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Learning Objectives

At the end of this session, participants should be able to:

1. Recall principles and strategies employed in formulary management for monitoring and managing high-cost drugs.

2. Identify methods one health system utilized to address challenges associated with approval workflows and reimbursement monitoring practices for high-cost drugs.

3. Recognize strategies for addressing payer uncertainties, ensuring innovation, and fostering ongoing financial sustainability in managing high-cost drug challenges.

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St. Luke's Health System

- Not-for-profit

- 1,020 Licensed Beds

- 17,000 Employees

- 8 Medical Centers

- 370+ clinics & centers

- Children's Hospital

- Cancer Center

- Largest employer in the state of Idaho

Source: https://www.stlukesonline.org/ Accessed 6/20/24

St Luke's Pharmacy Department

Misson

Delivering accessible, affordable & coordinated pharmacy services to the populations we serve, where, when & how they want it.

Vision

To be the region's leader in providing safe & effective pharmacy services across the continuum of care.

- 760 Team Members
- 9 Acute Care Locations
- 5 Retail Pharmacies & 3 Micropharmacies
- Specialty Pharmacy & Home Delivery
- 340B Eligibility across Health System
- Non-Oncology Infusion Services
- Oncology Services

- Children's Hospital
- Home Infusion Program
- Ambulatory Care Practice
- Residencies – 7 PGY-1 Acute Care; 3 Community Pharmacy; 1 PGY-2 ED; 3 PGY-2 Oncology
- PBM/Health Plan
- Medication Access Team
- Pharmacy Technician Apprentice Program & Tech Resource Pool

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Addressing Challenges With High-Cost Drugs

- **Understanding the Varied Nature of High-cost Drugs & the Drug Pipeline**

  - Differences in population size, administration logistics, clinical significance, & cost per patient & financial impact to heath system

    - Examples:

      - **GLP-1 Agonists for Weight Loss**

      - **Leqembi for Alzheimer's**

      - **CAR T-cell Therapies for Blood Disorders**

- **Establishing an organizational governance structure for formulary decisions**

- **Reimbursement Monitoring**

  - Strategies to ensure reimbursement for high-cost drugs

  - Addressing payer uncertainties & ensuring financial sustainability

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Importance of Addressing Payer Uncertainties & Fostering Innovation

Navigating Payer Uncertainties

- Importance of securing reimbursement for new high-cost drugs

- Strategies to communicate & negotiate with payers effectively

Ensuring Innovation

- Encouraging the adoption of emerging technologies & innovative services

- Leveraging real-world evidence & expert consultations for better decision-making

Financial Sustainability

- Balancing innovation with cost control

- Exploring alternative models to manage drug costs
  - Outcomes-based agreements

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Operational & Cultural Shifts for Effective Formulary Management

Cultural & Operational Shifts

- Importance of creating a culture that supports innovation & efficiency in formulary management

- Enhancing governance for formulary decisions & prescribing guidelines

Systemwide Pharmacy & Therapeutics (P&T) Committee

- Significance of a unified P&T committee

- Ensuring strategic alignment & visibility at the executive level to formulary decisions

Deliberate Process for High-Cost Drugs

- Necessity of a structured process for evaluating & adding high-cost drugs to the formulary

- Addressing key questions:
  - Should we be using a newer high-cost drug for our patient population?
  - Will we be reimbursed for providing this new drug added to the formulary?
  - Can patients afford this?
  - Is this newer drug worth it?

