

ADVANCING QUALITY OUTCOMES AND
INNOVATIONS:
Preparing pharmacy for the future



Evolving Healthcare Business Model

Re-defining Value and Risk

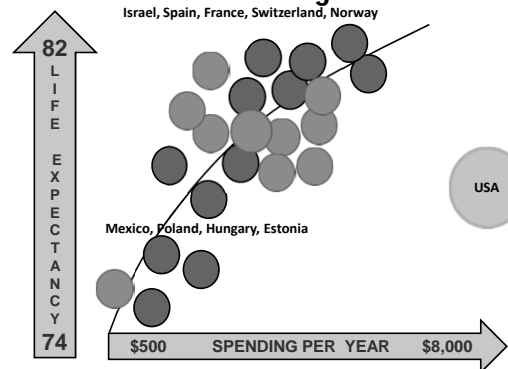
Phil Johnson MS RPh FASHP
Oncology Director, Premier Inc.
Tampa, FL

Objectives

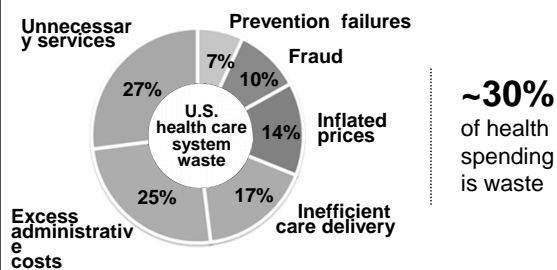
- Describe the business model transition from fee-for-service to capitated bundled payment after the passage of the Affordable Care Act
- Describe the stakeholders in the healthcare business model and analyze how they affect therapy decisions and financial outcomes
- Examine the new metrics that will be essential to define value and success in the emerging healthcare business model

Current Issues Driving Healthcare Change

International Value Argument for Reform



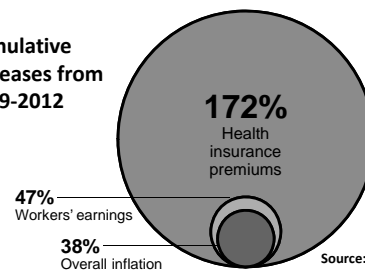
US healthcare system: \$750 Billion waste each year



Source: Institute of Medicine; 2009 data

Unsustainable Trends: Health care premiums are growing at 3x the rate of inflation and wages

Cumulative increases from 1999-2012



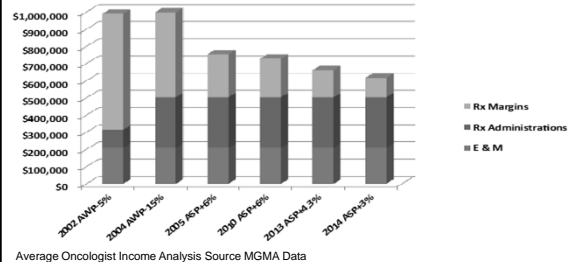
Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2012. Bureau of Labor Statistics, Consumer Price Index and Employment Statistics Survey

Payer Cost Per Average Oncology Patient



Drug Margins No Longer Drive Practice Incomes

- Oncology Drug Margin Compression Continues Post Sequestration



Specialty Drug Growth

Year 2012			
	Sales US\$BN	% Sales Share	% Growth
Total market	325.8	100%	-1.0%
Specialty drugs	89.0	27.3%	8.7%
Oncologic drugs	25.9	7.9%	7.8%
Autoimmune	14.8	4.5%	17.9%
HIV Antivirals	11.7	3.6%	12.1%
Multiple sclerosis	8.9	2.7%	17.8%
Immunostimulants	4.7	1.4%	3.2%
Erythropoietins	4.2	1.3%	-17.8%
All others specialty (<4US\$BN)	18.9	5.8%	6.3%
Non-specialty	236.8	72.7%	-4.2%

Source: IMS Health, National Sales Perspectives, Dec 2012

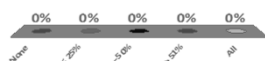
Oncology Projections From 2010 To 2020

- 13.8 to 18.1 million cancer patients
 - 45% increase in new cases annually
 - Cancer becomes the leading cause of death in US
- \$104 billion to \$173 billion annual cost of cancer drugs
 - Associated drug therapy costs rise 27%
 - More than 400 drugs in oncology related pipeline
 - Most new drugs are biologic with genetic target
- 20% to 65% Site of Care from MD Offices to Hospitals
- Therapy choice determined / paid differently
 - From Protocols to Pathways to Genomic / Proteomic Testing
 - From Fee For Service to Episodic Bundles to Population Health
- Many cancers have become a chronic disease
 - 35% increase in number of survivors (18 million by 2022)
 - Estimated cost of survivor year = \$16,000

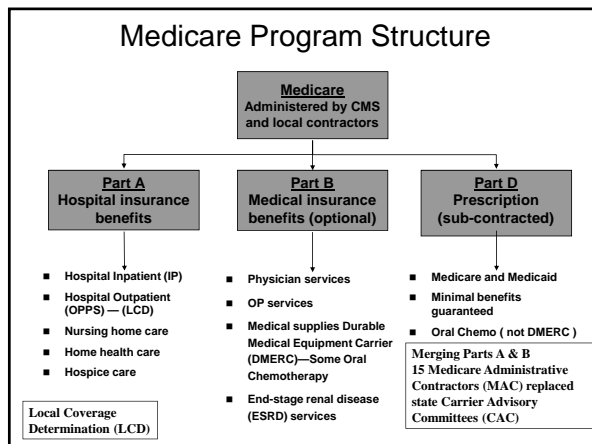
The state of cancer care in America, 2014; ASCO, JOP 3-10-14

What % of office practices are owned by your facility?

- None
- < 25%
- 26 – 50%
- > 51%
- All



Current CMS Structure



Medicare Rules Summary

	2011	2012	2013	2014
Part A OPPS UB92 / CMS 1450	1.06 ASP Pass-through 1.05 ASP Non-pass-through - Package <\$70	1.06 ASP Pass-through 1.04 ASP Non-pass-through - Package <\$75 - ACO incentives	1.04 ASP Pass-through* 1.04 ASP Non-pass-through* Package <\$80 ACO incentives * Effective 7-1-2013	1.06 ASP Pass-through and Non-pass-through 1.043 ASP as of 4-1-2014 5 Package categories related to function vs cost threshold
IP PPS	CS-DRG (Severity Adjusted) Required HOP-QDRP Indicators (2.0%)	CS-DRG (Severity Adjusted) Required HOP-QDRP Indicators (2.0%)	CS-DRG (Severity Adjusted) Required HOP-QDRP indicators (2.0%)	
Part B CMS 1500	1.06 ASP Pass-through 1.05 ASP Non-Pass-through - Package <\$70	1.06 ASP Pass-through 1.04 ASP Non-Pass-through - Package <\$75	1.04 ASP Pass-through* 1.04 ASP Non-Pass-through* Package <\$80 * Effective 7-1-2013	1.06 ASP Pass-through and Non-pass-through 1.043 as of 4-1-2014 5 Package categories related to function vs cost threshold
Part D OP Rx Benefit	- Tiers changed - Gap increased	- Same	- Same, but under discussion with Congress	

Important Government Links

FDA: New and Generic **Drug Approvals** (by month)
<http://www.fda.gov/Drugs/NewsEvents/ucm130961.htm>

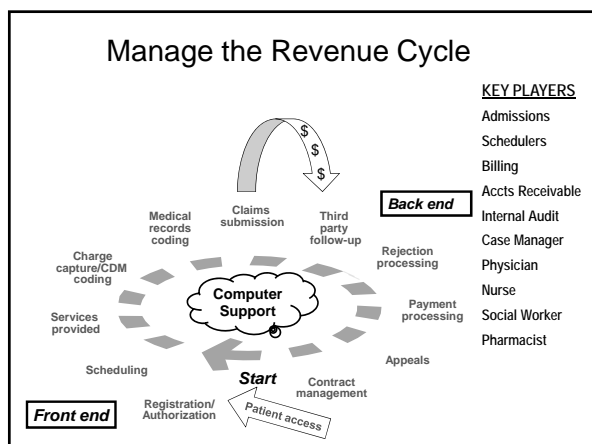
FDA: New **Drug Information** and **Drug Shortage** status
<http://www.fda.gov/Drugs/NewsEvents/ucm130958.htm>

CMS: Medicare Current **Average Sales Price (ASP)**
<https://www.cms.gov/McrPartBDDrugAvgSalesPrice/>

FDA: Current List and Status of all **REMS Drugs**
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientandProviders/ucm111350.htm?source=govdelivery>

CMS Quarterly **ASP and OPPS (Part B) Price Limits**
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDDrugAvgSalesPrice/index.html?redirect=/McrPartBDDrugAvgSalesPrice/>

Current Revenue Cycle



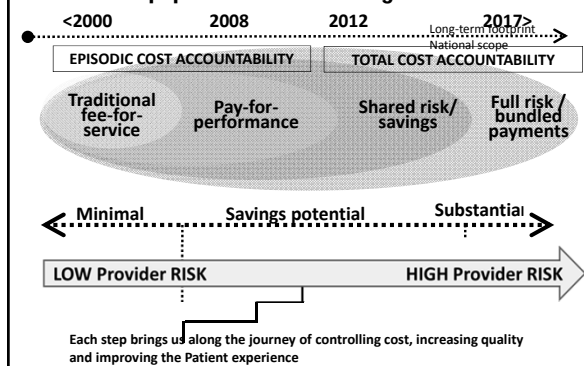
The Emerging World Order

What To Expect – ACA Impact

Paul Keckley, Deloitte Center for Health Solutions

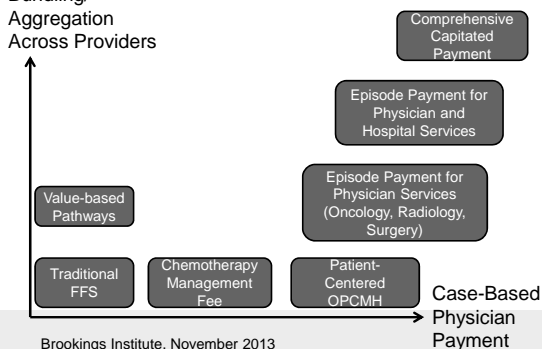
- Medicare will cut reimbursement to hospitals
- Medicaid will expand dramatically
- Employers will be active shoppers
- Manufacturers create new deals with hospitals
 - Value based
 - Shared risk
- Bad debt increases as margins for patient care shrink
 - Radical cost-reduction
 - Risk management
 - “Go big or get out” leading to a few very large groups
- Insurers will play hardball with hospitals
 - Some hospitals will “go at risk”
- Physicians will seek cover
 - New alignment with hospitals or large “group practices”

