

## Defining the treatment

### Challenges to identifying the treatment in observational CER

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### Outline

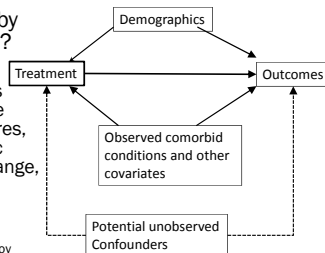
1. Challenges in defining what the treatment is in observational CER
2. Where to find data on treatments in observational data (specifically, Medicare data)
3. Challenges in identifying the treatment
4. Recommendations

### Defining the treatment in CER

- What do we mean by “treatment” in CER?

“Defined interventions compared may include medications, procedures, ...devices..., diagnostic testing, behavioral change, and delivery system strategies.”

Source:  
<http://effectivehealthcare.ahrq.gov>



## Challenges in defining treatment

Variations in treatment that can confound observational CER

1. Treatment history
2. Treatment dose
3. Context or environment in which treatment was delivered
4. Skill of provider of treatment
5. Complex treatments
6. Problems with a “no-treatment” comparison group
7. Timing of treatment
8. Repeated treatments (treatment adherence)

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## 1. Treatment History

Variations in treatment that can confound observational CER

- You identify your study cohort beginning in 2008 but some patients received treatment in 2007
- Problems:
  - Are previously treated no longer eligible for treatment?
  - Do previously treated have different unobserved behaviors because of previous experience with treatment?
  - Example: CABG reduces smoking
  - If so, then some of the “untreated” patients are poor counterfactuals for treated patients.
  - What else?

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## 2. Treatment dose

- Does treatment differ in dose or intensity?
  - Literal dose as in medication, or
- Examples:
  - Dose of an ACEI inhibitor for hypertension versus dose of a diuretic
  - Counseling for smoking cessation
  - What else?
- Problem
  - If Treatment A looks better than treatment B, how do you know it wasn't due to the fact that treatment B was under-dosed?

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### 3. Context or environment

#### Variations in treatment that can confound observational CER

- Examples
  - Treatment A is given mostly in lousy hospitals and treatment B is given mostly in good hospitals.
  - Financially sound clinics adopt electronic health records.
- Problem:
  - Difficult to tease-out effect of treatment from effect of environment
  - RCTs do this by stratified randomization by site (i.e., equal number of A's and B's at each site)
- Potential solutions
  - Difference in difference estimation or fixed-effects estimators (more on Wed)

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### 4. Skill of provider

#### Variations in treatment that can confound observational CER

- Skill of provider may affect estimates of treatment efficacy
- Examples:
  - Femoral artery versus trans-radial artery access for PCI
  - Robot assisted prostatectomy
- Problem
  - What is the counterfactual?
    - What would have happened to patient if all cardiologists had switched to trans-radial?
    - What would have happened to patient if s/he had switched to an experienced trans-radialist?
- Potential solution
  - Stratify by volume or experience

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### 5. Complex treatments

- Treatments can have multiple components
- Examples:
  - Nurse-led disease management
  - Patient Centered Medical Home
- Problem
  - How do you know what part of treatment worked?
  - How do you know whether people received the same treatment?
- Potential solution
  - Conceptual model.

#### Nurse-led disease management protocol for heart failure

- Counsel patient on self-monitoring of weight edema
- Counsel patient on self-management behaviors
  - Reduce dietary salt
  - Moderate exercise
  - Smoking/alcohol reduction
- Medication adjustment
  - Recommend ACEI/ARB at proven effective doses
- Coordinate care
  - Referral to social services for insurance, mental health

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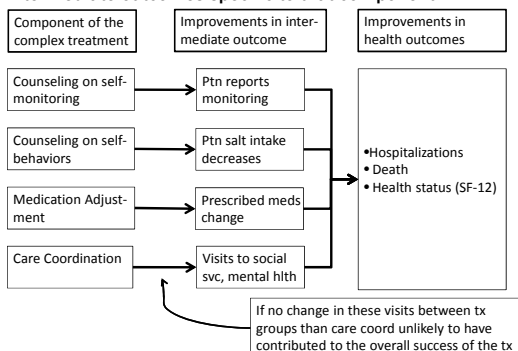
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**Measure the relationships between each component and the intermediate outcomes specific to that component**