UNLOCKING THE VAULT ON NEWER HIGH-COST MEDS

Kurt Vanden Bosch, PharmD
System Formulary Lead
St. Luke's Health System

Source: Getty Images. Used with permission from HealthTrust
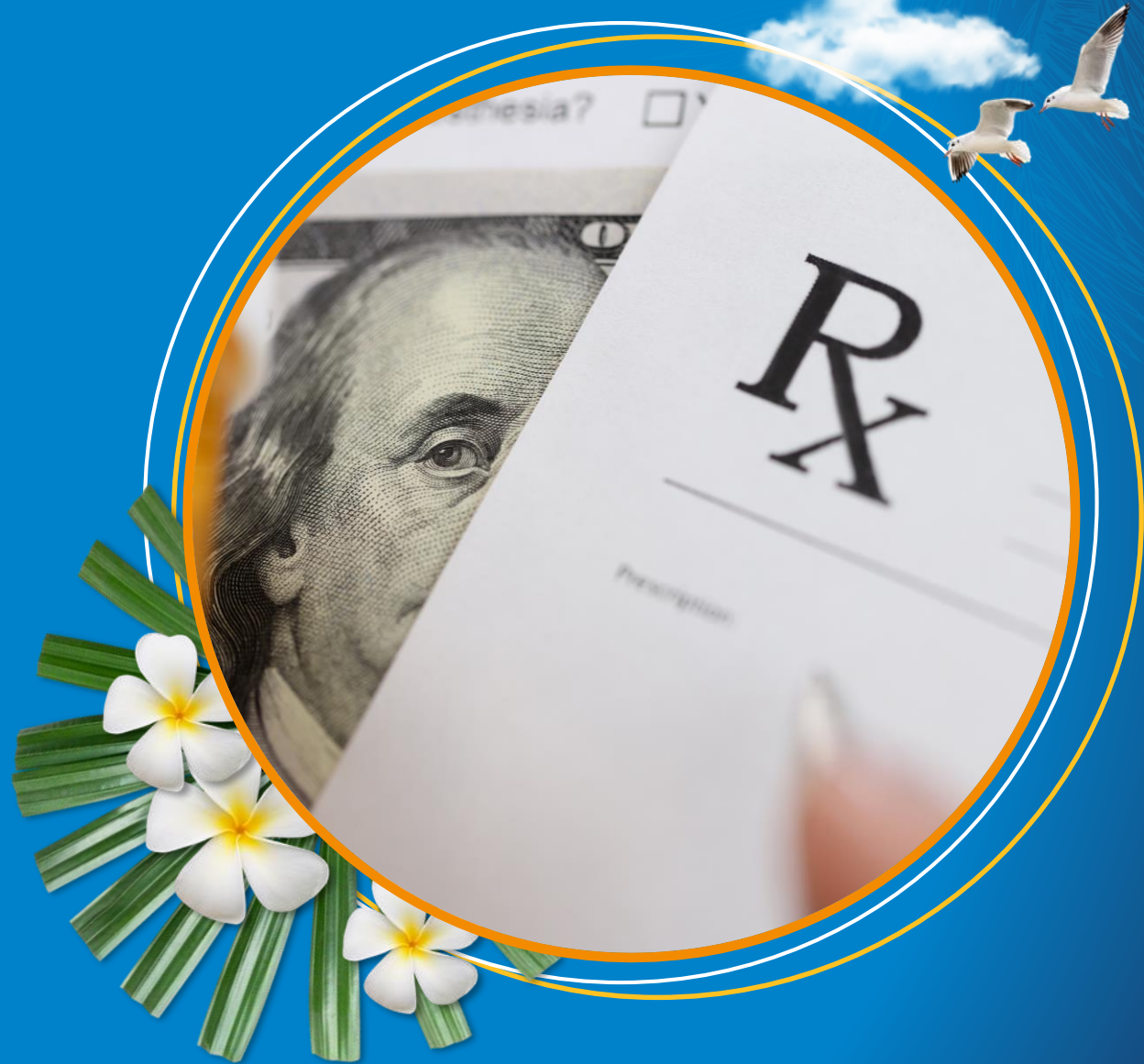
System P&T Scope

- Originally created as the System Formulary Workgroup in 2012

- Developed into the System Pharmacy & Therapeutics (P&T) in 2015 with oversight inclusive of:

  - Medication formulary

  - Med-related policies/protocols/procedures/guidelines

  - Med standardization across the health system

- In 2018, the System P&T scope was expanded to oversight of reimbursement of high-cost meds

  - Resource allocated to address the "Top 40"

System P&T Structure

Oncology P&T

Antimicrobial Subcommittee

System P&T Committee

Thrombology Collaborative

Children's P&T

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Source: Microsoft Stock Images

System P&T Specifics

- Membership of 20 individuals from Medical staff, Pharmacy & Nursing

- System P&T meets 23 times a year
  - Additional meetings designed to maximize System P&T performance:
    - System P&T agenda prep
    - Clinical Pharmacy Services meeting
    - Post-system P&T Operationalizing meeting

- Communication of System P&T decisions:
  - Synopsis to Medical Executive Committees following each meeting
  - Monthly Provider & Pharmacy newsletters
  - Formulary decisions updated in Archer, Lexicomp & in the Electronic Medical Record (EMR)

System P&T & Formulary Management

- Formulary Oversight

  o Meds administered in inpatient settings as well as in our clinics & infusion centers

  o Does not include what is prescribed for patients to fill at their community pharmacies to take at their home setting