Continuing movement towards accountability and population health management



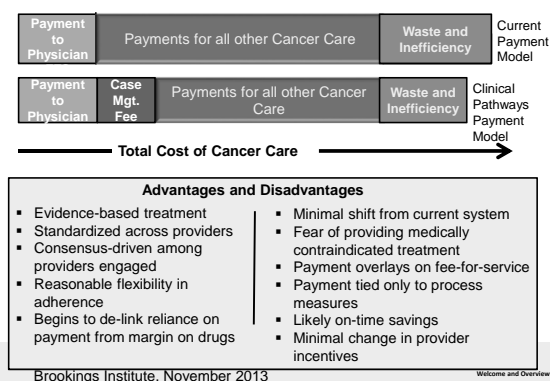
Charting Payment Reform Options

Bundling/
Aggregation
Across Providers



Brookings Institute, November 2013

Summary of Clinical Pathway Payment Model



Brookings Institute, November 2013

Welcome and Overview

Fee For Service vs Episode

- Study:
 - 5 groups treated breast, colon, lung
 - 810 patients
 - Quality and outcomes statistically similar
- Episode payment
 - Predicted cost based on fee structure = \$98,121,388
 - Actual cost = \$64,760,116 actual
 - Predicted cost of oncology drugs = \$7,519,504
 - Actual cost = \$20,979,417
- Overall cost decreased
- Paradoxical increase in oncology drug cost

Newcomer, et. al., “Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model”, JOP, July 8, 2014

Cancer: Unpronounceable Drugs, Incomprehensible Prices

- “Industry says rising drug costs reflect the rising costs of drug development and the business risks they must take when testing new drugs. I think they charge what they think they can get away with, which goes up each year.”
- Zykadia vs Xalkori:
 - Xalkori was first to market, opening this therapeutic category
 - Same FDA approved indications (subtype of lung cancer)
 - Zykadia has a slightly higher toxicity profile
 - Xalkori had twice as many studies and patients
 - FDA indicated Xalkori 1st line; and Zykadia 2nd line therapy
 - Xalkori (Pfizer) partnered with Abbott to develop the required companion diagnostic (Novartis got a “free ride”)
- Zykadia costs \$13,200 / month vs \$11,500 / month

<http://onforb.es/1mJnnTc>

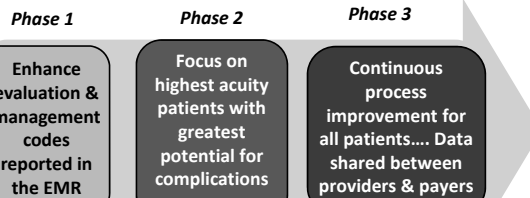
Peter Bach, Director, Center for Health Policy and Outcomes

Xalkori vs Zykadia

	Xalkori	Zykadia
Approval date	26-Aug-11	29-Apr-14
Indication	First line	Second line
Approval required RCT	NO	NO
Number of pivotal trials	2	1
Total sample size	255	163
Proof of concept approval	NO	YES
Time to complete trial	1.5 years	1.5 years
Cost (\$2013, at approval)	\$11,375	\$13,276
Cost (\$2013, current)	\$11,562	\$13,276
Frequency	twice per day	once per day
Companion diagnostic	YES	NO
Outcomes (Xalkori: Study A, Study B; Zykadia: Investigator assessment/WHO assessment)		
ORR	50% (42%, 59%)	54.6% (47, 62)
Duration of response (months)	61% (52%, 70%)	43.6% (36, 52)
Toxicities (grades 3/4, measures reported in both labels only)	9.7 (1.4+, 9.7+)	7.4 (5.4, 10.1)
	11.1 (0.9+, 17.7+)	7.1 (5.6, NE)
Diarrhea	<1%	6%
Nausea	<1%	4%
Vomiting	1%	4%
Abdominal Pain	<1%	2%
Constipation	<1%	0%
Esophageal disorder	1%	1%
Fatigue	2%	3%
Decreased appetite	1%	1%
Rash	0%	0%

<http://onforb.es/1mJmTc>

Commercial Transformation from Fee For Service to Budgeted (Bundled) Care over next 5 years

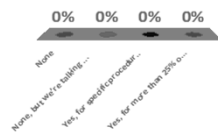


Payers Goals:

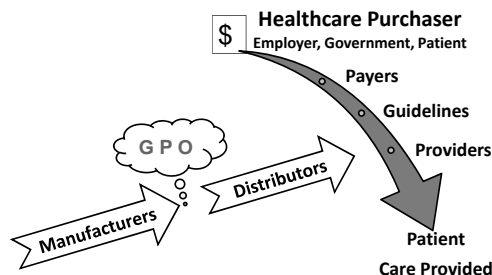
1. Predictable cost by disease stage or molecular / genetic subtype
2. Standardized process and therapy based on data and consensus
3. Connect disease stage with claims data requires staging reform

Do you have bundled payment arrangements in place now with commercial payers?

- a. None
- b. None, but we're talking about it
- c. Yes, for specific procedures such as BMT
- d. Yes, for more than 25% of our patients



Healthcare Stakeholder Money Flow

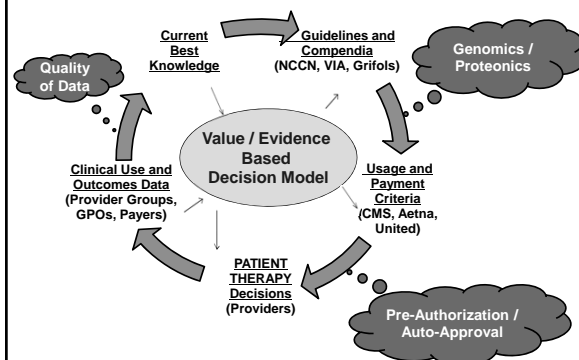


What Drives Therapy Decisions

and

Decision to Pay?

Current Oncology Therapy Decision Cycle



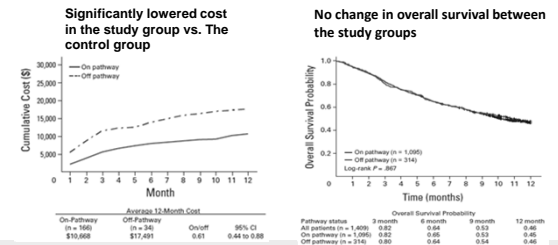
The New Era of Personalized Care Replacing population health whenever possible

- Designed for a specific patient's unique clinical profile
 - Traditional clinical metrics are still important
- Evidence rated Clinical Guidelines / Pathways
- Genomic profile
 - Gene results stored for future reference
 - Soon, 150+ gene panels for < \$1,000
- Therapy and Disease Considerations
 - Co-morbidity guidelines
 - Acuity Adjusted Patient Scale (AAPS)
- Impact of wellness programs and screening
- Outcomes / Cost = Value

Adherence to evidence based guidelines lowers cost without negatively impacting treatment efficacy

Purpose: Evaluate the cost effectiveness of evidence-based treatment pathways for NSCLC patients

Conclusion: Results of this study suggest that treating patients according to evidence-based guidelines is a cost-effective strategy for delivering care to those with NSCLC.



What Endpoints Does Manage Care "Care" About?

- "Hard" outcomes versus "soft"
 - Heart attacks vs. blood pressure
 - Overall survival vs. initial response
- Cost of outcomes
 - Adverse events resulting in additional therapy vs. localized irritation
 - Hospitalization or ER visit vs. outpatient office visit
 - Efficient delivery of care
- Outcomes aligned with quality metrics and CMS programs
 - Health Effectiveness Data and Information Set (HEDIS)
 - Physician Quality Reporting System (PQRS)
 - National Quality Measures Clearinghouse (NQMC)
 - Hospital Inpatient VBP Program
 - Hospital Readmissions Reduction Program
 - Hospital OP and IP Quality Reporting (OQR and IQR) Programs
- Evidence That Differentiates

Most Payers of Care Would Agree With This Strategy

- Drive efficient use of evidence-based medicine
 - platform that provides content and workflows
 - integrate into the Aetna and provider systems
 - simplify the administrative processes for providers
 - Improve the care experience for the members with cancer
- Avoid waste and misuse of medical services
 - better provider alignment, which includes transparency & reporting (e.g., Oncology Patient Centered Medical Home),
 - better network (narrow, tiered)
 - better decision support strategies
 - Better patient support in active treatment and care transitions
- Leverage and integrate the many current (and future) medical and pharmacy cancer-care initiatives
 - seamless, end to end cancer experience for members and providers

Clinical Fragmentation in Most Systems

Who is the Gatekeeper; the Patient Navigator ?

Multiple	Physicians	<ul style="list-style-type: none"> 2 primary , 5 specialists / ave. year No incentive to be the "Gatekeeper"
	Sites of Care	<ul style="list-style-type: none"> Hospitals, MD offices, home care, retail clinics, SNF
	Pharmacies	<ul style="list-style-type: none"> Hospital, Retail, Specialty
	Comorbid diseases	<ul style="list-style-type: none"> Chronic and Acute
	Payers	<ul style="list-style-type: none"> Primary and supplemental Member shift = 2.5 years Few incentives for "prevention"

"Clinical Integration...", Trend Watch, AHA, February 2010

Value and Risk

What is at Risk ?

- Provider financial margin
- Market share if “customer defined” standards are not met
- Medical liability if “standards of practice” are not met

Risk Contracts Are Inevitable

Risk contracts help medical groups' bottom line

Our financial performance associated with risk contracting between medical groups and insurers appears to be a thing of the past, according to “Capitation and Risk Contracting Survey” from the American Medical Group Association (AMGA). More than half of medical groups characterized their organizations' financial performance in risk contracts over the past two years as above average or excellent, with less than 10 percent citing poor financial performance. Seventy-five physician groups participated in the survey.

Thirty-six percent of participants reported that revenue derived from risk contracts is greater than half of their organizations' total revenue, and 55 percent said that less than 10 percent of revenue comes from risk contracts. Primary care and professional capitation are the most common contract types. Physician groups tend to participate in primary care

capitation with commercial HMO and point-of-service (POS) plans, but not with Medicare Advantage plans. Capitation is a fixed monthly amount paid to a provider for each patient enrolled regardless of the volume of services rendered. Risk contracting occurs when a contracting organization enters into a capitation arrangement assuming the risk of delivering agreed services to a covered population at a contracted amount.

