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### Save the Pharmacy Piggy Bank: Managing Mega High-Cost Drugs

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# Save the Pharmacy Piggy Bank: Managing Mega High-Cost Drugs

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# Learning Objectives

- Describe the current state of novel therapeutic agents
- Discuss the impact novel therapeutic agents have on financial, operational, and regulatory aspects of the health system
- Analyze tactical methods to avoid catastrophic financial implications on the health system
- Compare and contrast different approaches to using these agents based on the patient population and health system structure



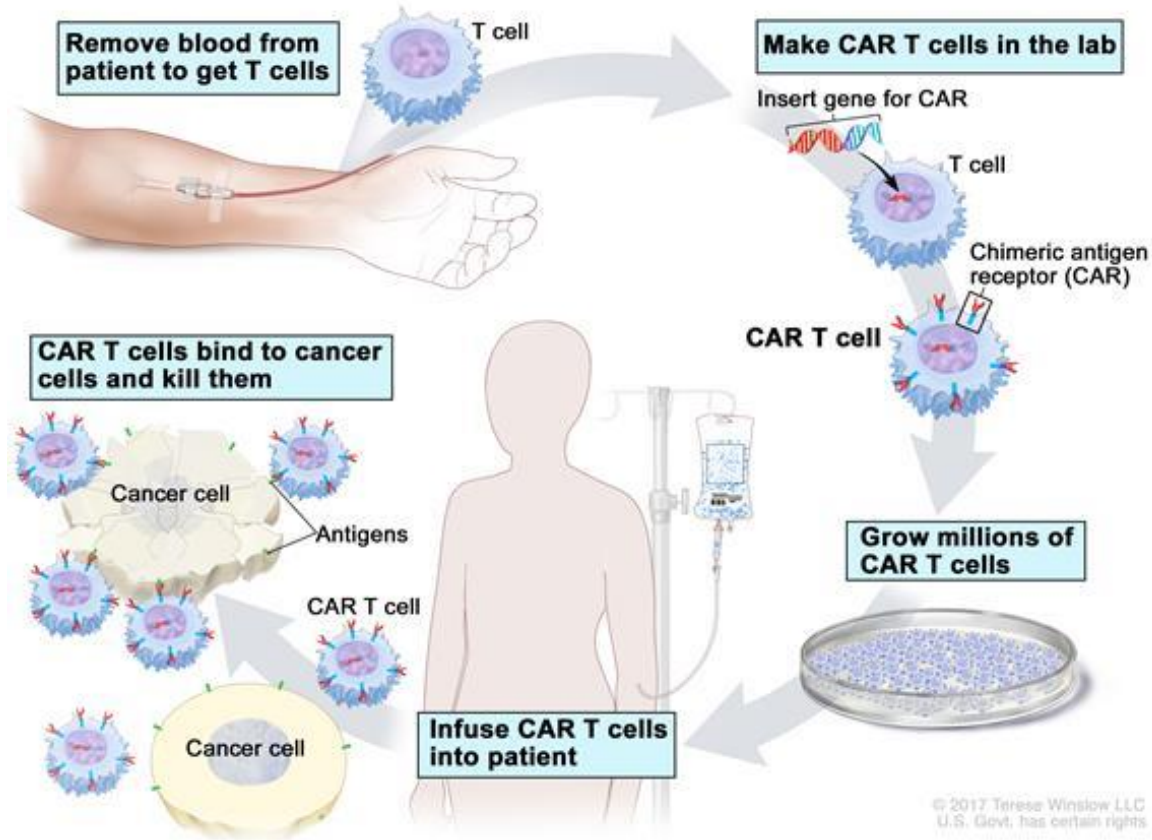
## Current Clinical Therapies

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# Spinraza (nusinersen)

- Binds to specific sequence of *SMN2* mRNA transcript and increase production of full-length SMN protein
  - Leads to survival of SMN
- Treatment of spinal muscular atrophy
- Manufactured by Biogen
- Dosing schedule is one intrathecal injection every 2 weeks for 3 doses
  - Intrathecal injection every 4 months
- Can be administered as an outpatient

