The Pharmacy and Therapeutics Process: A Case Study on Sincalide

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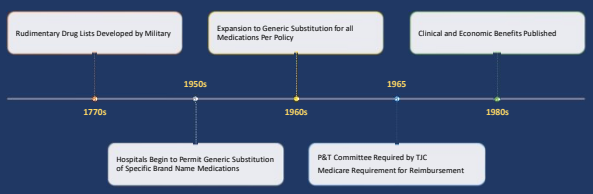
Formulary, Defined

- A regularly updated, *evidence-based* list of available medications
  - Hospital- or facility-maintained
  - Payer-maintained
- Includes medication-associated devices, products, policies, decision-support tools, ancillary information, and organizational guidelines
- Updates and changes executed by an organizational *formulary system*

Ciccarello C, Leber Bilstein M, Leonard MC, et al. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. Am J Health Syst Pharm. 2021. 78(10):907-918

2

Drug List to Pharmacoeconomic Framework



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Case Scenario (Part 1)

You are the manager of the local nuclear pharmacy. Your local clients reach out to you regarding the national shortage of sincalide that has impaired their ability to perform hepatobiliary imaging. Your pharmacy, due to its limited purchasing power, is also unable to purchase any sincalide. However, you are aware of a new manufacturer that has ample stock for sale. Which hospital committee would be the best point of contact regarding purchasing from this new supplier?

A. Radiation Safety Committee
B. Pharmacy and Therapeutics Committee
C. Medication Safety Committee

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The Pharmacy and Therapeutics (P&T) Committee

- Medical Staff Responsible for Formulary System Oversight
  - Prescribers, pharmacists, nursing staff, administrators, ancillary support staff
- Provide organizational evaluation, education, and advisement on all matters related to use of available medications
- Oversee all policies and procedures related to medication use
- *"Objectively appraise, evaluate, and select drugs for the formulary."*

Ciccarello C, Leber Billstein M, Leonard MC, et al. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. Am J Health Syst Pharm. 2021. 78(10):907-918
Baker D, Barrington C, Cannon E, et al. AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics Committees: What's Next? J Manag Care Spec Pharm. 2020;26(1):48-53

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The Pharmacy and Therapeutics (P&T) Committee

- Other P&T Responsibilities Include
  - Medication Use Evaluation (MUE)
  - Medication Safety
    - Adverse Drug Event Monitoring
    - Medication Error Prevention
  - Practice Protocol Development
  - Guideline Development
  - Clinical Pathway Development
  - Medication Use Restriction
  - Drug Shortage Management
  - Appropriate Selection of Manufacturers and Suppliers

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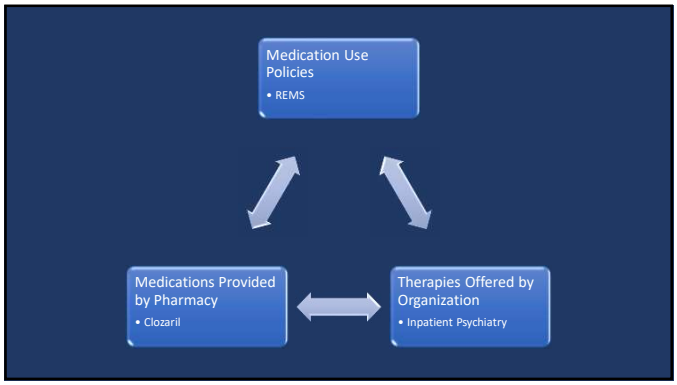

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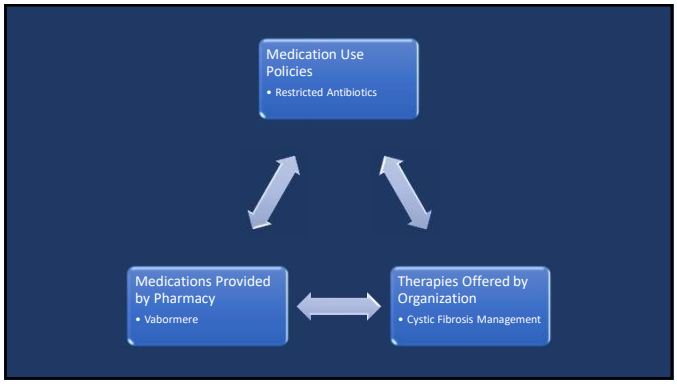