Primary care capitation contracts typically involve a primary care physician's office. In professional capitation, a medical group receives payments for services provided by both primary care doctors and by specialty physicians. Global capitation occurs when multiple hospitals and physicians band together to receive single fixed monthly payments for health plan members. In carve-out capitation, a managed care organization contracts with specialists to deliver specialty care required by members.



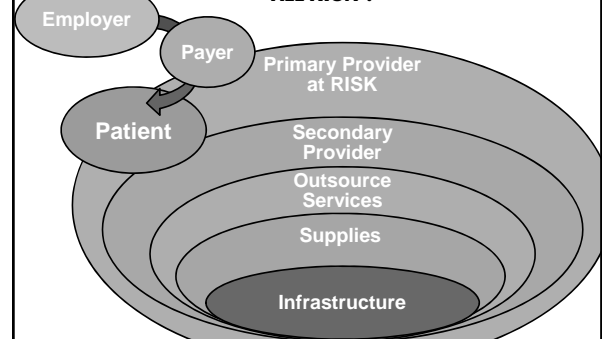
Source: Risk Management Consultants and the American Medical Group Association, “Capitation and Risk Contracting”

<http://www.managedcaremag.com/archives/0812/0812.compmon.html>

Who is at Risk ?

- Employers / Purchasers determine value
 - Develop performance contracts with Payers / Providers
- Payer is shifting full burden of risk to Providers
- Providers were paid less for quality & performance inadequacies
- Providers will be paid differently in the future:
 - Fixed “capitated” for a specific stage of a specific disease
 - Annual fee per “covered life” in a large population
- Manufacturers were rewarded for quantity of use
 - Lab, Radiology, Pharma
- Manufacturers will be paid only when product works as promoted
 - Manufacturers incentivized to develop better diagnostic / predictive tools

Will Eventual PRIMARY Provider Bundle Include ALL RISK ?



How does a Risk Contract Work ?

- Penalties for poor quality are not working as well as intended
- New Incentives for wellness, prevention, early detection
 - Cheaper to prevent, than treat what was preventable
 - Determine value of “health capital” as QOL and productivity
- Manufacturer costs must be honest and transparent
 - Cost to get new drug to market: \$125 million vs \$1.3 billion
 - Light (Harvard), Kantarjian (MD Anderson), AARP Bulletin, May, 2014, p22
 - Enable provider “bundle” to be competitive
- Promote only appropriate use
 - Guided evidence rated pathways / algorithms / guidelines / compendia
 - Able to predict response rate
 - Shared financial loss for failure to respond
- Missing essential IT tools
 - Process and communication effectiveness / efficiency
 - Consolidate versus fragment providers
 - Appropriate discrete metrics
 - Patient inclusion and accountability

Value / Risk Based Payer Contracts

- Performance Criteria
 - Guideline Adherence = Predictable Outcomes/Costs
 - 1st, 2nd, 3rd line therapy
 - Supportive Care, Co-Morbid Disease, End of Life
 - Population Health (Prevention, Screening)
 - Patient adherence to therapy plan
- Reimbursement Incentives
 - Outcome / Cost / Value Data Exchanged
 - Authorization Process Waived / Expedited
 - Lower reimbursement contractual deduction
 - Faster payment (< 30 days)
 - Preferred provider status

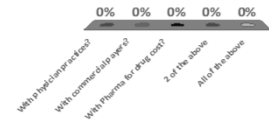
Value / Risk Based Purchasing Incentives

- Guideline adherence = committed volumes
 - Tiered Price Incentives
 - Adherence Metrics
 - Therapeutic / Biosimilar Substitution
- Single Class of Trade
 - Oncology or IDN / ACO
- Shared Risk Concepts
 - Non-performance penalties
 - ACO standards of care
 - Clinical non-performance of drug
 - Define ROI of each drug within a bundled payment
 - Cost adjustment formula to ensure positive margins
- Shared Outcomes Data

Has your organization developed Risk Adjusted Contracts



- With physician practices?
- With commercial payers?
- With Pharma for drug cost?
- 2 of the above
- All of the above



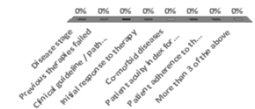
New Legislation Proposed

- Improving Medical Post-Acute Transformation (IMPACT) Act of 2014
 - US House Ways and Means Committee
 - Senate Finance Committee
 - Target implementation October 1, 2018
- Expands data and quality reporting for post-acute providers
- New clinical data reporting for acute care, critical access, cancer hospitals
 - Medical condition
 - Functional status
 - Cognitive function
 - Living situation
 - Other domains to be determined
- What is Impact on reimbursement if not collected?
- If Informatics isn't the Solution; they are the Problem

Do you have DISCRETE data fields (versus free text) in your EHR?



- Disease stage
- Previous therapies failed
- Clinical guideline / pathway followed
- Initial response to therapy
- Co-morbid diseases
- Patient acuity index for pharmacy
- Patient adherence to therapy
- More than 3 of the above



Hospital EHRs Inadequate for Big Data

- Crossing the Omic Chasm. A Time for –Omic Ancillary Systems
- EHR data systems are not sophisticated enough to handle or store the amount of electronic information created by currently available medical technology.
- EHRs are not currently capable of integrating genomics clinical decision support.
 - Genomics, epigenomics, proteomics, and metabolomics
- We need dynamic systems that can reanalyze and reinterpret stored raw data as knowledge evolves, and can incorporate genomic clinical decision support.
 - http://labsoftnews.typepad.com/lab_soft_news/2013/04/justin-starren-specialized-systems.html
 - Starren MD, JAMA, March 27, 2013, Vol 309, No. 12


Root Problem in US Healthcare Today

- More money is made from inefficient systems and perverse incentives that efficient / effective healthcare
 - Disease Treatment vs. Health and Prevention
 - More profitable to customize inadequate systems than create innovative new systems
- Human nature resists change
 - Maslow / Herzberg: basic comfort levels vs higher achievement
 - Known profitability vs innovation with unknown profitability
- Solution to the current dilemma
 - We need innovation champions
 - An IT vendor who "breaks the mold"
 - A payer who significantly rewards truly better outcomes
 - A provider who demands better systems
 - Government leaders who don't "give in" to lobbyists, or to win votes
 - Better educated patients who demand better care and value
 - Patients who are empowered to be more responsible

Summary

- The Healthcare Business Model is evolving rapidly
- Risk is shifting from Payers to Providers and Suppliers
- Contracting innovation is essential for provider survival
- Process innovation is essential for complex therapy with multiple providers
- New value oriented data will be required by all stakeholders
 - Diagnostic / Clinical
 - Financial / Value
 - Process
 - Legal
- Providers cannot be at Risk if they aren't equipped with knowledge (data), with a method to guide decisions and analyze outcomes, and a contract that rewards "doing the right thing".

Questions



Breakout Session Title

Phil Johnson Bonnie Kirschenbaum

PARKING LOT

Billing for Wasted Drug

Question: Can a hospital charge for the 'waste' of a medication when they have used a partial vial of a drug and there is not another patient scheduled who could receive the same drug?

Answer: Hospitals are encouraged to schedule patients in such a way that the hospital can use the drug most efficiently. However, if the hospital must discard the remainder of a single use vial after administering part of it to a Medicare patient, the provider may bill for the amount of drug discarded along with the amount administered.

To clarify, coverage of discarded drugs applies **only to single use vials**. An itemized bill should be submitted with the claim to verify how the drug was supplied. The claim should also include the amount of drug administered and the amount of drug "wasted" by referencing the appropriate JW modifier which signifies the "Drug Amount Discarded/Not Administered to Any Patient" as directed in the [CMS Publication 100-04, Chapter 17, Section 40](#).

Reporting the **JW modifier is not required**.

Date Posted: 09/15/2005, Date Revised: **12/01/2011**

Billing for Wasted Drug

Question: What information is needed in the medical record when billing for medications and/or billing for the 'waste'.

Answer: It is expected that the medical record will contain the name of the drug, dosage, route of administration, time and date given. When a portion of the drug is discarded, the medical record must clearly document the amount administered and the amount wasted.

Reporting the **JW modifier is not required**.

Date Posted: 09/15/2005, Date Revised: **12/01/2011**

Medicare Claims Processing Manual, Chapter 17:
<http://www.cms.hhs.gov/manuals/downloads/clm104c17.pdf>

Current Cost Bases

Relationship of Current Cost Bases

- Reimbursement Scheme Drives Cost Base Selection
- AWP (Ave Wholesale Price)
- WAC (Wholesale Acquisition Cost)
- ASP (Average Sales Price)
- AMP (Average Manufacturer Price)
- WAMP (Weighted AMP)

AWP	\$100 Base	\$100	Published
WAC	AWP – 16 to 22%	\$81	Published
ASP	AWP – 26 to 30%	\$72	Published
AMP / WAMP	AWP – 23 to 28%	\$74.5	Not Published

OIG: Medicaid Drug Price Comparison: ASP to AWP, OEI-03-05-00200, June 2005

Revenue Recovery

Loss Mitigation

ASHP Reimbursement

Welcome to the ASHP Pharmaceutical Reimbursement Resource Center

a comprehensive information site concerning
pharmaceutical reimbursement for health-system pharmacists.

