



WHITE PAPER

The Role of Health System Specialty Pharmacy in Cardiometabolic Disease Care

INTRODUCTION

Cardiometabolic disease (CMD) has become one of the greatest drivers of healthcare utilization and mortality globally. Two of its associated complications, diabetes and cardiovascular disease (CVD), account for an annual cost of \$1.3 trillion dollars and 31% of deaths respectively.^{1,2} The rising costs and prevalence are further compounded by the increasing incidence of individual diseases that constitute CMD, such as diabetes, hypertension (HTN), hypercholesterolemia, and metabolic disease-associated steatohepatitis (MASH). The estimated annual per patient cost for those that have one component of CMD is \$5,564, growing to over \$12,000 for a patient with four components.³

The price tags for CMD-related diseases are astronomical: \$100 billion for patients with metabolic dysfunction-associated steatotic liver disease (MASLD), over \$200 billion for those with cardiovascular disease (CVD), and over \$300 billion for patients living with diabetes.^{4,5,6} The human burden is additionally significant, from the need for daily medication, the stress and anxiety that come along with managing a chronic condition, to the time commitment for frequent medical appointments. Given the pathways that link these cardiovascular and metabolic conditions, it is imperative that CMD be treated comprehensively rather than by its individual disease state components. Today, CMD care is often siloed, which places burden on the patient to manage navigating their complex condition on their own.

This white paper will highlight the progression of CMD from its earliest stage (insulin resistance) all the way through its most costly and dangerous complications (CVD, kidney/liver disease, and stroke risk) and highlight how integrated health-system specialty pharmacy (HSSP) can play an invaluable role in providing better care for these patients.

WHAT IS CARDIOMETABOLIC DISEASE (CMD)?

Cardiometabolic disease begins with insulin resistance in patients. Various tissues and target organs exhibit a decreased response to insulin, necessitating higher levels of insulin (hyperinsulinemia) to achieve sufficient glucose uptake. Without appropriate care, treatment, and intervention, this insulin resistance progresses through states of “pre-disease”, disease, and further into complications of the associated disease states. There are many factors that contribute to insulin resistance. Some of these components include genetics, environmental factors, personal behavior, and most commonly, obesity. Evidence shows that conditions including diabetes, dyslipidemia, hypertension, and obesity go hand-in-hand with the presence of insulin resistance and hyperinsulinemia.

Pre-disease conditions include pre-diabetes, which is defined by the American Diabetes Association (ADA) as A1C between 5.7 and 6.4%; metabolic syndrome (See Figure 1.)⁷; and MASLD, where there is fat tissue accumulation in the liver without chronic alcohol consumption, hereditary disorder, or use of a drug that could induce steatosis.⁸

Clinical Criteria for Metabolic Syndrome^a

Risk Factor	NCEP ATP III Definition (2005 revision)	IDF Definition (2005)
Criteria	Any 3 of the 5 criteria below	Obesity, plus 2 of the 4 below
Obesity (waist circumference)	Men >40 inches (101.6 cm) Women >35 inches (88.9 cm)	N/A, central obesity already required ^b
Triglycerides	≥150 mg/dL	≥150 mg/dL
HDL cholesterol	Men <40 mg/dL Women <50 mg/dL	Men <40 mg/dL Women <50 mg/dL
Blood pressure	>130/>85 mmHg	>130/>85 mmHg
Fasting glucose	≥100 mg/dL	≥100 mg/dL

^a The metabolic syndrome is synonymous to the dysmetabolic syndrome X or insulin-resistance syndrome.

^b Criteria for central obesity differ by population; for ethnicity specific criteria see full text article . Prasad H. Postgrad Med. 2012;124(1):21-30.

Progression beyond pre-disease into the disease state includes conditions such as type 2 diabetes (T2D), metabolic disease associated steatohepatitis (MASH), hypertension, and hypercholesterolemia. Untreated or undertreated, these diseases can result in multiple complications including cardiovascular, liver, and kidney disease, which impact over 120 million, 100 million, and 35 million people respectively.

PHARMACY CHALLENGES IN THE CARDIOMETABOLIC SPACE

From the outset, those with insulin-resistance, many of whom are living with obesity, are more frequently turning to medication to help manage their condition. Evidence shows that use of GLP-1 medications like semaglutide and tirzepatide result in clinically significant weight loss that is on par with that of patients who opt for bariatric surgery. These medications, while providing help with weight loss, also help to regulate blood glucose levels, thus helping with both obesity and insulin resistance. However, patients frequently experience severe gastrointestinal side effects which lead to high rates of GLP-1 discontinuation, with 71% no longer taking them after 1 year and 85% no longer taking them after 2 years.⁹ In addition to these side effects, these medications also come with a high financial cost and will often require prior authorization through insurance. Approved for weight management, type-2 diabetes, and most recently MASH, the aforementioned challenges also significantly impact adherence.

