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Mini Review

A Brief Review of Clinical Considerations for Healthcare Provider-Administered Cardiovascular Risk Modifying Medications

Atif Ibrahim[1], Sumair Ozair[1], Gene Gerlach[1] and Berry Bertolet[2]*

[1]Internal Medicine Residency, North Mississippi Medical Center, Tupelo, Mississippi, USA

[2]Cardiology Associates, North Mississippi Medical Center, Tupelo, Mississippi, USA

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***Corresponding author:** Berry Bertolet, Cardiology Associates, North Mississippi Medical Center, Tupelo, Mississippi, USA,
E-mail: bbert@nmhs.net ; barrybertolet@comcast.net

ORCiD: https://orcid.org/0000-0003-4502-7074

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Abstract

Cardiovascular Disease (CVD) remains a major contributor to morbidity and mortality, with effective lipid management being essential in reducing Atherosclerotic Cardiovascular Disease (ASCVD) risk. While statins have long been the primary treatment, barriers such as intolerance, poor adherence, and clinical inertia often prevent patients from achieving optimal Low-Density Lipoprotein Cholesterol (LDL-C) levels. Despite the availability of alternative lipid-lowering therapies (LLTs), many patients still fail to meet recommended targets. The introduction of provider-administered LLTs, like inclisiran, presents a promising strategy to enhance adherence through in-office administration under a "buy-and-bill" model. This approach improves treatment continuity, reduces administrative hurdles, and may alleviate financial constraints, particularly for Medicare beneficiaries. Implementing this model successfully requires coordinated efforts, including provider education, infrastructure development, and streamlined reimbursement processes. As cardiovascular care continues to advance, provider-administered LLTs may play a critical role in improving patient outcomes and mitigating the burden of ASCVD.

Introduction

Cardiovascular disease is a significant cause of morbidity and mortality, leading to an estimated annual cost of $407.3 billion from 2018 to 2019 in the US alone [1]. High levels of Low-Density Lipoprotein Cholesterol (LDL-C) are a major contributor to Atherosclerotic Cardiovascular Disease (ASCVD), and prolonged exposure is associated with increased plaque buildup and cardiovascular risk [2]. Following evidence-based guidelines, including lowering LDL-C levels and lifestyle changes is critical in preventing ASCVD events, reducing mortality, enhancing quality of life, and lowering healthcare expenses [3,4]. For the last 40 years, statins have been the mainstay of management of lipid levels in ASCVD prevention, reducing LDL-C by over 50% and decreasing the risk of Major Adverse Cardiovascular Events (MACE) [2]. However, only 44% are prescribed statins and ~10% do not reach LDL-C targets due to "statin intolerance" and Statin-Associated Muscle Symptoms (SAMS) [5]. Despite the availability of non-statin alternative Lipid-Lowering Therapies (LLT) such as ezetimibe, bempedoic acid, and PCSK9 inhibitors registry studies indicate that 80% of US patients are still not achieving LDL-C goals for primary or secondary ASCVD prevention [6]. Challenges in reaching LDL-C goals include poor adherence to self-administered medications, side effects, clinical inertia, and complex processes for drug procurement, particularly for expensive specialty medications like PCSK9 inhibitors [7]. Inclisiran, a therapy administered by healthcare providers, has the potential to improve adherence due to its twice-yearly dosing, which could enhance persistence and reduce side

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effects compared to self-administered options [8]. Inclisiran's utilization under the "buy-and-bill" system could also simplify access, making it a promising approach for high-risk ASCVD patients [9]. Inclisiran has demonstrated efficacy in lowering LDL-C levels by approximately 50%, comparable to PCSK9 inhibitors while offering the advantage of twice-yearly dosing, which may improve adherence and persistence [25]. Unlike daily oral statins or self-administered injectable PCSK9 inhibitors, inclisiran's healthcare provider-administered model ensures better compliance and monitoring, potentially leading to superior long-term cardiovascular outcomes [26]. While long-term outcome studies like ORION-4 and VICTORIAN-2-PREVENT are ongoing, early data suggest that inclisiran's efficacy is non-inferior to existing non-statin therapies [27]. Additionally, cost-effectiveness analyses indicate that despite higher upfront costs, the reduced need for frequent dosing, improved adherence, and avoidance of coverage gaps in Medicare Part D may lead to overall healthcare savings, particularly for high-risk ASCVD patients [14].