Source: Getty Images. Used with permission from HealthTrust

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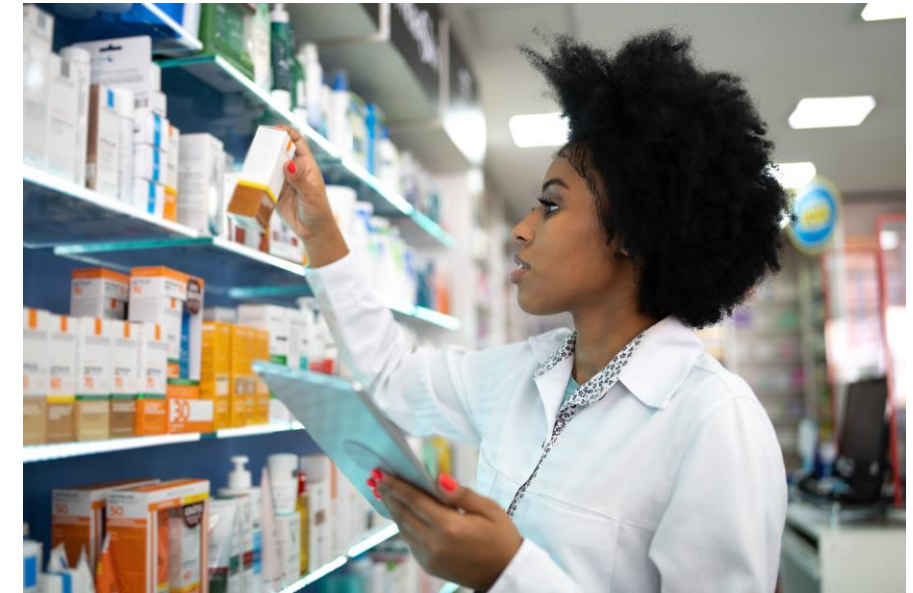
FDA Medication Approvals

- 53 approvals in 2023 along with 19 BLAs

- All are coming to market at high costs

- Many new drugs are being approved based on suboptimal comparisons

- Ongoing questions include the clinical study patient populations vs. real-world patients to receive this drug, etc.
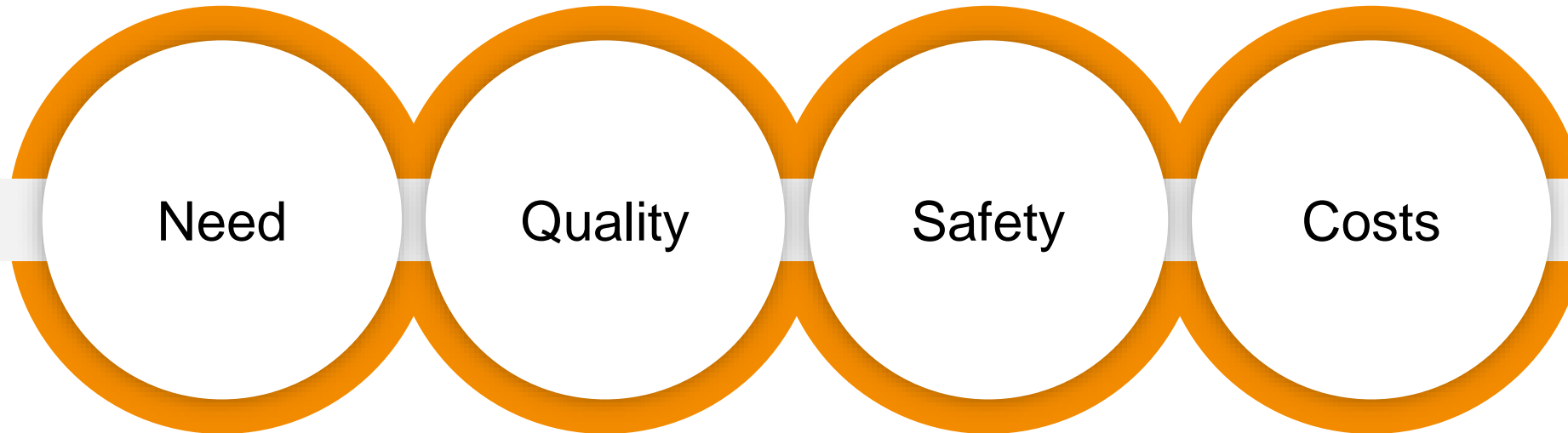
Formulary Management

- How does St. Luke's review these?

