



JOHNS HOPKINS
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Including Drugs in Bundled Payments And Catastrophic Spending in Part D

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Protecting Health, Saving Lives—*Millions at a Time*

The Faculty at Hopkins Are Studying Many Topics Involving Drug Pricing and Policy

- Consolidation in generic industry
- Specialty drug pricing and access to care
- Physician drug dispensing
- Medicare formulary
- R&D cost
- FDA backlog
- Limited distribution chains
- **Bundling**
- Determining a fair price
- Orphan drugs
- Coupons
- Pay for delay
- Limits on out of pocket costs
- Importation
- Proposition 61 in California
- **Medicare cost sharing in catastrophic Part D**



One Type Of Value Based Purchasing: Bundled Payments

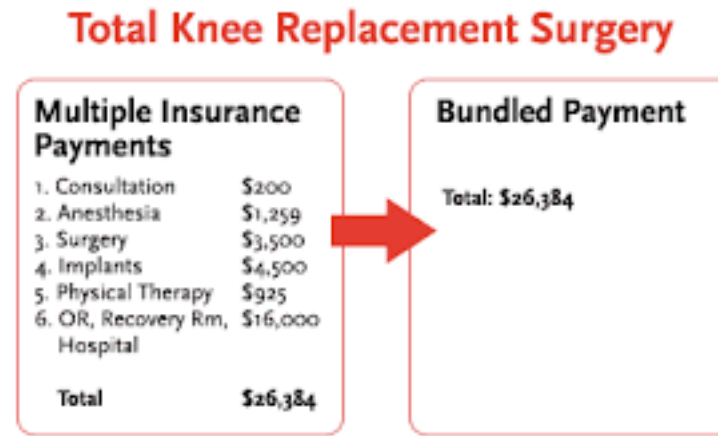
- Bundled payments combine payments for an episode of care into a single payment
 - DRGs were the first bundled payments
 - Public and private insurers are combining hospital, physician and post acute services into one bundled payment
- They create financial incentives for the entity receiving the bundled payment to keep spending for the episode of care below a predetermined amount by using the correct mix of services.
- Drugs are an important part of a treatment plan

And yet drugs are still paid fee-for-service



Knee and Hip Replacements

- Current demonstrations excludes Part D drugs



- There is clinical evidence demonstrating a tradeoff between spending on drugs and medical services for knee and hip replacements



Starting with Baby Steps

- Lets start with conditions where drugs are a small portion of spending like hips and knees and learn from the experience



- Once we can include Part D drugs in procedures with small amounts of drug spending we can expand to other areas with more spending such as chronic conditions



Why Include Part D Drugs in the Bundle?

- It allows the clinician to consider all the factors that influence the best treatment options for that specific patient
- Physicians can do this easier than PDPs or PBMs because the physician knows the patient better



ESRD Bundled Payment

- The one Medicare bundled payment program that already includes drugs including Part D drugs in certain cases
- Congress mandated that drugs be included in ESRD payments beginning in 2011
- OIG report - “By implementing the bundled rate, CMS sought to eliminate incentives to overuse separately billable drugs and to promote equitable payment and access to services in ESRD facilities that treat more costly patients”
- Much has been learned from this experience



Many there are technical challenges to overcome before drugs can be included

- **But**

- Using the principles of bundled payments for hospital, physician and post acute care
- Incorporating what we have learned from ESRD bundled payments that include drugs

We can incorporate drugs in bundled payments



Catastrophic Spending in Part D

- Increasing 3 times faster than overall drug spending in Part D
- Current cost sharing in catastrophic Part D
 - 5% - Beneficiary
 - 15% - Pharmaceutical drug plan
 - 80% - Medicare program

But the Medicare program has no ability to negotiate prices in spite of paying 80% of the price

For very expensive drugs the Medicare beneficiary is spending almost half of their social security payment on the specialty drug



MedPAC recommendation

- Shift the mix of cost sharing to:
- 20% - Medicare
- 80% - Pharmaceutical Drug Plan
- Increase subsidies to make the drug plan no worse off
- Eliminate cost sharing for beneficiaries
- Concern – there will be much greater incentives to discriminate against people with multiple chronic conditions or have conditions like hepatitis C where an expensive drug is available if the health plan pays 80% of the cost



