HOUSTON Methodist LEADING MEDICINE

HOUSTON METHODIST
PHARMACY & THERAPEUTICS NEWS
August 2022

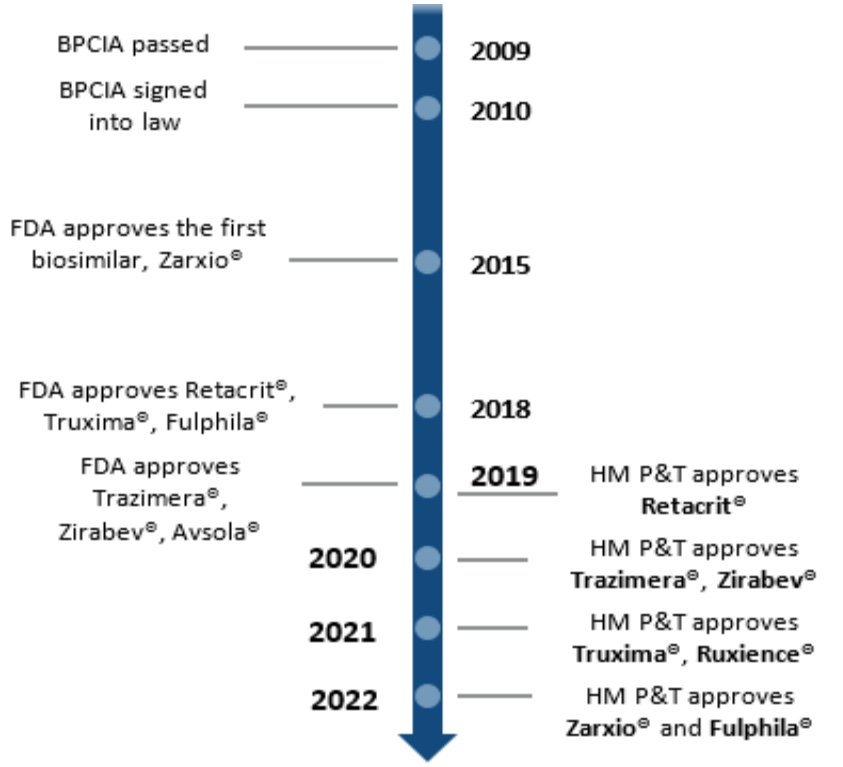
PHARMACOECONIMICS UPDATE:

A FOCUS ON BIOSIMILARS - PART 2

Laura M. Blackburn, PharmD

In our July 2022 P&T News Issue, we started a series on how biosimilars are being introduced to the market, their nomenclature, and products on HM formulary. This article builds on that information to provide additional regulatory perspective and pharmacoeconomic outcomes realized by HM with the inclusion of these products to our formulary.

The Biologics Price Competition and Innovation Act (BPCIA) of 2009 was signed into law in 2010 to allow drug manufacturers an abbreviated approval pathway for biologics that are shown to be similar to the innovator or reference product licensed by the Food and Drug Administration (FDA). This abbreviated process encourages competition and innovation by relying on existing safety and efficacy data instead of an application with full preclinical and clinical data. This intent of this abbreviated process is to allow for lower cost biosimilars and increase patient access to safe and effective therapies. The timeline for FDA approval and Houston Methodist Pharmacy & Therapeutics Committee (HM P&T) approval is outlined below in Graph 1.



(Continued on page 2)

The *Pharmacy & Therapeutics News* is dedicated to providing the most current information regarding medication-use policy and formulary issues. Each issue details recently approved actions from the system P&T committee as well as relevant patient safety, pharmacotherapy and drug distribution updates. Entity representatives to the system P&T committee structure can be found here.

MEDSAFETY MATTERS!

Amaris Fuentes, PharmD

ISMP Medication Safety Newsletter Links:
Acute Care& *NurseERR*

Preventing Uncontrolled, Rapid Infusion Rates

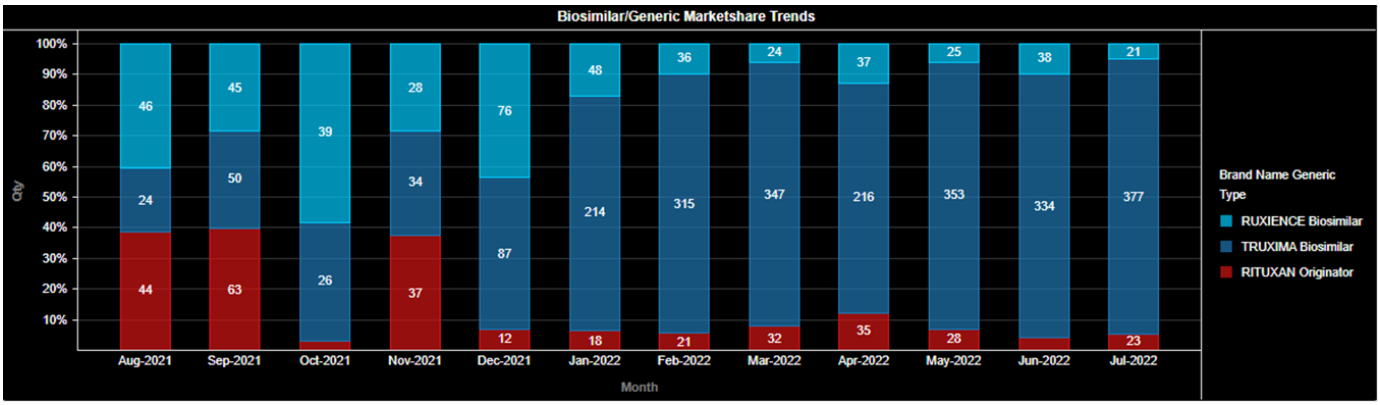
A recent ISMP Newsletter notes reports of rapid administration of high-risk medications. While various root causes were identified in these reported cases, bedside practices should be utilized to minimize the risk of uncontrolled administration of IV medications. These include:

- Utilizing smart infusion pumps for all IV medications
- Utilizing Dose-Error Reduction Systems (DERS) in smart infusion pumps (i.e. Alaris Guardrails®)
- Labeling all infusion lines at points of connection
- Tracing infusion lines from container to pump to connection port and to the patient
- Confirming lines before opening roller clamp
- Responding to pump “air-in-line” alarms by clearing and ensuring the line is placed back on pump
- Providing handoff reports to help with management of lines & infusions

(Biosimilars *continued from page 1)*

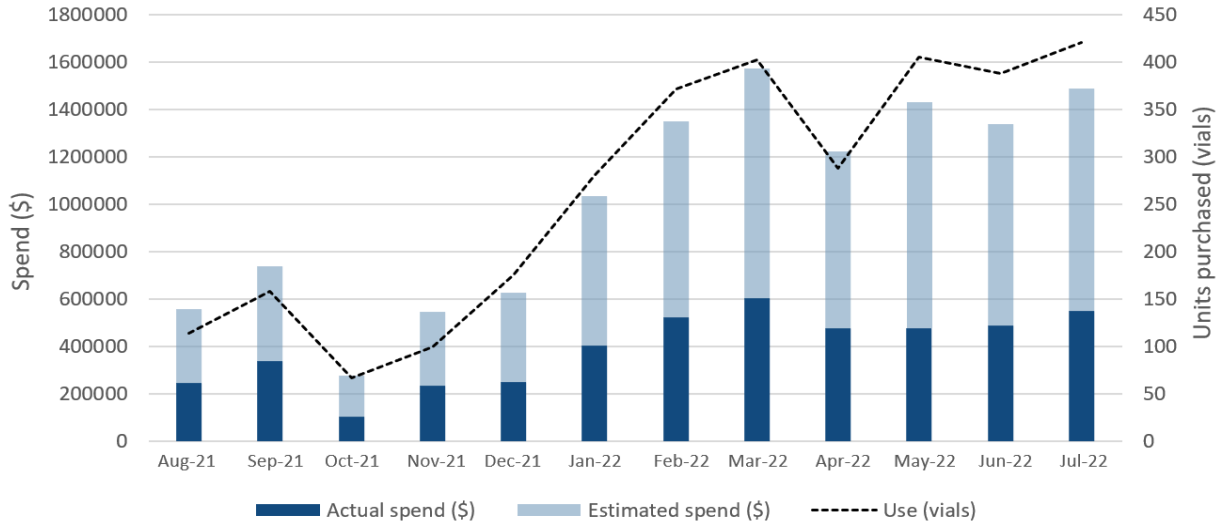
Looking at rituximab products over the last 12 months as a representation of our biosimilar initiative, substantial cost savings have been realized. The therapeutic interchange for biosimilar rituxumab products was approved by P&T in March 2021, and brand Rituxan® has been nearly phased out and comprises less than 20% of use on a per mg basis. The Figure below shows the market share trend over the last 12 months at Houston Methodist.

Graph 2. Originator compared to biosimilar product market share trends



When the first biosimilar agents were being introduced in 2015, the cost savings were estimated to be around 15% with the potential for increasing savings as competition increased. Figure 3 compares actual spend patterns with the estimated spend each month if 100% of rituximab purchases were the originator product. Actual savings approximate 27% during the last 12-month period.

Graph 3. Spend and use data per month



The most recent biosimilar interchange approved involved the short-acting granulocyte colony stimulating factor class. Zarxio® (filgrastim-sndz) will be the preferred agent starting September 2022. HM will continue to incorporate biosimilars into our formulary as they become available following a standard P&T formulary review assessment.

Have a medication needing Houston Methodist formulary review? **Click here and complete a request form**

NEWSLETTER STAFF

Editor-in-Chief: Michael G. Liebl, PharmD
Managing Editor: Laura M. Blackburn, PharmD
System P&T Committee Roster is available to view here.

