

## Potential Challenges to Pricing of Biotech Products: Medicare/Medicaid and Related Pricing Developments



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# Potential Challenges to Pricing During the Clinical Trial Phase of the Product Life Cycle

- Background: You want to sign up a number of clinical sites for a clinical trial for your new drug or biological. Alternatively, you are testing a new indication for an established drug or biological. Your staff have indicated that Medicare coverage and payment are impediments to garnering support from potential clinical sites. What issues factor in?

# CMS Clinical Trial National Coverage Decision

- Clinical Trial Requirements
  - Medicare requirements
    - Must involve the evaluation of an item or service that falls within a Medicare benefit category.
    - Test must have a “therapeutic intent.”
    - Must enroll patients with diagnosed disease rather than healthy volunteers.

# CMS Clinical Trial National Coverage Decision

- “Desirable characteristics” include
  - Principle purpose is to test whether the intervention potentially improves the participants’ health outcomes.
  - Trial is not unjustifiably duplicative of existing studies.
  - Trial is sponsored by a credible organization.
  - Trial complies with Federal regulations regarding the protection of human subjects.

# CMS Clinical Trial National Coverage Decision

- “Deemed” status applies to
  - Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA.
    - Includes trials supported by centers or groups funded by any of these agencies.
  - Trials conducted under an IND reviewed by the FDA.
  - Trials exempt from an IND.
  - Self-certification of “desirable characteristics” never implemented.

# CMS Clinical Trial National Coverage Decision

- Routine costs are covered, including
  - Items and services typically provided absent a clinical trial.
  - Items and services, such as administration of product, required solely for the investigation of the item, including appropriate monitoring of effects and prevention of complications.
  - Treatment of complications.

# CMS Clinical Trial National Coverage Decision

- Not covered are:
  - The investigational item itself.
  - Data collection not directly related to clinical management.
  - Items and services customarily provided by research sponsors free of charge.

# CMS Clinical Trial National Coverage Decision

- Proposed revisions
  - Medicare requirement will potentially include:
    - Registration of study on ClinicalTrials.gov
    - Explicit consideration of subpopulations (age, gender)
    - CED standards
  - Deemed status could potentially include:
    - Mandated post-market approval studies.
    - Allowing certain unspecified “deeming entities” to certify studies.

# Coverage and Payment for Other Clinical Trials

- Can the drug or biological and related services be covered if there is not yet any approved use for the product and it is furnished to inpatients?
  - Generally not covered unless CMS instructs to the contrary.
  - But inpatient stay may still be covered.
    - Assumption by Medicare that only covered services are being paid for.
    - Excluded are costs of the product itself as well as the costs of services related to the product, such as treatment of complications.
    - If, however, sole purpose of inpatient admission is the administration of an uncovered drug or biological, then the stay is not covered.

# Coverage and Payment for Other Clinical Trials

- Can the drug or biological and related services be covered if the product is being used off-label and it is furnished to inpatients?
  - Depends on whether the use is a generally accepted medical practice (as determined by Medicare fiscal agent).
    - Fiscal agents are to use various compendia, such as the USP-NF, as a guide.
    - Alternatively, can have approval by hospital P&T Committee.
    - Must represent a cost to the hospital.
    - Must also be reasonable and necessary for the particular patient receiving the product.
  - Payment on basis of DRG

## Coverage and Payment for Other Clinical Trials

- Can the drug or biological and related services be covered if there is not yet any approved use for the product and it is furnished to patients in an outpatient setting?
  - No coverage for these products under Medicare, or any services related to the administration of these products.
  - Reimbursement is on a procedure-by-procedure basis. Other unrelated procedures may separately qualify for coverage.

## Coverage and Payment for Other Clinical Trials

- Can the drug or biological and related services be covered if the product is being used off-label and it is furnished to patients in an outpatient setting?
  - **Requires:**
    - Must be included, or approved for inclusion, in USP-NF or other specified compendia.
    - Cannot be usually self-administered.
    - Must be furnished “incident to” a physician’s service.
    - Must be reasonable and necessary for the particular patient.
  - **Reimbursement is generally at ASP + 6%.**

# Potential Challenges to Pricing for Approved Drug Used for Inpatients

- Background: Congratulations. Your product has been approved for the indication for which it was tested. You now want to make sure that you are treated favorably under Medicare to maximize the appeal of the product to your customers. If these customers are hospitals intending to use the product in the inpatient setting, what considerations are there?

