



The cost of innovation:

Taking a closer look at specialty drugs

Blue Cross Master Class Webinar Series
January 24, 2019



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What you'll learn from today's session

Topics

- What are specialty drugs
- How they are impacting the pharmaceutical industry
- Why there has been an increase in utilization
- How Blue Cross manages specialty pharmacy
- How you can make the most of your pharmacy benefits

Today's speakers

Expertise from Blue Cross Senior Health leaders



Steve Marciniak, R.Ph.

Director, Medical Drug
Management



Trish Stievater, Pharm.D.

Director, Pharmacy Benefit
Clinical Services



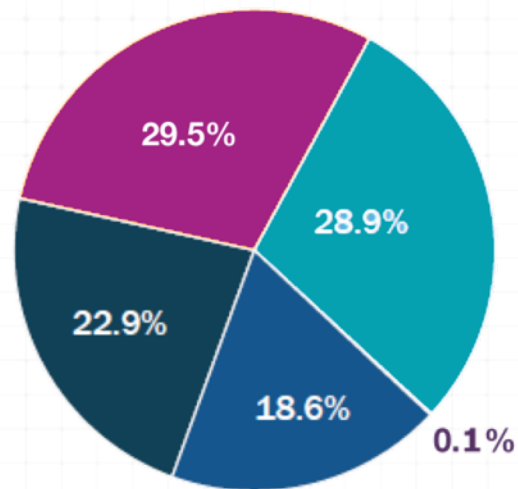
Jacob Chaffee, Pharm.D.

Clinical Pharmacist,
Clinical Services

Pharmacy is the most-used benefit

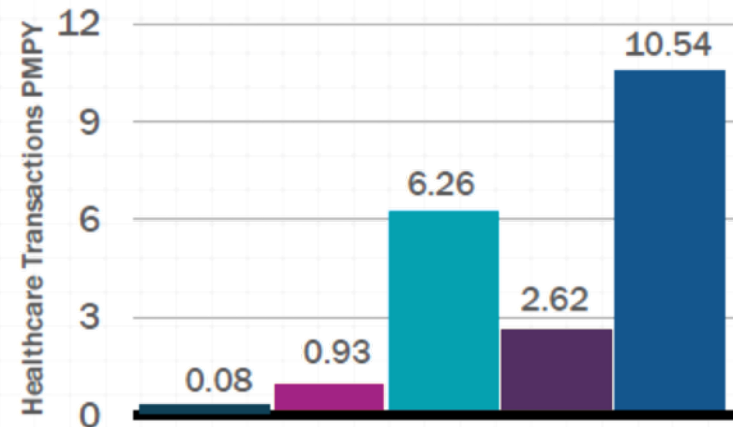
A look at the percentages

Health Spending Distribution



■ Inpatient ■ Outpatient ■ Physician ■ Ancillary ■ Pharmacy

Pharmacy Is the Most Widely Used Benefit



Specialty drugs accounted for

40.8%

Of pharmacy spend in 2017

At 1% of claims

(Express Scripts' 2017 Drug Trend Report)

Source: Express Scripts

What are specialty drugs?

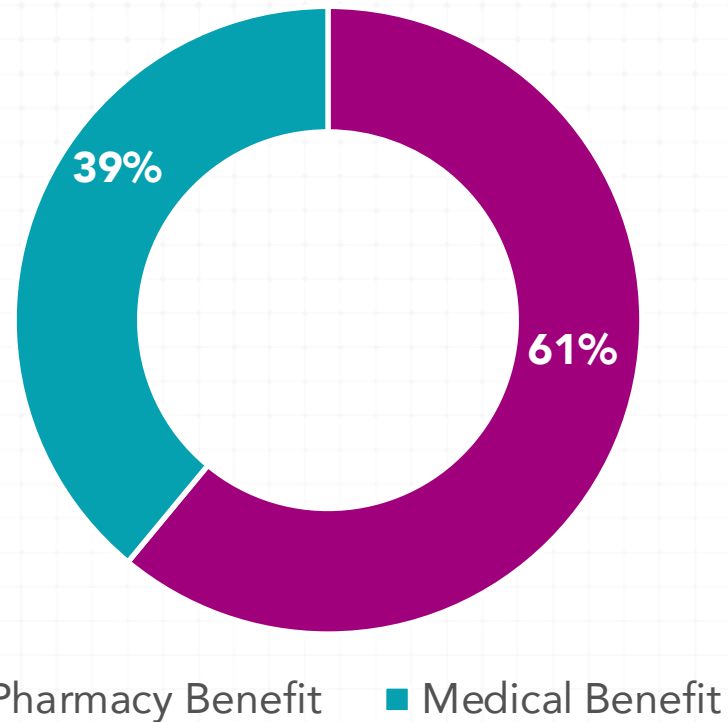
High complexity, high touch

- High-cost prescription medications that require specialized handling, distribution, administration or monitoring and treat complex conditions
 - Ex. Cancer
 - Ex. Hepatitis
 - Ex. Rheumatoid Arthritis
- Require patient care management to control side effects and ensure compliance