This resource center was created by the American Society of Health-System Pharmacists with the support from Amgen and was designed to provide education and guidance for pharmacists responsible for pharmaceutical reimbursement in their institution.

www.ashp.org/reimburse/



Partnership for
Prescription Assistance

www.pparx.org

Pharma.org

475 Public and Private Programs

150 Drug Company programs



HEALTHWELL
FOUNDATION®

www.healthwellfoundation.org

The HealthWell Foundation® is a 501(c)(3) non-profit, charitable organization that helps individuals afford prescription medications they are taking for specific illnesses. The Foundation provides financial assistance to eligible patients to cover certain out-of-pocket health care costs, including:

- Prescription drug coinsurance, copayments, and deductibles
- Health insurance premiums
- Other selected out-of-pocket health care costs

NeedyMeds.com

Information you need to get your medicine

- Patient Assistance Programs
 - Brand Name Drugs
 - Generic Drugs
 - Program List
 - Company List
 - PAP Applications
 - Help with Paperwork
- Discount Drug Cards
- Government Programs
- Resources & Links

**National
Network for Health**
Working Together to Promote Healthy and
Safe Individuals, Families and Communities

CYFERnet
 HPHC
 CYFAR
 USDA

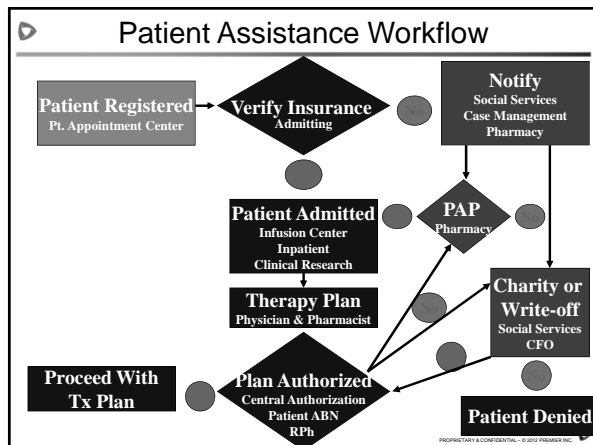
NATIONAL FOUNDATIONS

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z

Aetna Foundation, Inc.
151 Farmington Ave., Hartford, CT 06156-3180
Telephone: (860) 273-6382
Contact: Program Officer
<http://www.aetna.com/foundation/>
Total Giving: \$10,450,634

www.nnh.org

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Checklist for Pharmacists

- Identify target drugs
 - Learn specific rules
- Identify target patients
- Educate stakeholders
 - Develop working relationships
 - Define their role in screening for potential patients
- Obtain resources
 - Staff
 - Computer software
- Monitor rule changes
- Document and report impact

Information Sources

- www.needymeds.com
- www.rxassist.org
- www.helpingpatients.org
- www.pparx.org
- www.accc-cancer.com
- www.medicare.gov
- www.cms.hhs.gov/CMSForms/
- www.cancer.gov
- www.nnh.org
- www.ashp.org
- www.healthwellfoundation.org
- http://www.nccn.org/reimbursement_resource_room/default.asp
- copayment assistance (1.800.272.9376)

ADVANCING QUALITY OUTCOMES AND
INNOVATIONS:
Preparing pharmacy for the future

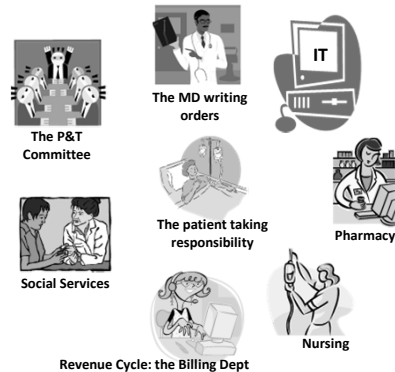
Financial Management Essentials: Strategies for Compliance & Revenue Management

Bonnie Kirschenbaum, MS, FASHP, FCSHP
Healthcare Consultant
Boulder, CO

Objectives

- Analyze issues affecting outpatient reimbursement including favorable pricing, pre-authorization, patient assistance, delayed revenue, contractual relationships and IT robustness
- Apply facility strategic planning related to changes resulting from bundled payment agreements
- Prepare to "own" the financial risk of medications in a similar manner to "owning" clinical management of medications by executing financial management strategies.

Reimbursement is everyone's responsibility!!



Are some essentials missing? complicit in reimbursement errors?

Get the facts about reimbursement

Is there someone who's following this?

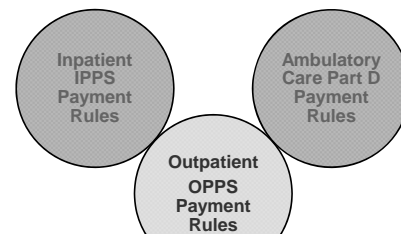
Do you know what's going on?

Use the facts once you have them

Can you and do you incorporate changes quickly?

Banish Barriers

- Attitude....**Not my job
- Naivety....**Not understanding a business model
- Helplessness....**No easy to use resources
- Short sightedness....**No appreciation of the impact on future services



"The Lost Boy"

-Not well understood

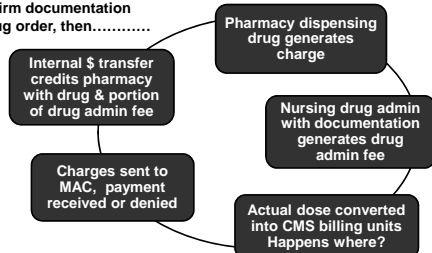
-Little attention

-Few tech toys

-but, oh so much potential!

Always, Always Follow the Money Do you do this? Can you do this end to end?

MD chooses drug
MD, Nursing & Pharmacy
determine Prior Auth/LCD/NCD
status & confirm documentation
MD writes drug order, then.....



CMS Payment for Drugs and Biologicals

Inpatient Setting Payment
No separate reimbursement, payment is included in the DRG payment to the hospital*

Purchasing
Purchase @ contract or list price

Outpatient clinic Payment
Separate payment for drugs >\$90/day with HCPCS codes and on the CMS payment list
NCDs/LCDs apply
Products may be bundled into payment packages

Purchasing
Purchase @ contract or list price
Use 340B pricing if eligible

M.D. Office Patient Payment
Separate payment for drugs >\$90/day with HCPCS codes and on the CMS payment list.
NCDs or LCDs may apply

Purchasing
Purchase @ contract or list price

What's going on with HCPCS codes for drugs, biologicals and immunologics?

Quick review of charging

- ICD9/ICD10 codes used to designate disease types (WHO)
- **CPT codes** (determined by the AMA)
 - used by physicians to describe procedures they do
 - may include payment for all products used for the procedure
- **HCPCS codes** are for products and may or may not be reimbursed
- DRGs apply to inpatients and only to Medicare patients
- APCs apply to outpatients and only to Medicare patients
- DRG & APC methodology often a template for other payors
- **Part B** covers drugs administered in an outpatient setting
- **Part D** covers drugs that are considered self-administered (most oral cancer drugs)

Status Indicators

Indicator	Indicator Description
A	Active code. These codes are separately paid under the physician fee schedule, if covered.
B	Bundled code. Covered services payment is always bundled into payment for other services not specified.
C	Carrier-priced code. Carrier will establish the RVUs and payment amounts for these services, generally on a individual case basis following review of documentation such as an operative report.
D	Deleted codes. These codes are deleted effective the beginning of the year.
E	Excluded from physician fee schedule by regulation, are for items and/or services CMS excludes. NO RVUs or payment amounts are shown, no payment may be made under the fee schedule for these codes. If covered payment continues under reasonable charge procedures.
F	Deleted/discontinued codes, not subject to 90 day grace period.
G	Code is not valid for Medicare purposes. Providers are to bill for these services using other codes.
H	Deleted modifier. This code had an associated TC and/or 26 modifier in the previous year. For the current year, the TC or 26 component has been deleted, and is shown with a status code of "H".

Status Indicators

Indicator	Indicator Description
I	Code is not valid for Medicare purposes. Medicare uses another code for the reporting of and payment.
J	Anesthesia services (no RVU or payment amounts for anesthesia codes on the database, only used to facilitate the identification of anesthesia services.)
M	Measurement codes, used for reporting purposes only.
N	Non-covered services.
P	Bundled or excluded code. No RVUs for these services. No separate payment should be made for them
R	Restricted coverage. Special coverage instructions apply.
T	Injections. There are RVUs for these services, but they are only paid if there are no other services payable under the physician fee schedule billed on the same date by the same provider.
X	Exclusion by law. These codes represent an item or service not within the definition of "physician service" for physician fee schedule payment purposes. Services are still paid under Medicare Part B.

The Importance of Codes

- Coding's the language describing what was done and what was used. It's the operational link between coverage and payment
- However, any payor at any time can look at what was done and on the merits of that, make a decision that they're not going to pay for it
- All reimbursable drug and biological HCPCS codes should be assigned Revenue Code 636
- Maintained by CMS-HCPCS working group with an annual release
- <http://www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/list.asp#TopOfPage>

CMS Billing Procedure on Uncoded New Drugs

- Hospitals receive 95% of AWP on newly approved drugs and biologicals used in an outpatient setting that have not yet been assigned a product-specific HCPCS code.
- Use Unclassified Drug or Biological HCPCS code C9399 plus the NDC #
- www.cms.hhs.gov/manuals/pm_trans/R188CP.pdf
- Using miscellaneous codes = \$0 once a code is assigned. Be careful, stay on top of this!!
 - (more details in appendix)

Brand Name Specific HCPCS Codes

Most HCPCS codes are listed generically, but a *few are unique to the brand name*
Develop unique CDM listings for Brand Name **products**

J0800	Corticotropin injection	40 UNITS
J0834	Cosyntropin cortrosyn inj	0.25 MG
J1459	Inj IVIG priven 500 mg	500 MG
J1460	Gamma globulin 1 CC inj	1 CC
J1556	Inj, Imm Glob Bivigam, 500mg	500 MG
J1557	Gammalex injection	500 MG
J1559	Hizentra injection	100 MG
J1560	Gamma globulin > 10 CC inj	10 CC
J1561	Gamunex-C/Gammaked	500 MG
J1566	Immune globulin, powder	500 MG
J1568	Octagam injection	500 MG
J1569	Gammagard liquid injection	500 MG
J1442	Inj, Filgrastim G-CSF 1mcg	1 MCG
J1446	Inj, tbo-Filgrastim, 5 mcg	5 MCG

The Biosimilar Market

- A rapidly-growing segment of the pharmaceutical industry
- US still in early stages of biosimilar regulation development but Europe/UK have surged ahead
- Several states are contemplating passing bills on biosimilar drug use: some passed, some rejected and some died
- Most biosimilars in development will be used predominantly in the outpatient area
- Must use their specific HCPCS codes for their specific labeled indications in the same way that you use brand specific codes for labeled indications
- ICD-10 codes in conjunction with HCPCS codes make it easy to follow up on how a specific drug was used.

Don't make assumptions

- **Granix (tbo-filgrastim)**
 - was approved as a new biologic product and not as a biosimilar
 - Effective 1-1-2014 has its own
 - HCPCS code (J1446)
 - billing unit designation (5mcg)
 - reimbursement rate
 - labeled indications
- Using the HCPCS code, billing unit designation and applying the reimbursement rate for filgrastim is not appropriate
- Neither is continuing to use a miscellaneous code

New CMS HCPCS code for Neupogen® (filgrastim)

- November 29, 2013: CMS released the Healthcare Common Procedure Coding System (HCPCS) code set updates that became effective January 1, 2014
- Effective January 1, 2014: CMS has assigned a new HCPCS code for Neupogen®, J1442 injection, filgrastim 1 mcg
- This new HCPCS code replaces the old Neupogen® HCPCS codes of J1440 for 300 mcgs and J1441 for 480 mcgs
- Critical to make sure billing unit conversion is working!!!
 - Must convert the dose administered into billing units to be billed
 - Neupogen® 300 mcg = 300/1 = 300 billing units of 1mcg (the single use vial)
 - Neupogen® 480 mcg = 480/1 = 480 billing units of 1mcg (the prefilled syringe)
- For additional details go to the CMS website: <http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>

Be careful with codes!!!