## 6. Untreated comparison group

Variations in treatment that can confound observational CER

- Compare treated to untreated patients
- Examples:
  - Bariatric surgery versus usual care (Matt)
  - Initiation of dialysis in the oldest old.
  - Prostatectomy vs. watchful waiting
- Problems
  - How do you know the untreated folks needed the treatment?
  - When do you start the clock for the untreated patients?
- Potential solution
  - Propensity score matching (Matt)

## 7. Timing of treatment

Variations in treatment that can confound observational CER

- Compare patients who started treatment early (aggressive) versus late (cautious)
- Examples:
  - Initiation of dialysis before the onset of symptoms?
  - Start steroids in anticipation of lupus flair?
- Problems
  - Lead time bias: If you start the clock when treatment starts, early-start patients will appear to live longer even if treatment is completely ineffective.
- Potential solution
  - Propensity score matching?
  - Statistics appropriate for dynamic regimes (e.g., Cain LE, et al)

Cain LE, et al. International Journal Biostatistics, (2010) 6(2):1-24

## 8. Repeat treatment

Variations in treatment that can confound observational CER

- Patient receives the same treatment repeatedly over time, but skips or discontinues treatment
- Examples:
  - Chronic disease medications
  - Veterans who switch back and forth between VA and Medicare.
  - What is the effect of VA care on costs and outcomes?
- Problems
  - Time-varying confounding.
- Potential solution (not covered this week)
  - Marginal structural models
  - G-estimation
  - Instrumental variables

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## Outline

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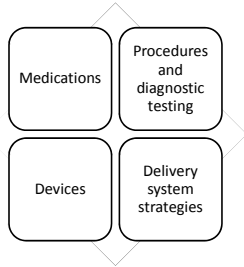
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## Types of treatments available in Medicare data?



## Overview of where to find treatments in Medicare data

Data file	Medications	Procedures	Devices
Carrier	HCPCS codes	HCPCS codes	--
MedPAR or Inpatient	Revenue Center codes	DRG codes ICD Proc codes	DRG codes ICD Proc codes
Part D	NDC-11 codes	--	--
Outpatient hospital		APC codes HCPCS codes	APC codes HCPCS codes
DME	--	--	HCPCS codes
Home health file	--	Revenue Center codes HCPCS	--

NDC-11: National Drug Classification - 11 characters)  
 HCPCS: Healthcare Common Procedure Coding System  
 APC: Ambulatory Payment Classification  
 ICD Proc: International Classification of Disease- Clinical Modification  
 9<sup>th</sup> edition Procedure codes

## Medications- Part B

Medicare has paid for specific drugs under Part B

- Generally, drugs that are administered in physician or other offices, used as part of infusion devices
- Some oral drugs used following organ transplant.
- Most (40% in 2001) are oncology drugs

Identified by HCPCS codes starting with "J" on DME claims

Drug name	% of Part B drug costs in 2001
Erythropoietin (anemia)	12.1%
Lupron (prostate Cancer)	10.4%
Ipratropium bromide (Asthma)	7.3%
Zolodex (prostate cancer)	6.8%
Albuterol (Asthma)	5.5%

Source: MedPAC Report to the Congress  
 Variations and Innovations in Medicare, June 2003

Example: Schrag, D., L. D. Cramer, et al. (2001). "Age and Adjuvant Chemotherapy Use After Surgery for Stage III Colon Cancer." *J. Natl. Cancer Inst.* 93(11): 850-857.

### Medicare Part D data

- Part D files
  - Enrollment data (Beneficiary Summary File)
  - Prescription Drug Event (PDE) data
  - Characteristics files
- Available to researchers
  - Via ResDAC
  - From Chronic Conditions Warehouse (CCW) of **Buccaneer** Computer Systems and Software, Inc.