# CAR T-cell Therapy



# CAR-T Options

- Axicabtagene ciloleucel (Yescarta)
  - Large B-cell lymphoma (relapsed or refractory)
  - Target dose:  $2 \times 10^6$  CAR-positive viable T cells/kg
- Tisagenlecleucel (Kymriah)
  - Acute lymphoblastic leukemia (relapsed or refractory)
    - <25 years and  $\leq 50$  kg: IV: 0.2 to  $5 \times 10^6$  CAR-positive viable T cells per kg body weight
    - <25 years and  $> 50$  kg: IV: 0.1 to  $2.5 \times 10^8$  CAR-positive viable T cells
  - Diffuse large B-cell lymphoma (relapsed or refractory)
    - IV: 0.6 to  $6 \times 10^8$  CAR-positive viable T cells
- Both may be administered outpatient

# Wholesaler Acquisition Cost (WAC) of Therapy

## Nusinersen

- \$125,000

## CAR-T

- Tisagenlecleucel
  - \$475,000
- Axicabtagene ciloleucel
  - \$373,000





# Formulary and Financial Management

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University of Wisconsin Health

# Strategies for Managing High Cost Medications



# Strategies for Managing High Cost Medications



# Organizational Background



- University of Wisconsin (UW) Health
  - Six hospital system
  - University Hospital, a 505-bed regional referral center
  - American Family Children’s Hospital, 87- bed facility
  - Additional 4 hospitals and 80 clinics within UW Health System
- UW Health Carbone Cancer Center
  - National Cancer Institute Designated Comprehensive Cancer Center
  - Member of NCCN (National Comprehensive Cancer Network)
  - Hazardous drug pharmacy

# Formulary Management

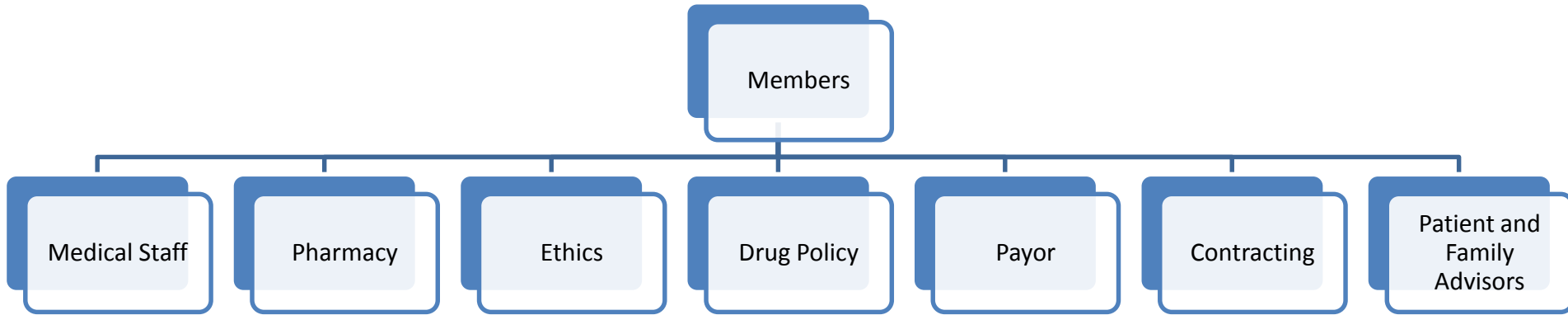
Consistent approach to evaluating therapies across the system

- All perspectives surrounding the use of the medication should be evaluated including:
  - Efficacy
  - Safety
  - Cost and reimbursement
  - Clinician practice/ research
  - Patient/family experience
  - Organizational missions
- Best practice is to have a dedicated committee to review these medications

# Formulary Management

## *UW Health Example*

- Breakthrough Therapy Subcommittee
  - Reports to UW Health P&T Committee



# Formulary Management

## *UW Health Example*

### Aim

*To maximize safe, efficient, evidence-based, rational use of breakthrough therapies at UW Health*

### Responsibilities

*To serve as an internal UW Health resource for the review of breakthrough therapies for relevant UW Health oversight committees prior to formulary addition or administration of such therapies*

It is on formulary...what now?!!