  - Following formulary request form submission – 33 were reviewed in 2023

    - Time frame is either Standard (6–12 weeks) or Expedited (4–6 weeks)

  - As part of the drug class review process – all 60 drug classes are reviewed annually

    - Class reviews include new drug evaluations, latest clinical guidelines, safety updates, pipeline information & usage & spend trends

      - All of these inform formulary recommendations for each drug

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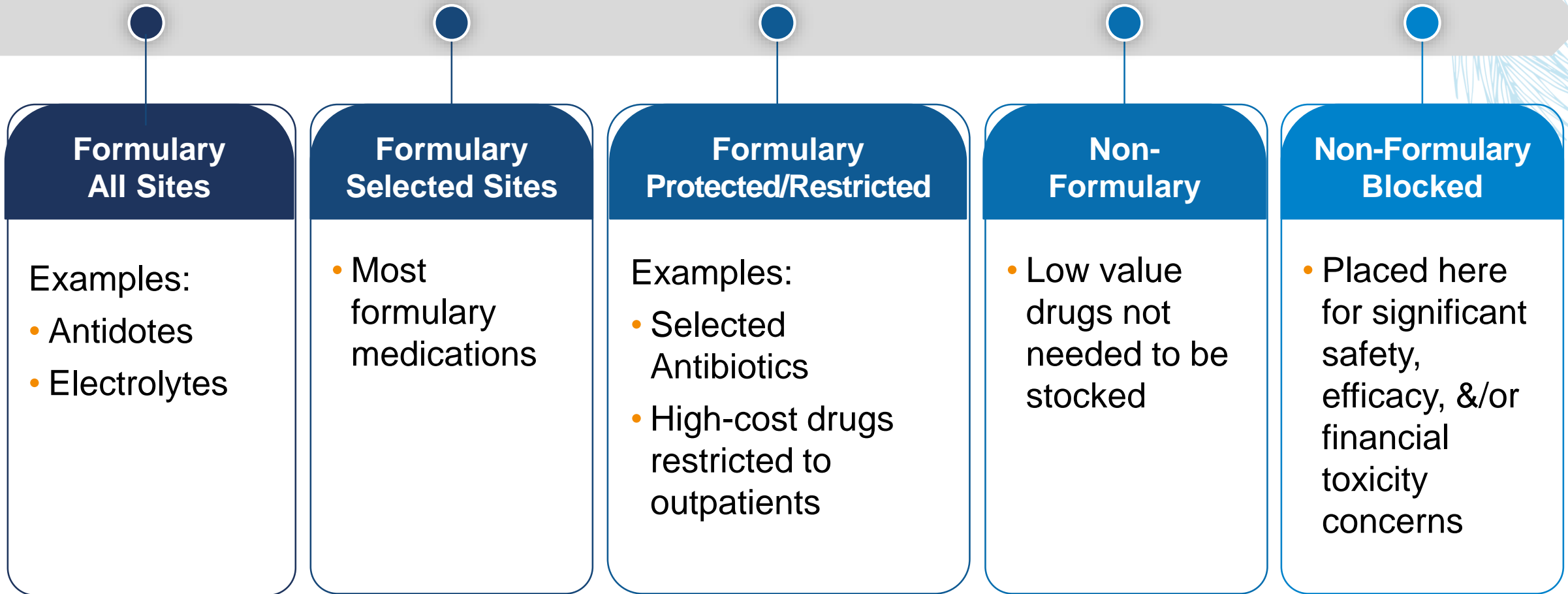
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Formulary Evaluation Criteria

Need   **Quality**   **Safety**   **Costs**

Source: Getty Images. Used with permission from HealthTrust

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Pharmacoeconomic & Value Determination

- Pharmacoeconomic evaluation
  - Cost per **quality adjusted life year** is the primary metric evaluated
  - Cost per **effective life year gained** also evaluated
  - Look to the national Institute for Clinical & Economic Review (ICER) first
  - If ICER has not yet reviewed, an incremental cost effectiveness ratio is calculated to help inform decisions
- Value labeling then applied
  - High Value
  - Medium Value
  - Low Value

SLHS Formulary Designations

Formulary All Sites	Formulary Selected Sites	Formulary Protected/Restricted	Non-Formulary	Non-Formulary Blocked
Examples: • Antidotes • Electrolytes	• Most formulary medications	Examples: • Selected Antibiotics • High-cost drugs restricted to outpatients	• Low value drugs not needed to be stocked	• Placed here for significant safety, efficacy, &/or financial toxicity concerns

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One-off Non-Formulary Requests

<$1,000/dose	Processing Pharmacist makes the call
$1,000 – 4,999/dose	Local Site Leader to make the call
≥$5,000/dose	System P&T Chair makes the call

