The Implications of the New Medicare Prescription Drug Legislation: Pathways to a Better Benefit

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Overview

- New Medicare Part D Prescription Drug benefit
  - Challenges in benefit design
    - Limitations on filling in the donut hole
  - Challenges in new standards for formularies and utilization management
    - “Quality” and “Cost”
  - Challenges in market-based prescription drug pricing
    - “Price”

Things I Think are Interesting but Don't Plan to Talk About

- Drug discount card
  - Provider of value?
- Significant employer subsidies to continue offering coverage
  - What will employers do: continue/add retiree drug benefits or send retirees to Part D?

Health Plans and Part D

- Providers of the Part D benefit and the endorsed card
- Will continue providing non-Part D retiree coverage for employers who seek subsidies instead
- Medicare will hopefully join health plans in seeking an enhanced evidence base
- Full risk vs reinsurance payment design
- Formulary rules being debated
- Will the "Best Price" exemption improve ability to negotiate prices?

Physicians

- More certainty that patients will follow through on prescribed therapies
  - especially low income patients
  - continuity of care concerns re donut hole
- Increased pressure for prescribing formulary drugs for a larger population
  - but no less inconvenience regarding a proliferation of formularies
- Longer term implications for current Part B covered drug
  - if dropped into Part D coverage, possibly lower levels of coverage
- Fundamentally uninvolved in drug use management

Can the Market Work?

- Kaiser Permanente as a model
  - Physicians practice as a group
    - they have access to comparative cost and effectiveness information
    - Cooperative group practice with a culture of fiduciary responsibility to the membership
  - Drug Information Service
    - Supports formulary decisionmaking
    - Clinical information provided to physicians
- How can Part D take advantage of this?

Can the Market Work?

- Physicians deal with a single formulary
  - A key, but simple, distinguishing factor, the benefit of which to physicians and patients is often overlooked and should not be underestimated
- Physician confidence in P&T and formulary review process is high
  - Formulary drug is prescribed 98 percent of the time
  - Incorporates clinical review of generics
  - Sequencing of concerns -- clinical then cost -- is critical
  - Open exception process
- Is this compliant with Part D?

Drug Use Initiatives

- Follows the formulary process
- Identifies relatively substitutable drugs
- Identifies potential economic benefit
- Promotes use of clinically appropriate alternative with same quality but lower cost
- May targets more expensive alternatives when needed by identifiable patients, when possible
- May target current patients, or only new starts, depending on the drug and the condition
  - Statins vs. SSRIs

Focus on Obvious Targets

- In 2001, five classes of drugs (16 drugs total) represented fully 22 percent of total US Rx spending (Total = $154 billion)
  - SSRI antidepressants (4 drugs/ $8.1 b)
  - Proton pump inhibitors (4 drugs/ $8.5 b)
  - LS antihistamines (3 drugs/ $4.4 b)
  - Lipid lowering statins (3 drugs/ $8.7 b)
  - Cox-2 anti-inflammatories (2 drugs/$4.4 b)

- Different strategies apply to each

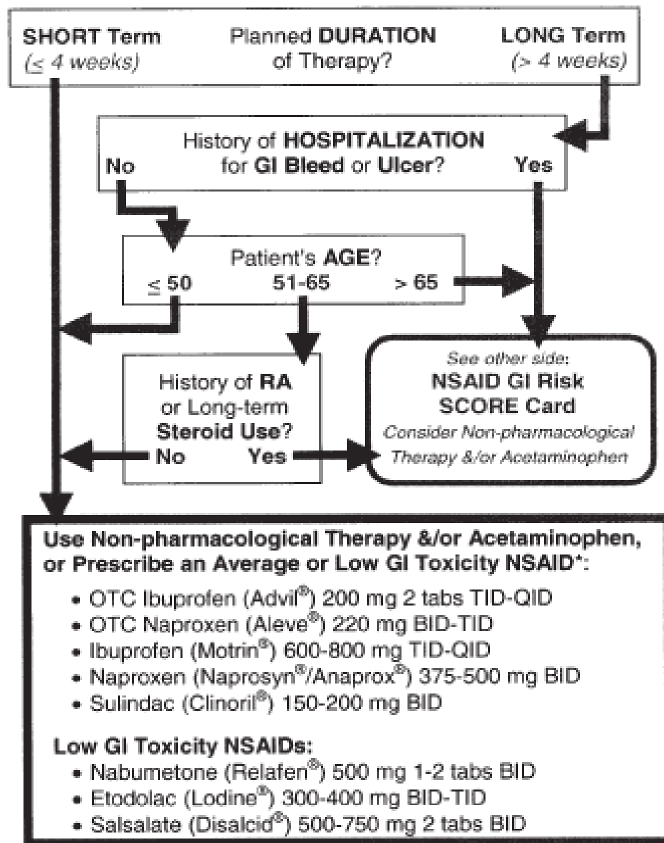
Clinical Guidelines Case Study

- Cox-2 inhibitors
- “Appropriate” treatment for between 4 and 5 percent of NSAID-using arthritis patients
  - In that group, benefit is reducing risk of GI bleeding from 1 in 75 to 1 in 200
- 50+ percent of new NSAID prescriptions in US are for Cox-2s
- KP use is approximately 5 percent
  - Result of careful application of patient criteria with support of physicians

Why did this work?