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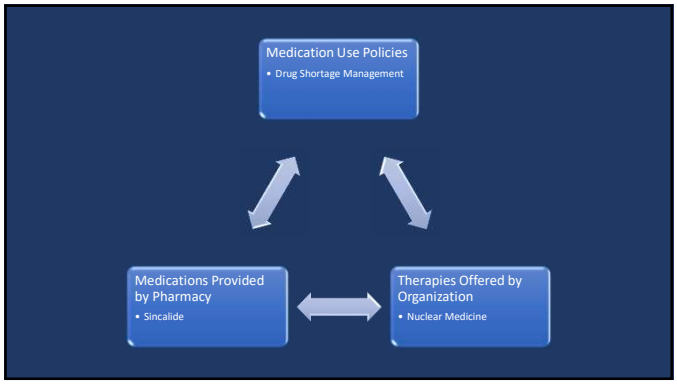

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Case Scenario (Part 2)

You are the manager of the local nuclear pharmacy. Your local clients reach out to you regarding the national shortage of sincalide that has impaired their ability to provide hepatobiliary imaging. Your pharmacy, due to its limited purchasing power, is also unable to purchase any sincalide. However you are aware of a new manufacturer that has ample stock for sale. Which P&T responsibility/ies does purchasing from this alternative supplier fall under?

A. Medication Safety
B. Appropriate Selection of Manufacturers and Suppliers
C. Drug Shortage Management
D. Both B and C

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Case Scenario (Part 2)

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D. Both B and C

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Generic Drugs

- In general, do *NOT* require approval by P&T committee
- Considered Bioequivalent by the FDA - "AB rated"
  - *Approved Drug Products with Therapeutic Equivalence Evaluations*
  - *"The Orange Book"*
- May be subject to a safety review
  - Look alike, sound alike
  - Narrow Therapeutic Index Medications

Ciccarello C, Leber Billstein M, Leonard MC, et al. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. Am J Health Syst Pharm. 2021; 78(10):907-918
Orange Book Preface. US FDA. Retrieved Oct 1, 2023 from https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface#rld

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Drugs Approved Using 505(B)(2) Pathway

- A portion of the drug application relies on investigations not conducted by the applicant
  - Applications can rely partially or completely on published literature
- Applications may rely on safety and efficacy data already evaluated and approved by the FDA
  - Similar to the process required for an ANDA
- *"An application submitted pursuant to 505(B)(2) of the Act is appropriate even when it could also be submitted in accordance with a suitability as defined at section 505(J)(2)(C) of the Act."*

Applications Covered by Section 505(b)(2). US FDA. Retrieved Oct 1, 2023 from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2

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Drugs Approved Using 505(B)(2) Pathway

- Approvals for New Chemical Entities/New Molecular Entities
  - Supporting data relies on published literature
  - Less likely to be based on previously approved safety/efficacy data
  - New botanical/natural substances or recombinant substances
    - Where studies are required to show substance is the same as that in a listed product
- Approvals for Changes to Previously Approved Drugs
  - Dosage forms, routes, strengths, formulations, dosing regimens, salt form, indication, new combination product of individually approved drugs, indications
- Bioequivalence
  - Generally, should be at least as good as reference drugs
  - Not a means for approval of drugs with poor bioavailability
  - May have more favorable or optimized kinetics

Applications Covered by Section 505(b)(2). US FDA. Retrieved Oct 1, 2023 from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2

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Reviewing Sincalide in "The Orange Book"

Mkt Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
Rx	Sincalide	Kinevac	N017697	Injectable	Injection	0.005 mg/vial		RLD	RS	Bracco Diag, Inc
Rx	Sincalide	Sincalide	N210850	Powder	Intravenous	0.005 mg/vial		RLD	RS	MAIA Pharm, Inc

URL: accessdata.fda.gov/scripts/cder/ob/index.cfm
Search by brand name, generic name, manufacturer, dosage form, etc.