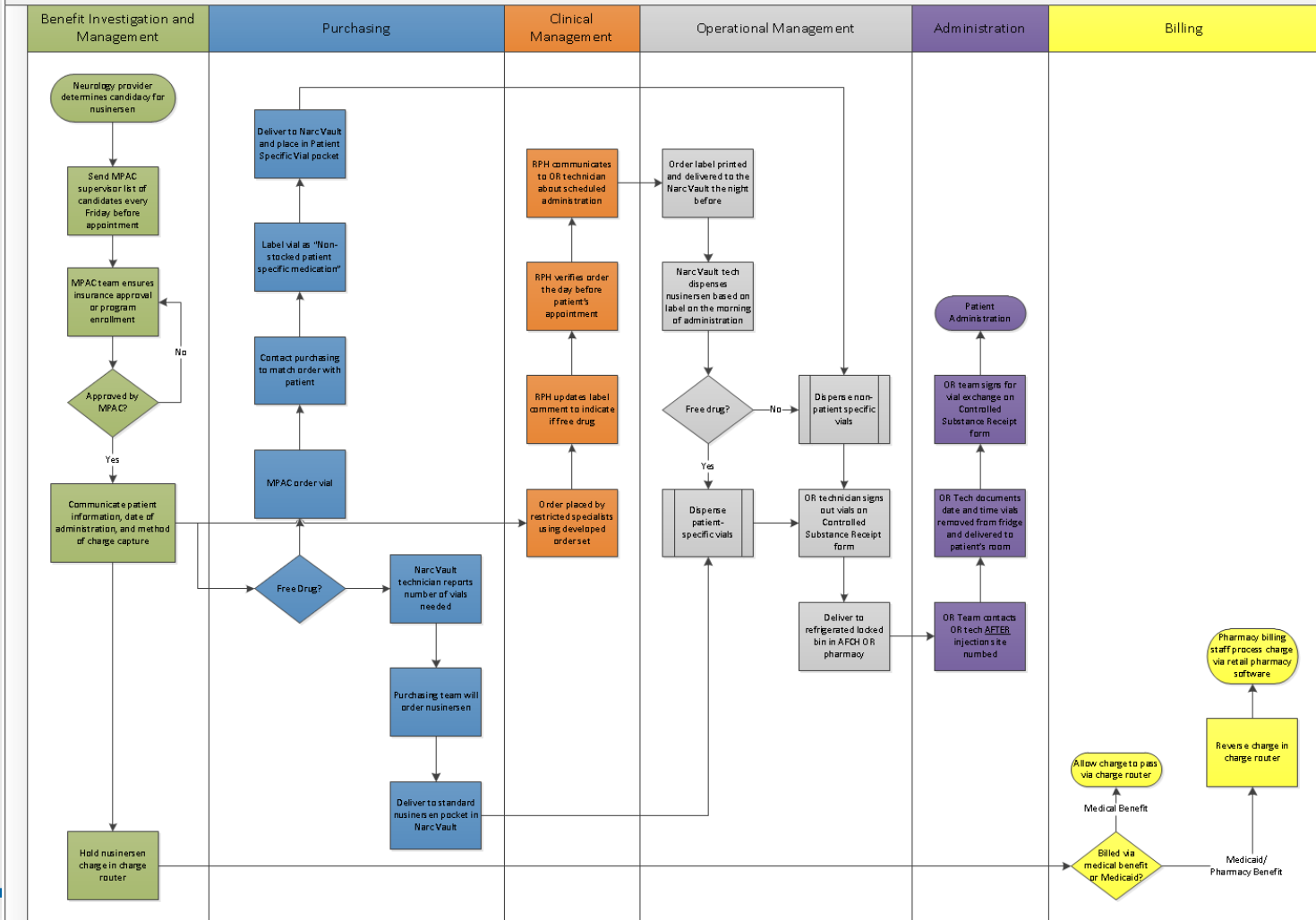


# Developing an Operating Procedure

<b>UWHealth</b> University of Wisconsin Hospital and Clinics	Effective Date: July 11, 2017	<input checked="" type="checkbox"/> Operations Manual <input type="checkbox"/> Policy and Procedure Manual Section:	Chapter: Inpatient and Clinic Operations Procedure
	<input checked="" type="checkbox"/> Original <input type="checkbox"/> Revision	Page 1 Of 8	Title: Spinraza® (nusinersen) Procedure

- I. **PURPOSE:** To standardize the ordering, verification, procurement, inventory management, dispensing, and charging of Spinraza® (nusinersen).
- II. **DEFINITIONS**
- A. Spinraza® (nusinersen) is a medication used to treat spinal muscular atrophy in pediatric and adult patients.
- III. **PRIMARY CONTACTS**
- A. UWH Pharmacy Director, Inpatient Operations and Pediatrics  
B. UWH Pharmacy Manager, Inpatient Operations and Perioperative Services  
C. UWH Pharmacy Manager, Supply Chain  
D. UWH Pharmacy Director, Ambulatory Services
- IV. **PROCEDURE**
- A. **Initial determination of insurance coverage**
- Nusinersen may be billed via the medical or pharmacy benefit depending on the patient's insurance. If not covered by insurance, the patient may be eligible for the Spinraza® free drug program offered through Biogen.
  - The Medication Prior Authorization Coordinator (MPAC) team is responsible for determining insurance coverage for all patients planned to receive nusinersen prior to the