Typically priced at more than \$1,000 per 30 day supply
(Magellan Rx Management 2016)

Specialty drugs covered under pharmacy and medical benefits



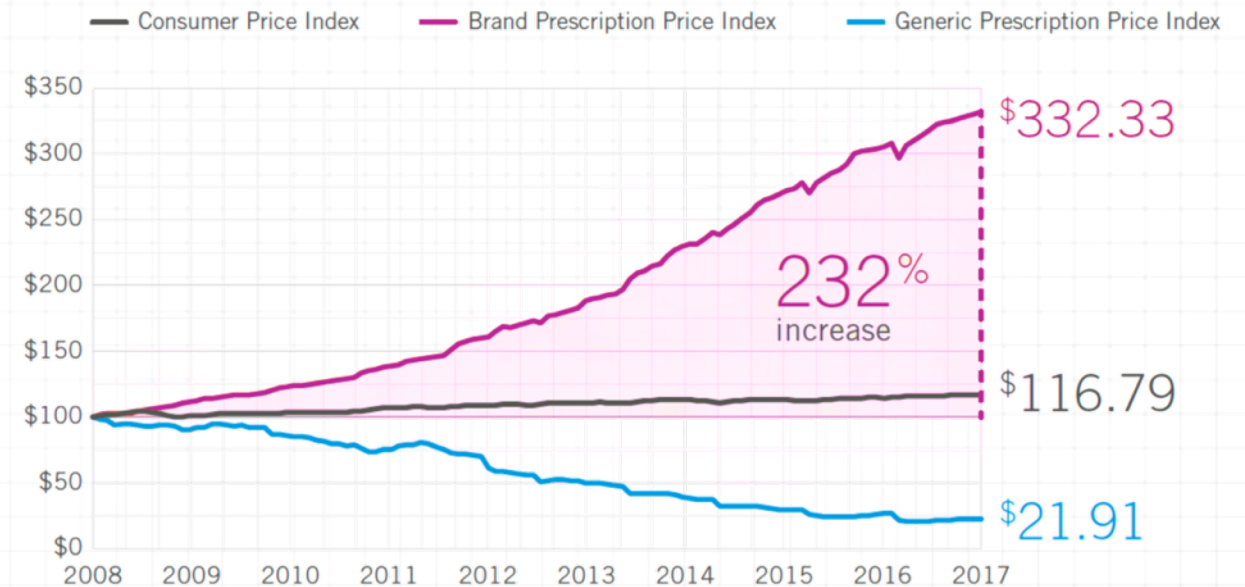
On average, plans attribute 61% of specialty drug costs to the pharmacy benefit and the remaining 39% to the medical benefit.

Specialty drug costs continue to rise

- Brand drug costs increased 232% since 2008
- Generics continue to moderate the costs, but the effect is weakening
- Specialty drugs are expected to account for **47% of U.S. pharmacy spend by 2022**

[Source: [2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Exhibit 70]

PRESCRIPTION PRICE INDEX



Source: 2017 Express Scripts 2017 Drug Trend Report.

Why are specialty drugs so expensive?

