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

<table>
<thead>
<tr>
<th>Pass-through drugs</th>
<th>SPNPT drugs</th>
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<tbody>
<tr>
<td>• New to market</td>
<td>• Not pass-through (established drugs)</td>
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<tr>
<td>• Cost must exceed three thresholds related to service payment rate</td>
<td>• Cost/day threshold (greater than $130 in 2021)</td>
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<td>• Have this status 2 to 3 years</td>
<td>• Excludes drugs that are supplies</td>
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<td>• No specified time limit</td>
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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

Note: NTAP (new technology add-on payment); IPPS (inpatient prospective payment system).
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.