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Formulary Addition Requests

Non-oncology Drugs

<$1 million/yr

System P&T

≥$1 million/yr

Med Value Advisory Council

System P&T

Clinical Value Standardization

Oncology Drugs

<$1.5 million/yr

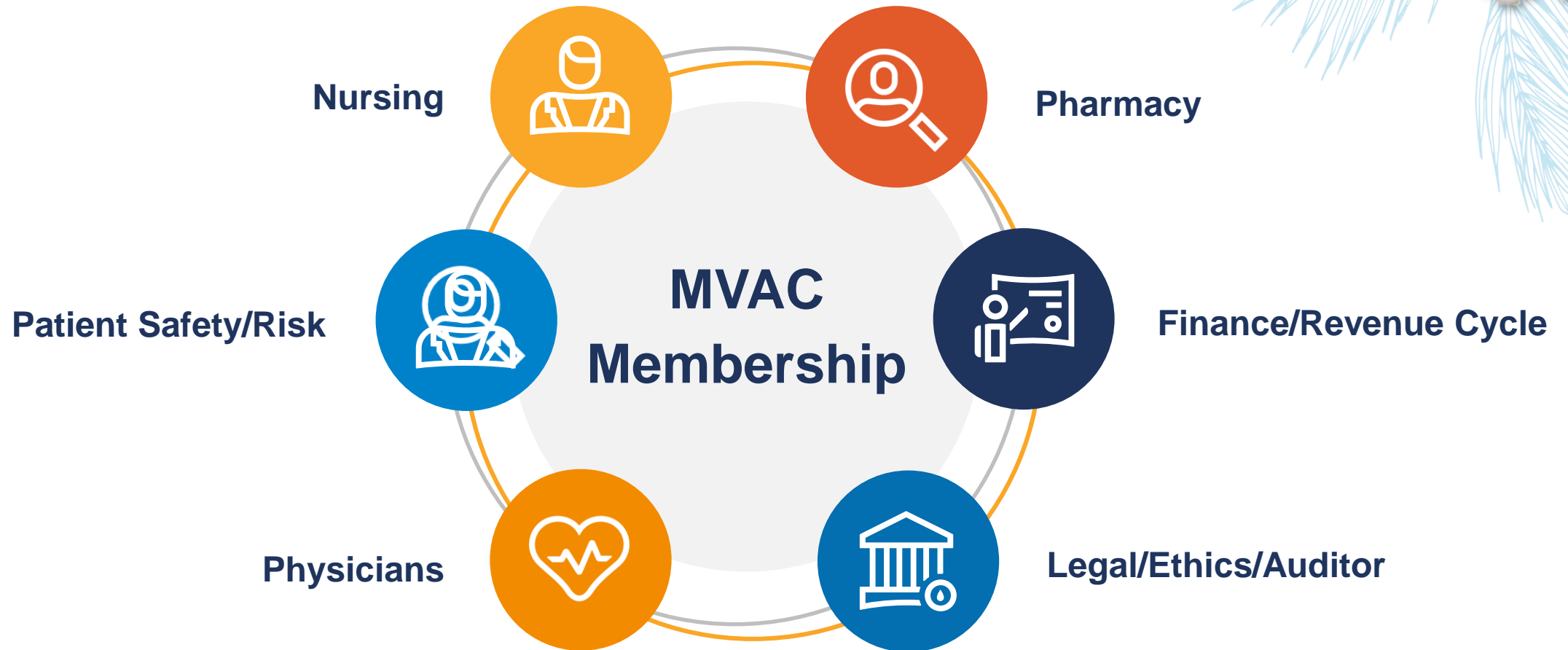Oncology P&T recommendation

System P&T

≥$1.5 million/yr

Oncology P&T recommendation

Med Value Advisory Council

System P&T

Clinical Value Standardization

| **CE Credit Deadline: 09/30/24**

Medication Value Advisory Council (MVAC)

Nursing

Pharmacy

Patient Safety/Risk

MVAC Membership

Finance/Revenue Cycle

Physicians

Legal/Ethics/Auditor

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MVAC Voting

Categories:

- Efficacy

- Safety/Risks/Operational Complexities

- Costs/Pharmacoeconomics/Reimbursement

- Missional Alignment/Societal Benefit

Source: Getty Images. Used with permission from HealthTrust

Each voting category is scored from 1–5

- A drug with an average score of ≥9.0 advances for additional approvals before being added to formulary; If <9.0, drug will stay non-formulary