Our Suggestion

- Allow Medicare to negotiate prices when the drug price costs more than \$7500 since this immediately puts the beneficiary into the catastrophic spending category and requires Medicare to pay 80% of the cost
- Means test the catastrophic benefit like Part D premiums to protect the low income Medicare beneficiary
- Drug companies will want their expensive drug to be covered by Medicare since Medicare coverage will help set the standard for the private insurers and the rest of the world.
- Medicare can use the value of the drug to set the price



Additional Slides That Explain
Bundling in More Detail
For All the Over Achievers



Overachiever



Hopkins Team Looking at Drug Pricing

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- Funding - Commonwealth Fund and Arnold Foundation



Bundling Is Expanding

- One of the important components of value based purchasing is bundled payments
 - 1983 - Medicare Prospective Payment
 - 1999 - Heart Bypass Demonstration combined MD and hospitals
 - Bundled Payments for Care Improvement includes post acute care
 - Comprehensive Care for Joint Replacement includes hospice
 - 30 day readmissions

NONE OF THEM INCLUDE PART D DRUGS

- some include Part B drugs



Problems Associated with Paying Separately for Drugs

- Still fee-for-service - Not value based purchasing
- Less care coordination if outside episode of care
- Does not permit clinical tradeoffs that would encourage cost effectiveness
- Less incentive to promote drug adherence
- Providers do not have incentive to negotiate lower drug prices
- Overall - Less technical and allocative efficiency



Congressional Budget Office

- Initially no substitution - no tradeoff between drug use and medical spending
- Recently reviewed the clinical and economics literature
- There is a tradeoff between drug spending and medical spending
- Under certain circumstances, CBO has suggested that they may assume that a 1% increase in drug spending is associated with a 0.2% reduction in medical spending.



Private Insurers Have Experimented with Including Drugs in the Episode of Care

- All small demonstrations - no rigorous evaluations
 - Prometheus
 - Arkansas health care payment improvement Initiative
 - United HealthCare head and neck cancer initiative
- United HealthCare tried an oncological demonstration that included drugs but paid for them separately
 - Drug spending increased 179% while medical spending declined



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Payment Method for ESRD

- Similar to other prospective payment systems
- Formula
 - Adjusters for case mix, co-morbidity, and low volume payment
 - Wage index and wage index floor
 - Outlier payments
 - Rural urban differentials
 - Budget neutrality factors
 - Allowances for home dialysis
 - Other adjustments



Additional Challenges When Drugs Included

- Several new challenges were encountered when drugs were added to the episode of care:
 - Which drugs to include in the bundle?
 - How to determine the payment rate for drugs?
 - How to adjust for changes in drug use?
 - How to monitor the quality and appropriateness of drugs used?



Which Drugs to Include in the Bundle?

- Most ESRD patients have co-morbidities
- They may be taking many different drugs – which ones to include in the bundle?
- Medicare analyzed drug use for ESRD beneficiaries
- Drugs were placed each into a “functional category” based on its mode of action
 - Anemia drugs is an example of “functional category”
 - Medicare could subsequently include new drugs or therapies in the bundle if those drugs have similar modes of action



Created Three Functional Categories

1. Drugs always used for ESRD treatment
2. Drugs never used for ESRD treatment
3. Drugs that may be used for ESRD treatment, but are also used to treat other conditions
4. Medicare included drugs in bundle
 1. Parts B and D if they were always used for ESRD treatment
 2. Only Part B drugs if sometimes used.



Setting the Payment Rate

- Challenge – Claims data is several years old
 - Data lags are common in prospective payment systems
 - Drug use might change more rapidly than other medical services
- Medicare used 2007 practice to set 2011 rates
 - Drug use changed substantially in 2007-11 time period before the bundled payment began
 - Drug use also changed during bundled payment period – EPO use declined by approx. 50%
 - Many of the changes involved EPO use which went off patent at this time
- Congress and CMS have subsequently reduced rates to reflect changes in drug use



Quality

- Concern is over stinting
- Revised quality metrics
 - Instituted a single comprehensive Dialysis Adequacy clinical measure
 - In-Center Hemodialysis Consumer Assessment of Healthcare Providers (ICH CAHPS) Attestation.



