



**PHARMACY
VISION
20/20**

CSHP SEMINAR 20 • OCTOBER 21-25
Disneyland
RESORT

HIGH COST PHARMACEUTICALS, DETERMINING THE VALUE EQUATION

HARMINDER SIKAND PHARMD, FCSHP, FASHP, FCCP

SCRIPPS MERCY HOSPITAL

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

1. Describe which members of an organization's healthcare team need to be involved to facilitate the cost-neutral prescribing of high-cost oncology drugs (such as lutetium Lu 177 dotatate)
2. Identify components of the healthcare team required for efficient and timely formulary management
3. Explain three methods to appropriately manage high-need medications during a shortage

The presenter has no conflict of interests in regards to this presentation

GOALS FOR TODAY

- Current landscape
- Traditional Formulary Management
- System P and T, 2.5 Years Later
- Medication Shortages, a New Culture
- Site of Care Administration Tools and Case Study
- Future Direction

Hospital Locations

Four (4) hospitals on five (5) campuses



**\$3.1 BILLION
IN REVENUE**

**15,000
EMPLOYEES**

**3,000
PHYSICIANS**

157 Medical Residents & Fellows
8 PGY1 Pharmacy Residents
2 PGY2 Pharmacy Residents
60 P4 Rotations

Not-for-profit, Integrated Health Care System in San Diego, California

Operating Two of San Diego's Six Trauma Centers

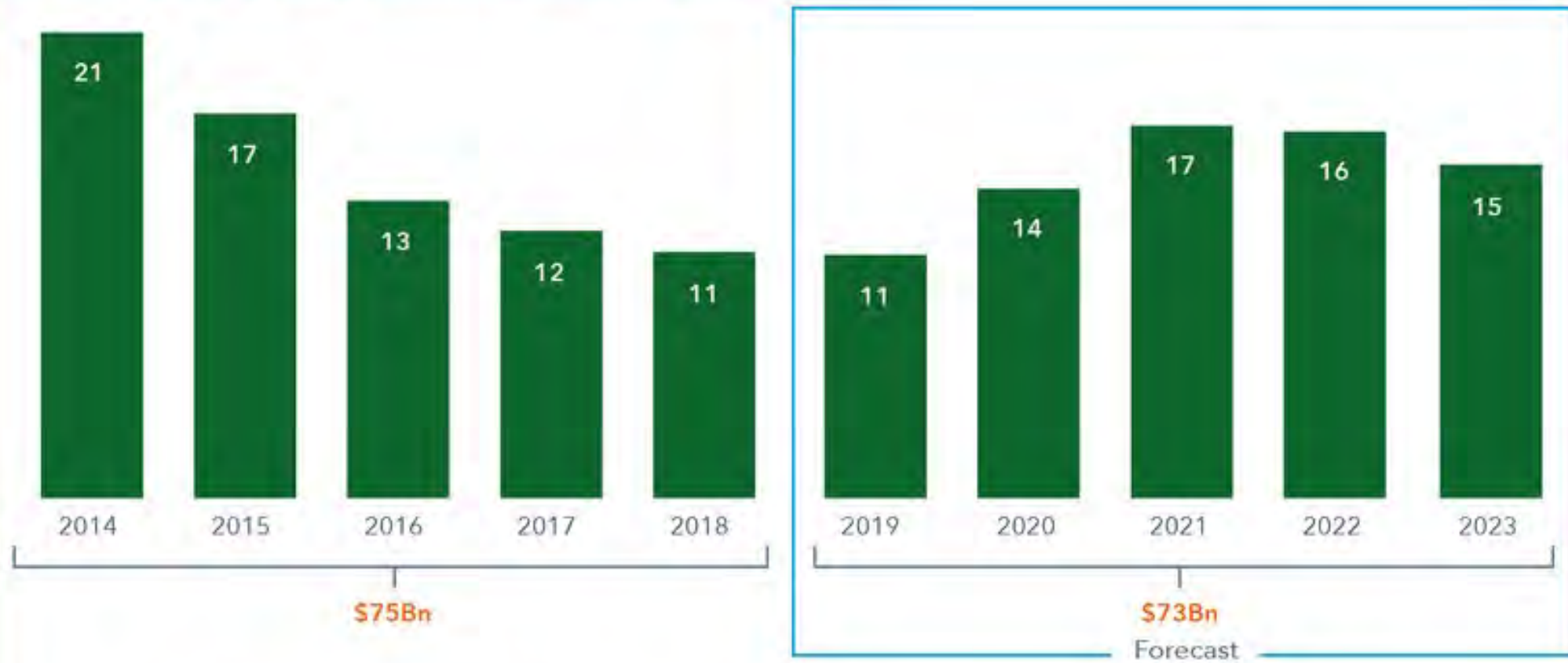
System includes 5 Scripps Hospital campuses, Scripps Clinic, Scripps Coastal Medical Centers,

Scripps Cardiovascular Institute and Scripps Home-Based Care



Current Landscape

Estimated Net New Brand Spending Growth, 2014–2023 US\$Bn



Source: IQVIA Market Prognosis, Mar 2019; IQVIA Institute, Apr 2019

Chart notes: NAS = new active substance. New brands are protected branded products on the market less than 24 months during the year reported. Net spending reflects company recognized revenue after off-invoice discounts, rebates and price concessions are applied. Includes all medicines in both pharmacy and institutional settings.

Report: Medicine Use and Spending in the U.S. – A Review of 2018 and Outlook to 2023. IQVIA Institute for Human Data Science, May 2019



- Cost of medications continues to rise at a rate of greater than 6%
- Specialty medication costs rising faster, 3 times the rate of non-specialty medications at 18–20%
- Top class of agents:
 - Antineoplastic
 - Disease-modifying
 - Immunomodulatory
- Average total drug spend/hospital admission increased 18.5% between 2015–2017

CURRENT PHARMACEUTICAL LANDSCAPE

Heredity angioedema

Pharmacogenomics
Alipogene

Generic reformulations

Shortages

Bupivacaine/meloxicam
HTX-011

Lutathera

Voretigene neparovec-rzyl
(Luxturna®)

Tisagenlecleucel (Kymriah™)
CAR-T cell

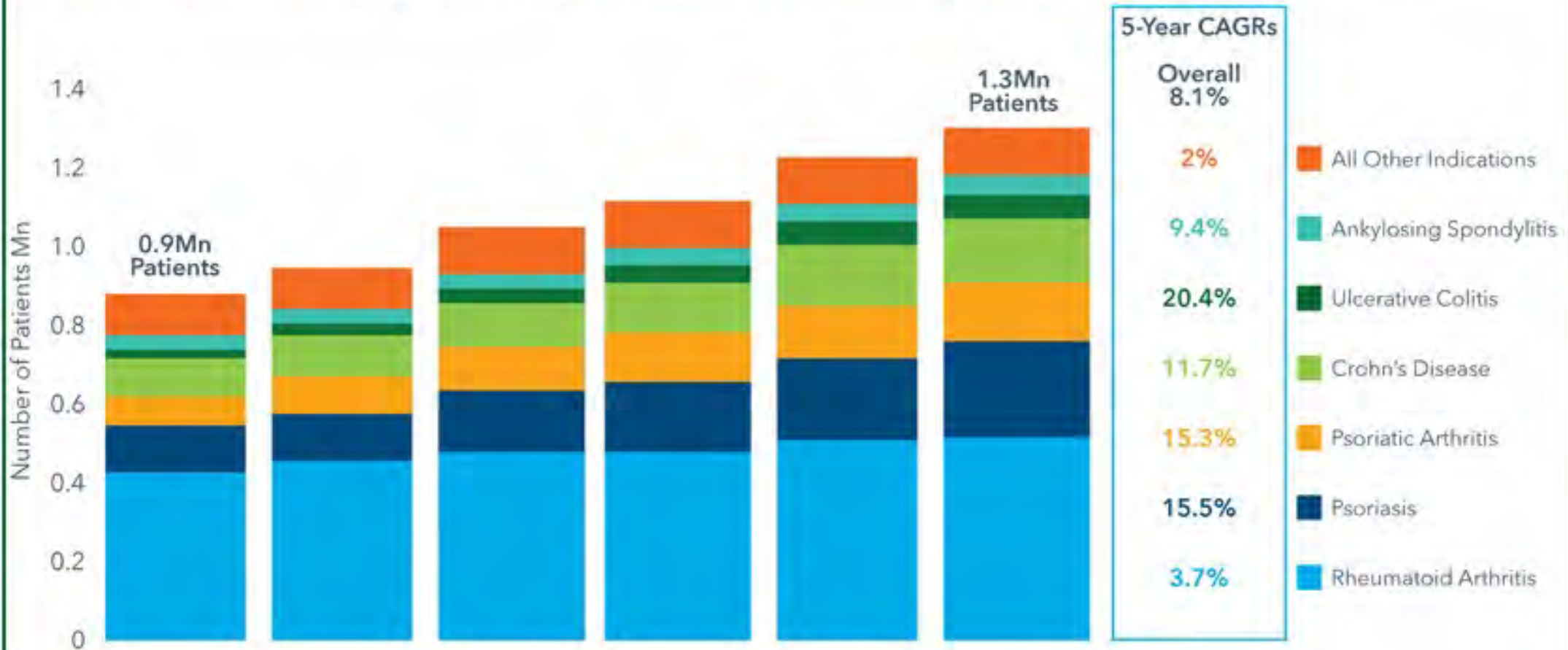
Axicabtagene ciloleucel (Yescarta™)
CAR-T cell

Hepatitis C

Hemolytic uremic syndrome

Biosimilars?