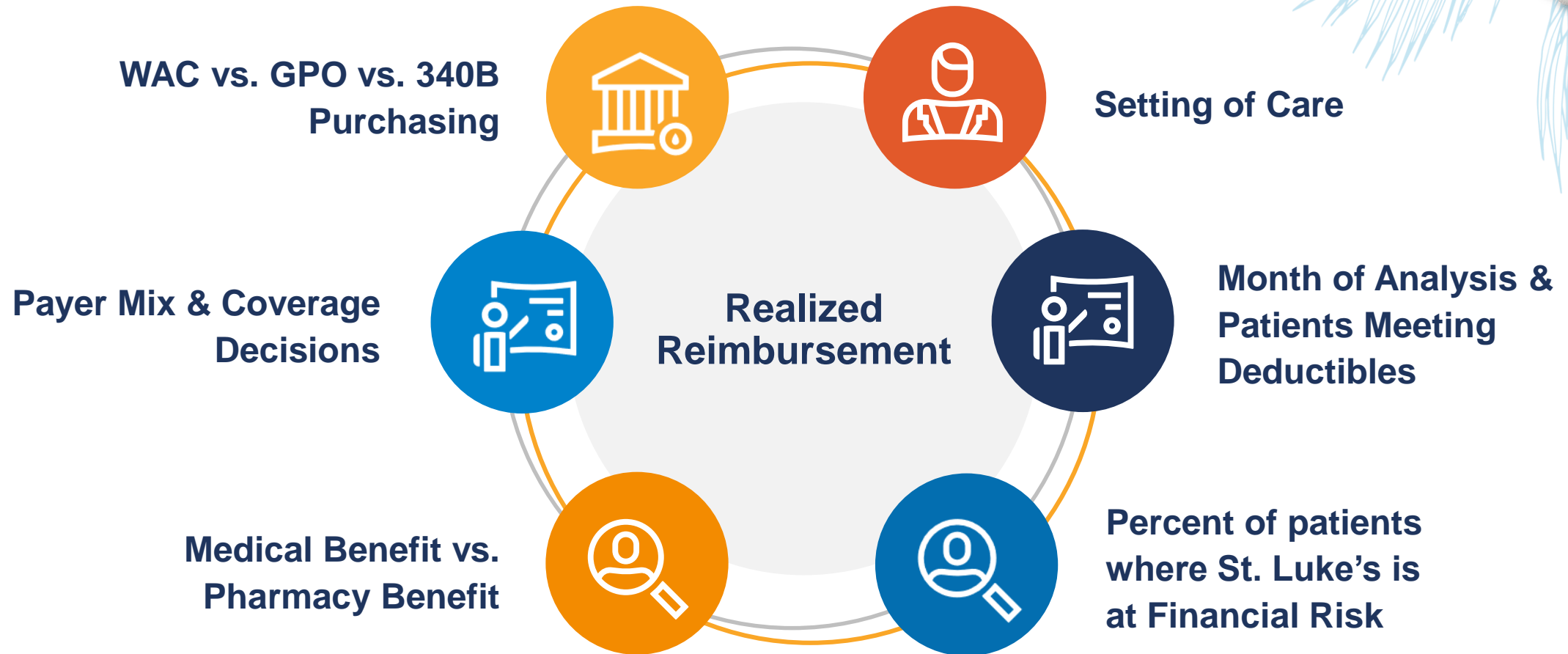# Medication Reimbursement Analysis

- Challenges/Complexities:
  - Payers may wait on decisions whether to cover new drugs
  - Transparency on coverage decisions may not be apparent
  - Prior Auth &/or Step Therapy requirements often differ among insurers
- Timing of SLHS formulary decision
  - How long to wait for payer coverage decisions?
  - Balance of providing the most cutting-edge effective therapy to our patients weighed against the financial stewardship needed to optimally cover our costs & provide affordable care
  - Coding challenges of newer meds (C vs. J vs. Q codes, etc.)
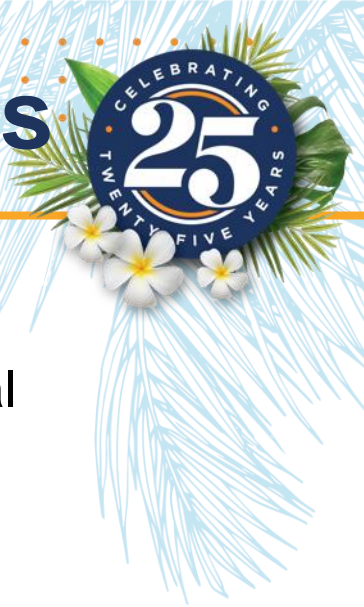
Formulary Approval Next Steps

- Assure proper EMR build is in place prior to go-live

- Many operational issues to work out prior to go-live

- Following go-live, assess reimbursements

- Since 2018, we have completed in-depth reimbursement analyses on over 90 drugs

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Medication Reimbursement Factors

