Retrospective Review of Home-based Monoclonal Antibody Infusions on Patient Safety, Long Term Adherence, and Overall Satisfaction

David Benedict, PharmD, BCPS, Keith Crawford, BA, Johanna Bezjak, Pharm D, BCNSP, Rebecca M. Tokarski, PharmD, BCNSP, Kayla Szabo, PharmD, BCNSP, Frank J. Thomas, BA

INTRODUCTION

Monoclonal antibodies (mAB) are therapeutic agents for the treatment and prophylaxis for several types of disease states. Approximately 50 mAB products have been approved in the United States. This important biotechnology is used in clinical practice to assist in mitigation of pathologies in the areas of infectious, inflammatory, immunological, and neoplastic conditions for patients representing all generations.

The mAB's possess unique characteristics. The larger molecular sizes and structures provide direction towards extracellular targets and prevent crossing of cellular membranes. Due to highly targeted specificity, low volume of distribution, longer half-life, and administration by intravenous infusion, the home setting is an attractive site of care option. Examples of possible negative consequences to these infusions include target-related toxicities, such as immunogenicity, infusion related reactions, and suppression of the immune system.
Home Infusion programs must have experienced clinicians, detailed protocols, physician champions, and turnkey workflows that drive the best patient experience to maximize positive outcomes.

OBJECTIVES

The purpose of this project was to validate our program for providing monoclonal antibody infusion in the home. Key metrics such as adherence, safety of naïve dosing, infusion related reactions, and overall patient satisfaction were examined.

MATERIALS & METHODS

This retrospective review of mAB administration was conducted reviewing electronic medical records (EMR). Patients were serviced by a home infusion/specialty pharmacy in Pittsburgh, Pennsylvania during the 2020 calendar year. Each formulary mAB therapy consisted of population predictive analytical protocols, employee clinical training, implementation of care via policy, and documentation of each patient journey in the EMR.

REFERENCES

Akarsu A, Soyer O, Sekerel BE, Hypersentivity Reactions to Biologicals: from Bench to Bedside. Curr Treat Options Allergy 2020; 7;71-83

Doessegger L, Banholzer ML, Clinical development methodology for infusion-related reactions with monoclonal antibodies. Clinical & Translational Immunology 2015; 4, e39.

Matucci A, Nencini F, Pratesi S, Maggi E, Vultaggio A, An overview on safety of monoclonal antibodies. Current Opinion Allergy Clin Immunol 2016; 16: 576-581.

Entyvio. [Package insert], Takeda Pharmaceuticals, USA Inc; 2020.

Stelara. [Package insert], Janssen Pharm Companies; 2019.

Benlysta. [Package insert], Human Genome Sciences; 2020.

Simponi Aria. [Package insert], Janssen Pharm Companies; 2020.

Remicade. [Package insert], Janssen Biotech, Inc; 2020.

Ocrevus. [Package insert]. Genentech, Inc. 2020.

Cyramza. [Package insert]. Eli Lilly and Company; 2020.

Rituxan. [Package insert]. Genentech, Inc; 2019.

Tepezza. [Package insert]. Horizon Therapeutic USA Inc; 2020.

Inflectra. [Package insert]. Pfizer; 2020.

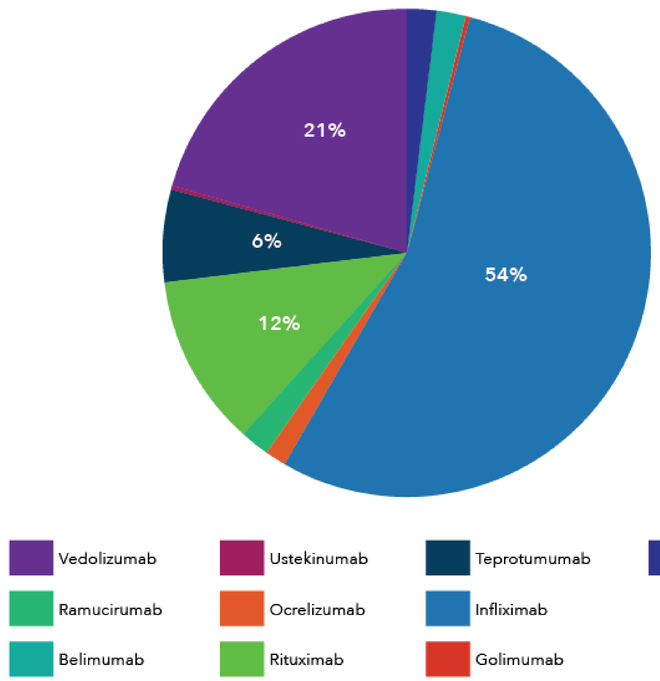
Renflexis. [Package insert]. Merck & Co. , Inc; 2019.