Retrieved Oct 1, 2023 from https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

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Market Status Includes Prescription, Over the Counter, and Discontinued Medications

Retrieved Oct 1, 2023 from https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

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The Specific Application Number Identifying the NDA or ANDA

Retrieved Oct 1, 2023 from https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

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Therapeutic Equivalence Code Assigned by the FDA

- *A Codes - Listed Drug Products are Considered Bioequivalent*
  - *AA, AB, AN, AO, AP, AT*
- *B Codes - Listed Drug Products are NOT Bioequivalent*
  - *B* - FDA removed A code based on new data*
  - *BP – Bioequivalance data pending review*
  - *BD – Documented issues with bioequivalance*

Retrieved Oct 1, 2023 from https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm
Orange Book Preface. US FDA. Retrieved Oct 1, 2023 from https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface#rld

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Reference Listed Drug

An approved drug that the FDA has ruled safe and efficacious

Retrieved Oct 1, 2023 from https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm
Orange Book Data Files. US FDA. Retrieved Oct 1, 2023 from https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files

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Reference Standard

The formulation, designated by the FDA, which must be used by drug developers for in vitro bioequivalence testing when submitting an ANDA for a new generic drug.

Retrieved Oct 1, 2023 from https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm
Orange Book Data Files. US FDA. Retrieved Oct 1, 2023 from https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files

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Case Scenario (Part 3)

You contact the director of pharmacy regarding purchasing sincalide from MAIA during the Bracco shortage. The director is willing to authorize purchasing from this alternative supplier but seeks clarification on the FDA approval status of this medication. Which of the following statements is true?

A. MAIA is a 503B outsourcing facility producing sincalide
B. MAIA sincalide is proven to be bioequivalent to Bracco sincalide
C. MAIA holds its own NDA for sincalide for injection, approved through the 505(B)(2) pathway

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C. **MAIA holds its own NDA for sincalide for injection, approved through the 505b(2) pathway**

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Selecting a Reliable Drug Supplier

- P&T develops policies and guidelines for supplier selection
- Department of pharmacy ultimately responsible for implementation
  - Quality of purchased medications
  - Sufficient quantity to meet demand
  - Ultimate source of all pharmaceuticals

Ciccarello C, Leber Bifstein M, Leonard MC, et al. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. Am J Health Syst Pharm. 2021. 78(10):907-918.

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Selecting a Reliable Drug Supplier

- Information to Gather and Present
  - Analytical Control Data
    - Sterility Data
    - Bioavailability Data
    - Bioequivalance Data
    - Raw Material and Finished Material Testing
  - Information on prior product recalls
- Preparations and testing should be consistent with USP requirements

American Society of Hospital Pharmacists. ASHP Guidelines for Selecting Pharmaceutical Manufacturers and Suppliers. Am J Hosp Pharm. 1991. 48:523-524

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503B Outsourcing Facilities

- FDA regulated and FDA inspected
  - Standard of care is 503B specific CGMP
  - Not required to be a licensed pharmacy
  - Licensed pharmacist shall oversee compounding activities
- May perform anticipatory compounding for distribution for office use
  - Medications labeled "Not for Resale"
- Copies of FDA approved medications can be compounded during shortages

American Society of Health-System Pharmacists. ASHP Guidelines on Outsourcing Sterile Compounding Services. Am J Health Syst Pharm. 2015; 72:1664-1675

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503B Outsourcing Facilities

- Important to Consider Quality Standards
- Limited number of Active Pharmaceutical Ingredients for bulk compounding
- FDA registration does not specify which types of activities may occur in a facility – only the conditions under which these activities should take place
  - e.g. No distinction between high risk and medium risk compounds

American Society of Health-System Pharmacists. ASHP Guidelines on Outsourcing Sterile Compounding Services. Am J Health Syst Pharm. 2015; 72:1664-1675
List of Bulk Drug Substances for which there is a Clinical Need under Section 503B of the FD&C Act. 87 Fed. Reg. 4240-4252. (01/27/2022)

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FDA-483, Inspectional Observations

- Notification of concerns or potential violations
  - Violations corrected during inspection
  - Facility may respond in writing with corrective measures within 15 days
- Not a final determination of non-compliance
- Does not indicate that findings have been resolved
- Listed on FDA website on date of inspection when issued

American Society of Health-System Pharmacists. ASHP Guidelines on Outsourcing Sterile Compounding Services. Am J Health Syst Pharm. 2015; 72:1664-1675

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Case Scenario (Part 4)

You now have approval to purchase sincalide from MAIA during drug shortage periods. What information can you provide to present MAIA as a reliable or unreliable drug supplier?