- Alimta, indicated for lung cancer, and Avastin, with various indications including one for lung cancer, have similar J-codes
- *Often times, providers trying to bill for Alimta will mistakenly transpose the numbers and bill for Avastin instead.*
 - Avastin is J9035
 - Alimta is J9305
- Both drugs are expensive, costing thousands of dollars a month, so cost is not likely to be a red flag

Another Coding peculiarity: often billing units aren't the same as vial sizes

HCPCS Description
Drug Product Size: Rituximab injection 10mg/ml
HCPCS Billing Unit: 100 mg
If the dose is 600mg, use 6 billing units of 100mg
Round up for partial units (580 mg = 6 billing units)
To ensure correct reimbursement, the Charge Description Master (CDM) must be adjusted accordingly or a crosswalk created.
Watch out! Billing units can change every year
Worse still...
The Medicare billing unit can be totally different from the quantity required for Medicaid

Kudos to CMS for Untangling the Billing Unit Web

- Using incorrect billing units for drugs in payment claims to Medicare and Medicaid has escalated to the point that this is one of the key findings during examinations of our billing systems by recovery audit contractors (RACs). So here are a few tips to stay clear of trouble.
- http://www.pharmacypracticenews.com/ViewArticle.aspx?ses=ogst&d=Operations+&+Management&d_id=53&i=ISSUE:+Septemember+2013&i_id=992&a_id=23974

What's all the fuss with NDC #'s?

- National Drug Code #'s that identify
 - The manufacturer (1st set of digits)
 - The drug (2nd set of digits)
 - The package size (3rd set of digits)
- NDC reporting is essential for Medicaid and 340B billing
 - Why? Because the manufacturer doesn't want to pay Medicaid rebates or offer 340B pricing if his drug wasn't the one being used!!!
 - CMS wants outpatient departments and clinics & physician offices to do a better job of reporting NDCs
<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1234.pdf>
- New HRSA 340b GPO exclusion language makes hospitals much more NDC centric: imperative that NDCs are accurate

April 2013 ASP NDC - HCPCS Crosswalk for Medicare Part B Drugs
Effective April 1, 2013 through June 30, 2013

Note 1: This crosswalk is based on published drug and biological pricing data and information submitted to CMS by manufacturers.
Note 2: Please submit comments on the crosswalk to e-mail address: sec30aspdata@cms.hhs.gov.

2013 C-Code	Short Description	MANUFACTURER NAME	NDC	Drug Name	TOYS dosage	PKG SIZE	PKG QTY	BILLING UNITS	BILLING RATE
J0585	Injection, onabotulinumtoxinA	Allergan Sales, LLC	00023-9232-01	Botox	1 UNIT	1	1	100	100
J0586	AbobotulinumtoxinA	Ipsen Biopharmaceuticals, Inc.	15054-0500-01	Dysport	5 UNIT	1	1	100	100
J0586	AbobotulinumtoxinA	Ipsen Biopharmaceuticals, Inc.	15054-0530-06	Dysport	5 UNIT	1	1	60	60
J0586	AbobotulinumtoxinA	Medics	99207-0500-30	Dysport	5 UNIT	1	1	60	60
J0587	Inj, rimabotulinumtoxinB	Solstice Neurosciences, LLC	10454-0710-10	Myobloc	100 UNITS	0.5	1	25	25
J0587	Inj, rimabotulinumtoxinB	Solstice Neurosciences, LLC	10454-0711-10	Myobloc	100 UNITS	1	1	50	50
J0587	Inj, rimabotulinumtoxinB	Solstice Neurosciences, LLC	10454-0712-10	Myobloc	100 UNITS	2	1	100	100
J0588	Incobotulinumtoxin A	Merz Pharmaceuticals, LLC	00239-1605-01	XEOMIN	1 UNIT	1	1	50	50
J0588	Incobotulinumtoxin A	Merz Pharmaceuticals, LLC	00239-1610-01	XEOMIN	1 UNIT	1	1	100	100
J0592	Buprenorphine hydrochloride	HOSPIRA, INC.	00409-1612-32	Buprenorphine Hcl	0.1 MG	1	10	3	30
J0592	Buprenorphine hydrochloride	AMERICAN REGENT	00517-0725-05	Buprenorphine HCl	0.1 MG	1	5	3	15
J0592	Buprenorphine hydrochloride	Bedford Laboratories	35190-0100-10	Buprenorphine Hcl	0.1 MG	1	10	3	30
J0594	Busulfan injection	Otsuka America Pharmaceutical, Inc.	35148-0070-91	BUSULFAN	1 MG	10	8	60	480
J0594	Busulfan injection	Otsuka America Pharmaceutical, Inc.	35148-0075-91	BUSULFAN	1 MG	10	8	60	480
J0595	Butorphanol tartrate 1 mg	West-Ward Pharmaceuticals Corp	00143-8864-10	STADOL	1 MG	1	10	1	10
J0595	Butorphanol tartrate 1 mg	West-Ward Pharmaceuticals Corp	00143-8867-10	STADOL	1 MG	1	10	2	20
J0595	Butorphanol tartrate 1 mg	HOSPIRA, INC.	00409-1623-01	Butorphanol Tartrate	1 MG	1	10	1	10
J0595	Butorphanol tartrate 1 mg	HOSPIRA, INC.	00409-1626-01	Butorphanol Tartrate	1 MG	1	10	2	20

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Average Selling Price (ASP)

- ASP Average selling price of manufacturer's sales of all US purchases for each NDC for one calendar quarter, divided by total number of units sold in that quarter
- Excludes nominal pricing and Medicaid "best price."
- Includes volume & prompt pay discounts, free goods, chargebacks, rebates
- For 2014, ASP calculations do not include 340B pricing
- Is updated quarterly, get on the distribution list!!
- <http://www.CMS.gov/McrPartBDrugAvgSalesPrice/01a172013ASPFiles.asp>
- CMS abandoned AWP and moved to ASP October 2005
- H.R. 800 would exclude prompt-pay discounts from manufacturers to wholesalers from the calculation of a drug's average sale price

ASP Methodology

- uses several sources of data as a basis for payment, including
 - ASP
 - wholesale acquisition cost (WAC)
 - average wholesale price (AWP).
- 2014 OPSS rules: the term "ASP methodology" and "ASP-based" are inclusive of all data sources and methodologies described therein.
- Additional information on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>

Keep your eye on ASP



- Is based on the price the manufacturer sells the product at to the distributor or specialty pharmacy
- Is not based on the price you pay
- Does not take into account or include any mark-ups you pay to purchase the product
- Lobby for ASP restructuring? Probably more important than the % mark-up!

CMS Posts ASP Drug Pricing Files Quarterly, Get them and use them!!

- A good review of applicable HCPCS codes and allowable billing units (go.cms.gov/16LuwS1)
- Visit 3 files are published quarterly
 - Payment Allowance Limits for Medicare Part B Drugs
 - ASP NDC - HCPCS Crosswalk for Medicare Part B Drugs
 - ASP NOC NDC - HCPCS Crosswalk for Medicare Part B Drugs

ASP vs. AMP

- current law permits CMS to substitute the average manufacturer's price (AMP) in determining payment if it's lower than ASP
- 2013 final rule: CMS specified that substituting AMP for ASP will be made only if ASP exceeds AMP by 5% or more for several quarters (to eliminate a short term anomaly) and payment would be based on 103% of AMP rather than 106% of ASP. No mention in 2014 rules
- 2013 rule: CMS added language to prevent AMP price substitution policy from taking effect if the drug & dosage form are on the FDA Current Drug Shortage list (or other FDA reporting tool identifying shortages of drugs)
- Aug 2013: HHS noted that "a new 'price substitution policy' proposed this year by CMS and planned to begin January 2014 is expected to save Medicare and its beneficiaries "

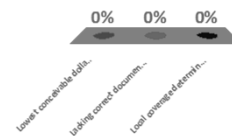
Surprise! AMP 1st appeared Oct 2013, still being used

Payment Allowance Limits for Medicare Part B Drugs Effective July 1, 2014 through October 31, 2014

HCPCS Code	Short Description	Billing Unit	Payment Limit
J1110	Inj dihydroergotamine mesylate	1 MG	33.334
J2675	Inj progesterone	50 mg	1.089
J3070	Pentazocine injection	30 MG	144.583
J7626	Budesonide non-comp unit	0.5 MG	4.900
J9190	Fluorouracil injection	500 MG	1.872
J9360	Vinblastine sulfate inj	1 MG	2.008
J3415	Pyridoxine hcl 100 mg	100 MG	7.205

The definition of an LCD is...

1. Lowest conceivable dollars that will be paid for a claim
2. Lacking correct documentation
3. Local coverage determination



Prior Approval vs. NCDs and LCDs

	Prior Approval (Payor)	NCDs and LCDs
Applies to:	3 rd party carriers (possibly Medicaid)	Medicare (possibly Medicaid)
Need Patient's payor status?	yes	yes
Drug tagged in CPOE/PDM?	yes	yes
Link to actual rule needed?	yes	yes
Rule Requirements:	Ask permission first before drug administration	Understand & follow requirements, document completely and thoroughly. Code correctly and as required
Payment:	Only if permission is given first	Determined after the fact and may be denied if not all rules followed

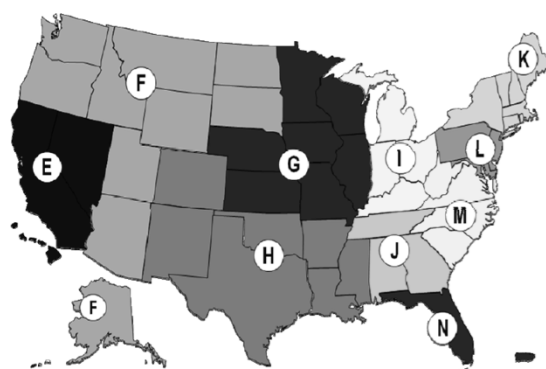
What's Covered and What's Not

- Even if a drug, device, procedure, or service has a HCPCS code and a payment rate under OPSS, doesn't imply Medicare coverage
- Indicates only how the product, procedure, or service may be paid if covered by the program.
- FI's/MACs determine if all program requirements for coverage are met, e.g. that it's reasonable and necessary to treat the beneficiary's condition and whether it's excluded from payment.