Industry Responses to Bundled Payments

- Lowered EPO use by approximately 50%
- Companies that offered ESRD services became more profitable and expanded
- No evidence of less pharmaceutical investment in ESRD



Quality Impact

- Limited data
- Slight increase in patients with anemia
- No statistically significant increase in hospitalization or death rates



Moving Forward: How Can We Incorporate Part D Drugs Into Bundled Payments?



Six Challenges To Overcome If Drugs Are To Be Included in Bundled Payments

Medicare

1. Because Part D drugs are “carved out” and paid separately from other medical services, it administratively difficult to create the bundles. (Easier for Part B)
2. It is difficult to determine which specific drugs to include in the bundle
3. It is difficult to assess savings
4. There could be free riders if bundled payments include coverage for people that have not purchased Part D drug coverage
5. Drug prices and drug treatments can change rapidly
6. It is necessary to monitor quality and assure that stinting is not occurring.

Fortunately, there are possible resolutions to each concern.



Practice Changes

- Drug use will change or prices change after the bundled rate has been set
- How do you adjust the bundled payment for changes in practice?
- Drugs are part of the DRG payment and hospitals have adapted
 - Outlier payments
 - Special adjustments for new drugs and devices
- Possible solution - Similar approach could be used for drugs



Carve Out

- Unlike Part B where the drugs are paid directly by Medicare in Part D the PDPs provide drug coverage
- PDPs submit bids to Medicare to provide drug benefits
- How do you know when the PDP submits a bid that the bid excludes the cost of the drugs in the bundle?
- Possible solutions
 - Option 1 – Eliminate PDPs
 - Option 2 – Determine the value of the cost of the drugs in the bundle and reduce the bid of the PDP accordingly



Which Drugs to Include in Bundle

- Similar to problem in creating all bundles
 - What hospital, physician, and post acute care services to include in the bundle?
- ESRD program created “functional categories” of drugs
 - Drugs that perform similar functions
- Possible solution - Compare drug use before, during, and after the episode of care using claims data
 - Pay only for the services directly related to the episode
 - Follow ESRD approach of creating functional categories and pay for Part D drugs when the the drug is always used in treatment
 - Compare to practice guidelines



Assessing Savings

- The value proposition for creating episodes of care can be expanded to include drugs
- Problem is that PDPs make bids and how do you know if the bids have been lowered to reflect the cost of the drugs in the bundle
- Possible solutions
 - Competitive market - Assume the PDPs lower the bids to reflect the cost of the drugs eliminated from the package
 - Regulatory approach - Medicare reduces the bids by the estimated cost of the drugs in the bundle
 - Price transparency approach - Have PDPs estimate the cost of the “carve out” and reduce the bid by that amount



Free Riders

- Only 69% of Medicare beneficiaries have Part D coverage
- Including drugs in the bundle gives them a benefit that they do not pay for
- Possible solutions
 - Bill the beneficiary, insurer, or PDP
 - Accept the loss



Quality

- **Concern over stinting**
 - Waiting for episode of care to pass before prescribing drugs
 - Providing less valuable drugs
- **Same solution as other bundling demonstrations**
 - No adverse effects detected in most PPS programs
 - ESRD has developed quality metrics to monitor



Providers Assume Risk

- Entities accepting the bundled payment may not want to accept the risk
 - New drugs on the market
 - Patient not responding to conventional therapy
- Hospitals have been accepting the risk on drugs since 1985
- Possible solution - Providers are in good position to negotiate prices
- They could use PBMs to negotiate rates



Patients Not Responding to Conventional Drug Treatment

- The bundled payment assumes that the average mix of drugs is used, however, some patients may need a different (more expensive) drug
- Possible solution
 - Outlier payments
 - High cost add-ons



Direct to Consumer Advertising for Drugs

- Patients may have seen an advertisement for a specific drug
- Solution - Physicians are the the most knowledgeable about the need for specific drugs for that patient and now will have a financial incentive to explain in more detail



Going Beyond Part D

- Part D may be the most challenging program to bundled payments because of the fact that drugs are paid separately by the PDPs
- Part B simpler since Medicare pays for drugs directly and not through PDPs
- Part C simpler because Medicare Advantage plans do not have to “carve out” drugs
- Private insurers are similar to Part C



Conclusion

- Drugs should be part of bundled payments
- There are many technical reasons why they have not been included to date
- There are possible solutions to each concern
- If adopted it would fundamentally alter the incentives in the pharmaceutical industry