WAC vs. GPO vs. 340B Purchasing

Setting of Care

Payer Mix & Coverage Decisions

Realized Reimbursement

Month of Analysis & Patients Meeting Deductibles

Medical Benefit vs. Pharmacy Benefit

Percent of patients where St. Luke's is at Financial Risk

Unlocking the Vault on Newer High-cost Meds

- Should we be using a newer high-cost drug for our patient population?

  o We assess the med's quality, safety, cost-effectiveness & missional alignment/societal benefit to determine if we will administer this drug at St. Luke's

- Will we be reimbursed for providing this new drug added to formulary?

  o We are conducting assessments of likely reimbursement patterns in advance of formulary decisions, & we have taken steps to more quickly assess actual reimbursements once the drug is in use

- Can patients afford this?

  o Team is assessing resulting co-pays/co-insurances as well as available patient assistance programs to help inform formulary decisions

- Is this newer drug worth it?

  o Pairing clinical outcome information with financial outcomes will help inform decisions about best medication care options into the future

Source: ChatGPT Image

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Future Considerations

- Strategically reviewing drugs expected to receive FDA approval
  - We are monitoring these, & they are included in each drug class review
  - Conducting anticipatory analyses (using IPD Analytics as a launching point) would be useful in getting a head start for high-cost drugs expected to receive FDA approval
- Greater formulary alignment among strategic partners
  - 1st Tier: System P&T, St. Luke's PBM & St. Luke's Health Plan
  - 2nd Tier: Financially-aligned health partner plans

UNLOCKING THE VAULT ON NEWER HIGH-COST MEDS

Renee Walker-Page
Pharmacy Business Manager
St. Luke's Health System

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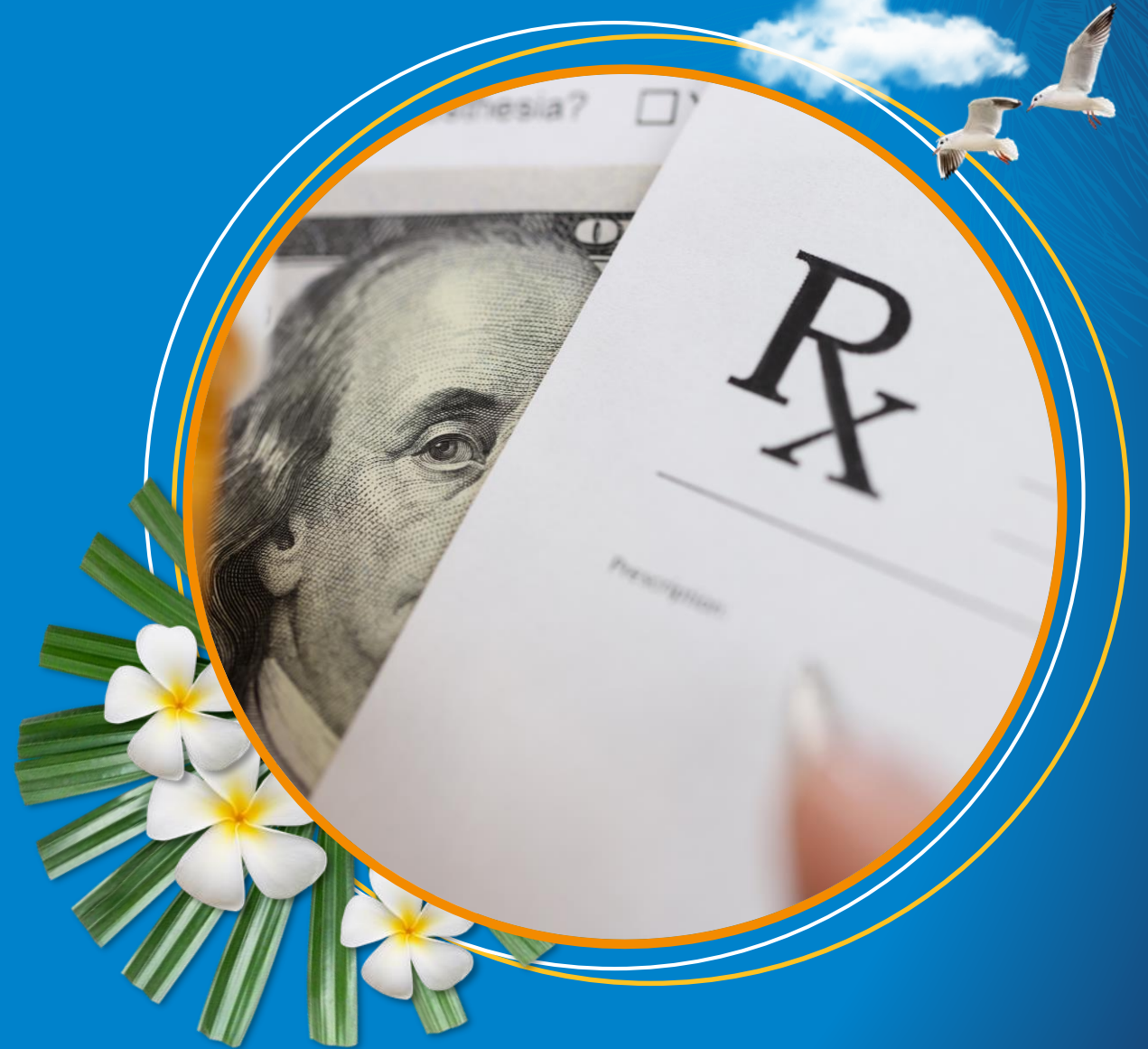
Pharmacy Payer Health System Navigator