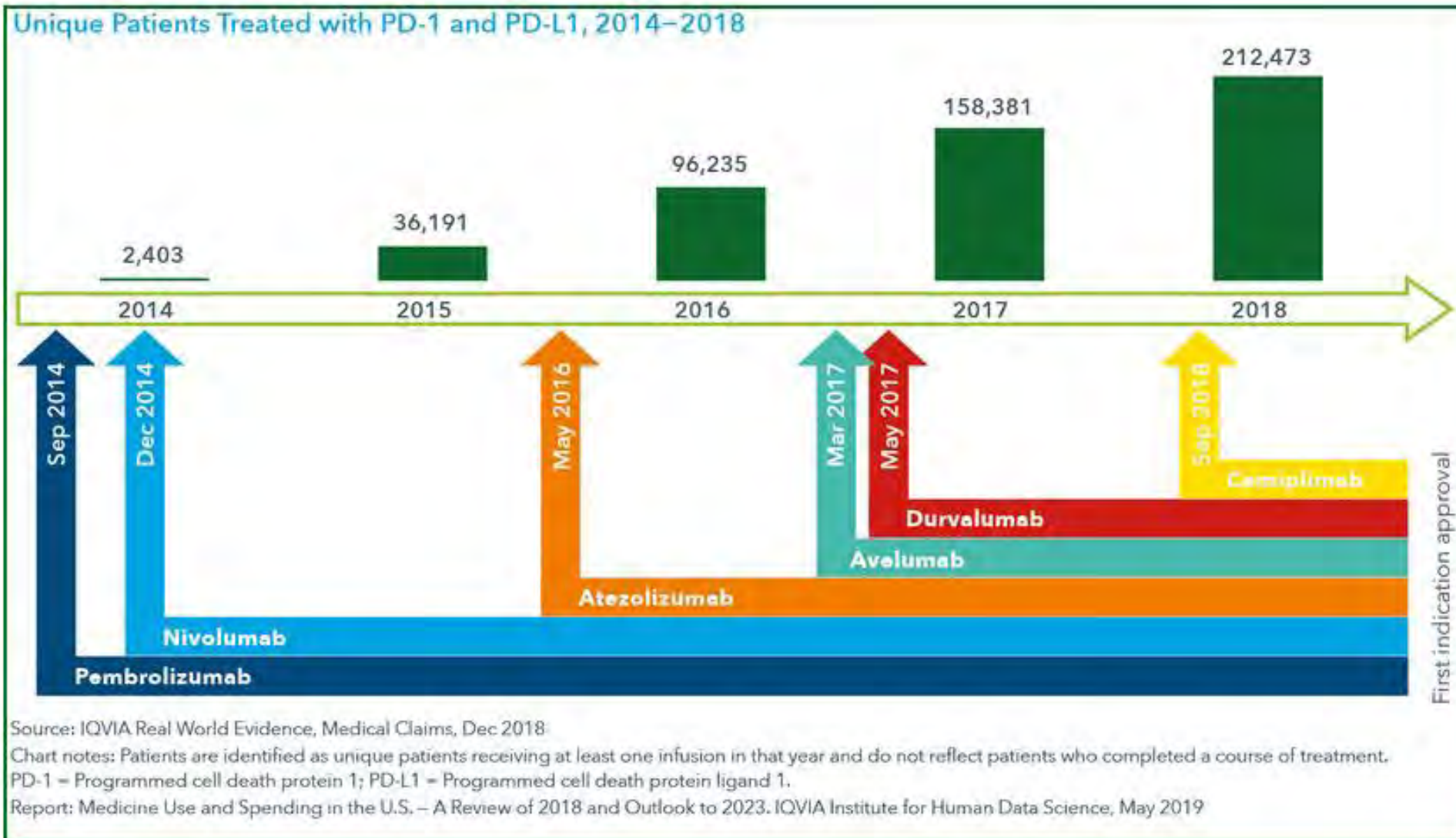
Number of Patients Receiving Treatment for Autoimmune Diseases by Indication, Millions



Source: IQVIA Real World Evidence, Longitudinal Prescription Data, Jan 2019

Chart notes: CAGR = Compound Annual Growth Rate. Anonymized patient data used to identify patients receiving at least one claim for prescription or treatment associated with relevant conditions.

Report: Medicine Use and Spending in the U.S. – A Review of 2018 and Outlook to 2023. IQVIA Institute for Human Data Science, May 2019

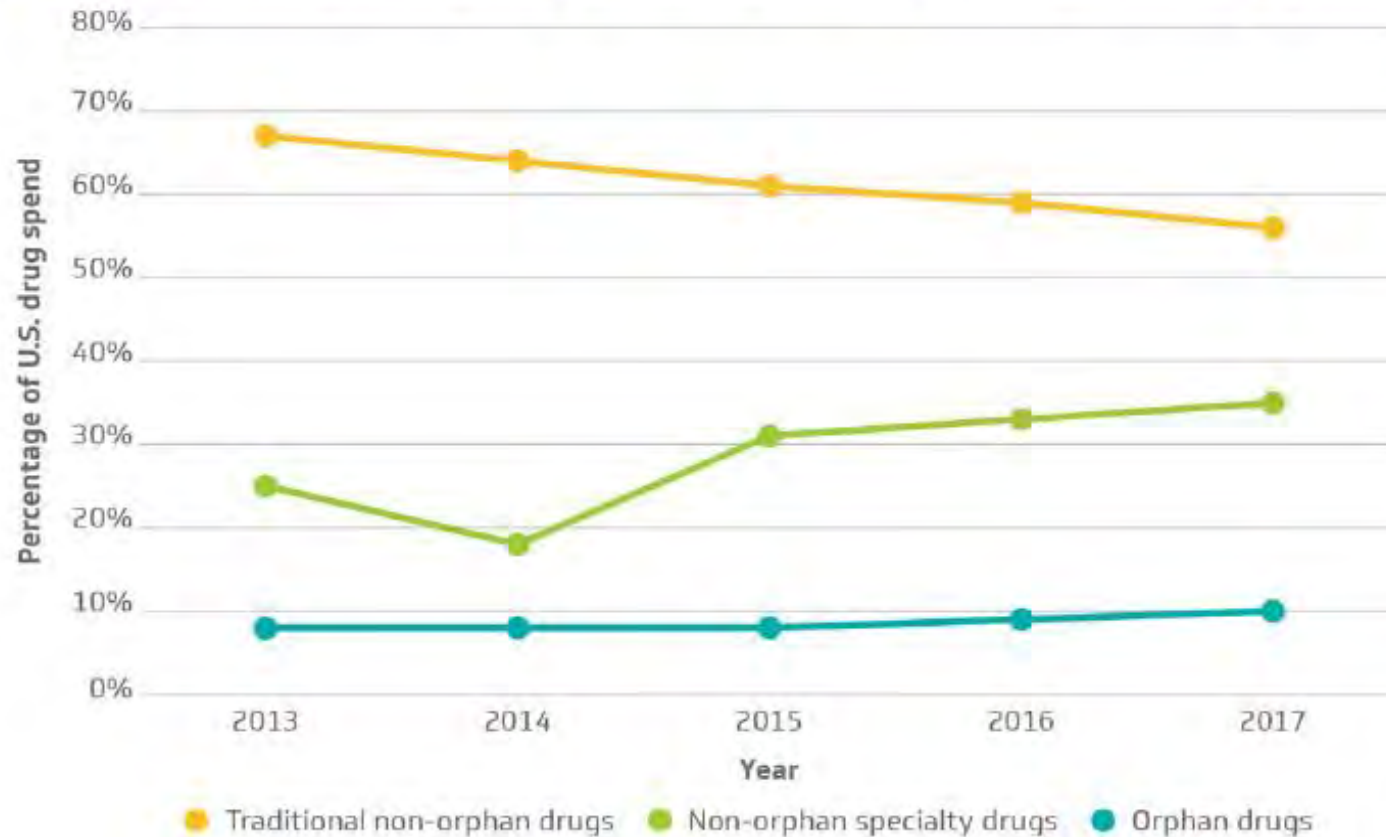


RISE IN MEDICATION SPENDING

Etiologies

- Increased cost, not increased utilization
- Persistent shortages
- Growing specialty medications
- Medications for rare and very rare disorders