Blincyto. [Package insert]. Amgen Inc; 2020

RESULTS

Current mAB infusions (bamlanivimab, belimumab, blinatumomab, golimumab, infliximab, ocrelizumab, ramucirumab, rituximab, teprotumumab, ustekinumab, vedolizumab) were administered within the parameters of package insert and internal policy. Population consisted of 329 home infused patients (female = 175, male = 154). Within this population, 37 patients met the pediatric classification (under 18 years old). The observation period contained 3,948 patient months and 1,871 infusions in the home setting. Fifteen infusions were administered as first doses in the home environment.

STUDY POPULATION (n = 329)

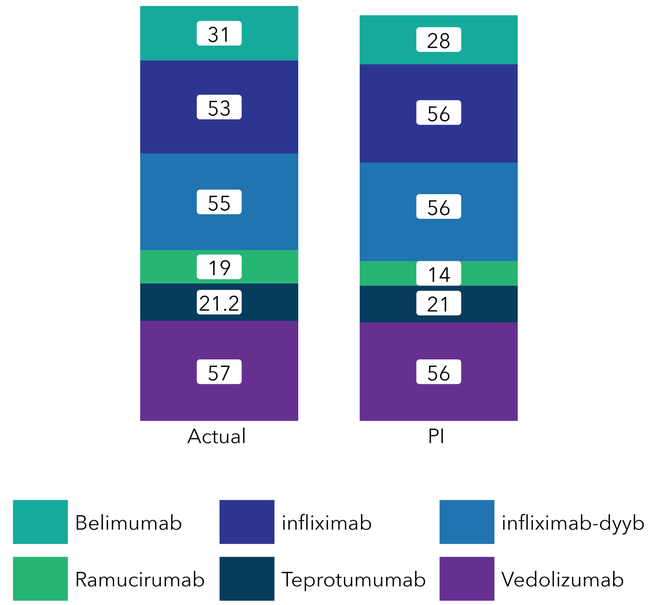


SAFETY			
CATHETER TYPE			
Peripheral	Ports	Central Catheter (Non-Tunneled)	Picc
279	37	8	5
NO LINE INFECTIONS			
This study population produced no acute infusion related reactions resulting in anaphylaxis and/or anaphylactoid reactions. Two (2) patients discontinued therapy due to the formation of antibodies detected in the infliximab therapy population.			

ADHERENCE

Interval durations (days) were evaluated amongst patients within each therapy type and compared with the associated package insert.

INTERVAL DURATION DAYS					
Belimumab	Infliximab	Infliximab Dyyb	Ramucirumab	Teprotumumab	Vedolizumab
31: 28	53: 56	55:56	19:14	21. 2: 21	57: 56



*Values Represents Administration Frequency in Days

SATISFACTION

In CY 2020, surveys were extended to 160 Infusion off-serviced patients per month (average mail out). The average monthly response rate was 38%.

A level of performance has been established for measures on the Patient Satisfaction Survey. Our organization reported a score of 99% Overall Satisfaction with Quality of Services provided by our organization in CY 2020. Goal = 95%.
Three specific mAB infusions (teprotumumab) where identified during this period as the off-service respondents self-unblinded their surveys, yielding an overall satisfaction of 100%.

CONCLUSION

Monoclonal Antibodies are widely used to treat rheumatic, autoinflammatory, and oncological pathologies and are gaining greater acceptance in a variety of administration settings.

The important criteria in successfully administering this class of medication is a mature program that includes experienced clinicians and well-defined policies. This organization's mAB specialty infusion care management model provides a viable option for patients to receive these infusions in the comfort of their homes.

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Home Infusion & Specialty Pharmacy
CHARTWELL
PENNSYLVANIA, LP