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### Important elements in the Part D PDE file

#### Beneficiary information

- Beneficiary ID
- Age, demographics (from enrollment file)

#### Drug information

- NDC 11 code to identify medication (called the "product service ID" in the Part D event file)
- Days Supplied

#### Prescriber Information

- Unique provider, eventually linked to a Prescriber Characteristic File
- Maybe Useful for Instrumental Variable (later)

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### National Drug Classification (NDC) codes

Three segments to each NDC code

- Labeler code - 4 or 5 digits
- Product code- 3 or 4 digits
- Packaging code- 2 or 1 digit

Always 10 digits of information, but not always the same format

- Eg., the segments lengths could be (4-4-2) (5-3-2) or (5-4-1)

Medicare/HIPAA solution: NDC 11

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**Example: Ramipril (Altace)**

	Labeler	Product	Packaging	NDC	NDC-11
1.25 mg capsules in a 100 capsule bottle	61570	110	01	6157011001	61570011001
2.5 mg capsules in a 100 capsule bottle	61570	111	01	6157011101	61570011101
2.5 mg capsules in a 500 capsule bottle	61570	111	05	6157011105	61570011105

Different product codes for 1.25mg vs 2.5mg

Different packaging code for 100 versus 500 capsules

NDC-11 inserts a leading "0" so the product code is 4 digits and the format is always 5-4-2

**Medications****Use Medi-Span/First Data**

- In sum: NDC codes are a tragedy to use
  - Organized by labeler (i.e., the firm marketing the product) not by type of drug.
  - May need to type in hundreds of NDC codes to find all doses, delivery modes (i.e., capsule, tablet, suppository, etc.), container sizes, etc.
- Potential Solution: Buy a subscription to Medi-Span or First Data Bank drug information databases
  - [www.medispan.com](http://www.medispan.com)
  - [www.firstdatabank.com](http://www.firstdatabank.com)

**Medications****Medispan's Therapeutic Classification System**

- Each drug is given a code (a GPI), that consists of a hierarchy of information.
  - Drug group (e.g., Diuretics)
  - Drug class (e.g., loop)
  - Drug name (e.g., "Furosemide")
  - Dosage form (e.g., tablet)
  - Dosage strength (20 mg)
- GPIs are linked to NDC codes so you can find you drugs using GPIs and merge with Part D data to identify medication users

37-00-00-00-00	*DIURETICS*
37-10-00-00-00	*Carbonic Anhydrase Inhibitors**
37-20-00-00-00	*Loop Diuretics**
37-25-00-00-00	*Mercurial Diuretics**
37-30-00-00-00	*Osmotic Diuretics**
37-40-00-00-00	*Potassium-Sparing Diuretics**
37-45-00-00-00	*Thiazides**
37-50-00-00-00	*Diuretics - Miscellaneous***
37-55-00-00-00	*Combination Diuretics**



## Medications

Identifying medications using Medispan databases

GPI code	
37-00-00-00-00	Diuretics
37-20-00-00-00	Loop diuretics
37-20-00-30-00-00-00	Furosemide
37-20-00-30-00-03-05	Furosemide Tab 20
37-20-00-30-00-03-10	Furosemide Tab 40
37-20-00-30-00-20-05	Furosemide Inj 10 MG/ML

## Medications

Identifying medications using Medispan databases

- Eg., if you want to find all the NDC codes for oral loop diuretics, just look for Medispan GPI codes that start with 3720
- Keep only those with GPIs that indicate a dosage form of tablet or capsule
- Get the NDC codes associated with these GPIs
- Merge these NDC codes with Part D PDE file to identify your treatment group

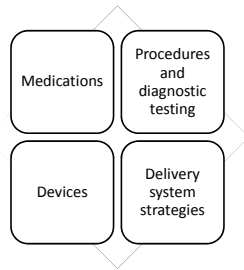
GPI code	Medication
37-00-00-00-00	Diuretics
37-20-00-00-00	Loop diuretics
37-20-00-30-00-00-00	Furosemide
37-20-00-30-00-03-05	Furosemide Tab 20
37-20-00-30-00-03-10	Furosemide Tab 40
37-20-00-30-00-20-05	Furosemide Inj 10 MG/ML

## Medications

Recommendations: Medispan/First Data Bank

- Medispan and First Data Banks subscriptions cost about \$5k per year.
- This might be a time saver if you are using CMS Part D data to investigate a large number of different drug categories.

