective payment system (PPS).

New ESRD drugs *not* in an existing functional category

- PAMA directed the Secretary to establish a drug designation process
  - How to include new injectable and intravenous products in the bundle
- For new ESRD-related drugs *not* in a functional category:
  - Facilities receive TDAPA equal to average sales price for at least two years
  - Thereafter, the drug is included in the bundle by modifying or adding a functional category, and ESRD PPS base rate is updated to account for the expansion to the bundle

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Transitional drug add-on payment adjustment (TDAPA). Average sales price (ASP). Prospective payment system (PPS).

New ESRD drugs in an existing functional category

- Initially, CMS included these drugs in the bundle, covering them under the existing base rate (i.e., no TDAPA)
- CMS expanded TDAPA eligibility to include some of these drugs
  - Applied criteria based on FDA approval pathways to include new molecular entities, drugs with new active ingredient, and biosimilars, among others
  - Excludes drugs that are “new” due to change in pill size or inactive ingredient, that were previously available over-the-counter, and generics
- TDAPA payment for new drugs in an existing functional category
  - Paid at average sales price for two years (in addition to full ESRD base rate)
  - Thereafter, the new drug is included in the bundle with no change to the base rate

Transitional drug add-on payment adjustment (TDAPA).

Payment issues with TDAPA policy for new drugs in an existing functional category

- Paying separately for drugs in a functional category temporarily unbundles the ESRD bundle
  - Inhibits competition among drugs in the same functional category
  - Fails to provide an incentive to reduce new drug launch prices
  - An ESA was introduced directly into the bundle in 2015: One-quarter of patients switched in the first year and ESA costs declined
- TDAPA payment is duplicative of bundled payment
  - TDAPA covers full cost of the new drug in addition to the payment for the functional category already included in the base rate
  - Paying TDAPA on a per unit basis in addition to the bundle increases the incentive to provide TDAPA-covered drugs and may promote their overuse

Transitional drug add-on payment adjustment (TDAPA).

TDAPA will increase payment for new drugs that offer no clinical improvement

- CMS does not require new ESRD-related drugs to meet substantial clinical improvement (SCI) criteria
  - SCI criteria applied to certain new technologies under inpatient and outpatient payment systems, and to certain new ESRD equipment and supplies
- Paying separately for biosimilars negates their main value by removing them from the bundle for two years
  - Biosimilars are not designed to offer clinical improvement over the reference biologic
  - Biosimilars can reduce drug prices through competition

Improving payment for new drugs in an existing functional category: Policy Options

1. Eliminate the TDAPA
   - New drugs would be included in the bundle upon entering the market with no update to the base rate

   OR

2. Limit the TDAPA to new drugs that offer clinical improvements
   - Apply SCI criteria to new drugs that are in a functional category
   - Reduce TDAPA payment by the cost of drugs in the same functional category already included in the bundle

- Under either option, the TDAPA policy for drugs *not* in an existing category would remain in place

Potential changes to the ESRD bundle over time

- The ESRD bundle has been fairly stable over time
  - New drugs have been incorporated directly into the bundle in recent years
- New add-on payments may provide incentive to create new technologies:
  - TDAPA for new drugs
  - Transitional add-on payment adjustment for new and innovative equipment and supplies
    - Requires SCI criteria to be eligible for payment adjustment
- Some stakeholders are concerned that the base rate may become insufficient to support new drugs, equipment, and supplies

Significant clinical improvement (SCI).

Addressing changes to the ESRD bundle

- The Commission monitors dialysis costs and payment adequacy, and makes recommendations to Congress every year
  - If payments become insufficient, the Commission could consider a recommendation to address the underlying issue
- If warranted, the Commission could consider a recommendation to rebase the ESRD PPS
  - Rebasing is the process of calculating a new base rate using current utilization patterns and prices
  - Rebasing the ESRD PPS requires Congressional authority
  - For example, the Congress required the Secretary to rebase ESRD PPS in 2014 due to changes in drug utilization

Prospective payment system (PPS).

Discussion

- Staff seek input on policy options revising the TDAPA policy for new ESRD-related drugs in an existing functional category:
  1. Eliminate the TDAPA, *or*
  2. Limit the TDAPA to new drugs that offer clinical improvements
- No change would be made to TDAPA policy for new ESRD-related drugs *not* in a functional category