Developing payment policy to promote use of services based on clinical evidence

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Today's session

- Medicare's payment policies generally reflect the cost of a service, not its clinical effectiveness relative to its alternatives
- Linking payment to clinical evidence better ensures that beneficiaries are getting the best value for their health care dollar
- At the March 2014 meeting, Commission discussed setting the payment rate of Part B drugs based on comparative clinical evidence

Medicare payment for Part B drugs

- Most Part B drugs are furnished by physicians
- Medicare pays physicians 106% of a drug's average sales price
- ASP is the manufacturer's average price for sales to all purchases net of rebates, discounts, and price concessions
- In 2012, Medicare spending for Part B drugs furnished in physicians' offices totaled about $13.2 billion, an increase of about 3 percent from 2011

Setting the payment rate of Part B drugs based on comparative clinical evidence

- Medicare applied the least costly alternative (LCA) policy to Part B drugs between 1995 and 2010
- For two or more drugs that clinicians prescribe for the same condition and produce a similar outcome, the policy sets the payment rate based on the least costly drug
- Intent of policy is to obtain the best price for beneficiaries

Applying the LCA policy to Part B drugs

- LCA policy affected drugs' payment rate
- LCA policy used existing statutory payment formulas; no additional pricing data was necessary
- Implemented by the contractors' medical directors in the local coverage process
- In one instance, LCA-type policy applied nationally under the hospital outpatient prospective payment system

Lawsuit successfully challenged use of LCA policy

- Policy implemented based on “reasonable and necessary” statutory provision
- A beneficiary and a manufacturer challenged use of policy to pay for Part B inhalation drug arguing that the drug should be paid based on its own average sales price plus six percent
- Federal courts agreed with the plaintiff
- In April 2010, LCA policies for Part B drugs were rescinded

Obtaining the best price for beneficiaries

- Case study 1: CBO estimated savings of $500 million if the LCA policy was applied to Part B drugs for drugs used for osteoarthritis of the knee
- Case study 2: OIG estimated one-year savings of $33 million if Medicare had continued its LCA policy for prostate cancer drugs
- We estimated reduced spending of $24 million for beneficiaries and $97 million for Medicare if LCA policy for prostate cancer drugs used April 2010-December 2012

Data are preliminary and subject to change.

Obtaining the best price for beneficiaries (continued)

- Case study 3: OIG estimated savings of $275 million for beneficiaries and $1.1 billion (in 2008-2009) if payment rate for biologics prescribed for wet age-related macular degeneration (AMD) based on lower priced one
- OIG found that majority of surveyed physicians who used lower cost product cited the cost difference as the primary decision factor
- We found differences in use of wet AMD products based on patients' supplemental coverage (in 2011)

Data are preliminary and subject to change.

Use of reference pricing by other organizations

- Gaining traction both domestically and internationally
- May be used for drugs, procedures, or other services
  - Most U.S. programs involve hospital services, but some also price drugs this way
  - Internationally, tends to be used for pharmaceuticals

Examples of reference pricing by other organizations

- Drug Effectiveness Review Project (DERP)
  - Currently 12 states participate
  - Conduct comparative effectiveness reviews for categories of drugs
- Germany's Pharmaceutical Market Restructuring Act
  - Independent board evaluates effectiveness of new drugs
  - Manufacturer sets initial price
  - Manufacturer and payers negotiate price discount if shown to be superior to standard treatment
  - If not, reference price is used for new drug
- CalPERS and Anthem
  - Reimburse for hip and knee replacements up to threshold amount
  - If beneficiary chooses to go to more expensive facility, pays difference

Concerns regarding LCA

- The effect of LCA policies on manufacturers' incentives to innovate
- Transparency and predictability of the LCA process
- The effect of LCA policies on clinicians' ability to treat beneficiaries

Arguments for LCA

- Medicare should ensure that beneficiaries are getting the best value
- Payment should not vary for products that clinicians prescribe for the same condition and produce a similar outcome
- Would further the sustainability of the Medicare program
- Precedent – OPPS and IPPS new technology add-on payments

Policy option: Restore the Secretary's authority to use LCA policy for Part B drugs

- Medicare would need legislative authority restored to apply the LCA policy to Part B drugs
- OIG recommended in 2012 that CMS seek legislative authority to apply the LCA policy for certain clinically comparable products under circumstances it deems appropriate
- Restoring Medicare's LCA authority could be coupled with a requirement that the program evaluate opportunities for its application

Development of a transparent and predictable process

- Considers evidence on the comparative clinical effectiveness of drugs
- Posts draft and final policies on-line
- Seeks and considers comments from beneficiaries and other stakeholders
- Includes a process for medically necessary exceptions
- Permits a beneficiary to purchase a more costly item if it is not deemed medically necessary
- Process for revisiting policy over time

For Commissioner discussion

- LCA policy is a way to improve value of spending for beneficiaries and the program
- The Secretary no longer has the legal foundation to apply the policy to Part B drugs
- Future opportunities to apply the LCA policy will increase as more information becomes available
- Seek comments about the policy option to restore the Secretary's authority to apply the LCA policy to Part B drugs