### Types of treatments available in Medicare data?




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### Outpatient procedures and diagnostic tests

- Defined by HCPCS in Carrier file (see earlier slides on HCPCS codes)
- Billed by physicians or other “non-institutional” providers therefore appear on non-institutional (i.e., Carrier) claims
- However, the physician component of in-patient procedures also appear on Carrier claims
  - Eg., an in-patient surgery generates both a Carrier claim from the surgeon and a MedPAR or Inpatient record. Both the HCPCS code and the place of service indicator on Carrier claims can be used to identify outpatient settings.

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### Level 1 HCPCS or CPT Codes Examples

00100 - 01999 Anesthesia  
 10040 - 69990 Surgery  
 70010 - 79999 Radiology  
 80049 - 89399 Pathology and Laboratory  
 90281 - 99199 Medicine\*  
 99201 - 99499 Evaluation and Management

\* Injection of medicine, such as vaccination, immune globulin, antitoxins, etc

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### Medicare Leading Part B Procedure Codes Ranked by Allowed Charges (2008)

HCPC Code	Description	Allowed Charges (\$)	% of total allowed charges
99214	Office/outpatient visit, est	6,031,239,662	5.3
99213	Office/outpatient visit, est	5,910,130,389	5.2
99232	Subsequent hospital care	3,241,808,414	2.8
66984	Cataract surg w/fof, 1 stage	2,072,478,375	1.8
99233	Subsequent hospital care	1,885,333,732	1.7
99285	Emergency dept visit	1,311,734,269	1.2
88305	Tissue exam by pathologist	1,174,412,562	1.0
78465	Heart image (3d), multiple	1,097,124,917	1.0
99244	Office consultation	1,082,579,794	1.0
99215	Office/outpatient visit,est	1,017,088,079	0.9

Source: 2009 Data Compendium, CMS

### Examples: Place of service codes from Carrier file

- 04 = Homeless Shelter
- 11 = **Office**
- 12 = Home
- 13 = Assisted Living Facility
- 20 = Urgent Care Facility
- 21 = Inpatient hospital
- 22 = Outpatient hospital
- 23 = Emergency room - hospital
- 24 = Ambulatory surgical center
- 32 = Nursing facility

Note: the place of service is specific to the HCPCS that appears on the same line-item

### Procedures performed in hospital

Procedures performed in hospital also generate a bill from the hospital—that is an institutional Inpatient claim or MedPAR stay record

Identified by ICD-9 Procedure codes

- Up to 6 per claim. First listed is the “primary” procedure
- Four digits of the form XX.XX with leading zero

## Examples ICD procedure codes

(35) Operations on valves and sept of the heart  
 (35.0) Closed heart valvotomy  
 (35.1) Open heart valvuloplasty without replacement  
 (35.2) Replacement of heart valve  
 (35.3) Operations on structures adjacent to heart valve  
 (35.4) Production of septal defect in heart  
 (35.5) Repair of atrial and ventricular septa with prosthesis  
 (35.6) Repair of atrial and ventricular septa with tissue graft  
 (35.7) Other and unspecified repair of atrial and ventricular septa  
 (35.8) Total repair of certain congenital cardiac anomalies  
 (35.9) Other operations on valves and septa of heart  
 (35.94) Creation of conduit between atrium and pulmonary artery

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## Revenue Center Codes

- Institutional hospital (i.e., MedPAR, Inpatient file) claims also have revenue center codes
- A little tricky to use
  - Up to 450 codes per hospital stay
  - Associated with each code is a number of unit and total charge
  - E.g. The cost center (e.g. ICU), the number of units (i.e., 2 days), and total charges (\$)
- Provides additional information on what was done to a patient, but are not very specific.
- E.g., In the MedPAR file, the revenue center group records charges for:
  - pharmacy (3 types--no information on what specific drugs given)
  - ICU (9 specific types),
  - coronary care unit (6 specific types),
  - radiology/oncology, diagnostic radiology, therapeutic radiology, CT scan, other radiological imaging, radiology nuclear medicine.
  - Transplant
- Important: the Inpatient file (but not the MedPAR) can contain HCPCS codes, but rarely populated

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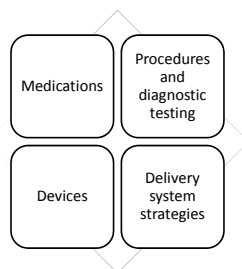
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## Types of treatments available in Medicare data?