# Nusinersen Procedure



# Benefits Management

- Determination of insurance coverage
  - Medical vs pharmacy benefit
  - Free drug program
- Leverage medication prior authorization team
  - Completed prior to appointment being scheduled (must be a hard stop)
- Once approved, need a strategy to communicate to all stakeholders

# Benefits Management

## *UW Health Example*

- Pharmacy notified early in the process and is handling PAs for all coverage options including medical benefits
- Negotiated with Medicaid to have Spinraza and Kymriah covered under pharmacy benefits
- Developed consistent email groups to communicate with all stakeholders about upcoming patients

# Benefits Management

## *Special Considerations*

### Spinraza

- Pharmacy coordinates free drug program

### CAR-T

- Pharmacy is handling PAs for induction therapy
- BMT coordinators are handling PAs for apheresis

# Financial Management

- Order-to-pay process must be closely monitored
  - Determine which department will be capturing the revenue and cost for the medications
- Ideally revenue and cost will post to the general ledger in the same month
  - Consider treating on-hand inventory as an asset

# Financial Management

## *Special Considerations*

### CAR-T

- Outcomes based contract (Kymriah)
  - Contract requires that you not bill insurer until it is confirmed that treatment was successful
  - Can create issues with requirements in payer contracts
- Apheresis
  - Who is covering cost? (pharmaceutical company or insurer?)
  - Purchase order must be sent **before** apheresis

# Spinraza Charging Workflow

- EMR has a charge queue that holds all charges with certain HCPCS
  - Separate queue that holds all charges > \$10,000

Free  
Drug

- Charge in EMR is reversed at the point of verification by pharmacist
- Label comments signal Narcotic vault technician to utilize free drug for patient

Medicaid

- Charge is held in queue based on HCPCS code
- Charge reversed in EMR
- Patient's insurance is billed through pharmacy benefits

Other  
Payers

- Charge is held in queue based on HCPCS code
- Charge is allowed to pass and patient's insurance is billed



# Financial Monitor

- Therapies have the potential to be financially toxic to health systems
- Long-term monitoring is necessary and pharmacy should lead this effort
- Pharmacy should have a consistent system in place to report financials to senior leadership

# Financial Monitoring

## *UW Health Example*

- Financial report is sent to CFO and VP/financial controller each month

<b>FY18 YTD Spinraza (All Patients)</b>			
	Net Revenue	Drug Expense	Net Margin
July	\$ 834,468	\$ 1,125,000	\$ (290,532)
August	\$ 1,875,826	\$ 2,000,000	\$ (124,123)
September	\$ 2,407,668	\$ 2,250,000	\$ 157,668
October	\$ 1,337,580	\$ 1,125,000	\$ 212,580
November	\$ 1,389,077	\$ 1,250,000	\$ 139,077
December	\$ 1,389,906	\$ 1,500,000	\$ (110,094)
January	\$ 1,837,305	\$ 1,625,000	\$ 212,305
February	\$ 1,358,678	\$ 1,250,000	\$ 108,678
March	\$ 353,309	\$ 250,000	\$ 103,309
<b>Total</b>	<b>\$ 12,783,816</b>	<b>\$ 12,375,000</b>	<b>\$ 408,868</b>

<b>FY18 YTD Spinraza (Non Capitated Patients)</b>			
	Net Revenue	Drug Expense	Net Margin
July	\$ 834,468	\$ 750,000	\$ 84,468
August	\$ 1,875,826	\$ 1,625,000	\$ 250,877
September	\$ 2,407,668	\$ 2,000,000	\$ 407,668
October	\$ 1,337,580	\$ 1,125,000	\$ 212,580
November	\$ 1,389,077	\$ 1,250,000	\$ 139,077
December	\$ 1,389,906	\$ 1,375,000	\$ 14,906
January	\$ 1,837,305	\$ 1,625,000	\$ 212,305
February	\$ 1,358,678	\$ 1,125,000	\$ 233,678
March	\$ 353,309	\$ 250,000	\$ 103,309
<b>Total</b>	<b>\$ 12,783,816</b>	<b>\$ 11,125,000</b>	<b>\$ 1,658,868</b>