Figure 1. Annual spend by drug type as a percentage of total U.S. drug spend



OPPORTUNITIES

- Develop system-wide physician credentialing in hospital systems
- Address organization market positions
 - Leverage 340B programs
 - Leverage outpatient site of care
 - Home infusion
- Maximize market opportunity
 - Biosimilar

NEW DYNAMIC IN FORMULARY MANAGEMENT—THE STRATEGY

Traditional

Innovative

Real time/Nimble

STRATEGY—HUMAN FACTOR

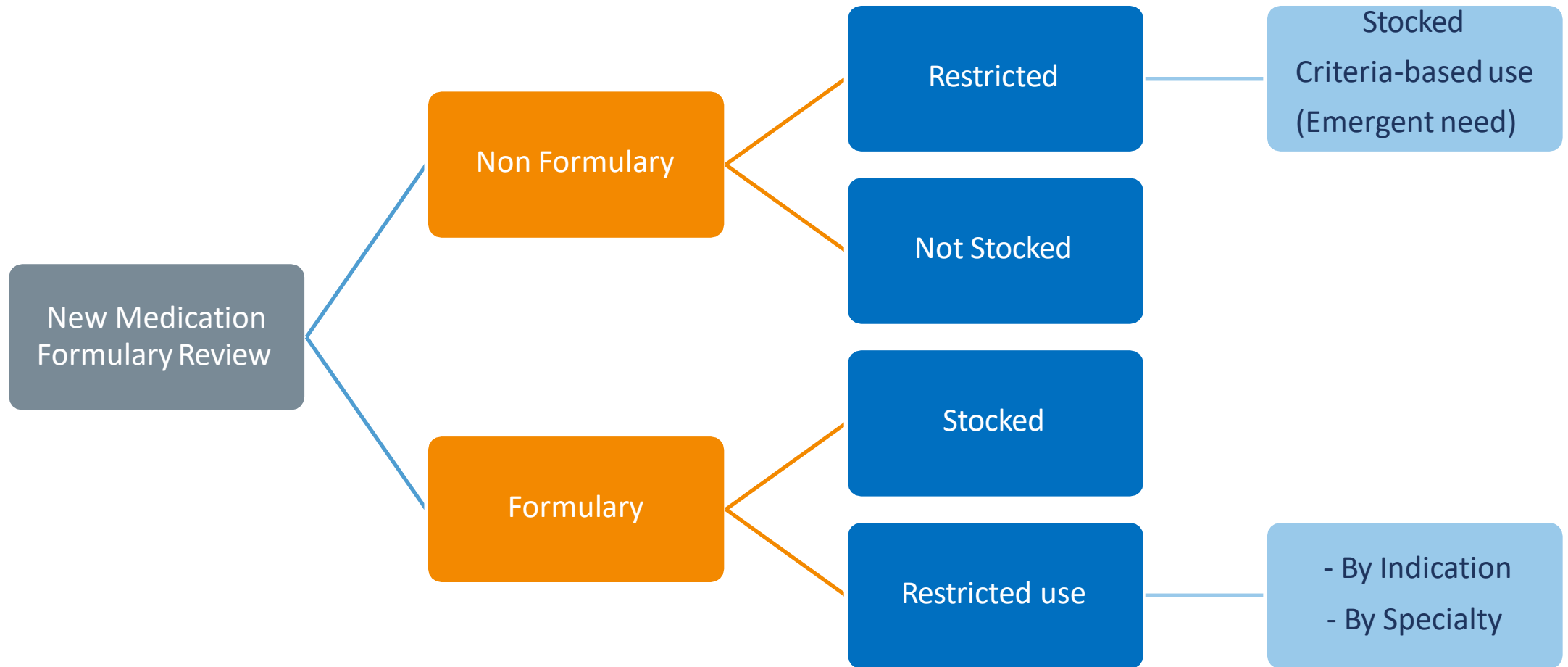
Credibility

Trust

Team

Decision Steps

TRADITIONAL—FORMULARY MANAGEMENT



| Biosimilars—Time to Maximize Utilization

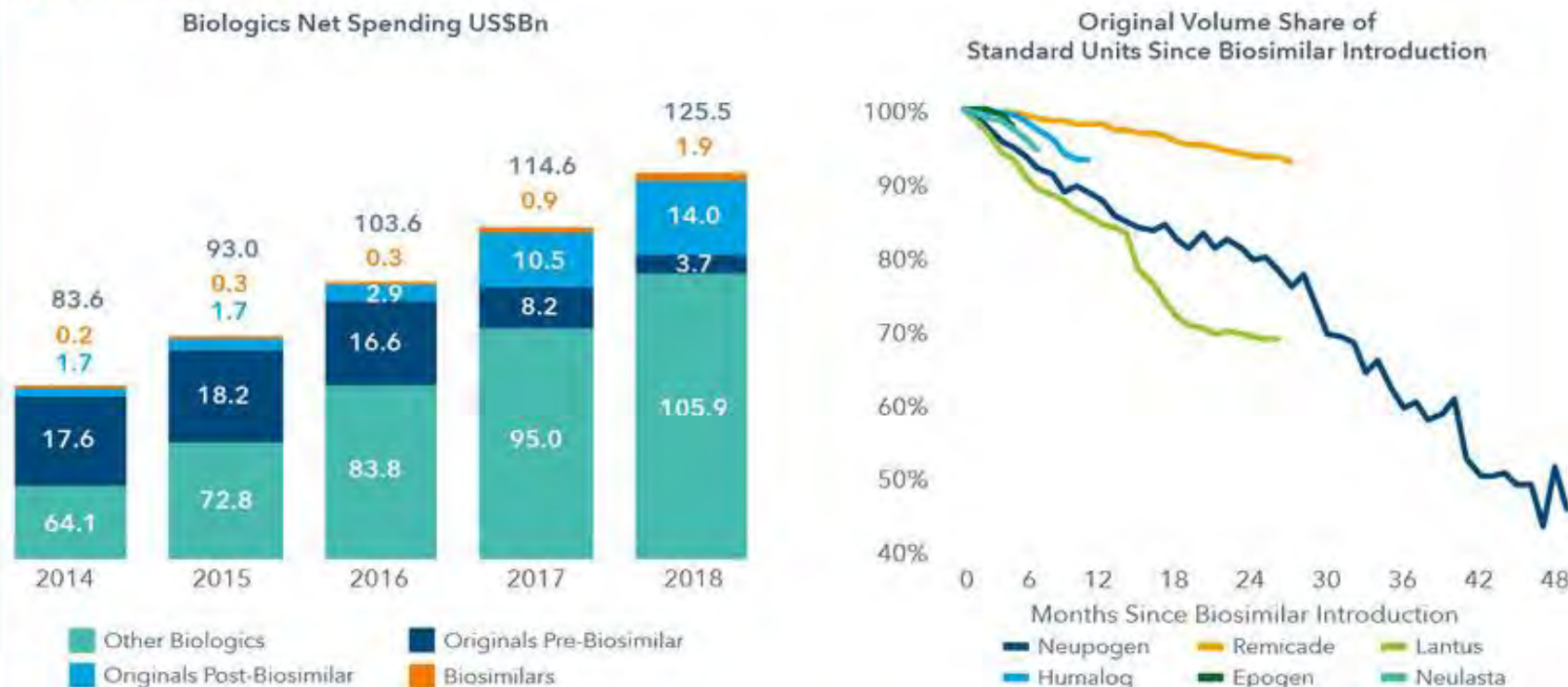
July 2019

- 23 approved in US
- ~10 currently marketed
 - Patent protection/exclusivities
- CMS unique reimbursement code
 - Pass through recognition for all biosimilars

Medications

- **Pegfilgrastim-jmdb/cbqv**
- Infliximab-dyyb/qbtx
- **Rituximab-abbs**
- **Trastuzumab-**
qyyp/pkrb/dttb/dkst/ykro/anns
- **Bevacizumab-bvzr**
- **Adalimumab - 2023**
- Eternacept-szsz/ykro
- Filgrastim-sndz/aafi
- Epoetin alfa -epbx

Impact of Biosimilars



Source: IQVIA National Sales Perspectives, IQVIA Institute, Jan 2019

Chart notes: Biologics are defined by IQVIA as clearly identifiable molecules of biologic origin, including but not limited to products created with recombinant DNA technology and without necessarily adhering to classifications by regulatory bodies, which are sometimes inconsistent with this approach. Biosimilars are abbreviated biologic approvals made with reference to an original biologic and demonstrating similarity to the reference product. Non-original products approved outside the official biosimilar pathway have been noted as "biosimilar". Original biologics that have later faced competition have been shown separately in the chart based on whether or not they are facing competition in that period. Includes all medicines in both pharmacy and institutional settings.

