Assessing payment adequacy and updating payments: Outpatient dialysis services

Nancy Ray and Andy Johnson
January 16, 2020
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**
  - Growth in provider supply and capacity
  - Positive marginal profit (18%)
  - Positive

- **Quality of care**
  - Modest increase in home dialysis use
  - Mortality and readmission rates steady
  - Stable

- **Access to capital**
  - Continued entry of for-profits
  - Sector viewed favorably by investors
  - Positive

- **Medicare payments and providers’ costs**
  - 2018 Medicare margin: 2.1%
  - 2020 projected margin: 2.4%
  - Positive
Improving the ESRD PPS: Refining the transitional drug add-on payment adjustment (TDAPA)

Andy Johnson and Nancy Ray
January 16, 2020
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
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

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<th>New ESRD-related drugs that:</th>
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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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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
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
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
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
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