# Potential Challenges to Pricing for Approved Drug Used for Inpatients

- Coverage
  - **Requires generally:**
    - Service must fall within a Medicare benefit category.
    - Service must be rendered by a qualified provider.
    - Services must be reasonable and necessary and not statutorily excluded.

# Potential Challenges to Pricing for Approved Drug Used for Inpatients

- Can be determined based on:
  - Individual claims determination.
  - Local coverage determination (LCD).
  - National coverage determination (NCD).
- Denials can be appealed, but not by manufacturers.

# Potential Challenges to Pricing for Approved Drug Used for Inpatients

- Reimbursement
  - Generally DRG assignment. Based on “predecessor” technology.
  - Can qualify for add-on payment as a new technology, if:
    - New product.
    - Payment rate otherwise inadequate.
    - Substantial improvement over existing technologies.

# Potential Challenges to Pricing for Approved Drug Used in Outpatient Settings

- Background: Your product is to be used for an approved use in the outpatient setting. What considerations are there?
- Coverage – must meet the conditions for coverage for all covered outpatient drugs, and must otherwise be furnished by a qualified person and be reasonable and necessary.

# Potential Challenges to Pricing for Approved Drug Used in Outpatient Settings

- How are physician offices and freestanding clinics reimbursed for covered products?
  - Payment is at ASP + 6%, which is calculated in one of two ways, depending upon whether product is “single source” or “multiple source”.
    - Multiple source drugs share all of the following:
      - therapeutical equivalence;
      - pharmaceutical equivalence; and
      - bioequivalence.
    - Single source drugs are either:
      - biologicals; or
      - drugs that do not qualify as multiple source drugs; and are produced or distributed under an NDA.

# Potential Challenges to Pricing for Approved Drug Used in Outpatient Settings

- For multiple source drugs, payment is calculated as the weighted average of the sales of all multiple source drugs in the group, multiplied by 106%.
  - Certain exemptions apply.
- For single source drugs, payment is calculated as the average sales price of that drug, multiplied by 106%.
  - Same exemptions apply.
- Represents a departure from traditional CMS coding policy.

# Potential Challenges to Pricing for Approved Drug Used in Outpatient Settings

- Reimbursement to Hospital Outpatient Departments for covered products.
  - Packaged; or
  - ASP + 6%.
  - Factors used to determine whether a drug is packaged or paid separately include: (a) whether the cost per administration is over \$55; (b) whether the drug qualifies as a “new technology”; and (c) whether the drug ever had pass-through payment status.

## Potential Challenges to Pricing Raised during Sales Contract Negotiations

- Background: Manufacturer has entered into negotiations to sell the product to a large MCO, the 800 pound gorilla that is expecting significant concessions. What governmental pricing considerations are there?
- ASP issues. Generally will figure into sales that affect ASP.

# Potential Challenges to Pricing Raised during Sales Contract Negotiations

- Medicaid drug rebate obligations.
  - Applies to covered outpatient drugs, which includes biologicals.
  - For single source and “innovator multiple source” drugs, the rebate amount is calculated by taking the difference between average manufacturers price (AMP) and best price (BP), and multiplying by Medicaid utilization.
    - AMP is generally the average of prices to the retail class of trade.
      - HMOs and hospitals generally excluded, but Part D PDPs are included.
    - BP is best price to any bulk customer, except for certain governmental entities, safety net hospitals, SPAPs, Part D PDPs, and others.
      - BP exceptions are ASP exceptions as well.

# Potential Challenges to Pricing Raised during Sales Contract Negotiations

- Compliance issues.
  - Do discounts qualify for safe harbor treatment?
  - Are items or services being purchased from customer which aren't needed and will not be used?
    - If not a “bona fide service fee”, CMS proposes to include in AMP and BP calculations.
    - Schering Plough \$345 million settlement – among other things, alleged that purchased utilization data that the company did not use.