Report: Medicine Use and Spending in the U.S. – A Review of 2018 and Outlook to 2023. IQVIA Institute for Human Data Science, May 2019



SYSTEM FORMULARY MANAGEMENT OLD & NEW ROLES

AUDIENCE POLL QUESTION: #1

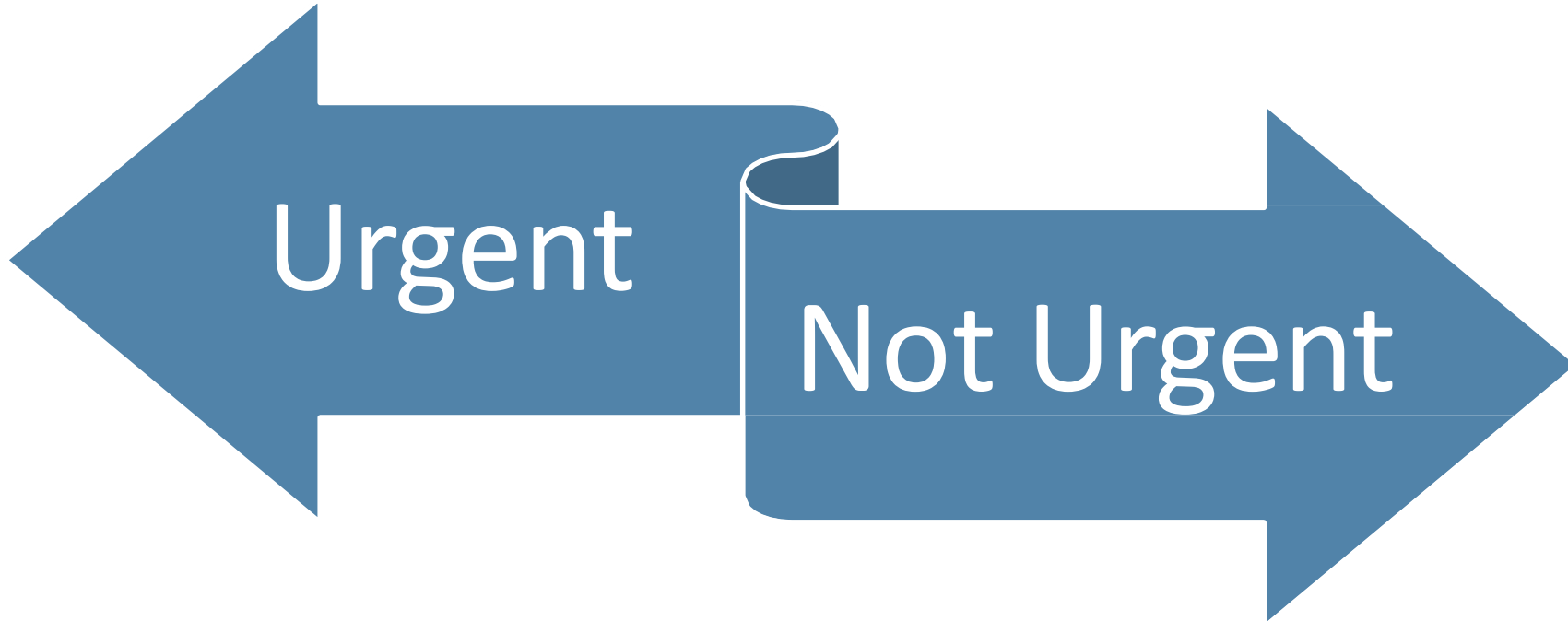
How many practice at a hospital that is part of a system that has a system level Pharmacy and Therapeutics committee making formulary decisions ?

- a. YES
- b. NO



SYSTEM FORMULARY MANAGEMENT

PHARMACY AND THERAPEUTICS COUNCIL



Scripps System Pharmacy and Therapeutics Council (PTC) engaged physician leaders across the enterprise in decision-making for formulary and medication management (2016)

- A system P&T was attempted at Scripps years ago, however did not survive
- PTC 2.0 – Lessons from second attempt at system P&T
- Define the scope of the problem, roles and goals
- Develop a platform that is transparent and known to all
- Involve physicians early and often
- Let physicians' lead
- Value quality over speed
- Incentivize Medical Staff
- Communicate
- Evolve practices to improve problem-solving ability of complex issues
- Re-scale efforts to remain relevant during challenging times

Actions Supporting System-Wide P&T Committee Success



Incentivize care line participation

- Appoint strong physician leader to head system PTC to add legitimacy among physicians
- Educate physician leadership and care line councils on cost savings and quality benefits for full system buy-in
- Create budget for stipend to pay physicians for council participation



Delineate clear responsibilities for system- and site-level committees

- Utilize responsibility matrix to avoid redundancies
- Mandate strict time frame for approval from system to site
- Create clear system governance model to monitor financial impact, utilization of the system formulary, and management of review calendar



Create clinical pharmacy support team

- Provides data and gathers multidisciplinary stakeholder feedback for system-wide P&T council (PTC) decisions
- Led by system clinical pharmacy leader and physician PTC chair
- Established a communication cascade to provide transparency around PTC decisions and upcoming implementation

Disciplines Represented:

Medical Staff

- Physician Leadership Council
- Emergency Medicine
- Critical Care Medicine
- Internal Medicine
- Hospitalists
- Trauma
- General Surgery
- Anesthesia

Department of Pharmacy

Executive Sponsorship

Nursing Leadership

Care Line Council Leadership

Clinical Support Team (CST) ... the driving force of the PTC

- Site and system Clinical Pharmacy Leaders
- Financial analyst

- Affiliated PTC Efforts
- Site P&T Committees
 - System Antimicrobial Stewardship
 - System Opioid Stewardship

Scripps Health

System Pharmacy & Therapeutics Council (PTC)

Scope of work includes medication management

Committee Composition

Site P&T
Committee
Leaders

Stakeholders

Medical Staff,
Pharmacy,
Nursing, etc.

SYSTEM P AND T FORMULARY REVIEW PROCESS



Scope of PTC: \$20,000/treatment or \$100,000/Year change

Proposed rubric for formulary decision making

IMPACT to PATIENT CARE	IMPACT on COSTS of CARE	DECISION
Strong evidence of improvement in patient outcomes – clinical and/or experiential	Significant increase per year	▪ Approve but needs authorization from finance to justify increase
	Moderate increase per year	Approve
	Minimal impact	
	Measurable savings	
Weak evidence of improvement in patient outcomes - clinical and/or experiential	Significant increase per year	Deny
	Moderate increase per year	Discuss and decide based on facts presented
	Minimal impact	
	Measurable savings	▪ Provisional approval – subject to re-review at set time, must show intended outcome achieved
No evidence of a change in patient outcomes	Significant increase per year	Deny
	Moderate increase per year	
	Minimal impact	▪ Discuss and decide based on facts presented, or Deny, or Provisional approval – subject to re-review at set time, must show intended outcome achieved
	Measurable savings	Provisional approval – subject to re-review at set time, must show intended outcome achieved
Belief that there is already a demonstrably better alternative	Significant increase per year	▪ Deny (regardless of impact)
	Moderate increase per year	
	Minimal impact	
	Measurable savings	

Note: Therapies with weak evidence and significant costs should be denied per rubric

Scripps Health System Formulary Review

Grading Quality of Evidence

High	<p>Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes</p> <ul style="list-style-type: none"> ▪ 2 consistent, higher quality randomized controlled trials (RCTs) that yield consistent and directly applicable results, or ▪ Multiple, consistent observational studies with no significant methodological flaws showing large effects ▪ Further research is very unlikely to change our confidence in the estimate of effect
Moderate	<p>Evidence is sufficient to determine effects on health outcomes, but the number, quality, size, or consistency of included studies limits the strength of the evidence</p> <ul style="list-style-type: none"> ▪ Limitations include: biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events ▪ Evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention also considered moderate quality ▪ Further research will have an important effect on confidence in the estimate of effect and may change the estimate
Low	<p>Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality studies, important flaws in study design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes</p> <ul style="list-style-type: none"> ▪ Observation studies typically rated low* quality due to risk for bias ▪ Further research is very likely to have an important effect on confidence in the estimate of effect and will probably change the estimate

* Quality of evidence may be rated as moderate or even high, depending on circumstances under which evidence is obtained from observational studies. Factors that may contribute to upgrading the quality of evidence include a large magnitude of the observed effect, a dose-response association, or the presence of an observed effect when all plausible confounders would decrease the observed effect.