## Which of the following are perspectives to consider when adding a mega high-cost therapy to formulary?

- A. Efficacy
- B. Safety
- C. Cost and reimbursement
- D. All the above



## Operational Strategies

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Yale New Haven Health

# Strategies for Managing High Cost Medications



# Operational Considerations

- **Decision-Making**
  - Establish process for urgent requests
  - Establish governance/oversight for complex therapies
- **Ordering**
  - Establish pathways to trigger required work queues
  - Capture required documentation
- **Prior Authorization**
  - Verify prior to dispensing
  - Test work queues/processes
  - May require SOP

# Operational Considerations

- **Storage**
  - Segregated
    - In Pharmacy vs In Clinic
  - Limited Access (Vault)
- **Distribution**
  - Deliver patient specific vs store in automated dispensing cabinet
  - May require SOP
- **Communications**
  - Engage key stakeholders: business office; IT; finance; nursing
  - Establish process for urgent vs proactive drug reviews

# Case Example: Spinraza Non-Formulary (NF) Request

- **Situation:** Neurologist requests 4 patients to receive nusinersen
- **Background:** All NF requests reviewed by Sr. Clinical Pharmacist, Drug Information and Pharmacy Leader (if high cost)
- **Assessment:** Pharmacy deemed appropriate; approved by Sr. VP Children's Hospital
- **Recommendation:** Enter order via NF pathway; coordinate insurance authorization, purchase of drug and delivery to outpatient clinic



# Outcomes



- 4 patients received therapy in outpatient neurology suite
- All patients tolerated therapy well and responded positively



- All claims hit high cost drug queue and were denied
  - Started a firestorm of emails
  - No PA obtained
- Vials purchased at WAC
  - Processed via split billing software

# Request for High Cost Drugs

## Expedited Review

- Expert subgroup reviews clinical/safety data
- Finance and Formulary Assessment Committee (FFAC) reviews for drug cost >\$20K
- Corp Director, Pharmacy Procurement approves orders >\$100K

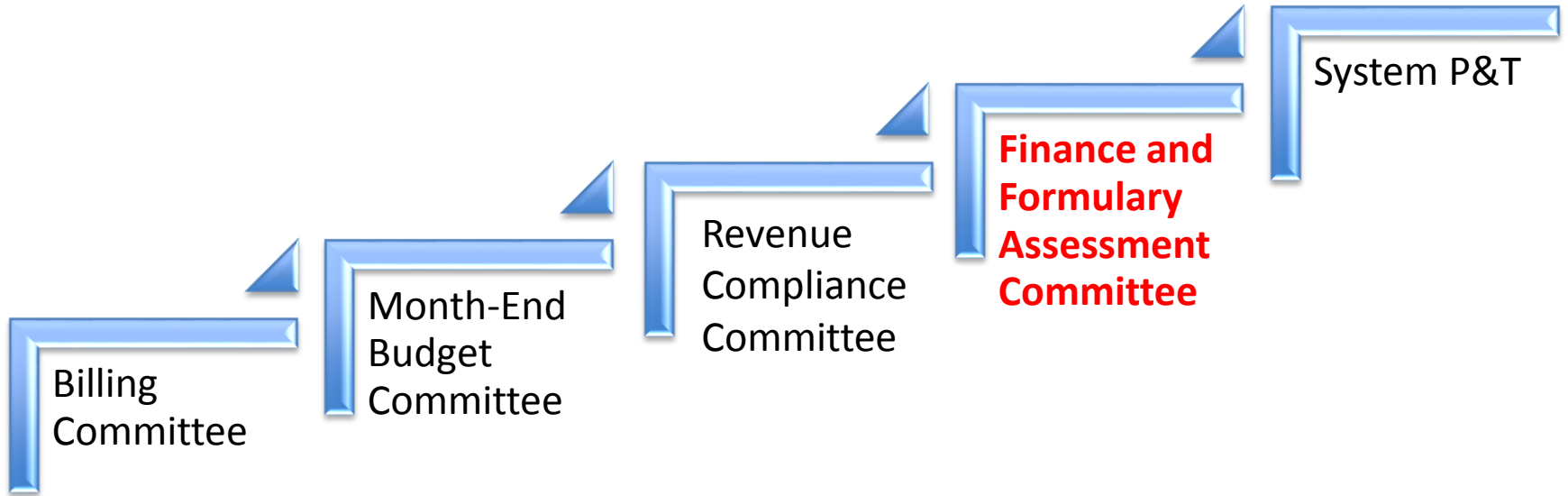
## IT Build

- ITS develops therapy plan; reviewed by pharmacy/prescribers
- Add to High Cost Drug Audit List (drug cost per dose >\$1K)