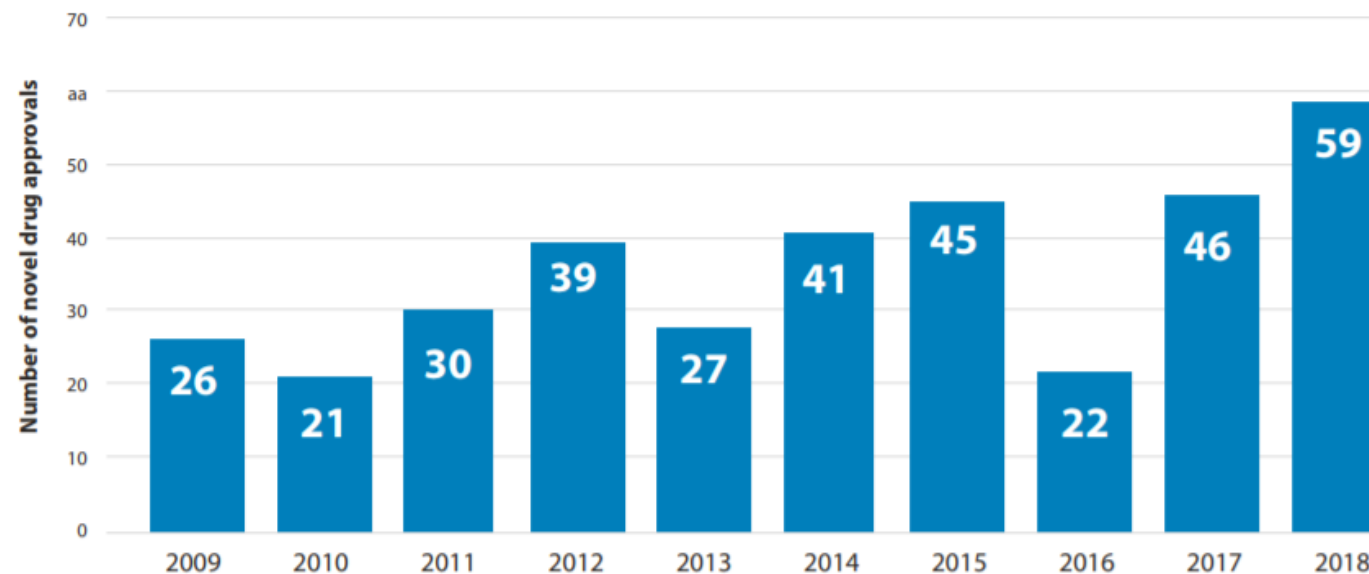
Research, development, availability

1. Exclusivity, low competition in market place
2. Small patient populations, so need higher cost to recoup investment
3. Higher cost manufacturing processes – ex. biologics, gene therapy



Specialty drug approvals continue to grow

- In 1990, according to [The American Journal of Managed Care](#), there were 10 specialty drugs on the market.
- By 2008 that number had increased to 200
- In 2018, the FDA approved 59 novel drugs, an all-time high. Today there are hundreds of specialty drugs available, giving patients unprecedented access to potentially life-changing treatments.

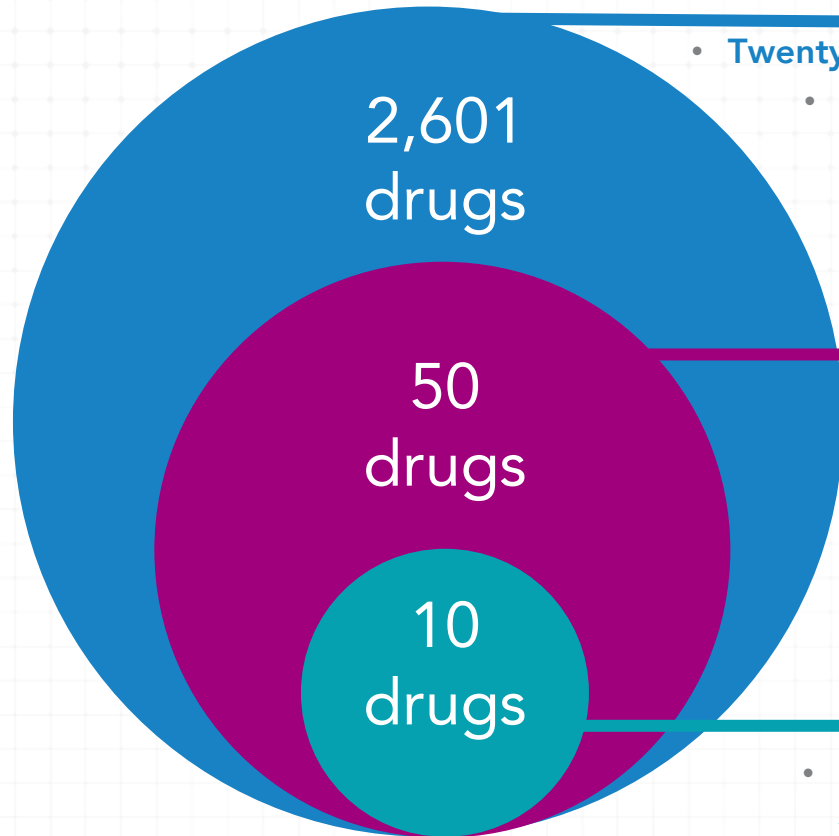


FDA Novel Drug Approvals (2009-2018)

What's coming:

Medical and pharmacy drug pipeline through December 2019

TOTAL NEW PIPELINE DRUGS



- **Twenty-nine percent** of pipeline drugs are for **oncology** therapy.
 - High-cost **cell and gene therapies** have over 140 unique treatments currently in late stage development.
 - **Alzheimer's disease, epilepsy and pain management** drugs are leaders in the **neurological therapy** pipeline.