A. A list of previous drug recalls (or lack thereof)
B. Information on product sterility, stability and bioavailability testing
C. FDA-483 forms and their findings (or lack thereof)
D. All of the above

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Case Scenario (Part 4)

You now have approval to purchase sincalide from MAIA during drug shortage periods. What information can you provide to present MAIA as a reliable or unreliable drug supplier?

A. A list of previous drug recalls (or lack thereof)
B. Information on product sterility, stability and bioavailability testing
C. FDA-483 forms and their findings (or lack thereof)
D. All of the above

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Pharmacoeconomic Evaluations

- Evaluations are made from patient, prescriber, and payer perspectives
- Cost-effectiveness analyses
  - Shows the minimum cost per margin of clinical advantage
  - Rely on very high-quality data and evidence
- Cost-utility analyses
  - Incremental quality of life benefit per incremental cost of investment
  - May be useful – include patient perspective of medication use
- More commonly:
  - Demonstrate negative clinical outcomes associated with cheaper alternatives
  - Demonstrate bioequivalence and select cheaper alternative

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Coding Considerations

- Nuclear Medicine Departments Frequently Housed in Hospitals
  - Inpatient Imaging Performed
  - Outpatient Imaging Performed
  - Patient Admission Status Affects Billing
- Inpatient Billing Coded Using ICD-10-PCS
  - Diagnosis-Based Coding System Maintained by CDC
  - Nuclear Medicine Category
    - Stratified by Planar vs Tomographic
    - Stratified by Organ System Imaged
    - Stratified by Radionuclide utilized (e.g. Tc99m vs Other)

Overview of Coding and Classification Systems. CMS. Retrieved Oct 1, 2023 from https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coding/overview-coding-classification-systems

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Coding Considerations

- Outpatient Procedure Billing Coded Using HCPCS Level I and II Codes
  - ICD-10-CM
    - Diagnostic Information
  - HCPCS Level I Codes
    - Identify Services and Procedures Provided
      - Evaluation and Management
      - Anesthesiology
      - Surgery
      - Radiology
      - Pathology and Laboratory
      - Medicine

Overview of Coding and Classification Systems. CMS. Retrieved Oct 1, 2023 from https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coding/overview-coding-classification-systems

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Coding Considerations

- Outpatient Procedure Billing Coded Using HCPCS Level I and II Codes
  - HCPCS Level II
    - Expand Upon/Clarify Level I Codes
    - Identify Products, Supplies, and Services
      - Ambulance Rides
      - Certain Drugs and Biologicals
      - Durable Medical Equipment
    - Modifiers and miscellaneous codes
      - Special Circumstances
        - Used Equipment
        - No HCPC level II code available for newly approved products

Overview of Coding and Classification Systems. CMS. Retrieved Oct 1, 2023 from https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coding/overview-coding-classification-systems
Healthcare Common Procedure Coding Systems Level II Coding Procedures. CMS. Retrieved Oct 1, 2023 from https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf

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Coding Considerations

- "J Codes" - HCPCS Level II Codes for Certain Medications
  - Payable under Medicare Part B (Not Part D)
  - Physician Administered, Procedural, Clinic Based, Infusions, etc.
- Linked to groups of NDCs that specify billable products/packages
  - Listed under NDC-HCPCS crosswalks updated quarterly by CMS
  - Leverage selection of specific NDCs for utilization

October 2023 ASP NDC-HCPCS Crosswalks. CMS. Retrieved Oct 1, 2023 from https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files

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Sincalide Injection J Code

- J Code: J2805
- Billable units: 1
- HCPCS dosage: 5 mcg
- Covered NDC Numbers and manufacturers
  - Bracco Diagnostics: 00270-0556-15
  - Fresenius Kabi USA: 63323-0579-05
- MAIA sincalide is NOT included under J2805