Renee Walker-Page
Pharmacy Business Manager
St. Luke's Health System

- Why a Pharmacy Health System Navigator

  - Identifying the need for the role

  - Skill set/background for the role

  - Role responsibilities

The Complex Opportunity

- Our strategic vision is to foster a collaborative partnership between the Pharmacy Team, Managed Care/Payer Team & Revenue Cycle Team to ensure holistic patient care, while optimizing reimbursement.

- Holistic Health System approach with payer relationships –
  - Retail/Specialty Pharmacy & PBM vertical integration
  - Infusion/Home Infusion

Get Pharmacy a Seat at the Table

- Relationship Building

    o Managed Care/Payer Team
    o Revenue Cycle Teams – coding & reimbursement
    o Local/Largest Payers
    o Drug manufacturers
    o IHT/Data analytics

- Pharmacy vs. Medical Benefit Education Gap

    o Pharmacy Benefit Management (PBM) Contracts vs. Payer Agreements vs. Single Case Agreement (SCA)

    o Average Wholesale Price (AWP) vs. Wholesale Acquisition Cost (WAC) vs. Average Sales Price (ASP)

- Connect the Dots

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High-cost Medication – Reimbursement Integrity

- Our journey

  o Gain Payer philosophy/coverage of high-cost meds insight

  o Utilize Drug MFG for support & insight

  o Tighten up internal workflow

Assessment Question #1

Which of the following is NOT a typical function of a hospital Pharmacy & Therapeutics Committee?

A. Determination of the health system medication formulary

B. Review of a medication-related policy

C. Setting the price of a new drug in order to maximize reimbursement

D. Standardizing how a new drug added to the formulary may be used in the hospital

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Correct Answer Question #1

Which of the following is NOT a typical function of a hospital Pharmacy & Therapeutics Committee?

A. Determination of the health system medication formulary

B. Review of a medication-related policy

C. **Setting the price of a new drug in order to maximize reimbursement**

D. Standardizing how a new drug added to the formulary may be used in the hospital

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Assessment Question #2

When determining whether to add a new high-cost medication to the hospital formulary, which of the following is NOT a core evaluation criteria?

A. Need
B. Quality
C. Costs
D. Safety
E. None of the above

| **CE Credit Deadline: 09/30/24**

When determining whether to add a new high-cost medication to the hospital formulary, which of the following is NOT a core evaluation criteria?

A. Need
B. Quality
C. Costs
D. Safety
E. **None of the above**

Assessment Question #3

When a newly FDA-approved high cost medication is being reviewed for potential formulary addition, which of the following can provide insight into the value of that medication?
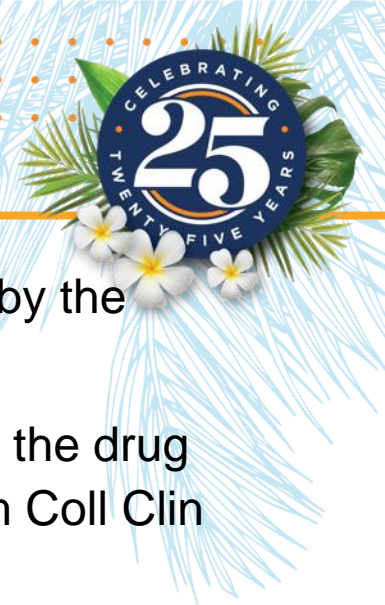
a. ICER
b. CPI
c. HHS
d. FDA

Answer Question #3

When a newly FDA-approved high cost medication is being reviewed for potential formulary addition, which of the following can provide insight into the value of that medication?

a.ICER
b.CPI
c.HHS
d.FDA

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Thank you…

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