# Potential Challenges to Pricing Resulting from Patient Assistance Programs

- Background: Manufacturer wants to assist patients with the costs of its product. Some of the patients to receive assistance are indigent and want a full or partial reduction in the entire cost of the drug or biological. Other patients have insurance, perhaps Medicare Part B or Part D, and they are seeking a reduction in their coinsurance obligations.

# Potential Challenges to Pricing Resulting from Patient Assistance Programs

- Can the manufacturer offer reductions in the coinsurance obligations for Part D enrollees?
  - **Only acceptable if the PAP is operated:**
    - Through a bona fide non-profit entity or coalition;  
or
    - Outside of the operation of the Part D program.

# Potential Challenges to Pricing Resulting from Patient Assistance Programs

- Can manufacturers offer reductions in coinsurance obligations for drugs reimbursed under Part B to Medicare beneficiaries?
  - Could be viewed as remuneration to physicians and beneficiaries for a referral of Federal business.
  - See OIG Advisory Opinions 02-13 and 03-3 (pointing out that these programs incentivize patients to look at cost factors rather than quality; that the government does not necessarily benefit; and that, as an alternative, the programs could be designed to avoid any billing to the Federal government).

# Potential Challenges to Pricing Resulting from Patient Assistance Programs

- Medicaid drug rebate implications
  - Under a current CMS proposal, could affect both AMP and BP, unless the rebate is redeemed directly with the manufacturer.
    - Affects all classes of patients, and not just Medicare and Medicaid beneficiaries.

# Developments Regarding Product Discounting

- Price discrimination/Class of trade issues
  - What classes of purchaser distinctions are defensible?
  - *Drug Mart Pharmacy Corp. v. American Home Products Corp.* (E.D.N.Y., Jan. 25, 2007)
- Multi-product discounting/bundling
  - Antitrust tying challenges
    - *Ortho Biotech Products, L.P. v. Amgen, Inc.* (D.N.J. 2006)
  - Antitrust monopoly leveraging challenges
    - *Schor v. Abbott Laboratories* (7<sup>th</sup> Cir. 2006)

## Developments Regarding Product Discounting (cont'd)

- **CMS Consideration of bundling**
  - CMS proposed rule (Dec 2006) – when multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across the drugs in the bundle
  - Medicare Payment Advisory Commission (MedPAC) report (Jan. 2007) – recommendation regarding calculation of average sales price of drugs sold in a bundle
  - Gov't Accounting Office Report, *Bundling Medicare's Payment for Drugs with All ESRD Services Would Promote Efficiency and Clinical Flexibility* (Dec. 2006)

# Developments Regarding Comparative Effectiveness

- First comparative effectiveness trial of pioneer drugs by National Institutes of Health, announced Feb. 2007
  - Comparative trial of two Genetech drugs (Lucentis - \$2,000/dose and Avastin - \$40/dose)
  - Asserted potential Medicare savings of \$1 billion/year
- Suggested creation of a U.S. comparative effectiveness review agency
  - Similar to U.K.'s National Institute for Health and Clinical Excellence
- Increasing impact of payor considerations on development decisions
  - Termination by Pfizer of codevelopment agreement with Organon (Dec. 2006) for asenopine – asserting comparative effectiveness information as the most important factor in determining whether to continue compound development.

# Developments Regarding Pricing Limits/Controls

- Congressional pressure on CMS concerning drug reimbursement levels
  - House Ways and Means Comm. (Dec. 2006) – call for immediate changes to reimbursement systems for Amgen’s Epogen
  - Proposals to revise the Medicare Modernization Act of 2003 to allow direct government price negotiations for Medicare Part D drugs with manufacturers
  - Proposed legislation creating regulatory pathway for approval of generic biologics to deal with cost concerns
    - Effects on biotech company valuation

# Developments Regarding Pricing and Scope of Clinical Trials

- Pricing concerns generating new focus on pharmacoeconomics at early product development stages
  - E.g., Johnson & Johnson's decision in 2005 to train its drug research scientists in pharmacoeconomics, to incorporate cost-effectiveness at an early stage in the R&D process
- Focus on labeling and reimbursement in clinical trails
  - Importance of assessing and selecting among potential indications for a proposed product and the likely relative reimbursement levels among them in deciding on the focus of clinical trials.