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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



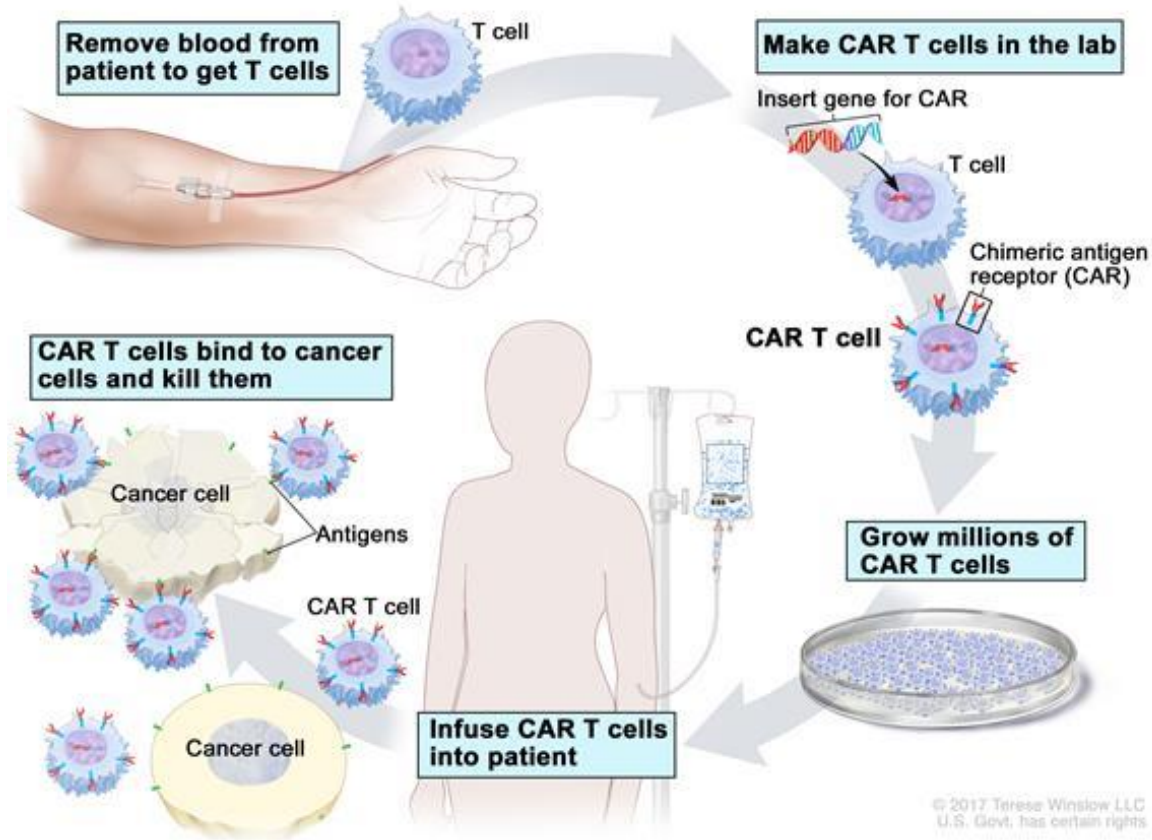
Current Clinical Therapies

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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: 2×10^6 CAR-positive viable T cells/kg
- Tisagenlecleucel (Kymriah)
 - Acute lymphoblastic leukemia (relapsed or refractory)
 - <25 years and ≤ 50 kg: IV: 0.2 to 5×10^6 CAR-positive viable T cells per kg body weight
 - <25 years and > 50 kg: IV: 0.1 to 2.5×10^8 CAR-positive viable T cells
 - Diffuse large B-cell lymphoma (relapsed or refractory)
 - IV: 0.6 to 6×10^8 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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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

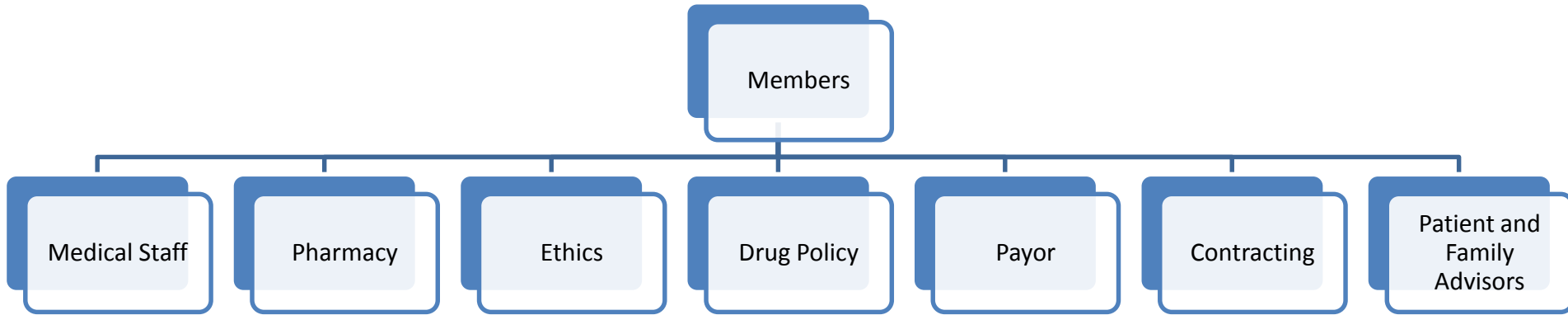
Consistent approach to evaluating therapies across the system

