Separately payable drugs in the hospital outpatient prospective payment system

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November 10, 2020

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Overview of presentation

- How drugs are paid in the outpatient prospective payment system (OPPS)
- Policies for separately payable drugs, including problems
- Improving the OPPS approach for separately payable drugs

Overview of payment bundles in the OPPS

- Most payments are for primary services (reason for a visit)
- Payment bundle: Cost of ancillary items packaged with primary service
  - Example: Clinic visit (primary service), chest x-ray (packaged ancillary with clinic visit)
- Important: Cost of packaged items reflected in payment rate of related primary service
- Compared with fee schedule (separate payments for everything), payment bundles encourage efficiency

The OPPS packages many drugs

- Many drugs in the OPPS are ancillary and are not costly in relation to the applicable primary service
- The OPPS generally packages the cost of these drugs into the payment rate of the related service
  - Do not meet cost thresholds or
  - Policy packaged (supplies to a service)
- Packaging is generally beneficial; encourages providers to be efficient because combination of inputs determines financial gain or loss

Separately payable drugs in OPPS

- Some drugs are separately payable, meaning drug gets separate payment from the services provided in the same visit
- Spending on separately payable drugs rose from $5.1 billion in 2011 to $14.8 billion in 2019
- Two OPPS policies for separately payable drugs
  - Pass-through drugs
  - Separately payable non-pass-through (SPNPT) drugs

Background on pass-through and SPNPT policies

- Pass-through policy:
  - Payments began in August 2000
  - New drugs, because cost and use data not available to include in payment rates for related service
  - Mitigates providers' financial risk, some stakeholders argue it maintains incentive for innovation
- SPNPT policy:
  - Payments began in 2004
  - Provides separate payment for relatively costly drugs established in the market
  - Excludes drugs that are ancillary; focus is drugs that are the reason for a visit

Criteria for separately payable drugs

Pass-through drugs

- New to market
- Cost must exceed three thresholds related to service payment rate
- Time limited to 2 to 3 years

SPNPT drugs

- Established drugs
- Cost/day threshold (greater than $130 in 2020)
- Not “policy packaged”
- No specified time limit

Improve policies for separately payable drugs in OPPS

- Want to balance benefit of packaging drugs (efficiency) with paying separately for drugs when appropriate
- In June 2020 Report, identified features of an effective system for identifying separately payable drugs:
  - Strong rationale to pay separately for drugs that are the reason for a visit because they are not ancillary
  - Strong rationale to require ancillary drugs (not the reason for a visit) to show clinical superiority to be paid separately for a limited period of time
- Goal: Apply these two features to the SPNPT and pass-through policies

Identifying drugs that should be separately payable in the OPPS

- OPPS drugs fall into two broad categories:
  - Reason for a visit: Not ancillary, costly, treat a condition, usually administered by infusion
  - Ancillary: Not a reason for a visit; adjunct to a service
- Conclusion: Pay separately for drugs that are reason for visit; package drugs that are ancillary as much as possible, but pay separately if providers would face excessive financial risk

Pass-through policy: Potential improvements

- What to keep
  - Exclusively for new drugs
  - Drug cost must be high in relation to payment rate of applicable service
  - Limit pass-through status to 2 to 3 years
- What to change
  - Exclude drugs that are reason for visit; pass-through not needed because these drugs would be separately paid as SPNPT drugs
  - Require ancillary drugs to show clinical superiority over drugs included in bundle of the applicable services

Pass-through policy: Require clinical superiority

- In FFS Medicare, several clinical superiority requirements for new technology:
  - Devices in OPPS
  - Drugs and devices in NTAP (IPPS)
  - Devices in ESRD system
- Criteria in NTAP could be applied to pass-through drugs

Note: FFS (fee for service), OPPS (outpatient prospective payment system), NTAP (new technology add-on payment), IPPS (inpatient prospective payment system), ESRD (end-stage renal disease).

SPNPT policy: Potential improvements

- What to keep
  - Continue to consider established drugs for separate payment
  - Maintain cost per day threshold (currently $130, but could be changed)
  - Focus on drugs that are not ancillary
- What to change
  - Explicitly require a drug to be the reason for a visit
  - Expand to include new drugs that are the reason for a visit

Summary of proposed policy changes on pass-through and SPNPT policies

Pass-through drugs

- New to market
- Ancillary
- Costly relative to service
- Clinically superior
- 2 to 3 years

SPNPT drugs

- New or established
- Reason for a visit
- Cost/day greater than threshold*

* Cost threshold for SPNPT drugs is currently $130 per day.

Impacts of proposed policy changes

- Fewer pass-through drugs: Limit to ancillary drugs and require clinical superiority
- Pass-through drugs that are reason for visit moved to SPNPT category
- On net, fewer separately paid drugs and more packaged drugs

Next steps

- Respond to Commissioner comments/directions
- With sufficient interest, develop recommendations for spring 2021
- Thoughts on broader application of clinical superiority requirements throughout FFS Medicare