Discontinuation Rates for GLP-1:⁹

71%

No longer taking them after **1 year**

85%

No longer taking them after **2 years**

Another class of medications, sodium-glucose cotransporter 2 (SGLT2) inhibitors, have demonstrated to be an effective treatment for type-2 diabetes, with additional benefits in both cardiovascular and kidney disease. Despite their value in therapy, as much as 25% of patients discontinue them within 1 year due to side effects such as genital infections, urinary tract infections, and frequent urination.¹⁰

Medication adherence rates amongst patients taking antihypertensive medications and statins, which are used to lower cholesterol levels, are persistently low. The American Heart Association (AHA) shows an adherence rate to antihypertensives at 54.4% and studies have shown average discontinuation rate to statin therapy as 50%.^{11,12}

HOW HEALTH SYSTEM SPECIALTY PHARMACY CAN SUPPORT PATIENTS WITH CMD

As highlighted above, there are several factors that contribute to low medication adherence in CMD patients such as the need for prior authorization, financial assistance, ease of access to a pharmacy, or side effects. The Shields Health Solutions (SHS) network of HSSP's can address each of these challenges. Our network average turnaround time (TAT) for prior authorization is 1.9 days. Our average prescription copay is \$11.48, and our liaisons contact patients monthly to set up delivery of medications directly to patients. Our team of pharmacists is also available to help patients minimize side effects through medication counseling and, in collaboration with the care team, patient-tailored dose escalation.

Clinical pharmacists are well positioned to ensure that patients with hypertension and hypercholesterolemia receive guideline-directed treatment and meet blood pressure and cholesterol goals. Through specialty pharmacy support, patients interact with their clinical pharmacist as often as once a month, whereas they may see their physician less than 4 times a year.¹³ These frequent touchpoints allow a pharmacist to continuously assess if patients are meeting their goals, adjust therapy if part of a collaborative practice agreement, or make clinical recommendations to providers. The SHS clinical pharmacist team has an acceptance rate of 92.8% for their clinical recommendations made to providers.

Likewise, a clinical pharmacist's skillset is well-suited to help patients continue therapies like SGLT2 inhibitors and GLP-1 RA's that they might otherwise discontinue. Both classes of medications are known to have high discontinuation rates within the first year of therapy, despite their known clinical benefits. As previously highlighted, one of the most common reasons for discontinuation is undesirable side effects. Working closely with a clinical pharmacist can help minimize side effects, improving both adherence and clinical outcomes. The direct support of a team of clinical pharmacists allows for timely patient education and support and patient tailored dose titration.

Removing Pharmacy Burden from Patient & Clinic



Prior authorization

CMD medications often require PAs which our liaisons turnaround in less than two days, alleviating considerable work and stress from clinic and patient.



Financial assistance

CMD medications are often high-cost which our model addresses by securing financial assistance for patients.



Clinical pharmacist services

Given the complexity of CMD and the potential side effects of CMD medications, regular consultations with a clinical pharmacist is a critical part of optimizing treatment.



Refill coordination

Our liaisons proactively reach out to patients to coordinate refills to avoid any lapses in medication adherence.

For more information on ambulatory clinical pharmacist (ACP) support for patients on GLP-1 therapy, [click here](#)



1% reduction in HbA1C (A1C) leads to risk reduction and cost reduction

Microvascular complications (risk reduction)	37%
Deaths related to diabetes (risk reduction)	21%
Any end point related to diabetes (risk reduction)	21%
Myocardial infarction (risk reduction)	14%
Diabetes-related total healthcare costs (reduction)	\$736
All-cause total healthcare costs (reduction)	\$429

For the above information, see reference 14

Current Shields Impact on CMD-Adjacent Disease Areas

	Diabetes	Congestive Heart Failure (CHF)	Hyperlipidemia
Adherence PDC	92%	93%	94%
Copay 85 th perc	\$13	\$10	\$35

Key Disease State Clinical Outcomes

2.5%

Diabetes

Avg A1C Reduction
(Baseline: A1C >9)