What are Fiscal Intermediaries or MACs?

- US is divided into several geographical regions, each assigned to a Fiscal Intermediary (FI) or Medicare Administrative Contractor (MAC)
- FI/MAC receives billings from the hospital and OP clinics and submits them to CMS for payment
- Knowing who your FI/MAC is and what peculiarities may affect your region is important
- Each FI/MAC has a toll free number
 - See www.cms.hhs.gov/medlearn/tollnums.asp
- CMS releases updates & software to FIs/MACs quarterly
- Provider education articles available shortly after a CR is issued. Sign up at: cms.hhs.gov/medlearn/matters

Consolidated A/B MAC Jurisdictions



Off Label Indications

- A dilemma often arises when the literature supports and a patient is treated for an off-label indication.
- The fact that it is off-label may be sufficient grounds for the MAC to deny payment.
- Patient and billing assistance programs offered by several pharmaceutical companies may be helpful in providing support in attempting to have these denials overturned.
- Officially Accepted Compendia can be used to support the off-label decision. Be aware of what they are!
- <http://www.cms.gov/Medicare/Coverage/CoverageGenInfo/compendia.html>

National Coverage Determination (NCD)

NCD for Abarelix for the Treatment of Prostate Cancer (110.19)

- The evidence is adequate to conclude that abarelix is reasonable and necessary as a palliative treatment in patients with advanced symptomatic prostate cancer: (1) in whom GnRH agonist therapy is not appropriate; (2) who decline surgical castration; and (3) who present with one of the following:
 - risk of neurological compromise due to metastases,
 - ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or,
 - severe bone pain from skeletal metastases persisting on narcotic analgesia.
- Searchable database:
 - <http://www.cms.hhs.gov/mcd/search.asp?clickon=search>

Local Coverage Determination (LCD)

LCD for **Pemetrexed injection** (billing unit 10mg)

- Medicare established the following limited coverage for CPT/HCPCS code J9305:

Covered for:

- 158.8 Malignant neoplasm of specified parts of peritoneum
- 162.2–162.5 Malignant neoplasm of trachea, bronchus, and lung
- 162.8–162.9 Malignant neoplasm of trachea, bronchus, and lung
- 163.0–163.1 Malignant neoplasm of pleura
- 163.8–163.9 Malignant neoplasm of pleura
- 164.0 Malignant neoplasm of thymus
- 183.0 Malignant neoplasm of ovary and other uterine adnexa, ovary
- 183.2 Malignant neoplasm of fallopian tube
- 188.0–188.9 Malignant neoplasm of bladder
- V10.11 Personal history of malignant neoplasm of bronchus and lung
- V10.43 Personal history of malignant neoplasm, ovary

Clinicians Note!!

This clinical decision must be made and documented before the drug is ordered and given.
No payment if you try to fix this after the fact.

Jurisdiction H (JH) Local Coverage Determination (LCD) and Article Updates

<https://www.novitas-solutions.com/policy/index.html>

This JH MAC Local Coverage Determination (LCD) has been retired effective 1-18-2013:

- o Drugs and Biologicals: Antiangiogenic Therapy for Ophthalmic Conditions (L32642)

<https://www.novitas-solutions.com/policy/jh/l32642-r4.html>

This JH MAC Local Coverage Determination (LCD) has been revised:

- o Collagenase Clostridium Histolyticum Injections (L32719)

<https://www.novitas-solutions.com/policy/jh/l32719-r5.html>

These JH MAC Local Coverage Determinations (LCDs) have been revised to reflect the Annual CPT/HCPCS Updates effective for dates of service on and after January 1, 2013:

- o Botulinum Toxin Types A and B (L32624)

<https://www.novitas-solutions.com/policy/jh/l32624-r5.html>

- o Intravenous Immune Globulin (IVIg) (L32712)

<https://www.novitas-solutions.com/policy/jh/l32712-r5.html>

- o Thrombolytic Agents (L32756)

<https://www.novitas-solutions.com/policy/jh/l32756-r5.html>

This JH MAC Local Coverage Article has been revised to reflect the Annual

CPT/HCPCS Updates effective for dates of service on and after January 1, 2013:

- Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents (A52018)

<https://www.novitas-solutions.com/articles/jh/a52018-r1.html>

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112 MAC (new) | 30 MAC Transitions | Hot Topics | Beneficiaries/Patients | Section 1011

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Medical Policy - Browse LCDs by Title

Search LCDs | Search Articles | LCDs by Title

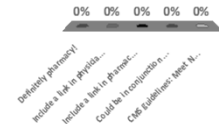
Previous | 21-40 of 120 (Next)

A/R	LCD #	LCD Title	Article	Status	Eff. Date
[X]	L32693	CHI CHEST X-RAY	N/A	Current	None
[X]	L32718	CHI Diagnostic Services	N/A	Current	None
[X]	L32694	CHI CIRCULATING TUMOR CELL ASSAY	N/A	Current	None
[X]	L32719	CHI COLLAGENASE CLOSTRIDIUM HISTOLYTICUM INJECTIONS	N/A	Current	None
[X]	L32695	CHI Colonoscopy, Diagnostic	N/A	Current	None
[X]	L32698	CHI Complex Diagnostic, Diagnostic (CDD) for Lymphedema	N/A	Current	None
[X]	L32750	CHI Computed Cardiac Tomography (CCT) and Computed Tomography Coronary Angiography (CTCA)	N/A	Current	None
[X]	L32696	CHI Computed Tomography (CT) Colonography	N/A	Current	None
[X]	L32703	CHI COMPUTED TOMOGRAPHY OF THE THORAX	N/A	Current	None
[X]	L32763	CHI Cosmetic and Reconstructive Surgery	N/A	Current	None
[X]	L32709	CHI COLONOSCOPIC ABDOMINAL, ABDOMINOPELVIC AND RENAL ANGIOGRAPHY	N/A	Current	None
[X]	L32642	CHI Drug and Biological, Antineoplastic Therapy for Ovarian Cancer	N/A	Current	None
[X]	L32697	CHI Drug and Biological, Colon Stimulating Factors	N/A	Current	None
[X]	L32721	CHI Electrocardiogram (ECG or EKG)	N/A	Current	None
[X]	L32723	CHI Electrodiagnostic Studies (NCS/EMG)	N/A	Current	None
[X]	L32720	CHI Endotracheal Stimulating Agents (ESAL - Non-Dialysis)	N/A	Current	None
[X]	L32718	CHI EXTERNAL COUPLERS/ARTS (ECG)	N/A	Current	None
[X]	L32729	CHI EXTRACRANIAL SHOCK WAVE THERAPY (ESWT)	N/A	Current	None
[X]	L32707	CHI Facet Joint Injections	N/A	Current	None
[X]	L32730	CHI Flow Cytometry	N/A	Current	None

Accession 1 | 2 | 3 | 4 | 5 | 6 | Total

Who should be working on this?

- Definitely pharmacy!
 - Include a link in physician order entry
 - Include a link in pharmacy order entry
- Could be in conjunction with the billing team or certified coders
- CMS guidelines: Meet NCCN guidelines and/or Medicare LCDs/NCDs and complete documentation *before the product is dispensed and administered.*



Proposed: OPPS 2015: 5 drug payment ways

New drugs not yet assigned unique HCPCS Code

No Change from 2013

95% of AWP

Use code C9399, unclassified drugs or biologicals

New pass-through drugs

ASP+6%

Payment based on WAC + 6% until enough ASP data gathered

9 pass-through products have an **expired** status

22 products either keep or gain pass-through status

Specified covered out-patient drugs (SCODs) costing > \$90/day

MD Office+6%

OPPS ASP+6%

No longer exempting (paying separately) 5 -HT3 drugs except for Palonosetron

Includes blood factor products

Lower-cost packaged products costing < \$90/day

No change from 2014

Regardless of cost, products used in packaged services

No separate reimbursement, drug costs bundled into the procedure

CMS Clarifies When To Treat Outpatient Drugs as Supplies

- June 8 policy document: CMS explains when to treat self-administered outpatient drugs as supplies related to a medical procedure
- The cost of these drugs is packaged within procedural codes and cannot be billed to the patient
- The document also announces new billing codes and updates CMS's list of pass-through drugs
- <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7847.pdf>

What's in your bundle? Anything missing?

All non separately payable drugs < \$90/day in 2014

Pass through drugs

Clinic visit

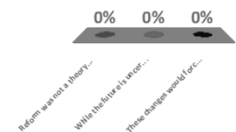
Separately payable drugs

Drug Administration

Accurately billed wastage

How are you getting paid for your part of the bundle?

- Reform was not a theory about industry structure but an effort to change the payment structure. It was really about insurance and payment changes. And the changes meant providers were going to get paid less.
- While the future is uncertain, assume that bundled payments or payments for episodes of care become increasingly prevalent, if not dominant.
- These changes would force the industry to develop new structures and make clinical integration an economic necessity.



Part B Drugs

Drugs are tied to physician services and fall under the medical benefit

- Injectables furnished incidental to a physician's service and not usually self-administered
- Drugs administered via nebulizer or pump furnished by CMS
- Immunosuppressive drugs for organ transplant
- Hemophilia blood clotting factors
- Certain oral anticancer treatments
- Oral antiemetics (only 1 paid)
- Pneumococcal, influenza and hepatitis B vaccines
- Erythropoietin-like drugs for trained home dialysis patients
- Iron dextran, vitamin D injections, and erythropoietin-like drugs administered by facilities caring for ESRD patients
- Osteoporosis drugs

Medicare Payment for IV drugs

	Drug >\$90/day in 2014	Drug <\$90/day in 2014	Specialty Drug or Patient Assistance Drug or Nominal Price Drug
Do I get paid for Patient clinic visit?	yes	yes	yes
Do I get paid for the drug?	Yes with a HCPCS code	Not separately, included in the bundle \$	no
Do I bill for the drug?	yes	yes	Yes @ \$0 charge
Do I get paid for IV drug administration?	Yes with the correct CPT code & documentation	Yes with the correct CPT code & documentation	Yes with the correct CPT code & documentation

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Drug Administration

Services included in the CPT Drug Admin codes:

- Use of local anesthesia
- Starting the IV
- Access to IV, catheter or port
- Routine tubing, syringe, and supplies
- Preparation of drug
- Flushing at completion
- Hydration fluid

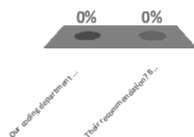
Drug Administration Services-the Quirks

CPT codes 96401-96450 \$\$\$\$ (chemotherapy and immunotherapy)

- advanced practice training and competency for staff
- special considerations for preparation, dosage, or disposal
- patient risk and frequent monitoring
 - Examples: frequent changes in infusion rate, prolonged presence of the nurse administering the solution for patient monitoring and infusion adjustments, and frequent conferring with the physician about these issues

Fact or Myth?