Success By Numbers FY2018 YTD

PTC IMPACTS TO FORMULARY

FY2017

- 42 - Formulary Reviews
 - 9 - Formulary additions
 - 9 - Formulary restrictions
 - 12 - Non-Formulary designations
 - 10 - Medication Class Reviews
- 6 - Medication Use Evaluations
- 18 - Protocols, Criteria for Use, Guidelines, Policies
- 1 - Decision Appeal
- 8 - Agenda items approved per meeting (average)

Online Requests

- 7 - Addition to Formulary Requests
- 39 - Non-Formulary Requests (Patient-Specific Use)

FY2018 YTD

- 16 - Formulary Reviews
 - 3 - Formulary additions
 - 3 - Formulary restrictions
 - 9 - Non-Formulary designations
 - 1 - Medication Class Reviews
- 7 - Medication Use Evaluations
- 24 - Protocols, Criteria for Use, Guidelines, Policies
- 0 - Decision Appeals
- 8 - Agenda items approved per meeting (average)

Online Requests

- 2 - Addition to Formulary Requests
- 20 - Non-Formulary Requests (Patient-Specific Use)



PTC Decisions—Transparency and Communication

Last step in the process is implementing the decisions

- 5 weeks following the PTC decision
- Implementation occurs at once, across all sites

The screenshot shows the Scripps Pharmacy & Therapeutics Council website. It features a navigation menu on the left with options like Libraries, Site Pages, Shared Documents, Lists, Calendar, Tasks, Discussions, Team Discussion, and Site Contents. The main content area includes sections for Formulary Requests (with buttons for Non-Formulary, System Formulary Addition, and PTC Appeal), PTC Meeting Minutes (listing meetings from 2016 to 2018), PTC Formulary Updates (listing updates from January 2017 to March 2018), and a PTC Calendar (with a link to the calendar and details for June 2017 meetings, including Phosphate-free low-volume bowel prep review, Angiotensin II review, Aprepitant review, Alvimopan MUE findings, Methylnaltrexone and Naloxegol MUE findings, and Carparazine review).

FORMULARY and MEDICATION MANAGEMENT UPDATE

- The Pharmacy and Therapeutics Council met May 17th 2017
- **Implementation of decisions effective on Tuesday, June 27th 2017**
- More information [found](#) on [insidescripps.org](#) ► Patient Care ► Pharmacy Resources ► Formulary Requests

SUMMARY of DECISIONS		
FORMULARY DESIGNATION: FORMULARY	<p>Clear Fast Beverage Formulary</p> <ul style="list-style-type: none"> • Preoperative carbohydrate loading is but one of many interventions linked to the success of ERAS-guided therapy. • Clear Fast designated Formulary • Supplied by Supply Chain for inpatient use (pre-hospital, outpatient use, Clear Fast provided at Pre-Surgical Education, MD Office, or through Scripps Community Pharmacies or other retail pharmacy) 	<p>Oxacillin Formulary (Nafcillin Non-Formulary)</p> <ul style="list-style-type: none"> • Scripps has two formulary anti-staphylococcal Penicillins, both recommended and utilized as first-line options for methicillin-sensitive Staphylococcus aureus (MSSA) infections • Oxacillin and Nafcillin are used interchangeably due to similar spectrum, PK profile and efficacy; Oxacillin has a preferred adverse event profile. • Oxacillin designated Formulary, Nafcillin designated Non-Formulary.
	<p>Ophthalmic Agent Standardization Formulary</p> <p>12 Ophthalmic medication classes reviewed, formulary-preferred agents selected as preferred Formulary</p>	
DESIGNATION: NON FORMULARY	<p>Diclofenac IV and Ibuprofen IV Non-Formulary / Not-Stocked</p> <ul style="list-style-type: none"> • Diclofenac IV and Ibuprofen IV do not provide added benefit over formulary preferred IV NSAID, Ketorolac • Diclofenac IV and Ibuprofen IV designated Non-Formulary, and Not-Stocked • Other formulations of Diclofenac and Ibuprofen remain Formulary 	<p>Icatibant (Firazyr) Non-Formulary</p> <ul style="list-style-type: none"> • Icatibant is a first-in-class agent used to treat acute attacks of hereditary angioedema (HAE); is designed for patient self-administration • Cost per dose (30mg) of Icatibant = \$9,441, compared to \$7,035 for human derived C1-INH (Berinert) and \$60 for 2 units of FFP. • Icatibant designated Non-Formulary as it does not appear to provide clinically significant inpatient benefits for either HAE or ACE-I/AE, and a less costly agent is already on formulary (Berinert)
	<p>Jayhawk Juice Non-Formulary / Not Stocked</p> <ul style="list-style-type: none"> • Jayhawk juice is a compounded mucolytic solution containing terbutaline/ N-acetylcysteine (NAC) / methylprednisolone that is used for bronchoscopic lavage • Limited information is available regarding the safety and efficacy of Jayhawk Juice • NAC is a first-line therapy for acetaminophen overdose; its use should be restricted to that indication • Jayhawk Juice designated Non-Formulary, and Not-Stocked • Alternative – Hypertonic Saline – will be offered if orders received 	
PROTOCOL UPDATE	<p>Renal Dosing Protocol UPDATE:</p> <ul style="list-style-type: none"> • Added table of weight calculation when dosing for obese patients 	<p>Cost Card UPDATE:</p> <ul style="list-style-type: none"> • Annual review of Medicine cost card

Review [Calendar of Deliverables](#) for upcoming PTC agenda items
 NEXT PTC MEETING: Wednesday, June 21st 2017

Stakeholder communication reminds physicians of the PTC decision, and need-to-know details

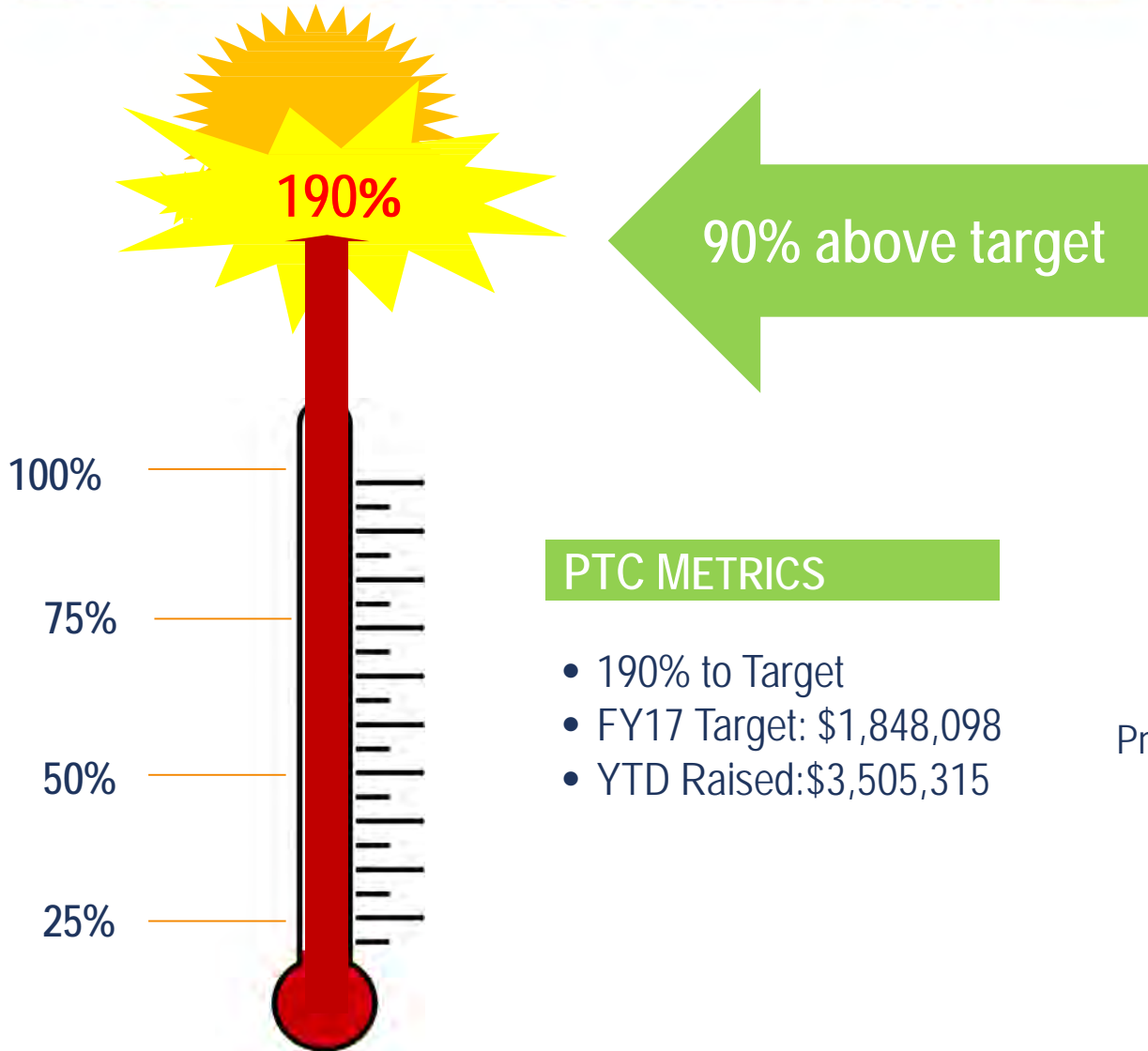
PTC information accessible for all on System website