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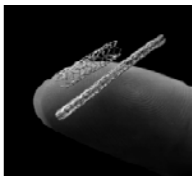
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### Medical devices delivered as part of an in-patient procedure

- The charges for some devices are included in the hospital's payment for the procedure, so look for them using DRG or ICD-9 procedure codes on MedPAR or Inpatient file
- E.g., Identifying coronary stents
  - DRG: 246 Percutaneous cardiovascular proc w drug-eluting stent w MCC
  - ICD 36.07 Insertion of drug-eluting coronary artery stent(s)




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### Medical devices in outpatient settings

- Surgical implantation of devices conducted in an outpatient hospital setting, look at the Hospital Outpatient file
- Hospital Outpatient SAF contains facility charges for outpatient services
- The physician charges for an encounter with a Medicare beneficiary appear in Carrier file
  - The hospital clinic charges for that encounter appear in the Outpatient SAF
- Since August 1, 2000, hospital reimbursement has been based on prospective Ambulatory Payment Classifications (APCs).
- Costs of devices are built in to some APCs
- For example, placement of a drug eluting stents in outpatient generates:
- Hospital outpatient SAF claims.
    - APC 0656: Transcatheter Placement of Drug-Eluting Coronary Stents
    - HCPC G0290 Transcatheter placement of a drug eluting intracoronary stent(s).
  - Carrier file claims
    - HCPCS 92980 Transcatheter placement of an intracoronary stent(s)

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### Durable Medical Equipment (DME)

- Durable equipment identified in the DME file
- DME file contains diagnoses, HCPCS codes, charges and beneficiary information
- Equipment is identified by level 2 HCPCS codes
  - E.g. **HCPCS K0800**: Power operated vehicle, group 1 standard, patient weight capacity up to and including 300 pounds




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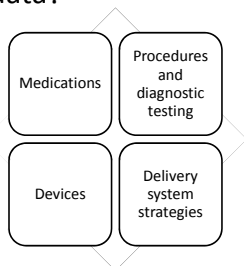
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### Types of treatments available in Medicare data?




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### Opportunities for CER on delivery system strategies using Medicare data

#### Fee-for-service versus managed care

- Limited because encounter level data are not available for Medicare Advantage enrollees
- Death date and month of enrollment and disenrollment are available

E.g., Atherly A, Hebert PL, Maciejewski ML. An Analysis of Disenrollment From Medicare Managed Care Plans by Medicare Beneficiaries With Diabetes. *Medical Care* 2005;43(5):500-506.

#### Volume-Outcome analyses

- Compare outcomes for high volume versus low volume providers of a procedure

E.g., Halm EA, Lee C, Chassin MR. Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature. *Annals of Internal Medicine* 2002;137(6):511-520.

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### Opportunities for CER on delivery system strategies continued

#### Comparisons of outcomes by hospital characteristics

- Link hospital provider ID on Inpatient or MedPAR records to the Hospital Cost Report Information System (HCRIS)
- HCRIS has information for each hospital on
  - Bed size
  - Graduate medical education
  - Disproportionate share payments
  - Profit status (13 categories of nonprofit, proprietary, religious, government, etc...)

– Schrag D, Bach PB, Dahlman C, Warren JL. Identifying and Measuring Hospital Characteristics Using the SEER-Medicare Data and Other Claims-Based Sources. *Medical Care* 2002;40(8):IV-96-IV-103.

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## CER on delivery system strategies

continued

- Care provided by specialist versus generalist
  - Carrier claims contain a field for the specialty of the provider of the associated HCPCS procedure
  - UPIN/NPI on Inpatient file can be used to identify specialty of admitting physician
  - Eg. C D Frances, et al Does physician specialty affect the survival of elderly patients with myocardial infarction? *Health Serv Res.* 2000 December; 35(5 Pt 2): 1093–1116.
- Special-topics databases
  - Dialysis Facility Compare
    - Profit status and quality information for dialysis facilities
  - OSCAR: Data from surveys of long-term care facilities

## Outline

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## How accurate are the codes?