64%

CHF

Avg Reduction
in Admissions

\$2,649

Average TME
Reduction in
Patients A1C>9.0

The Impact of Clinical Pharmacist Support in CMD



The clinical pharmacist-run Diabetes Care Coach program at the UMass Memorial Medical Center's Diabetes Center of Excellence is just one example of how HSSP clinical pharmacists can make a significant impact on patient care and clinical outcomes in the CMD patient population. One Care Coach patient, Kathy, was referred to the program by her endocrinologist in the fall of 2021. Kathy is a type 2 diabetic, 54-year-old female who at the start of the program had hypertension, an A1C of 9.1% and weighed 260 pounds. When entering the Care Coach program, her diabetes medications included a basal/bolus insulin regimen consisting of four injections a day along with a daily injectable GLP-1 and twice daily metformin. Her daily insulin use exceeded 200 units/day. She had tried and failed an SGLT-2 inhibitor due to intolerable side effects and had tried several GLP-1 receptor agonists attempting to find the right balance of effectiveness and manageable side effects.

Upon starting in the program, her Coach was able to get her set up on a continuous glucose monitor (CGM). This tool allowed her to watch her blood sugar values 24/7, see trends, as well as receive alarm notifications when her blood sugars were too high or low. With this technology she was able to work with her Coach to gain insight about how her lifestyle and behaviors impacted her blood sugar control. Using the information from her CGM and support from her Coach, she

made significant lifestyle changes to reduce her need for insulin over time. The Care Coach was able to work with her through frequent touchpoints to safely lower her insulin doses. Throughout her time in the program, the Coach also worked with the endocrinology team to optimize her GLP-1 regimen, eventually switching from a daily injectable medication to one that was administered weekly. Once her blood sugars were more consistently stable, she was once again able to try an SGLT-2 inhibitor. Through support of her Coach with tips on how to minimize side effects and appropriately increase the dose, she was finally able to stay on her SGLT-2 inhibitor. The involvement of the pharmacist not only helped with avoidance of side effects on these medications, but also ensuring she was able to consistently have affordable medication supply with no adherence issues.

At three months of coaching, she was down to an A1C of 6.9% and at six months down to 5.8%. Over the next 18 months she was able to stop both insulin and metformin, resulting in a simplified medication regimen of a weekly GLP-1 and daily SGLT-2 inhibitor. Her blood pressure also showed dramatic improvement, dropping from 158/71 mmHg at the start of the program, into the 110s/60s, allowing her to also stop her antihypertensive medication. During this time, she also lost close to 90 pounds of body weight through medication adherence, lifestyle modifications, and support from her dedicated Coach. Kathy successfully graduated from the program in October 2023.

[Watch Kathy's Full Story](#)



CONCLUSION

The management of cardiometabolic disease (CMD) requires a comprehensive and integrated approach due to its complex nature and the significant burden it places on both patients and healthcare systems. The rising prevalence and costs associated with CMD and its complications, such as diabetes, cardiovascular disease, and metabolic disease-associated steatohepatitis (MASH), highlight the urgent need for effective and coordinated care strategies. Health System Specialty Pharmacies (HSSPs) play a crucial role in addressing the challenges faced by CMD patients, including medication adherence, affordability, side effect management, and access to limited distribution drugs (LDDs).

By leveraging the expertise of clinical pharmacists and the resources of HSSPs, patients can receive personalized care that ensures they are on the most appropriate therapies, have access to necessary medications, and are supported in managing side effects and adherence issues. The frequent touchpoints with clinical pharmacists and pharmacy liaisons allow for continuous monitoring and timely adjustments to treatment plans, ultimately improving patient outcomes and reducing the overall burden of CMD.

As the landscape of CMD treatment continues to evolve, the role of HSSPs will become increasingly important in providing high-quality, patient-centered care. By addressing the multifaceted needs of CMD patients, HSSPs can help mitigate the impact of this pervasive disease and contribute to better health outcomes and quality of life for those affected.

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ABOUT SHIELDS HEALTH SOLUTIONS

Shields Health Solutions (Shields) is the premier specialty pharmacy accelerator in the country. The Shields Performance Platform, an integrated set of solutions, services and technology, is intentionally designed to elevate payer and drug access for specialty pharmacies, elevate health outcomes for complex patients, and elevate growth throughout the entire health system. As the foremost experts in the health system specialty pharmacy industry, Shields has a proven track record of success including access to over 90 percent of all limited distribution drugs (LDDs) and most (health insurance) payers in the nation; and a clinical model proven to lower total cost of care by 13%. In partnership with more than 80 health systems across the country through national-scale collaboration, Shields has a vested interest in delivering measurable clinical and financial results for health systems.



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