October 2023 ASP NDC-HCPCS Crosswalks. CMS. Retrieved Oct 1, 2023 from https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files

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Sincalide Injection J Code

- J Code: J2806
- Approved J Code for sincalide by MAIA.
  - NDC: 70511-0131-84
- Applicant suggested language: "Sincalide Injection, Extended Life"
- Approved language: "Injection, sincalide (maia) not therapeutically equivalent to J2805, 5 micrograms"
- *As a result, sincalide purchased from MAIA cannot be coded using the same J code as other sincalide products.*

CMS HCPCS Application Summaries and Coding Recommendations. First Quarter 2023 HCPCS Coding Cycle. CMS. Retrieved Oct 1, 2023 from https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-1-2023-drugs-and-biologicals-updated-07/05/2023.pdf

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Other Reimbursement Considerations

- Reimbursement no longer centered on
  - Manufacturer Contracts
  - Wholesaler Agreements
  - Inpatient Reimbursement
- Must consider reimbursement programs from Medicare/Medicaid, commercial and private payers, and programs such as 340B
- Site of care decisions and determinations of where medications will be administered may affect reimbursement considerations

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340B Drug Pricing Program

- Created in 1992 under the Public Health Service Act
  - *"To stretch scarce federal resources to reach more eligible patients and provide more comprehensive services."*
- Manufacturers required to offer rebates
  - For outpatient medications
  - To specific safety net organizations
- Patients and covered entities indirectly benefit from savings
  - Funds can be re-allocated at the discretion of the covered entity

Radford A, Slifkin R, Schur C, et al. Rural Hospitals: are you missing out on drug savings? Healthc Financ Manage. 2008 Jun; 62(6): 82-85
Rana I, von Oehsen W, Nabulsi NA, et al. A comparison of medication access services at 340B and non-340B hospitals. Res Social Adm Pharm. 2021 Nov; 17(11): 1887-1892

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340B Drug Pricing Program

- Covered entities provide care to indigent and underserved populations
  - Federally Qualified Health Centers (e.g. Tribal Health Centers)
  - Ryan White HIV/AIDS Program Grantees
  - Hospitals
    - Childrens' Hospitals
    - Critical Access Hospitals
    - Disproportionate Share Hospitals
    - Free Standing Cancer Hospitals
    - Rural Referral Centers
    - Sole Community Hospitals
  - Specialized Clinics (e.g. Black lung clinics, TB clinics, STD clinics, etc.)

June 2022. *340B Eligibility*. HRSA. Retrieved Oct 1, 2023 from https://www.hrsa.gov/opa/eligibility-and-registration

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340B Drug Pricing Program

- Only patients of covered entities under 340B can receive medications purchased at 340B discounted prices
- Duplicate rebates are forbidden on 340B medications
  - Not eligible for participation in Medicaid rebate programs
  - "Carve in" entities plan to use 340B to supply medications for Medicaid patients
  - "Carve out" entities do not use 340B to supply medications to Medicaid patients
  - Claims must be distinct and separate
- 340B medications cannot be used for inpatients
- Covered entities must certify that 340B medications will not be purchased under a GPO.

Radford A, Slifkin R, Schur C, et al. Rural Hospitals: are you missing out on drug savings? Healthc Financ Manage. 2008 Jun; 62(6): 82-85
July 2020. *Duplicate Discount Prohibition*. HRSA. Retrieved Oct 1, 2023 from https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion

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Medicaid Drug Rebate Program

- Manufacturers enter into National Drug Rebate Agreements
  - State departments of Medicaid agree to cover most medications manufactured by a participant in exchange for rebates from the manufacturers
  - Payers must be notified by manufacturer of newly marketed drugs as they are developed
- Manufacturers issue quarterly rebates to state Medicaid programs
  - Outpatient pharmacy claims for prescriptions only
  - Office use and physician administered prescriptions may be submitted
- MDRP participants are required to enroll in 340B and Federal Supply Schedule (VA)

29 Dec 2022. *Medicaid National Drug Rebate Agreement (NDRA)*. CMS. Retrieved Oct 1, 2023 from https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-national-drug-rebate-agreement-ndra/index.html