Challenges in identifying the treatment

- Generally, pretty good
  - Final action claims
  - Things that result in payment (like procedures) are audited and therefore more accurate
  - No comprehensive studies since early 1990s, but recent studies suggest codes are reasonably accurate

Warren, J.L., et al., *Utility of the SEER-Medicare Data to Identify Chemotherapy Use.* *Medical Care*, 2002. **40**(8): p. IV-55-IV-61.  
 Du, X.L.M.D.P., et al., *External Validation of Medicare Claims for Breast Cancer Chemotherapy Compared With Medical Chart Reviews.* [Article]. *Medical Care* February, 2006. **44**(2): p. 124-131.  
 Shahian, D.M., et al., *Comparison of Clinical and Administrative Data Sources for Hospital Coronary Artery Bypass Graft Surgery Report Cards.* *Circulation*, 2007. **115**(12): p. 1518-1527.

## Codes are generally pretty good, however

### Challenges to identifying the treatment, continued

- Fraud (especially durable medical equipment) and DRG Creep exists
  - Variation in coding by Carrier and provider
- Some treatments that seem relatively easy to find are in fact quite complex.

For example, Murphy et al, (2004) required multiple combinations of diagnoses and procedure codes to identify patients who got a renal artery angiogram or stent during a coronary artery procedure (i.e., a "drive-by" renal angiography)

Murphy TP, Soares G, Kim M. Increase in Utilization of Percutaneous Renal Artery Interventions by Medicare Beneficiaries, 1996-2000. *Am. J. Roentgenol.* 2004;183(3):561-568.

## Challenges to identifying the treatment using Medicare claims

- How specific are the codes?
- How complete are they?

For new technologies, coverage decisions vary by Carrier\*

Coding rules are complex, and there are many ways to code for some procedures (see right panel)

### \*Options for coding drug-eluting stents on outpatient claims

In Transmittal A03-051, CR 2771, CMS implemented payment under APC 0656, Transcatheter Placement of Drug-Eluting Coronary Stents, for two HCPCS codes that describe drug-eluting stents and their placement. CMS did not establish new HCPCS codes for the drug-eluting coronary stents; however, CMS indicated that hospitals could include the charge for the drug-eluting stent in the charge for G0290 and G0291.

CMS also indicated that, alternatively, hospitals could bill separately for the stent using an appropriate Revenue Code, making certain that the charge for the G0290 and G0291 did not include the charge for the stent. Payment for placement of the stents, and the stents themselves, are made under APC 0656.

As of January 1, 2004, CMS reinstituted C codes for devices for cost reporting and cost tracking purposes. Therefore, hospitals have a third option to report charges for drug-eluting stents. That is, hospitals may report HCPCS code C1874, "Stent, coated/coated, with delivery system" with an appropriate Revenue Code to report their charge for drug-eluting coronary stents. When using HCPCS code C1874 to bill separately for drug-eluting stents, hospitals should make certain that the charge for G0290 and G0291 for placement of the stents does not include the stent charge. Payment for C1874 is packaged into the payment for APC 656, but reporting a separate charge for the stent(s) provides important data that affects future updates of the OPPS.

\*Footnote 58, et al Resolving The Tug-Of-War Between Medicare's National And Local Coverage. *Health Aff* 2004;23(4):108-123.

## Outline

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## Recommendations

Check the literature.

- Some algorithms have been developed to identify specific types of treatments
- E.g., Randolph WM, et. al Using Medicare Data to Estimate the Prevalence of Breast Cancer Screening in Older Women: Comparison of Different Methods to Identify Screening Mammograms. *Health Services Research* 2002;37(6):1643 - 1657

Check with MAC (formerly Carrier) for whether new or emerging technologies are covered

Cast a wide net...

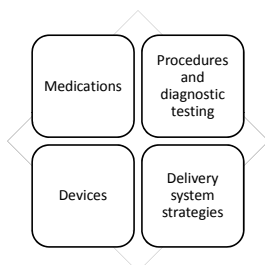
- To account for the wide variety of coding options search for all the relevant codes in each SAF

...then make sensible restrictions. E.g.,

- Consider requiring an in-hospital surgical procedure (MedPAR or Inpatient) also has a physician (Carrier) claim from a surgeon on the same date.
- Eliminate claims conducted in unreasonable places of service, unreasonable lengths of stay, or other unreasonable data

## Conclusion

- A number of important challenges in defining the treatment in observational CER studies
- Medications, procedures, devices, and delivery system strategies can be identified and used as treatments in CER using administrative claims data



## References & Resources

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