

Separately payable drugs in the hospital outpatient prospective payment system

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Overview of presentation

- Unit of payment in the outpatient prospective payment system (OPPS)
- How drugs are paid in the OPPS
- Current OPPS policies for separately payable drugs, including concerns about those policies
- Improving Medicare payment for separately payable drugs

Unit of payment in the OPPS

- Most payments are for primary services (reason for a visit)
- Payment bundle: Package cost of most ancillary items with payment of primary service
 - Example: ED visit (primary service), x-ray (packaged ancillary with ED visit)
 - Important: Cost of packaged item is reflected in payment for related primary service
- Benefit of packaging ancillaries: Incentive for providers to seek lowest cost, most efficient way to furnish primary service

OPPS includes both packaged and separately payable drugs

- Many drugs are ancillary supplies to primary services; some are reason for a visit
- Under OPPS, many drugs are packaged; some are paid separately
- Spending on separately payable drugs rose from \$5.1 billion in 2011 to \$14.8 billion in 2019
- Two policies for separately payable drugs
 - Pass-through policy, created by the Congress
 - Policy for separately payable non-pass-through (SPNPT) drugs, largely created through regulation

Background on policies for pass-through and SPNPT drugs

- Pass-through policy:
 - New drugs, concern that cost and use data not available to include in payment rates for related services
 - Mitigates providers' financial risk from using costly new drugs
 - Includes both drugs that are supplies and drugs that are the reason for a visit
 - Those that are supplies are packaged when pass-through status ends
- SPNPT policy:
 - Established drugs
 - Provides separate payment for relatively costly drugs
 - Implicitly includes only drugs that are reason for a visit

Criteria in the two OPPS policies for separately payable drugs

Pass-through drugs

- New to market
- Cost must exceed three thresholds related to service payment rate
- Have this status 2 to 3 years

SPNPT drugs

- Not pass-through (established drugs)
- Cost/day threshold (greater than \$130 in 2021)
- Excludes drugs that are supplies
- No specified time limit

Concern: Pass-through and SPNPT policies both include drugs that are the reason for a visit

- Makes administration of OPPS system of drug payment unnecessarily complex
- For 340B providers, financial advantage for using some pass-through drugs rather than similar SPNPT drugs
 - Statute: Pay all pass-through drugs at ASP + 6%
 - Regulation: Pay SPNPT drugs at ASP – 22.5% if obtained through 340B; at ASP + 6% if obtained outside 340B

Concern: Pass-through policy does not require clinical superiority

- The pass-through policy:
 - It is not restricted to drugs that are supplies to a service
 - It does not have a clinical superiority requirement
- Without clinical superiority requirement, Medicare can make additional payments for a new and potentially much higher cost drug that is no more effective than similar competing drug already on the market

Improving Medicare payment for drugs that are supplies to a service

- Restrict the pass-through policy to drugs that are supplies to a service (exclude drugs that are reason for a visit)
 - Would level the payment rates among drugs that are the reason for a visit
- Add clinical superiority requirement to the current criteria for pass-through eligibility
 - Would raise the bar for drugs to qualify beyond simply being costly
 - Manufacturers would have incentive to devote resources to develop drugs that offer better clinical performance
 - Could use the criteria for drugs to show clinical superiority in the NTAP Program under the IPPS

Improving Medicare payment for drugs that are the reason for a visit

- Expand policy for SPNPT drugs to include new drugs that are the reason for a visit, these drugs are currently paid separately under pass-through policy
- SPNPT policy with this features would mitigate the financial benefit from using some pass-through drugs rather than similar SPNPT drugs
- Under SPNPT policy:
 - Continue to require cost per day to exceed a threshold (not clear if \$130 is the right threshold)
 - Continue to exclude drugs that are supplies to a service

Criteria in policies for separately payable drugs with proposed modifications

- Pass-through drugs
 - **New drugs that are supplies (excludes drugs that are the reason for a visit)**
 - **Must show clinical superiority**
 - **Cost must exceed 3 thresholds related to service payment rate**
 - **Have this status 2-3 years**
- SPNPT drugs
 - **Applies only to drugs that are the reason for a visit**
 - **Both new and established drugs**
 - **Must exceed cost per day threshold**
 - **No specified time limit**

Summary of effects

- Clinical superiority requirement would raise the bar for drugs to have pass-through status beyond being high cost
- Drugs that are the reason for a visit would no longer be eligible for the pass-through policy
 - All drugs that are the reason for a visit would obtain separately payable status under the SPNPT policy
 - Would level the payment rates among drugs that are the reason for a visit