WATCH LIST DRUGS (LARGE BUDGET IMPACT)

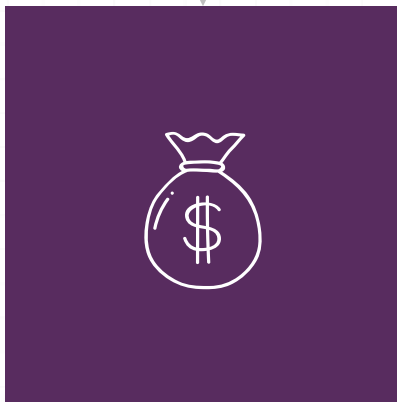
- Gene therapy for **spinal muscular atrophy** with an anticipated cost of **\$1 million** per course of treatment.
- Gene therapy for **hemophilia** patients with an anticipated cost of **\$1 million** per course of treatment.
- Improved versions of **immunotherapies for cancer** which are expected to have **applications to other diseases** such as **HIV**.

ALERT DRUGS (POTENTIAL BUDGET BUSTERS)

- **Migraine** drugs are an expanding field of therapies. Migraines occur in **over 10 percent of Americans**; costs for new therapies are projected to **exceed \$5,000** per member, per year.
- **Progressive fatty liver disease** has a **30 to 40 percent prevalence** in America (especially among **overweight and diabetic adults**); projections suggest this therapy will **exceed \$5,000** per member, per year.

Specialty drugs approved in 2018

symdeko



\$270,000

Novel cystic
fibrosis treatment

 **KYMRIAH™**
(tisagenlecleucel) Suspension
for IV infusion

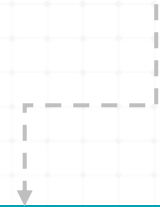
 **YESCARTA™**
(axicabtagene ciloleucel) Suspension
for IV infusion



\$525,000 - \$700,000

Cellular immunotherapy for cancer
("CAR-T")

 **LUXTURNA™**
voretigene neparvovec-rzyl
for subretinal injection



\$425,000 per eye

Gene therapy for
childhood blindness

Specialty drug trends

Gene therapy and one-time treatments

EXAMPLE

- Gene therapy seeks to modify or manipulate the expression of a gene or alter living cells for therapeutic use
- Technique to modify a person's genes to treat or cure disease

Zolgensma gene therapy for spinal muscular atrophy Type 1

- Incidence: one in 10,000 live births
- Current treatments: Spinraza (nusinersen) and supportive care
- Estimated FDA action: May 2019
- Estimated cost: \$2 million to \$4 million
- Limited treatment center network
- Outcomes-based contract

Specialty drug trends

Orphan drugs

- Orphan drugs or biological products are a subset of specialty drugs that treat a rare condition or disease
- Rare diseases are defined as any disease or condition that affects **fewer than 200,000** people in the United States
- Approximately **7,000 rare diseases exist**
- A total of 30 million Americans, or **1 of 10 people, have a rare disease**

Orphan drugs cost U.S. patients an average of \$147,308 in 2017 — more than four times the average cost of non-orphan drugs at \$30,708.



Specialty drug trends

Biosimilars as cost-effective alternatives to biologics

- **Biologics** are medicines made from living cells through highly complex manufacturing processes and must be handled and administered under carefully monitored conditions.
- A **biosimilar** is a biological product that is developed to be highly similar with no clinically meaningful differences to an already FDA-approved biologic, known as the reference product

EXAMPLE

Examples of biologics with biosimilar options:

- Remicade (infliximab) (reference product) → Inflectra and Renflexis (biosimilars)
- Neulasta (pegfilgrastim) (reference product) → Fulphila and Udenyca (biosimilars)
- Epogen/Procrit (epoetin) (reference products) → Retacrit (biosimilar)
- Biosimilars for Humira and Enbrel approved, delayed launch

Specialty drug management at Blue Cross

Right treatment, right place, right time

- Managing utilization
- Monitoring the pipeline
- Managing integrated medical and pharmacy benefits
- Site of Care optimization
- Biosimilar strategy



Specialty drug management

Managing utilization

- Prior authorization
- Step therapy
- 15-day specialty drug limitation program
- High-cost drug review