1. Online requests
2. Calendar – agenda items scheduled months in advance
3. Meeting minutes and updates

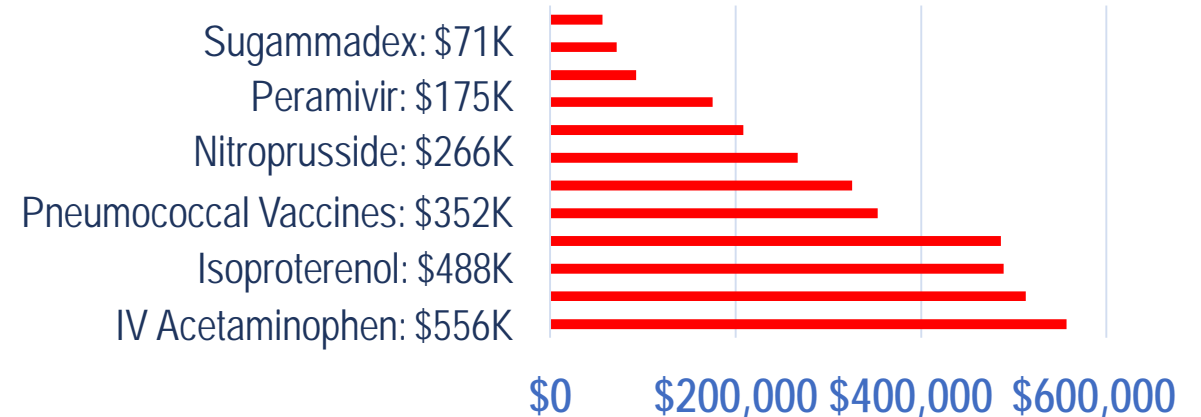


MEDICATION	CONTROVERSIES	OUTCOME
Andexanet (Andexa)	Increase in cost Evidence moderate	<ul style="list-style-type: none"> • Non Formulary, Not Stocked • Neurosurgery, Trauma, ED, ICU stakeholder buy in <p><u>Prescriber Opinion</u> = First NOAC reversal agent. Legal concerns <u>Evidence</u>: non compelling. Outcomes similar to PCC. Increased thrombotic events</p>
Angiotensin II (Giapresa)	Increase in cost Evidence Moderate	<ul style="list-style-type: none"> • Non Formulary. Stocked with Orderset build. Criteria established with restricted prescribing • ICU Intensivist and Trauma buy in <p><u>Prescriber Opinion</u>: Distributive septic shock benefit. Can use as last resort. Intensivists know how to use the drug. <u>Evidence</u>: Clinical outcome data lacking</p>

MEDICATION	CONTROVERSIES	OUTCOME
Sugammadex (Bridion)	Increase in cost Evidence high	<ul style="list-style-type: none"> • Formulary (unrestricted) • Cost-Neutral • Favorable decision – anesthesia stakeholders <p><u>Prescriber Opinion</u> = inappropriate use, over spending will result if added <u>Evidence</u> = standard of practice</p>
IV Acetaminophen (Ofirmev)	Increase in cost Evidence moderate	<ul style="list-style-type: none"> • Restricted Formulary • Lowered overall use system wide • Continuous evaluation of evidence/utilization/strategies <p><u>Prescriber Opinion</u> = miracle drug; improved pain scores, patient satisfaction, LOS <u>Evidence</u> = quicker onset</p>
Bupivacaine Liposomal (Exparel)	Increase in cost Evidence low	<ul style="list-style-type: none"> • Non-Formulary • Continuous evaluation of literature <p><u>Prescriber Opinion</u> = improved pain control and better patient outcomes <u>Evidence</u> = non-compelling, when compared to standard of practice</p>



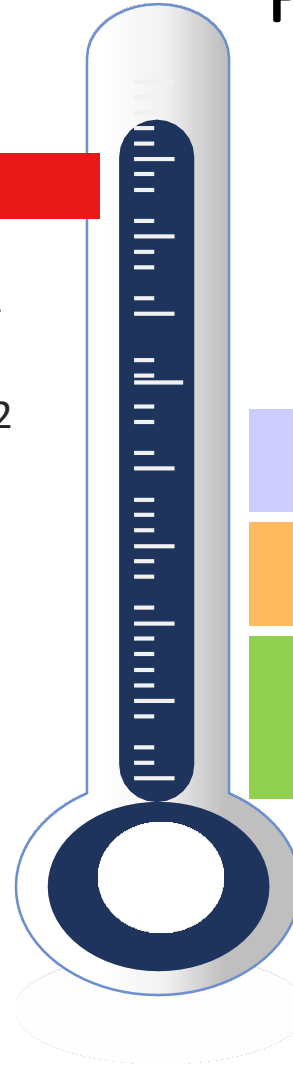
PTC Performance Improvement Leaders FY2017



PHARMACY OUTCOME MEASURES YEAR 2 JULY 2018 (YTD)

All Pharmacy P.I.s

- 86.5% to Target
- 83% through Fiscal Year
- FY Target: \$24,080,000
- YTD Raised:\$20,840,262



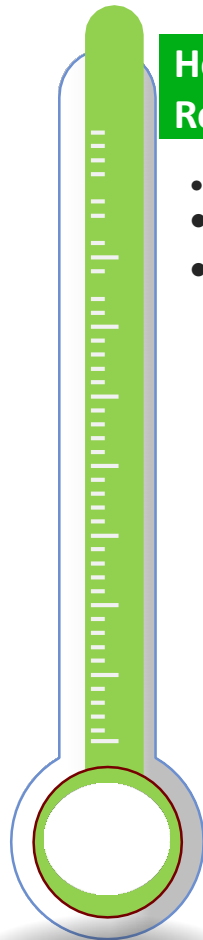
Operations \$5,068,932

Retail \$2,244,604

Drug Cost Reduction \$12,501,865

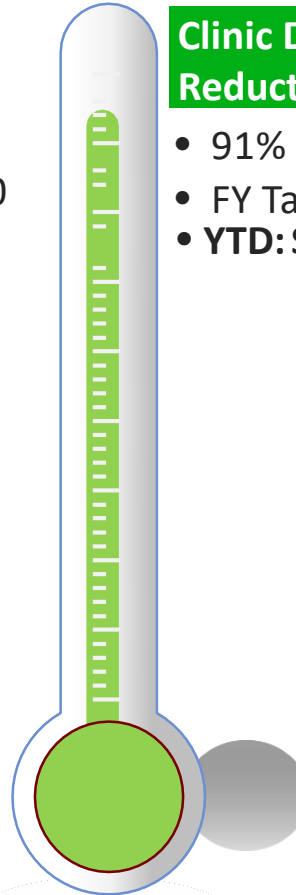


DRUG COST CONTROL—UTILIZATION OUTCOME MEASURE



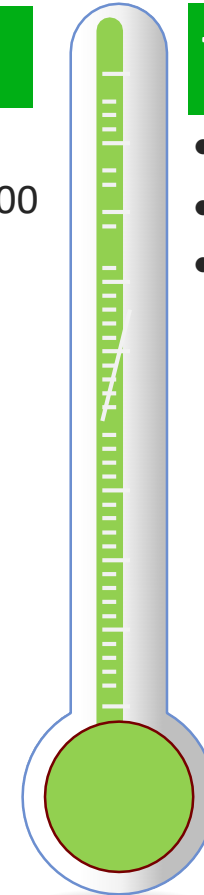
Hospital Drug Cost Reduction

- 118% to Target
- FY Target: \$4,020,000
- YTD: \$4,755,587



Clinic Drug Cost Reduction

- 91% to Target
- FY Target: \$8,500,000
- YTD: \$7,746,278



Total

- 99.8% to Target
- FY Target: \$12,520,000
- YTD Raised: \$12,501,865

PTC CONTINUOUS IMPROVEMENT Survey Results – SEPTEMBER 2016

Survey sent through same communication cascade as all other PTC information

	Efficient and Organized	Communication of Decisions	Physician Engagement	Formulary Management and Standardization	Evidence Based Decisions	Input from Multiple Stakeholders
Very Good	38	37	26	28	48	35
Good	34	26	32	43	28	28
Average	25	20	25	20	19	25
Below Average	3	12	9	8	2	8
Poor	0	5	8	1	5	4

high scoring 48% of responders stated PTC decisions were evidence based

Challenges—Specific solutions for problem medications

- **Non-Formulary designation**

- Create toll-gates to provide evaluation of the request, when requested

- **Restricted-Formulary designation**

- Develop Criteria of Use Guidelines with subject experts
- Indication-specific and Specialty-specific