- Early recognition of limited benefit and oncoming advertising blitz
- Clinical research with Stanford and development of validated NSAID GI Risk SCORE Card
- Close monitoring and clinician feedback
- Medical Group support, based on the science

NSAID GI Risk Strategizer



*COX-2 inhibitors:

- Are **NO better** than NSAIDs at relieving pain and inflammation
- **Cause adverse renal, HTN, and CHF effects** similar to NSAIDs
- Have similar rates of dyspepsia and nausea as NSAIDs
- **Do NOT eliminate the risk of GI bleeding.** ALL beneficial effects appear to be lost with low-dose aspirin use

NSAID GI Risk SCORE Card

To determine your patient's SCORE (Standardized Calculator of Risk for Events), enter the points in the right-hand column corresponding to the appropriate answer. The total of the points is the patient's SCORE.

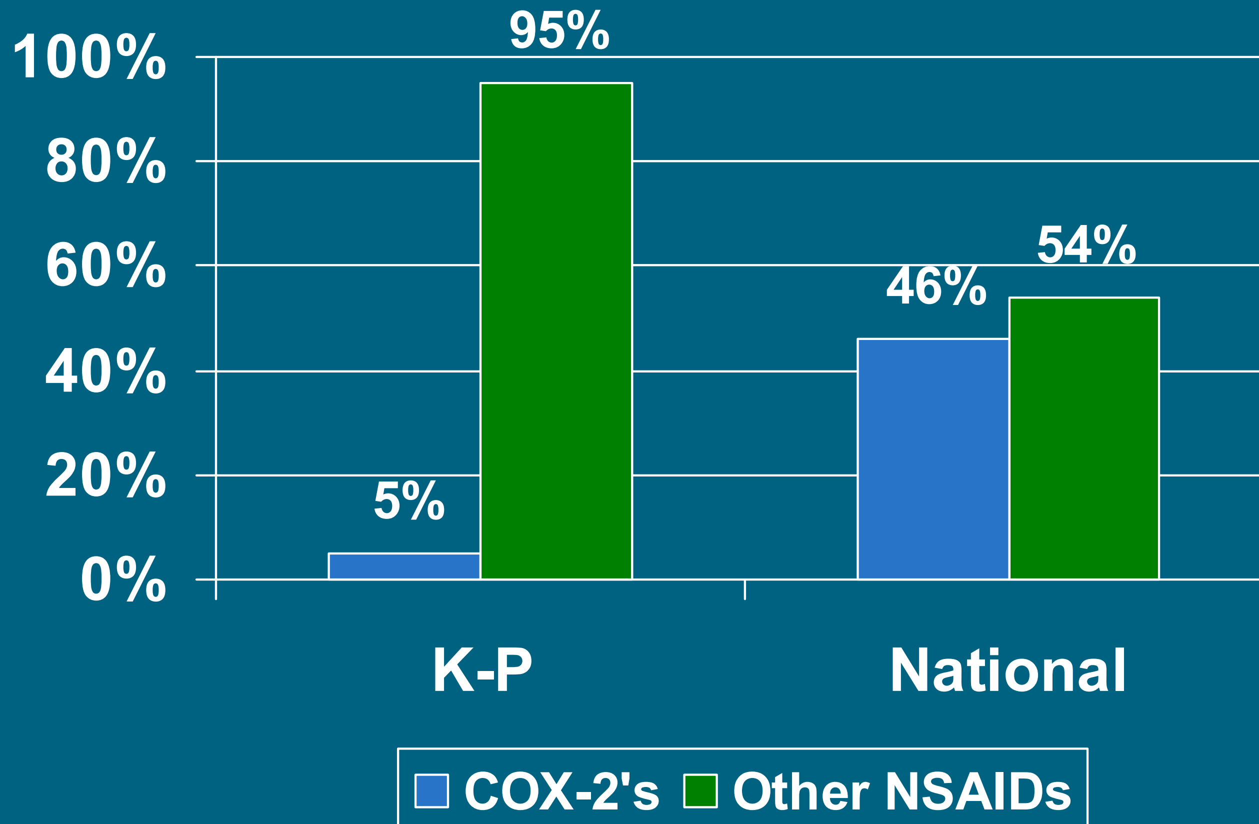
#	Question		POINTS
1.	Patient's age in years? **46 – 50** .... 8 points **51 – 55** .... 9 points **56 – 60** .... 10 points **61 – 65** .... 12 points	**66 – 70** .... 13 points **71 – 75** .... 14 points **76 – 80** .... 16 points **81 – 85** .... 17 points **>85** .... 18 points	
2.	Current health status as rated *by the patient*? **Very Well** ...... 0 points **Well** .... 1 point **Fair** .... 2 points	**Poor** .... 3 points **Very Poor** ...... 4 points	
3.	Does patient have *rheumatoid arthritis*? **No** .... 0 points	**Yes** .... 2 points	
4.	Use of oral prednisone or other oral steroids in past year? **0** mo .... 0 points **1-3** mo .... 1 point **4-6** mo .... 3 points	**7-10** mo .... 4 points **11-12** mo ...... 5 points	
5.	Hospitalized for a GI bleed or an ulcer? (*If "Yes", skip #6)* **No** .... 0 points	**Yes** .... 8 points	
6.	Has patient had GI side effects when taking NSAIDS? **No** .... 0 points	**Yes** .... 2 points	
		Total SCORE *(add all points)*: →	