- 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?!!

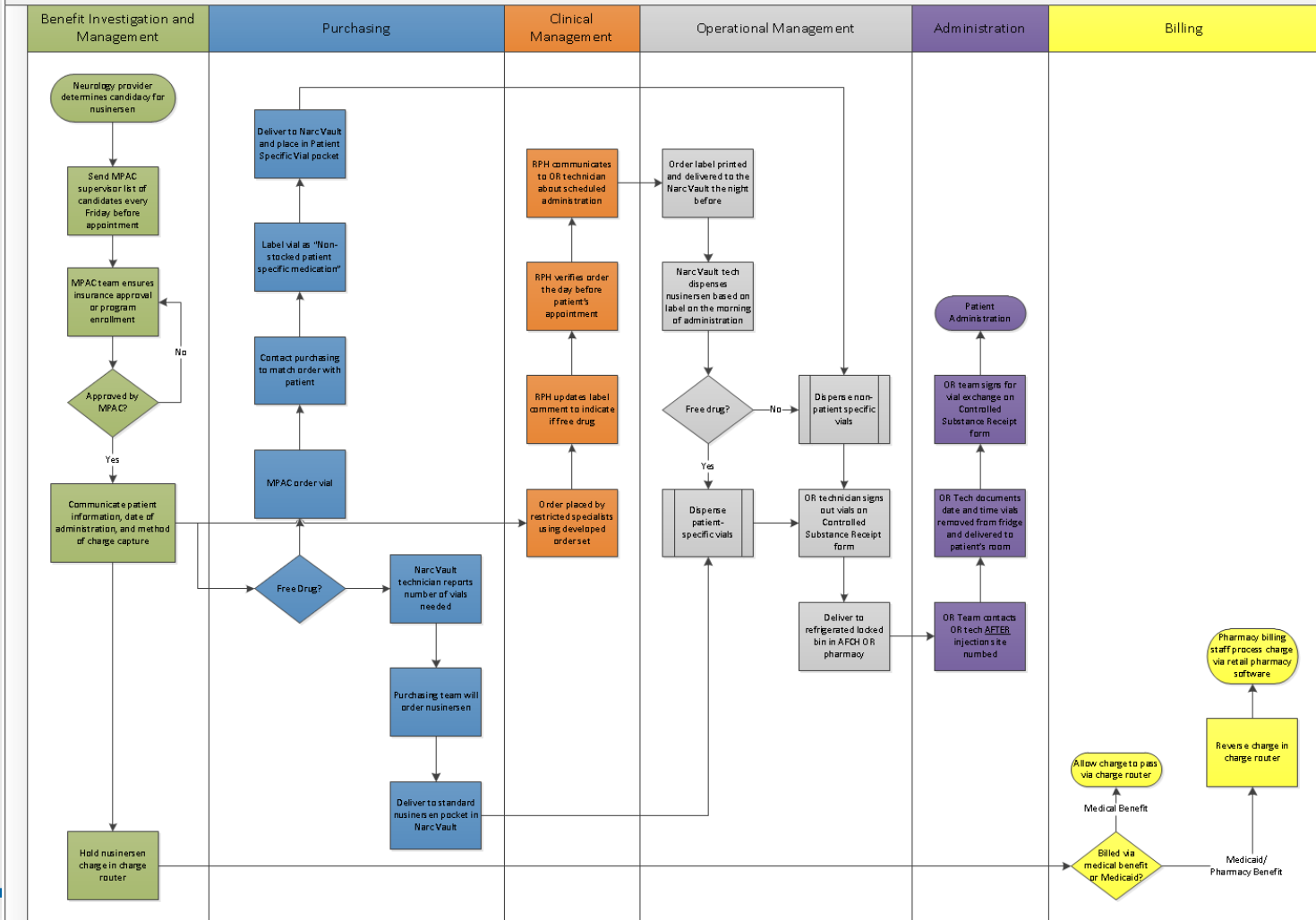


Developing an Operating Procedure

UWHealth 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

FY18 YTD Spinraza (All Patients)			
	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
Total	\$ 12,783,816	\$ 12,375,000	\$ 408,868