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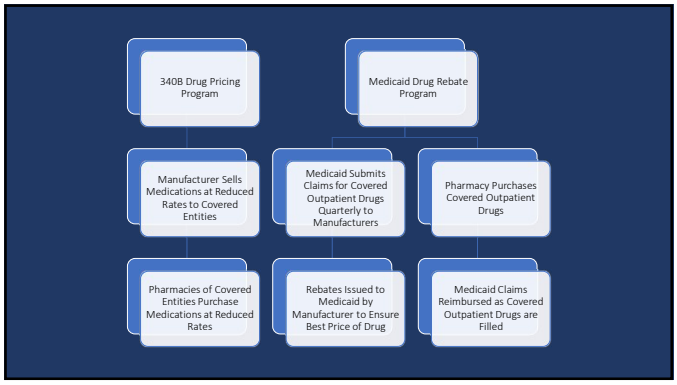

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Case Scenario (Part 5)

The director of pharmacy at one of your client hospitals realizes that sincalide produced by MAIA is not available through the GPO that her hospital network uses, but she can purchase a supply directly from the manufacturer, which will help mitigate drug supply interruptions. How can you help to ensure proper billing for sincalide by MAIA?

A. Notify Billing that J2806 must be used when MAIA sincalide is used.
B. Implement barcode scanning that automatically links NDC to J code
C. Consider reserving sincalide by MAIA for inpatient studies only
D. All of the above

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Case Scenario (Part 5)

The director of pharmacy at one of your client hospitals realizes that sincalide produced by MAIA is not available through the GPO that her hospital network uses, but she can purchase a supply directly from the manufacturer, which will help mitigate drug supply interruptions. What can be done to ensure proper billing for sincalide by MAIA?

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B. Implement barcode scanning that automatically links NDC to J code
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D. All of the above

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Case Scenario (Part 6)

The director of pharmacy at one of your client hospitals realizes that sincalide produced by MAIA is not available through the GPO that her hospital network uses. She can purchase a supply directly from the manufacturer at a substantially reduced rate using 340B pricing. Which considerations must be made when utilizing the 340B pricing of sincalide?

A. Whether sincalide use will be for inpatient or outpatient studies
B. Claims submitted to Medicaid under 340B must be distinct and separate from non-340B claims
C. Prospective plans for the cost savings under 340B
D. Both A and B
E. All of the above

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Preparing an Application for P&T Review

- Create an Objective Drug Monograph for P&T Review
  - Safety
  - Cost
  - Efficacy
- Research and Assess the Available Literature
  - Randomized Controlled Trials
  - Meta-analyses
  - Clinical Practice Guidelines
  - Manufacturer Information
  - Internal Experiences with Requested Drug

Baker D, Barrington C, Cannon E, et al. AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics Committees: What's Next? J Manag Care Spec Pharm. 2020;26(1):48-53.

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Preparing an Application for P&T Review

- Most formulary decisions are made from a clinical standpoint
  - Clinical Trials and Practice Guidelines
- Newer emphasis on real-world data provides additional support for P&T committee decisions
  - Locally gathered data on experience with a specific drug
  - Useful in retrospective evaluations of formulary updates vs new additions
- Humanistic outcomes
  - Value frameworks, expert opinions, and patient advocacy group publications

Baker D, Barrington C, Cannon E, et al. AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics Committees: What's Next? J Manag Care Spec Pharm. 2020;26(1):48-53

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Preparing an Application for P&T Review

- Monographs generally should provide *more* information than what can be found in package inserts
  - Monographs contain drug comparison data to support P&T decision making
- Commonly overlooked/excluded data in monographs
  - Off label drug uses
  - Disadvantages of the proposed drug
  - Treatment of drug side effects
  - Drug-drug, drug-disease, drug-lab interactions
  - Comparisons with established treatments
  - Risk vs benefit analyses

Majerisk PL, May JR, Longe RL, Johnson MH. Evaluate of Pharmacy and Therapeutics Committee Drug Evaluation Reports. *Am J Hosp Pharm*. 1985; 42:1073-1076

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Preparing an Application for P&T Review