ANTIMICROBIAL STEWARDSHIP

Shivani Patel, PharmD

Clinical Guidance for Monkeypox at HMH

As of August 29th, 2022, 445 cases of Monkeypox have been identified in Houston, Texas according to the Houston Health Department. While this emerging situation is dynamic, latest information as of August 29th, 2022 for clinicians caring for patients who either have been exposed to monkeypox, tested positive, or suspect a monkeypox infection can be found here.

COVID Treatment Updates

Houston Methodist's COVID guidelines have been in place and actively updated since the beginning of the pandemic to support Houston Methodist needs. With nationally published guidelines available from the NIH and IDSA, HM will align our internal reference document formats and recommendations with national guideline structure. Link here for the HM COVID treatment algorithm that is also available on the home intranet page under COVID-19 Preparedness and Response. Key adjustments to our inpatient treatment strategy approved at System Antimicrobial Stewardship Committee and P&T:

Inpatient Management of COIVD-19	
Mild COVID-19: Hospitalized but does not require oxygen, incidental COVID in high-risk patient	Remdesivir x 3 days **OR** Monoclonal antibody x 1 dose **(Reserved for patients unable to tolerate remdesivir)**
Moderate COVID-19: Hospitalized and requires supplemental oxygen, high-flow oxygen, or NIV	Dexamethasone **AND** Remdesivir x 5 days if symptom onset <10 days
Severe COVID-19: Hospitalization requiring mechanical ventilation or ECMO	Dexamethasone **AND** Tocilizumab or baricitinib if within 24 hours of admission ***Remdesivir is not recommended***

Policy and Procedure Updates

Standing Medical Orders and Pharmacist Consults to Adjust Medication Doses for Renal Function:

Go-live date: , Thursday September 1st

As a reminder, the approved medical staff policy allowing pharmacists to make dose changes for certain renally adjusted medications automatically per standing delegation order will start on September 1st. Dose changes will be ordered per-policy for medications listed in policy if needing adjustment up or down as long as the patient remains on the medication. Should dosing recommendations support discontinuation of therapy, providers will be contacted.

Influenza Vaccination Program Starts Thursday, September 1st

On Thursday September 1st, 2022, all inpatients may be vaccinated under the nurse-driven protocol with Flucelvax®; a "standard dose", inactivated, four-component (quadrivalent) flu vaccine. When HM receives our HD Fluzone® inventory (expected in mid-September), patients 65 years and older; or Solid Organ Transplant (SOT) recipients will default in EPIC to receive the High-Dose four-component (quadrivalent) inactivated influenza vaccine (Fluzone®). Guidance from the CDC for the administration of flu vaccines in COVID-19 patients can be found here. Per CDC, patients with known active COVID infection should defer any COVID-19 or flu vaccination, including booster vaccination, at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met. Link here for the CDC report on seasonal Influenza Vaccination. Link here for the continuously updated Houston Methodist Flu Tracker.

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ANTICOAGULATION USE SAFETY

Alan Luu, PharmD, PGY2 HSPAL Resident

Quality Review: Pharmacy-Managed LVAD Warfarin Consult for LVAD Patients

Background: Left ventricular devices (LVADs) used for the management of severely advanced heart failure patients require anticoagulation to prevent device failure and stroke while balancing the risk from over-anticoagulation and bleeding events. Houston Methodist has a pharmacist driven dosing protocol consultation service aimed to optimize anticoagulation for this indication.

A CQI review of 148 LVAD patients (27 index and 121 readmitted) was conducted to assess efficacy and safety-related events occurring during pharmacist-managed care. A retrospective cohort analysis included LVAD warfarin pharmacy consult patients from January 2020-2021. Patients having less than 5 days of INR values or whose INR target values were modified during the encounter were excluded. Efficacy endpoints included the percent time in therapeutic range and time to first therapeutic INR while maintained on the pharmacy consult. Safety endpoints included bleeding and thrombotic events.

Study Findings:

Safety:

- No major bleeding or thrombotic events were noted while patients were managed on consult services though several patients had daily warfarin doses held due to supratherapeutic INRs

Efficacy:

- 78% of the index LVAD patients initiated on warfarin, obtained their first therapeutic INR within the desired 7 days
- Using a slightly expanded range of +/- 0.2 from the stated target INR range, patients were maintained within the therapeutic range ~56% of the time while admitted signifying good anticoagulation control

Efficiency Opportunities and Continuous Improvement Actions:

- To improve communication between providers and the consulted pharmacist about the patient's goal INR, Epic will include the LVAD INR goal as a selection option. See the figure below
- Progress notes by pharmacists will also indicate the patient's percent of time in therapeutic range (TTR%)
- The Warfarin Dosing Guide pharmacists use will be updated to include recommended ranges for specific LVAD devices

The warfarin LVAD dosing program will be monitored on an every three year basis moving forward given the reproducibility of the outcomes observed over the last 5 years of annual monitoring.

New Warfarin order with LVAD INR targets within Epic