- **Leverage your EHR**

- Carry over PTC decisions to order content
- Make selections obvious and provide decision support as needed

PTC physician engagement

Speak to colleagues and medical staff at their sites regarding inappropriate use

Determine education

Routine methods or more in-depth MEMO from Chief Medical Officer, PTC Chair or Site P&T Leader

Medication Shortages

SODIUM
BICARBONATE

Thiamine

Pantoprazole

Shortages

PCC IV

Opioids IV

Pip/tazo

WE DEAL WITH MEDICATION SHORTAGES IN ONE OF THE FOLLOWING WAYS:

- a. In “real time” with automatic Pharmacist authorities to make conversions
- b. Reactively after minimal supply remains
- c. Limiting medication to key patient care areas
- d. All of the above

MEDICATION SHORTAGE MANAGEMENT

- PIVOT and Nimble
- Collaboration with Key Opinion Leaders BEFORE they are emergent
- Scripps Intranet

Temporary Pharmacist Authorities (Drug Shortage Management)

- PHARMACIST MANAGED OPIOID IV TO PO CONVERSION 
- PHARMACIST MANAGED THERAPEUTIC INTERCHANGE OF LOCALLY INJECTED LIDOCAINE 
- PHARMACIST MANAGED THERAPEUTIC INTERCHANGE OF OPHTHALMIC DROPS FOR SURGICAL CASES 
- PHARMACIST MANAGED THERAPEUTIC INTERCHANGE OF INJECTABLE PANTOPRAZOLE 

MEDICATION SHORTAGES—PHARMACIST AUTOMATIC AUTHORITY

Pantoprazole IV

Original IV pantoprazole order received	Pharmacist will convert order to:
Pantoprazole continuous infusion ordered for patient with active upper GI bleed	Pantoprazole 40 mg IV push BID
Pantoprazole continuous infusion OR intermittent IV push ordered on non-GI bleed patient. Patient meets criteria for acid suppression (see table below)	<p>If oral/enteral route unavailable: Famotidine 20 mg IV push BID (20 mg IV push daily if CrCl <50 mL/min)</p> <p>If oral/enteral route is available: Pantoprazole 40 mg PO daily OR lansoprazole 30 mg ODT per gastric tube daily</p>
Any IV pantoprazole order on a patient that does NOT meet criteria for acid suppression	Discontinue pantoprazole order

Acid Suppression Criteria for Use

Utilize H2-receptor blockers (H2RAs – ie: Famotidine) for the following indication:

- GERD
- History of peptic ulcer disease (PUD) or duodenal/gastric ulcer disease

Limit PPI use to the following indications:

- Stress ulcer prophylaxis for ICU patients with one of the following risk factors*
- Known or suspected upper GI hemorrhage
- Peptic ulcer/ duodenal ulcer disease for treatment
- Hypersecretory conditions (Zollinger-Ellison, major small bowel resection)

PPI use requires documented GI approval for:

- Chronic steroid use
- Erosive GERD
- Dual antiplatelet therapy

MEDICATION SHORTAGES—PHARMACIST AUTOMATIC AUTHORITY

Examples

OPIOIDS IV to PO

Inclusion

- Functioning GI Tract
- On scheduled oral medication and/or tolerating $\geq 50\%$ of full liquids or $\geq 50\%$ of goal for tube feeding for 24 hours with no vomiting

IV Opioid	PO Opioid
Morphine	
Morphine 1 mg	Morphine 2.5 mg
Morphine 2 mg	Morphine 5 mg
Morphine 3- 4 mg	Morphine 10 mg
Morphine 5- 6 mg	Morphine 15 mg
Morphine 7- 8 mg	Morphine 20 mg
Morphine 9- 10 mg	Morphine 30 mg
Hydromorphone	
Hydromorphone 0.2 – 0.3 mg	Hydromorphone 1 mg
Hydromorphone 0.4 – 0.7 mg	Hydromorphone 2 mg
Hydromorphone 0.8 – 1 mg	Hydromorphone 4 mg
Hydromorphone 1.1 – 1.5 mg	Hydromorphone 6 mg
Hydromorphone 1.6 mg – 2 mg	Hydromorphone 8 mg
Fentanyl	
Fentanyl 25 mcg	Morphine 7.5 mg
Fentanyl 50 mcg	Morphine 15 mg
Fentanyl 100 mcg	Morphine 30 mg

Medication Shortage Dosing Modification

Prothrombin Complex Concentrate (Kcentra)

Order of Use	Warfarin	NOAC (Rivaroxaban/Apixaban/Edoxaban)	Coagulopathy of Liver Disease Reversal in Anticipation of Surgery	Coagulopathy of Liver Disease Active Life-Threatening Bleeding
FIRST LINE	Fixed Dose 4F PCC (KCentra) <ul style="list-style-type: none"> Vitamin K 10 mg IV x 1 and KCentra 1500 units IV x 1 Repeat INR 15min If INR>1.5 can give another 500 units (consider if going to surgery) 	4F PCC (KCentra) <ul style="list-style-type: none"> KCentra 25 units/kg IV x 1 If inadequate hemostasis achieved, consider an additional 25 units/kg IV X1 NTE 5000 units irrespective of body weight 	Fixed Dose 4F PCC (KCentra) <ul style="list-style-type: none"> Vitamin K 10 mg IV x1 and KCentra 500 units IV x1 Consider FFP 2 units IV x 1 <p><i>Check and replete fibrinogen (> 150 mg/dL) with cryoprecipitate, platelets (>50,000mg/dL)</i></p>	Fixed Dose 4F PCC (KCentra) <ul style="list-style-type: none"> Vitamin K 10 mg IV x1 and KCentra 1,500 units IV x1 FFP 2 units IV x 1 <p><i>Check and replete fibrinogen (> 150 mg/dL) with cryoprecipitate, platelets (>50,000mg/dL), support with pRBC</i></p>
SECOND LINE	3F PCC (Profilnine) <ul style="list-style-type: none"> Vitamin K 10 mg IV x 1 and Profilnine 30 IU /kg IV x 1 FFP 2 units IV x 1 NTE 4000 units irrespective of body weight 	FEIBA (activated PCC) <ul style="list-style-type: none"> FEIBA 25 u/kg IV x 1 If inadequate hemostasis achieved, consider an additional 12.5 units/kg IV X1 	3F PCC (Profilnine) <ul style="list-style-type: none"> Vitamin K 10 mg IV x1 and Profilnine 500 units IV x 1 Consider FFP 2 units IV x 1 <p><i>Check and replete fibrinogen (> 150 mg/dL) with cryoprecipitate, platelets (>50,000mg/dL)</i></p>	3F PCC (Profilnine) <ul style="list-style-type: none"> Vitamin K 10 mg IV x1 and Profilnine 1500 units IV x 1 FFP 2 units IV x 1
For Sites without immediate access to FFP	FEIBA (activated PCC) <ul style="list-style-type: none"> Vitamin K 10 mg IV x 1 and INR< 5 FEIBA 500 units IV x 1⁴ OR INR≥5 FEIBA 1000 units IV x1⁴ 			

IS THERE A PROCESS TO USE LUTETIUM LU 77
DOTATATE - LUTATHERA[®] CURRENTLY AT
YOUR INSTITUTION?