FY18 YTD Spinraza (Non Capitated Patients)			
	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
Total	\$ 12,783,816	\$ 11,125,000	\$ 1,658,868

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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Manager, Oncology Pharmacy Services
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

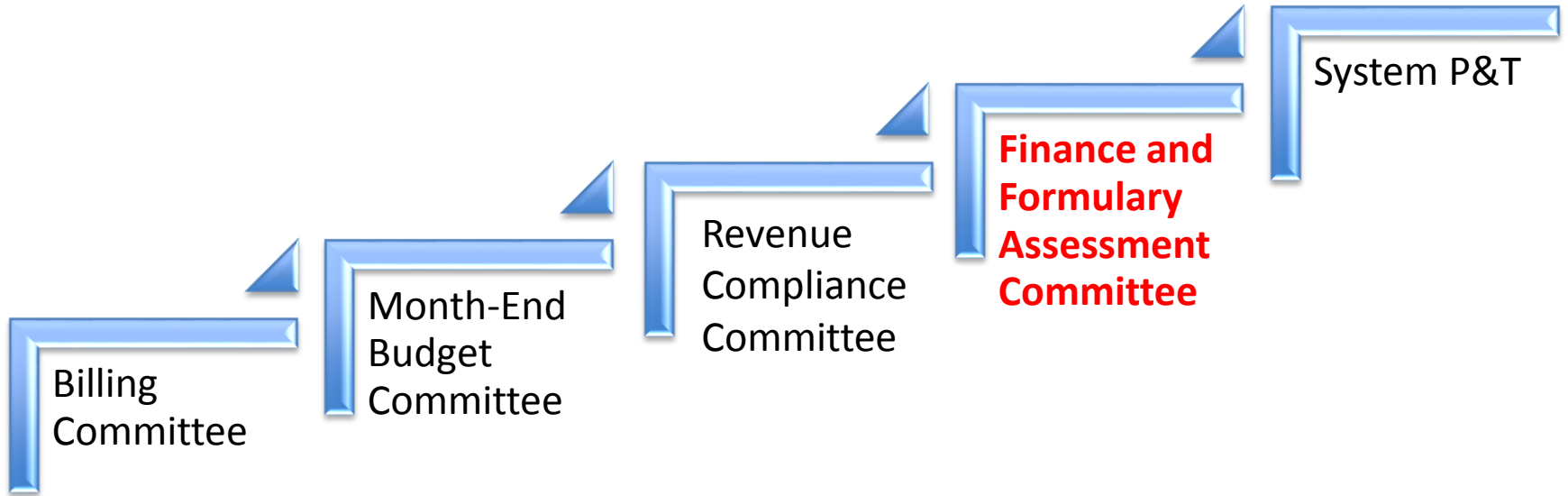
IT Build

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

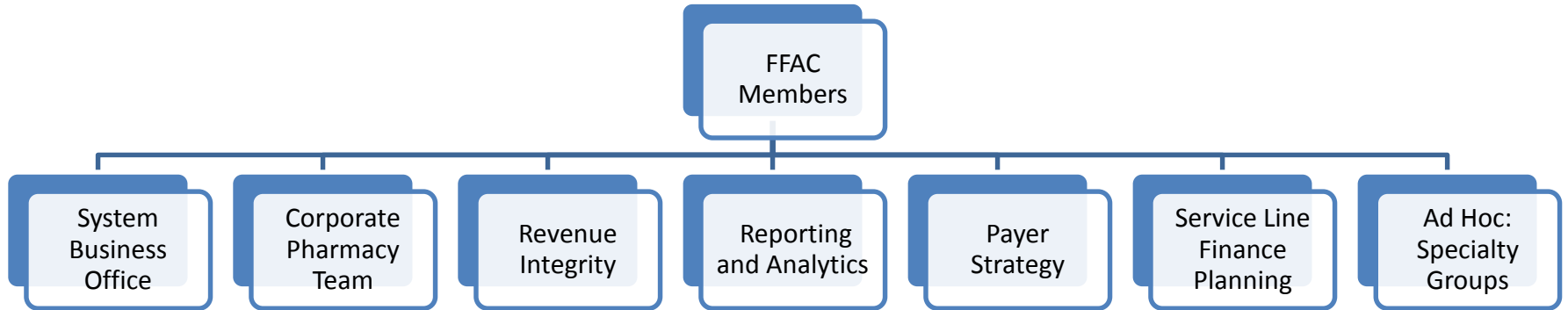
Formulary Decision

- 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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- Sam Abdelghany, osama.Abdelghany@ynhh.org



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