Specialty drug management

Monitoring the pipeline

Emerging Therapies Workgroup

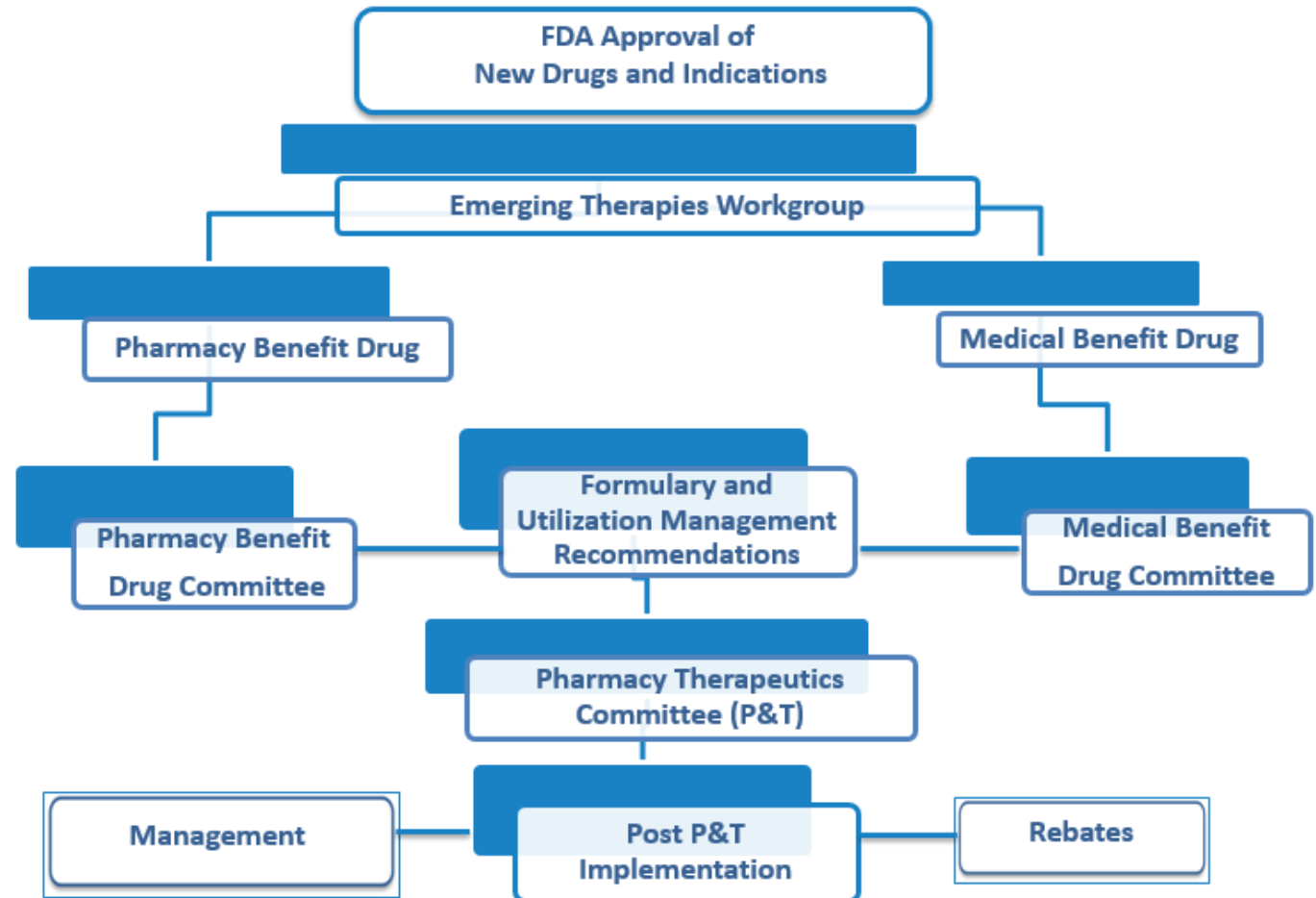
- Proactive approach for new high-cost products coming to market
- Medical policy recommendations for how to cover
- Recommendations on drug management