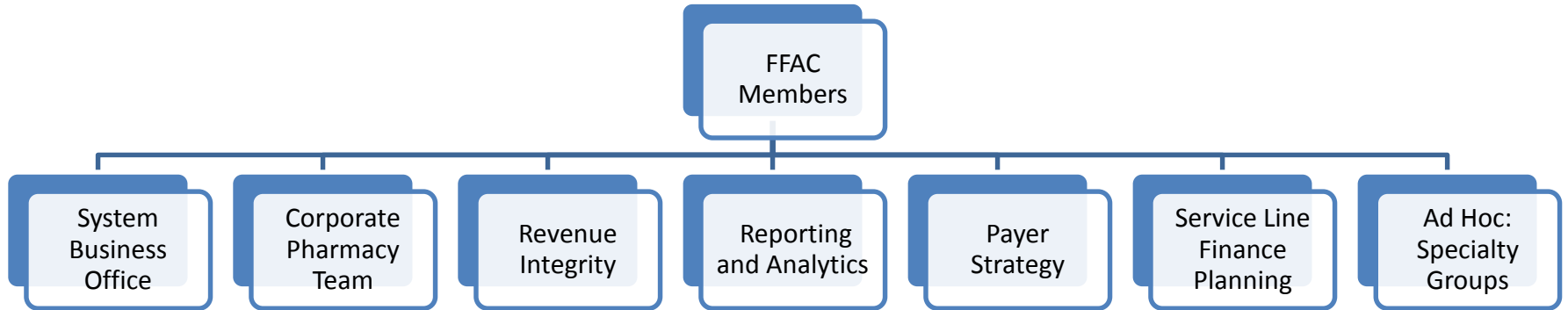
## Formulary Decision

- Prioritize full evaluation at P&T
- If denied, removal of ERX; communication across system of NF status, inability to use

# Communication and Governance



# Finance and Formulary Assessment Committee



# Operational Strategies for CAR-T

- Oversight
  - Steering committee and 3 subcommittees
- Engagement
  - Internal and external communication plan
  - Members: physicians, pharmacy, IT, cell processing, finance, nursing, pediatric oncology, educators, firm chiefs, BMT, apheresis, PICU, MICU

# Responsibilities & Expectations

- CAR-T Steering Committee
  - Oversee the safety and progress of CAR-T therapies
  - Make key decisions and provide guidance to the 3 subcommittees
  - Resolve any concerns or problems
- Protocol Review Subcommittee
  - Prioritize cell therapy trials and standard therapy activation
  - Assess capacity and allocate resources
  - Perform mandatory and feasibility analysis of all therapies

# Responsibilities & Expectations

- Inpatient/Outpatient Patient Care Subcommittee
  - Develop SOPs and workflows
  - Develop education for MDs, nursing, pharmacy, and other staff
- Cell Collection & Processing Subcommittee
  - Develop SOPs related to cell collection, processing, chain of custody procedures
  - Develop workflows between Apheresis, Cell Processing, and Nursing

# Business Planning

- Separate cost center built for CAR-T
- Side-effect management to be tracked under pharmacy
  - Up to \$56K per patient
- Resources added to build the program
  - 1 FTE – Patient Finance Assistance Representative
  - 2 FTE – Cell processing lab technician
  - 2 FTE – Clinical RN (Apheresis Unit)
  - 1 FTE – Nurse Educator
  - 1 FTE – Stem cell coordinator
  - 1 FTE – Clinical Pharmacist
  - New apheresis machine



# Lessons Learned

- 1) Identifying the right team is critical
- 2) Use existing processes whenever possible
- 3) Developing operating procedures and process maps are often necessary
- 4) Monitoring long-term financial outcomes is critical
- 5) Pharmacy must play an important role in managing these medications



# Panel Discussion

It's time to hear from you!!

# Questions for the Audience

- 1) What are the different management strategies in 340B/non-340B institutions for high-cost medications?
- 2) How do organizations who treat patients across state lines manage their processes for these medications?
- 3) How do organizations that have to partner with other facilities for cell processing manage?
- 4) How do organizations that don't handle the CAR-T agents as medications manage it?

# Open Discussion/Forum

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- Jerame Hill, [jhill2@uwhealth.org](mailto:jhill2@uwhealth.org)
- Sam Abdelghany, [osama.Abdelghany@ynhh.org](mailto:osama.Abdelghany@ynhh.org)



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