- a. Yes
- b. No



CASE STUDY



340B

- Therapies with marginal or negative reimbursement
- Focused services at 340b eligible site
- Develop preferred providers to funnel approval and care
- Service lines
 - Rheumatology
 - Oncology
 - Immunotherapy
- Insurances
 - Medicare
 - Capitated arrangements (IPA)
 - Managed care/HMO
 - Employee health plan

SITE OF CARE OPTIMIZATION



U.S. Food and Drug
Administration approval
January 2018

Projected cost per single
treatment AWP
\$ 48,000

4 cycles per treatment
\$ 192,000

CASE STUDY—LUTETIUM LU 77 DOTATATE - LUTATHERA®

Indication:

Treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

Delivery: Nuclear Medicine

Prescriber Specialty: Oncology

Administration : Inpatient OR **Outpatient** Therapy

HIGH COST MANAGEMENT MODEL

Total Cost of Therapy

Analytics

- PTC review
- Projected need

Right Site of Care

Location of Care

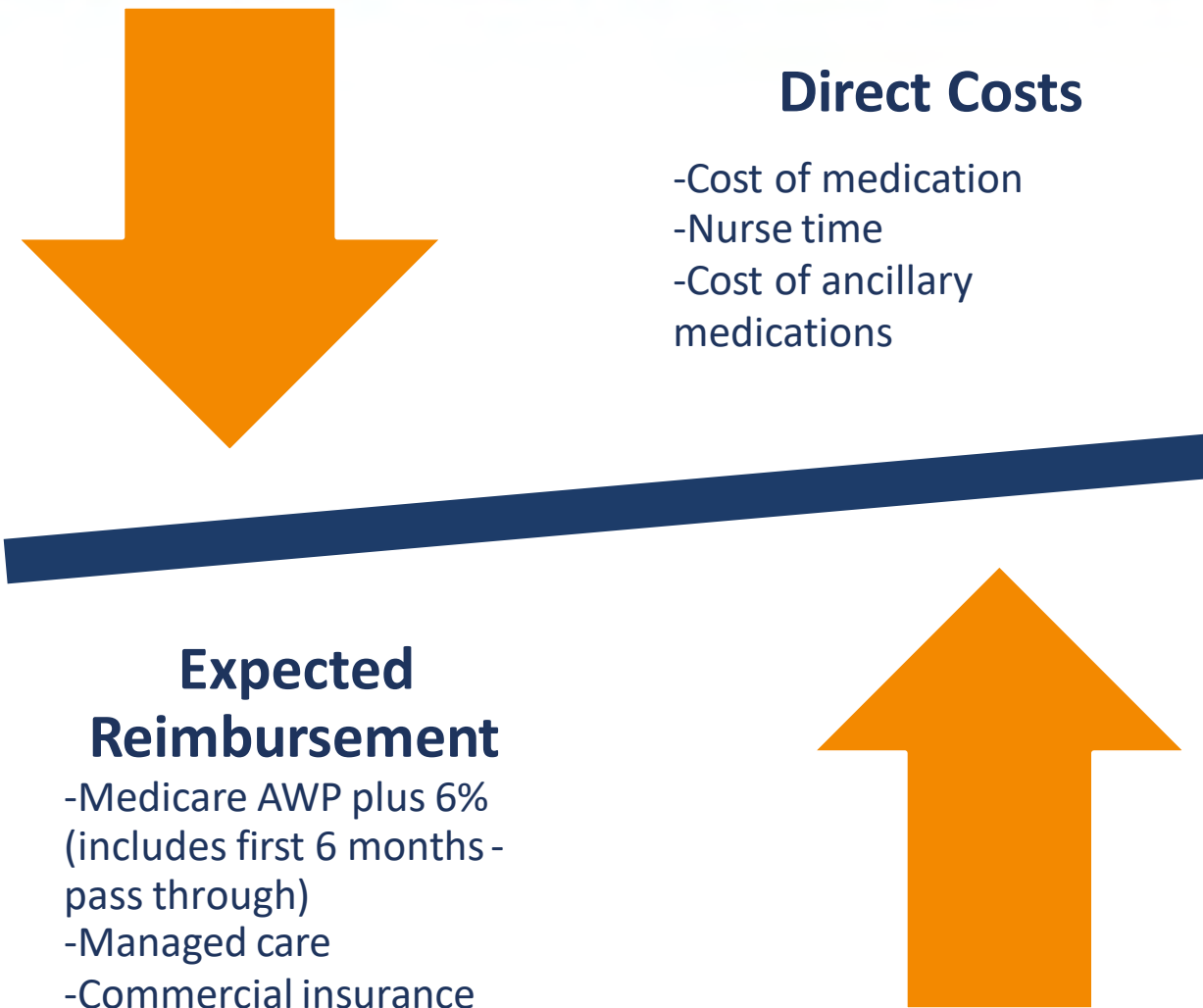
- Physician privileging
- Nuclear Med (outpatient)

Right Patient, Right Access

Provider Approval Team

- Oncologist
- Radiologist

Lutetium Lu 77 Dotatate -
Lutathera®



Lutetium Lu 77 Dotatate - Lutathera®

- Initial Model Case Mix Projection (Cost of Drug Only)

	Per Treatment	Per Case
Total Direct Cost	\$54,000	\$ 214,000
Operating Loss	(\$ 14,000)	(\$ 56,000)

- 340B Program Projection Same Case Mix

	Per Treatment	Per Case
Total Direct Cost	\$ 38,000	\$ 151,000
Operating Loss	(\$889)	(\$3,600)

MODEL DEVELOPMENT—FINANCIAL IMPACT, FIRST ITERATION

MODEL DEVELOPMENT—FINANCIAL IMPACT, SECOND ITERATION



Total Cost of Care

- Non 340B Hospital

	Per Treatment	Per Case
Total Direct Cost	\$53,494	
Weighted Average Reimbursement	\$53,186	
Operating Profit/(loss)	(\$308)	(\$1,231)

- 340B Hospital

	Per Treatment	Per Case
Total Direct Cost	\$37,826	
Expected Reimbursement	\$62,251	
Operating Profit/ (loss)	\$24,425	\$97,700

LUTATHERA OUTCOMES

October 2018 – April 2019

- Goal per Model = 20 patients
- Number of Patients YTD = 15
- Insurance = 70% Medicare, 30% Commercial, No Capitation

What Changed?

- ✓ Moved all patient care to **one** hospital
- ✓ Prescriber privileging restricted
- ✓ Optimized 340B reimbursement

Expected Performance \$1.4 Million

TRANSITION OF CARE: ACUTE CARE TO NON-ACUTE CARE

EXAMPLES

Medication	Indication	Approximate Cost Avoidance (minus hospital stay)	Outcome
Bezlotoxumab IV x 1	Recurrent C difficile s/p 2 Fecal Microbiota Transplants	\$2,000	No ED readmits
Dalbavancin IV x 1	MRSA SSTI and osteomyelitis	\$9,500	No ED readmits

PERFORMANCE IMPROVEMENT OUTCOMES—TAKE HOME POINTS

Through May 2019

Hospitals	
Drug Cost Savings	\$397,700.00
Contribution Margin	\$791,767.00
Biosimilar Conversion	\$389,646.00
340B Mixed Use Increase	\$379,059.00
Hospitals Total	\$ 1,958,172.20

- **Drug Cost Savings:**
 - Lutathera (340B)
- **Drug Utilization Savings:**
 - Esmolol product switch
 - Aprepitant (Cinvanti) conversion
 - Advair interchange
 - Anavip conversion
 - Vasopressin product conversion
 - IV levothyroxine hold parameter
- **Biosimilar Conversion:**
 - Zarxio interchange
 - Inflectra/Renflexis uptake



FUTURE STEPS



EXECUTIVE VALUE ANALYSIS COMMITTEE (EVAC)

Purpose

The Executive Value Analysis Committee is a the group that adjudicates high cost drugs and therapies, providing financial stewardship in combination with ensuring appropriate patient care for the system. The committee will take into account organizational objectives and strategy and ensure the process is both ethical and transparent.



Trigger Points

CRITERIA FOR REVIEW BY EVAC

- Option One:
 - >\$1,000,000 annually (total projected annual cost) OR
 - ≥ \$20,000 per dose or device

- Option Two:
 - >\$50,000 annually (total projected annual cost) per dose or device

- Option Three:
 - Supplies: >\$50,000 annually (total projected annual cost)
 - Pharmaceuticals:
 - ✓ >\$1,000,000 annually (total projected annual cost) OR
 - ✓ ≥ \$20,000 per dose

MEMBERS:

- Physician Operating Executives
- Clinic Vice Presidents
- Chief Medical Officer – Scripps Health
- Chief Medical Officer – Scripps Health Plan
- Operational Chief Executives
- Chief Financial Officer
- Pharmacy Leadership
- Supply Chain Leadership
- Finance

POST TEST QUESTIONS

1. What are the top three medications classes that will account of increased pharmaceutical expenditure?
 - a) Antineoplastic, asthma, infectious disease
 - b) Immunomodulatory, psychiatric, infectious disease
 - c) Antineoplastic, disease modifying, immunomodulatory
2. Rise in medication spending is due to increase cost and not increased utilization .
True or False
 1. Success of a system P and T relies on
 - a) Strong governance
 - b) Stakeholder input
 - c) Evidence based rubric for formulary reviews
 - d) All of the above

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Questions

THANK YOU...

Harminder Sikand

Sikand.Harminder@scrippshealth.org

**SESSION
CODE:**



**PHARMACY
VISION
20/20**

CSHP SEMINAR 20 • OCTOBER 21-25
Disneyland
RESORT