Specialty drug management

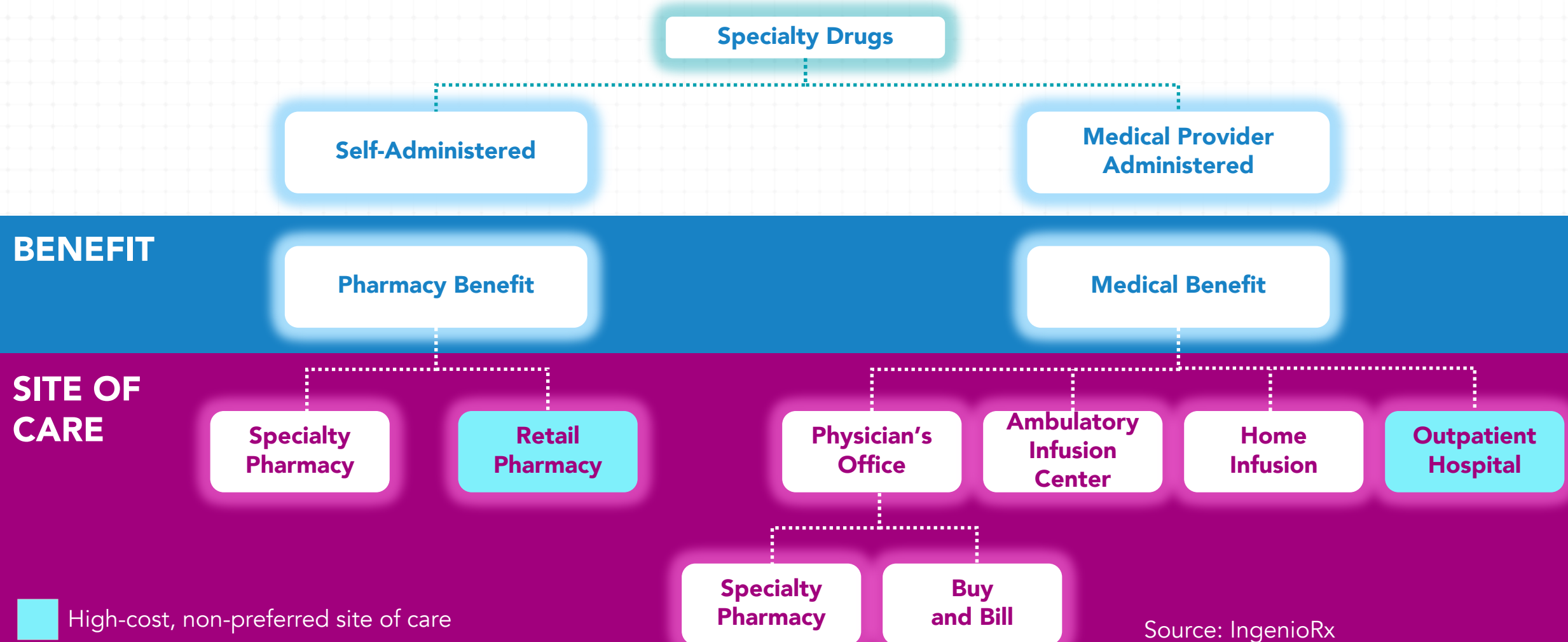
Pharmacy & Therapeutics Committee

- Pharmacy and medical benefit drug committees comprised of BCBSM clinical staff – Pharmacists and medical directors
- P&T Committee comprised of BCBSM clinical staff and practicing primary care and specialist physicians