- Our coding department has recently been advised not to bill CPT code 96413 - Chemo IV Infusion for the administration of Q2049 Doxorubicin (changed from J9001 due to drug shortage)
- Their recommendation? Bill it as a therapeutic infusion 96365 since Q2049 does not fall into the J9000 - J9999 sequence of HCPCS codes



Drug admin myths

- Our coding department has recently been advised not to bill CPT code 96413 - Chemo IV Infusion for the administration of Q2049 Doxorubicin (changed from J9001 due to drug shortage)
- Their recommendation? Bill it as a therapeutic infusion 96365 since Q2049 does not fall into the J9000 - J9999 sequence of HCPCS codes
- BAD IDEA costing the facility \$\$\$\$\$ in losses
- Better idea: work with pharmacy to identify the few drugs that fall outside the arrange and remove the hard edit from them.

- CMS guidance regarding the use of "chemo" versus "non chemo" administrations is in the Medicare Claims Processing Manual, Chapter 12, Section 30.5 (excerpt below) Note the caveat that local carriers may have further details (i.e. preferences)
- *Chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs; to anti-neoplastic agents for treatment of noncancer diagnoses (eg: cyclophosphamide for auto-immune conditions) or to monoclonal antibody agents, and other biologic response modifiers*
- *The category of monoclonal antibodies includes: infliximab, rituximab, alemtuzumab, gemtuzumab, and trastuzumab*
- *The category of hormonal antineoplastics includes: leuprolide acetate and goserelin acetate.*
- *The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. Local carriers may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare.*

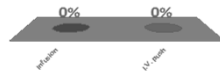
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Therapeutic, Prophylactic, & Diagnostic Injection & Infusion codes (96365-96379) \$\$

- Stop times on infusions- 16 minutes or more = infusion. If <16 or no stop time (or other substantiating documentation), must be reported as an "iv push" at a lower reimbursement rate
- IV push of same substance within 30 minutes is not reported again
- Hydration
 - Incidental when used as a vehicle for drugs
 - TKO rate
 - Up to 30 mEq/KCL per liter
 - Not reported if less than 30 minutes
- Not reported if "integral to the procedure"
 - e.g. Contrast media given by IV push during CT scan—administration services not reported

An ED patient receives a Levaquin 500 mg IVPB (in 100 ml). The doctor has ordered the infusion over 30 minutes. The medical record documentation is: "Levaquin IV, started at 0930". There is no "end time" or "stop time" recorded on the eMAR or Nurses notes. How should the administration of the drug be reported?

1. Infusion
2. I.V. push



Part D Drugs

Drugs fall under the pharmacy benefit

- Benefits only apply to "covered Part D drugs"
- Generally, a Part D drug is a prescription drug that is prescribed and dispensed for self-administration
- Also includes
 - Biological products
 - Insulin
 - Medical supplies associated w/insulin injection (syringes, needles, alcohol swabs, and gauze)
 - Certain vaccines not covered under Part A or B

Part B Drugs vs. Part D Drugs

- Medicare and other insurers have distinct medical and pharmacy benefits
- Medicare medical benefit ensures that physician services, including physician-administered drugs, and hospital services are covered
- Pharmacy benefit usually covers self-administered drugs (orals and some subcutaneous injectables)
- High copays can cause financial difficulties
- 1 in 4 patients who filled their Rx and incurred >\$500 in copays did not return to pick it up or follow up with a new oncology medication within 90 days
 - Streeter SB, Schwartzberg L, Husain N, Johnsrud M. Patient and plan characteristics affecting abandonment of oral oncolytic prescriptions. *J Oncol Pract*.2011;7(3 Suppl):46s–51s.

A new and growing trend...

Move drugs out of the medical benefit (B) and into the drug benefit (D) to be controlled by the plan administrator

The next steps often...

**Move these into new payment tiers
Put these under specialty pharmacy control.**

Drug Administration for White Bagged Drugs, Patient Assistance Drugs or No Charge Items

- MACs have found that in some cases administration codes are billed without a corresponding drug on the same date of service
- Drug administration billed without a corresponding drug will result in a denial of the administration code
- When the drug is white bagged, the facility/physician should:
 - Bill the HCPCS code for the drug administered with the correct quantity (according to the dose per unit specified in HCPCS) and a zero charge
 - Append the modifier stipulated by your MAC to all of the administration codes billed for the same date of service

Billing Drug Administration Codes: (12/22/2011) TrailblazerHealthcare
Notice ID: 14067

Billing Drug Administration Codes

- Drug administration billed without a corresponding drug will result in a denial of the administration code. e.g. White bagging or brown bagging
- Bill the HCPCS code for the drug administered with the correct quantity of billing units and a zero charge
- Check with your MAC and append the modifier recommended to all of the administration codes billed for the same date of service
- no HCPCS code? Use Not Otherwise Classified (NOC) "J" code - J3490 or J3590 (non-chemotherapy) or J9999 (chemotherapy), the NDC # and a zero charge
- Append the MAC recommended modifier to all of the administration codes billed for the same date of service
- Drug administered can't be in the Self-Administered Drug Exclusions list
- Only chemotherapy drugs and monoclonal antibodies are billed with chemotherapy administration codes

How do I do this?

- Create a CDM # for each complimentary product
 - Infliximab 10mg/ml CDM# 12345
 - Infliximab, no charge CDM # 12346
- Pharmacy will create a corresponding PDM entry for these complimentary products and link it to the CDM#
- When the complimentary product is used, pharmacy *must* use the order entry for the complimentary product, not for the purchased product
- Bill for the appropriate drug administration fee(s)

Appendix of Additional Background Material

I've heard you can bill for drug waste

...

how does this work?

Answer these 4 questions

- Is the drug being used for a Medicare patient being treated in an outpatient area?
- Are you using a single dose vial of the drug?
- Does the product have a HCPCS code?
- Does the dose fall into the pass-through or separately payable category and not the <\$90/day bundle or any other packaged or bundled payment category?
- If yes, proceed to waste billing
- If no, then there's nothing to do

Steps to Take

- Review the MAC requirements for your geography
- Determine which drugs are going to be waste candidates
- Create a CDM # for each one
 - Drug A CDM #123456
 - Drug A waste CDM# 123457
- Convert the dose administered into billing units, round up to the next whole billing unit as needed
- Document the dose administered in the medical record
- Determine the number of billing units wasted
 - The # in the vial (use the NDC ASP CMS Qtrly update) minus the number of billing units used for the dose
- Document the amount wasted & the reason why in the medical record
- Bill for the dose administered using billing units
- Bill for the amount wasted using billing units

reducing reimbursement Loss or compliance errors

Billing for waste is not mandatory but if trying to recoup those \$, then.....

- Know the rules your contractor requires you to follow
- May or may not need to use a modifier (JW)
- Decide which products your outpatient department is going to apply this to. e.g. may decide to only apply this to a handful of expensive agents in the infusion clinic or specialty outpatient clinics.
- Develop a P&P and orient your staff
- Make use of IT but do frequent compliance checks
- Ensure that required documentation is actually happening and in the manner specified by the MAC/FI

October 2012 ASP NDC - HCPCS Crosswalk for Medicare Part B Drugs Effective October 1, 2012 through December 31, 2012										
Note 1: This crosswalk is based on published drug and biological pricing data and information submitted to CMS by manufacturers. Note 2: Please submit comments on the crosswalk to e-mail address: nc303aspdata@cms.hhs.gov .										
2012 CODE	SHORT DESCRIPTION	LABELER NAME	NDC #	DRUG NAME	HCPCS DOSAGE	PKG SIZE	PKG QTY	BILLING UNITS	PKGS	BILLING UNITS
J029	Abatacept injection	Bristol-Myers Squibb Company	00003-2187-10	Abatacept	10 MG	1	1	25	25	
J010	Abacavir injection	El Lilly and Company	00002-7140-01	Abacavir	10 MG	5	1	1	1	
J012	Acetylsalicylic acid injection	Cambrex Pharmaceuticals Inc.	00220-0207-30	ASPIRIN	100 MG	30	4	60	240	
J013	Acyclovir injection	Bedford Laboratories	55390-0612-10	Acyclovir Sodium	5 MG	1	10	100	1000	
J013	Acyclovir injection	Bedford Laboratories	55390-0612-20	Acyclovir Sodium	5 MG	1	10	200	2000	
J013	Acyclovir injection	APP Pharmaceutical	63323-0205-10	Acyclovir Sodium	5 MG	10	10	100	1000	
J013	Acyclovir injection	APP Pharmaceutical	63323-0205-20	Acyclovir Sodium	5 MG	20	10	100	1000	
J013	Acyclovir injection	APP Pharmaceutical	63323-0205-20	Acyclovir Sodium	5 MG	20	10	200	2000	
J015	Adalimumab injection	Abbott Laboratories, Inc.	00074-3799-02	Humira	20 MG	0.8	2	2	4	
J015	Adalimumab injection	Abbott Laboratories, Inc.	00074-4339-02	Humira	20 MG	0.8	2	2	4	
J015	Adalimumab injection	Abbott Laboratories, Inc.	00074-4339-06	Humira	20 MG	0.8	6	2	12	
J015	Adalimumab injection	Abbott Laboratories, Inc.	00074-4339-07	Humira	20 MG	0.8	4	2	8	
J015	Adalimumab injection	Abbott Laboratories, Inc.	00074-5074-02	Humira	20 MG	0.4	2	1	2	
J015	Injection adenosine 6 MG	ASTELLAS PHARMA US, INC.	00489-8234-12	Adenosine	6 MG	2	1	1	1	
J015	Injection adenosine 6 MG	ASTELLAS PHARMA US, INC.	00489-8234-14	Adenosine	6 MG	4	1	2	2	
J015	Injection adenosine 6 MG	West-Wire Pharmaceuticals Corp.	00641-6113-10	Adenosine	6 MG	2	10	1	10	
J015	Injection adenosine 6 MG	SICOR PHARMACEUTICALS, INC.	00703-8771-03	Adenosine	6 MG	2	10	1	10	
J015	Injection adenosine 6 MG	SICOR PHARMACEUTICALS, INC.	00703-8771-01	Adenosine	6 MG	4	1	2	2	
J015	Injection adenosine 6 MG	West-Wire Pharmaceuticals Corp.	00709-0603-03	Adenosine	6 MG	2	10	1	10	
J015	Injection adenosine 6 MG	Alcon	17478-0642-02	ADENOSINE	6 MG	2	10	1	10	
J015	Injection adenosine 6 MG	Sagent Pharmaceuticals Inc.	25021-0301-02	Adenosine	6 MG	2	10	1	10	
J015	Injection adenosine 6 MG	Sagent Pharmaceuticals Inc.	25021-0301-04	Adenosine	6 MG	4	10	2	20	
J015	Injection adenosine 6 MG	Sagent Pharmaceuticals Inc.	25021-0301-12	Adenosine	6 MG	2	10	1	10	
J015	Injection adenosine 6 MG	Sagent Pharmaceuticals Inc.	25021-0301-16	Adenosine	6 MG	4	10	2	20	
J015	Injection adenosine 6 MG	AS Mediation Solutions	64488-6410-00	Adenosine	6 MG	2	1	1	1	
J015	Injection adenosine 6 MG	Bedford Laboratories	55390-0607-10	Adenosine	6 MG	2	10	1	10	
J015	Injection adenosine 6 MG	Bedford Laboratories	55390-0608-01	Adenosine	6 MG	4	1	2	2	