Total SCORE	**TREATMENT RECOMMENDATIONS:** *First consider* non-pharmacological therapy, acetaminophen (Tylenol®), or narcotics (e.g., Tylenol® w/ Codeine, Vicodin®)
RISK LEVELS 1 & 2 ≤ **15** points *Lowest Risk Patients*	• OTC Ibuprofen (Advil®) 200 mg 2 tabs TID-QID • OTC Naproxen (Aleve®) 220 mg BID-TID • Ibuprofen (Motrin®) 600-800 mg TID-QID • Naproxen (Naprosyn®/Anaprox®) 375-500 mg BID • Sulindac (Clinoril®) 150-200 mg BID • *Alternatives:* Any NSAID from Risk Level 3 *(see below)*
RISK LEVEL 3 **16–20** points	• Nabumetone (Relafen®) 500 mg 1-2 tabs BID • Etodolac (Lodine®) 300-400 mg BID-TID • Salsalate (Disalcid®) 500-750 mg 2 tabs BID
RISK LEVEL 4* > **20** points *Highest Risk Patients*	• *Avoid NSAIDs if possible* • *Reconsider APAP or narcotics* • If NSAID can't be avoided, use PPI + low or average GI toxicity NSAID.

COX-2 are not proven safe in patients at high risk.

COX-2 Market Share

KP vs. National



Initiative Case Study

- Statins
  - Conversion program from brand simvastatin to a therapeutically equivalent dose of generic lovastatin of existing simvastatin patients
  - Requires absolute physician confidence in safety and appropriateness of the switch
  - In the process, identify patients who are not at goal and get them there
  - Overall, significant improvement in care and improvement in cost-effectiveness of the drug benefit

A Complex Demand Market

- Physicians prescribe, pharmacists dispense, patients use and insurance pays for drugs
- Patients are insulated from cost and are being stimulated, without full information, to seek specific drugs from physicians
- Physicians, plans and pharmacies are disaggregated
  - Incentives are misaligned
  - Physicians do not practice as groups
  - Physicians must use multiple formularies
  - makes purchaser cooperation difficult
- Lack of comparative data

How Does Part D Match up?

- Physicians prescribe, pharmacists dispense, patients use and Part D pays for drugs through PBMs
- Patients are somewhat insulated from cost, but coinsurance design is a useful tool
- Physicians, plans and pharmacies are disaggregated
  - Incentives are somewhat misaligned
  - Most physicians do not practice as groups
  - Physicians will use multiple formularies
- Comparative Effectiveness research funded?

Can Part D Do This?

- Physicians are only distantly involved
- Is there another way?
  - PBMs or other new entities as provider practice prescribing support infrastructure
  - Medicare has an opportunity, but it won’t happen organically

Formulary Management

- Formulary and utilization management
  2 in each class? Really?
- Likely politicization of formulary design process
  - If too onerous, likely to have separate Medicare formularies, making management more complex

Sec. 1860D-4(b)(3)(C)(i)

- Title -- "Inclusion of Drugs in All Therapeutic Categories and Classes"
- Text -- "In General--The formulary must include drugs in each therapeutic category and class of covered part D drugs, although not necessarily all drugs within each category or class."
- Report language doesn't resolve the ambiguity -- parrots text, but doesn't state that conferees considered the differences, let alone chose one approach over the other

Sec. 1860D-4(b)(3)(B)(ii)

- Text -- “In developing and reviewing the formulary, the committee shall-- take into account whether including in the formulary (or in a tier in such formulary) particular covered Part D drugs has therapeutic advantage.”

- Report --“ . . .whether including a particular covered drug in the formulary (or in a particular tier in a formulary) had therapeutic advantages . . . ”

A Short Discourse on Medicaid Best Price

- And what it implies for Medicare and market pricing of prescription drugs