Specialty drug management

Integrated medical and pharmacy benefits



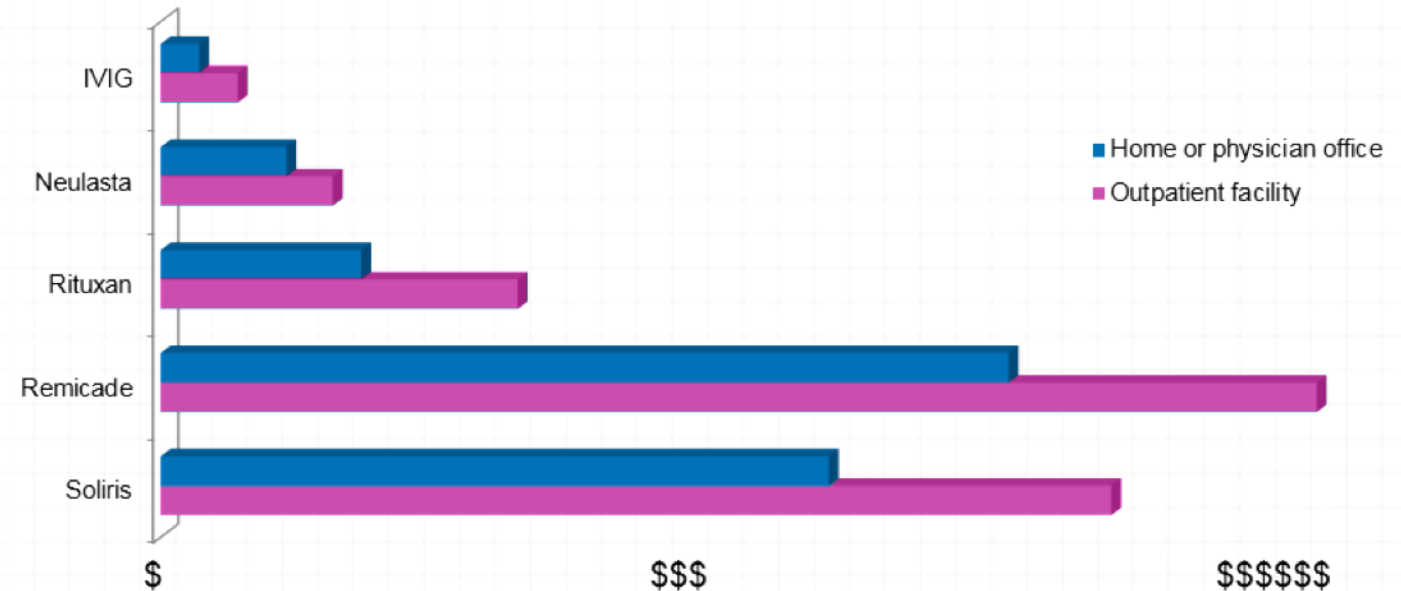
Source: IngenioRx

Specialty drug management

Site of Care optimization

Transitioning medical specialty drugs from high cost sites of care to lower cost sites of care

- Improves the member experience of care
- Reduces per capita cost of health care
- Improves the health of the populations



Site of Care case study:

Home infusion increases comfort and convenience, lowers cost

- Hospital infusions--time-consuming, inconvenient and expensive
 - Middle school student receiving infusions at hospital
 - Whole process took 3.5 hours – missed school and work for family
 - Patient was concerned about grades.
- Required move to home therapy was “a little nerve-wracking” at first.
 - Required change, family was nervous
 - Coordinating nurse made them feel comfortable
- The family adapted and loves home infusion.
 - More sleep, less missed work/school – mom could choose appointment times
 - Mom could choose appointment and medication was delivered at home
 - Patient could relax during infusions and developed a relationship with consistent caregiver



Specialty drug management

Biosimilar strategy

WHAT IT IS:

- Used to treat chronic inflammatory conditions such as rheumatoid arthritis, ulcerative colitis, and psoriasis
- Is infused over a few hours, most often in a home or other professional setting, or in a hospital out-patient facility. Patients are usually infused every 4-8 weeks.
- Highest spend medical drug in total allowed amount for BCBSM (~\$140 million annually for all commercial LOB), with about 23,000 annual infusions
- FDA-approved biosimilars

OUR STRATEGY IN 2018:

- Monitored the uptake and utilization of biosimilar infliximab nationally
- Engaged with the brand and biosimilar manufacturers for contracting opportunities.
- Developed a co-preferred strategy for infliximab products that allowed the uptake of biosimilars without disrupting providers.
- Result: A similar pricing after rebate for both brand and biosimilar infliximab.

Specialty drug management

Blue Cross biosimilar strategy for infliximab in 2019

Based on evidence supporting the clinical use of biosimilar infliximab, our 2019 strategy includes:

- **HMO**
 - All members* currently utilizing Remicade will be required to switch to Inflectra
 - All new starts will be required to use Inflectra
 - Planned implementation date is 04/01/19
- **PPO**
 - No change planned at this time. HMO and broader utilization will be monitored and PPO position will be re-assessed as biosimilar market share increases

**This strategy is modeled
to deliver a net savings of
\$9.2 million**

* Pediatric members are eligible, but excluded from the mandate. Pediatric definition mirrors that use in the site of care program: under 15 yo, or under 18 yo AND <50kg

Integrated specialty drug management

MIGRAINE EXAMPLE

Patient-centered approach to treatment migraines headaches

- Botox on medical benefit (managed)
- New CGRP injections on pharmacy benefit: Aimovig, Emgality
- Coordination with care management and total cost of care focus

SAFE. COST-EFFECTIVE. COORDINATED.



What you can do

- Encourage your employees to understand their pharmacy benefits
 - Help your employees make informed decisions about drug costs and uses, particularly if you have a high-deductible health plan
- Learn more about how specialty drugs, when managed appropriately, can save on long-term costs
 - Ensure you're taking advantage of all utilization and cost management programs available with your pharmacy plan
 - Ask about exclusive specialty programs

For more information:

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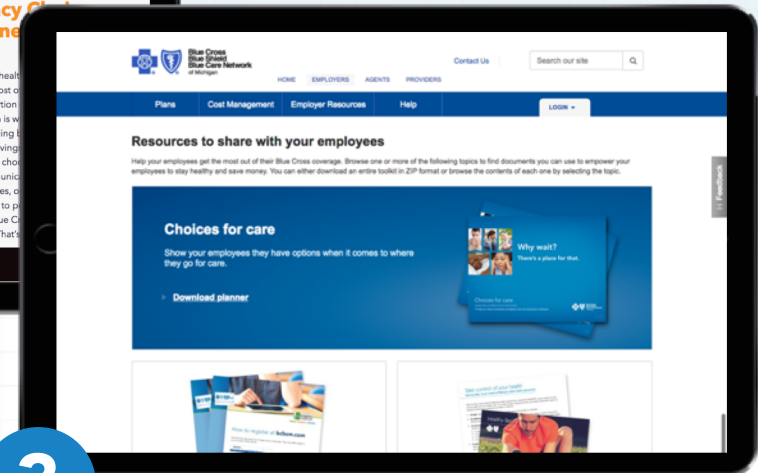
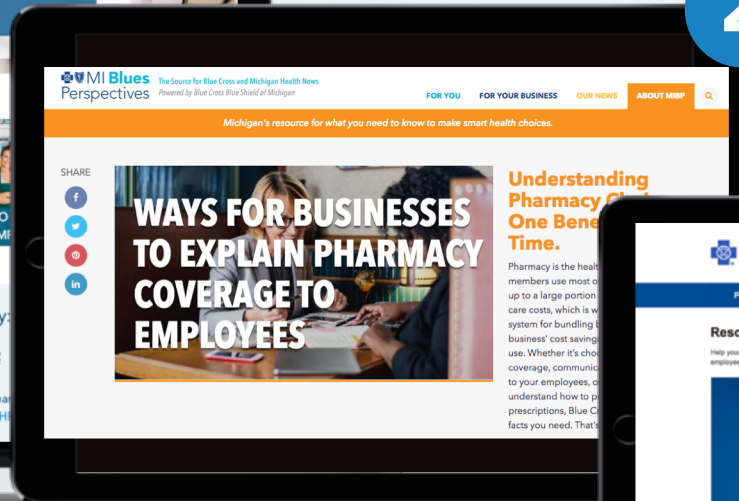
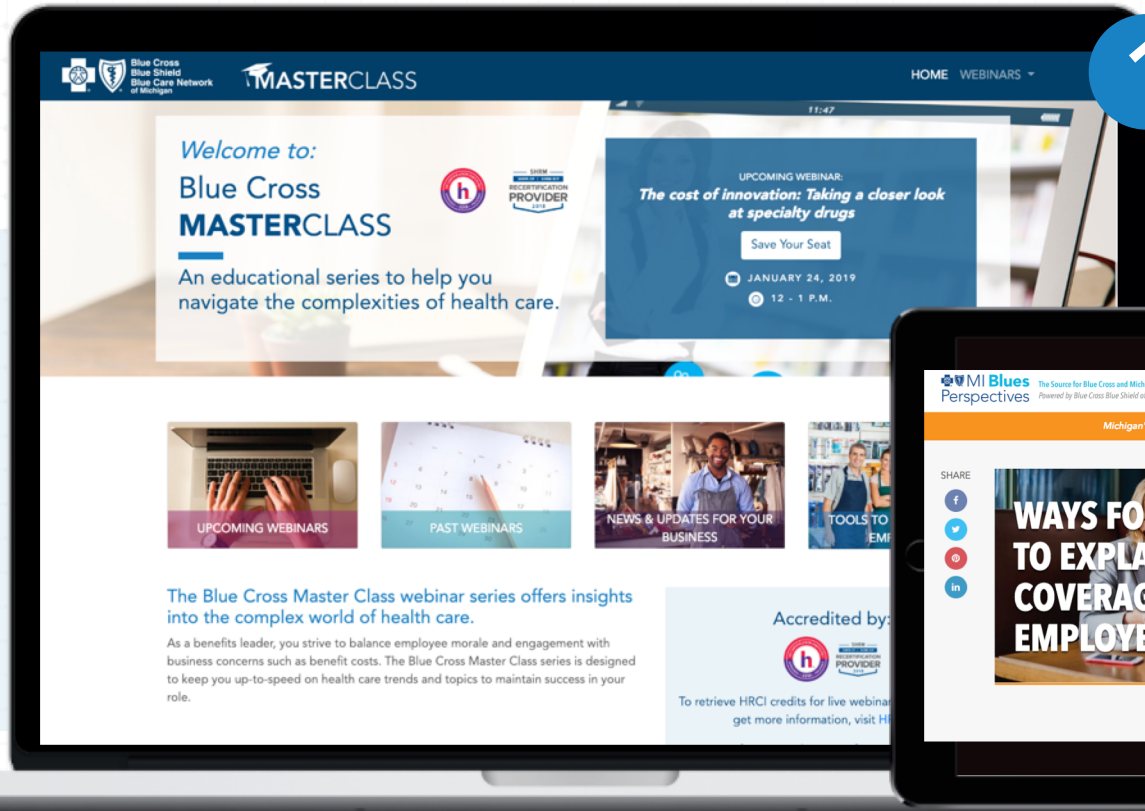
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