- Monograph Discussion of Medication Safety
  - Review published literature for adverse effects
    - Include treatments and antidotes
      - Measures for extravasation injury
      - Reversal agents available
      - Pre-medications as needed
  - Discuss appropriate storage, handling and stability
    - Hazardous drug storage and handling
    - Appropriate drug administration (central line only, etc.)
    - Special equipment needed for drug storage (sub-zero freezer, etc.)
  - Pharmacy will need to ensure proper facilities and access to proper medications to support safe utilization of new medication

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Preparing an Application for P&T Review

- Monograph Discussion of Medication Efficacy
  - Focus on randomized controlled trials and clinical practice guidelines
    - New Drug Indications for Existing Drugs
    - Novel Therapeutics
  - Manufacturers may supply information for generics
    - Bioequivalence Data submitted to FDA
    - MAIA Sincalide NDA
      - Focus on improving shelf life
  - Review experience with drug if used while non-formulary in past

28 February 2018. MAIA Announces Tentative FDA Approval of NDA for Sincalide Injection. American Pharmaceutical Review. Retrieved Oct 1, 2023 from https://www.americanpharmaceuticalreview.com/1315-News/347562-MAIA-Announces-Tentative-FDA-Approval-of-NDA-for-Sincalide-for-Injection/

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Preparing an Application for P&T Review

- Monograph Discussion of Medication Costs
  - Facility-specific costs may need to be clarified with pharmacy procurement
    - Different pricing from different wholesalers
    - Impact of GPOs on drug supplier availability
  - Discuss drug program eligibility and participation of manufacturer
    - 340B pricing for outpatient procedures
  - Review NDC/HCPCS crosswalk for product specific J codes
  - Drug specific factors for administration
    - Mandatory inpatient admission for administration
    - Need for supportive care during administration

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Preparing an Application for P&T Review

- Applications typically require a Physician Champion
  - Radiologists for adjuvants to studies
  - Other qualified physicians for therapies
    - Oncology
    - Endocrinology
    - Interventional Radiology
- Applications may require endorsement by department directors
  - Involve end – user level directors for added support
- Applications submitted to director of pharmacy for presentation

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Case Scenario (Part 7)

The director of pharmacy at your local hospital wants to discuss the potential benefits of adding sincalide by MAIA to the list of available productions on her hospital formulary. Which of the following statement(s) applies?

A. Sincalide by MAIA is formulated to have a longer shelf life than Kinevac
B. Sincalide by MAIA is available for purchase at 340B pricing
C. Sincalide by MAIA provides an alternative supply to help mitigate drug shortages
D. All of the above

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Case Scenario (Part 8)

To draft a complete and honest P&T application for sincalide by MAIA, you also want to disclose any potential challenges that inclusion may cause. Which of the following statement(s) is true?

A. Sincalide by MAIA is more expensive than Kinevac
B. Sincalide by MAIA is not considered therapeutically equivalent to Kinevac by CMS
C. Sincalide has a different HCPCS Level II code (J Code) than Kinevac
D. Both B and C are true

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Future Directions

- The October 2023 NDC-HCPCS crosswalk lists a third alternative
  - Generic sincalide manufactured by Fresenius Kabi
  - Shares J2805 with Kinevac
  - Approved by the FDA as an ANDA and not a 505(B)(2)
- ASHP drug shortages lists a fourth alternative
  - Not listed in NDC-HCPCS crosswalk
  - Not listed in FDA Orange Book
  - Manufacturer Fosun Pharma
- In general, approved generics listed as AB rated to a reference listed standard do not necessarily need to be reviewed by P&T!
  - Ensure a J code is linked to the generic NDC

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Conclusions

- Pharmacy and Therapeutics Committees are Responsible for the Maintenance of and Administration of Health System Formularies
- When Reviewing Medications for Inclusion on Formulary, the P&T Committee Considers the Safety, Cost and Efficacy of the Drug
- Applications Submitted to the Pharmacy and Therapeutics Committee Should be Detailed Documents with both Clinical and Economic Information Included
- Sincalide by MAIA and Kinevac are currently FDA approved under their own NDAs, but generic formulations of sincalide are also being reviewed and approved by the FDA

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Would You Add Sincalide by MAIA to Your Formulary?

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The Pharmacy and Therapeutics Process: A Case Study on Sincalide

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