A new drug is approved....
what should I do?

What to do with a new drug

- Contact your GPO to determine pricing, contract status and other negotiated terms
- Contact the manufacturer for information on
 - patient assistance programs
 - reimbursement programs or assistance that outline the steps for documentation required for reimbursement
- Assign a Charge Description Master (CDM) # and a price
- Link the CDM # to the CMS billing code for new drugs
- Be aware of the billing units assigned to the product and create the necessary crosswalk

What to do with a new drug

- Stay aware of assignment of a designated code to replace this (Unfortunately no easy-to-use recap available, just quarterly CMS website updates)
- Submissions using the wrong code are rejected
- If used in Outpatient settings, ensure the code assigned matches the billing units being reimbursed, consider crosswalks to correct automatically (commercial product or in-house created)
- Activate the drug in the Pharmacy Computer Drug Master File and link it to the CDM # (Don't forget to change miscellaneous codes for actual and designated ones as soon as they're assigned)
- Contact the Pharmacy Computer Vendor if new drug data is not provided on a timely basis
- Avoid miscellaneous CDM numbers and "in-house-created" drug entries. They're a reimbursement *kiss of death*

Specialty Pharmacy & White Bagging

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What is white bagging?

- The practice of having patient specific medications or supplies delivered directly to the practice setting (outpatient infusion center, physician office, hospital) for use by a specific patient
- May be pre-paid or complimentary
- No billing for these products/supplies transpires



How is this different from brown bagging?

- Brown bagging is the practice of the patient bringing medications to the practice setting, also known as "meds from home"
- Product integrity, storage, etc., become issues



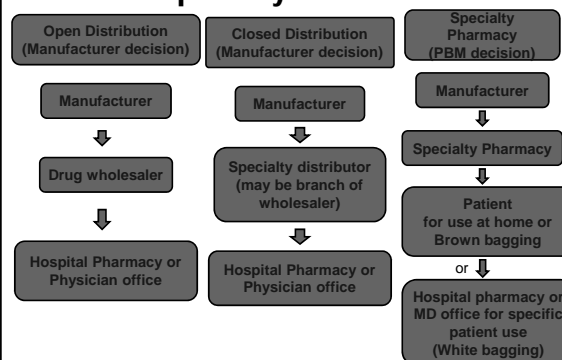
Why white bagging evolved

- Requirements of some insurance carriers mandating the use of specialty pharmacy
- Requirements of some manufacturer supported Patient Assistance programs
- Some FDA assigned REMS programs

Patient Assistance Programs

- Determine availability of manufacturer's patient assistance program www.needymeds.com, www.rxassist.org
- Obtain necessary patient documentation (W-2 forms, check stubs, etc.) and submit to the pharmaceutical manufacturer
- Manufacturer will contact the practitioner or clinic staff regarding patient eligibility
- Brown bagging occurs If manufacturer provides home delivery option and med is administered in the clinic,
- White bagging happens when the med is delivered directly to the practice site on the patient's behalf

Specialty Channels





What do white bagging and specialty pharmacy have to do with each other?

- The specialty pharmacy shipping the product directly to the practice site on behalf of the patient (white bagging) has already billed the insurance company for the product and collected the co pay from the patient/secondary insurer
- There is no opportunity for the practice site to bill for the product

What to do?

Decisions, decisions, decisions.....

When could these specialty products and offerings become an issue for you?

Location of patient	Problems?
Lives at home, uses meds at home	No issues
Seen at OP Clinic, uses meds at home	No issues
Seen at OP clinic, meds administered in clinic	Need a hospital policy
Admitted as inpatient, meds needed during stay	Need a hospital policy

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What is the Win-Win Position?

Specialty Products	Pharmacy-Centric	Patient-Centric	Who bears drug cost?	\$\$\$ Collection?
Don't allow	✓	No	Hospital	No
Re-dispense, charge for meds & admin.	✓	No	Hospital	No
Allow, charge for admin.	✓	✓	Specialty Distributor	For CPT code drug admin. only
Allow with no charges	No	✓	Specialty Distributor	No

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If Specialty Pharmacy's Involved, Should I Be Pharmacy-Centric or Patient-Centric?

	PharmacyCentric	Patient Centric
Where Patient sees MD	Hosp OP or MD Clinic Hosp Collects \$	Hosp OP or MD Clinic Hosp Collects \$
Who provides patient support services?	Hospital OP or MD Clinic	Hospital OP or MD Clinic & Specialty Pharmacy
Who provides drug & supplies?	Hospital OP or MD Clinic No Revenue	Specialty Pharmacy
Where is drug administered?	Hospital OP or MD Clinic Hosp/MD Collects \$ Home (no \$)	Hospital OP or MD Clinic Hosp/MD Collects \$ Home (no \$)
Who provides MTM?	OP Pharmacy Possible \$ Specialty Pharmacy	OP Pharmacy Possible \$ Specialty Pharmacy

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Think about it.....

Specialty pharmacy is about managing logistics. Do you really want to add a huge financial burden to a patient because you can't figure out the logistics?

Steps to White Bagging

- Form a multidisciplinary team to include
 - Patient navigators
 - C-Suite representative
 - Hospital insurance team rep
 - Infusion Pharmacy Director/Facility Pharmacy Director
 - Infusion Clinic Director(s)
 - Anyone else??
- Determine participating outpatient clinic areas
- Identify medications to be white bagged
- Determine the Specialty Pharmacies used by predominant payers
- Vet the specialty pharmacies that will be a part of the program
- Design the flow to ensure product availability at the time of the administration clinic visit

More Steps: Examine infrastructure and correct weaknesses

- The Infusion Clinic
 - doesn't have a patient navigator
 - doesn't have a person who consults with the patient to determine insurance coverage and understand it's nuances
- CDM lacks appropriate descriptions to capture drug administration codes for situations where the drug administered has a zero charge
- Outpatient pharmacy serving the infusion clinic doesn't have sufficient refrigerated storage for segregating patient specific white bag drugs
- Pharmacy
 - doesn't have an inventory system in place for Patient Assistance, Specialty Pharmacy or complimentary products
 - doesn't know the payer status of the patient when receiving a medication order
 - doesn't have a working relationship with the patient navigators
 - doesn't have a working relationship with the Insurance Team
 - doesn't know how to vet a specialty pharmacy

Some Pharmacy Specific Responsibilities

- develop an inventory program for Patient Assistance, Specialty Pharmacy and Complimentary products
- even if at minimum this could be an excel spreadsheet that tracks all complimentary/not purchased drugs
- patient specific products cannot be placed general inventory, both physically and for documentation purposes
- must be able to manage both drugs that are sent one dose at a time and drugs sent for the entire course of therapy.
- All of this is a lot of work for a department that's not getting any \$ credited to their bottom line.
 - Don't underestimate the impact of this on attitude of cooperation or not
- Pharmacy should be getting an allotment of drug admin fees paid (most aren't, haven't even asked for it or have been rebuffed)
- A savvy insurance person at the facility should be advocating for a handling fee to be paid to the pharmacy department for their role

**Don't feel helpless,
there's lots of
RESOURCES out
there.
Do you know where to
get them?**

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- If you missed any of the MLN Matters Articles notices as of June 2007, please review the archive available at: <https://list.nih.gov/cgi-bin/wa.exe?A0=MLNMATTERS-L>
- Centers for Medicare & Medicaid Services Medicare Learning Network at <http://www.cms.hhs.gov/MLNProducts/downloads>
- MAC/Fl websites, use the one for your area
- Professional organization websites e.g. ACCC at <http://www.cms.ACCC-cancer.org>
- SE1234 – Important Information Concerning the Medicare Crossover Process and State Medicaid Agency Requirements for National Drug Codes (NDCs) Associated with Physician-Administered Part B Drugs
 - <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1234.pdf>

ACCConnect

A bi-weekly newsletter for members of the Association of Community Cancer Centers

NEW! ACCC Oncology Drug Database Tool
Now Available

ACCC is excited to announce the launch today of our new online Oncology Drug Database. This comprehensive, robust resource is for any cancer care team member who needs quick access to information on oncology drug coding, billing, and reimbursement—including physicians, nurses, pharmacists, administrators, practice managers, coders and billers, and financial advocates.

ACCC's Oncology Drug Database is easy to use. Typing the drug name (generic or brand) into a search box directs you to a drug-specific webpage with all of the information for that drug, including:

- Billing (HCPCS, NDC) and diagnosis (ICD-9) codes
- Reimbursement amounts
- FDA-approved indications
- Drug manufacturer information, including contact information for the medical affairs department and reimbursement specialists (for drugs that remain under patent protection).

Access Oncology Drug Database and learn more here.

8/6/2014

READ OUR BLOG

2015 Proposed Rules: Not So Bad?

ACCC EVENTS

31st National Oncology Conference
October 8-10, 2014
San Diego, Calif.

Financial Advocacy Network Announces Regional Meetings

September 16, 2014, New Brunswick, N.J.

November 6, 2014, Schaumburg, Ill.