Novel approach: Healthcare provider-administered LLTs

Specialty drugs in the US are classified based on their method of administration and are covered by either Medical Benefit (Medicare Part B) or Pharmacy Benefit (Medicare Part D) plans. Healthcare provider-administered drugs are typically covered under Medical Benefits and are given in settings such as a physician's office, hospital, or alternative care sites. These drugs are obtained through a "buy-and-bill" process, where the healthcare provider buys the drug, administers it, and then seeks reimbursement from the insurance provider [10]. This is different from self-administered drugs, which are usually acquired from specialty or retail pharmacies. The buy-and-bill approach has been widely used for medications in oncology, vaccines, and specific specialty drugs for conditions like immunology, asthma, and dermatology [11,12]. It provides benefits such as improved treatment adherence, patient preference (for those unwilling or unable to self-administer), and better inventory management and control [9,13]. For patients with Traditional Medicare, in-office administered drugs under Medicare Part B rarely require prior authorization, and up to 100% of patients in a study were approved for inclisiran without prior authorization [14]. Moreover, Medicare patients with co-pay supplement plans often face no out-of-pocket costs for these medications, unlike self-administered drugs covered under Part D, which could push patients into the coverage gap (Donut hole) [15]. However, for patients with commercial insurance or Medicare Advantage, prior authorization is typically necessary, with lower approval rates (25%) and potential additional requirements such as prior PCSK9 use or site-of-care restrictions [16]. Patients with commercial insurance may encounter co-insurance or co-payment costs, which vary based on their plan, potentially leading to disparities in access [17]. While inclisiran is the first FDA-approved healthcare provider-administered drug in cardiovascular care, other medications may follow this trend, and appropriate mechanisms for their provision need to be developed.

The buy-and-bill process: A practical solution for cardiology practices

The process of buy-and-bill is necessary for obtaining reimbursement for specialty drugs under Medicare Part B. Establishing this process requires a systematic approach and expertise, as well as the development of infrastructure. Coordinating across various functions within the healthcare provider's office, such as hiring new staff, providing training, and developing infrastructure, is essential. Key elements include contracting with an accredited distributor, conducting benefits investigations, and managing patient co-payment/co-insurance collection processes. Staff members need to be proficient in coding, billing, and patient education, and the office should have the necessary infrastructure for product storage and stock management. Regular cross-functional meetings involving population health, finance, billing, and pharmacy are crucial for coordinating the setup. The provider evaluates the patient's health plan to determine available benefits and whether prior authorization is necessary. This involves checking for provider restrictions, step therapy edits, or site-of-care limitations. If prior authorization is denied, appeals can be submitted [18]. Following the benefits investigation, the office establishes the fee schedule (Medicare, commercial, or Medicaid) [19]. Co-payment and out-of-pocket costs are explained to the patient. Patients in need of assistance with co-payments may be eligible for programs like the HealthWell Foundation® [20]. Medication administration is scheduled once approval is obtained. The provider places an order for the medication from the supplier/distributor. The drug can either be kept in inventory or ordered to arrive before the patient visit. It is essential to maintain a clear separation between buy-and-bill inventory and specialty pharmacy inventory [1,18]. The patient receives the medication at the provider's office. Insurance details are verified at each visit, and co-payment or co-insurance (if applicable) is collected. After administration, patients should be monitored for adverse effects, and future appointments should be scheduled. Proper EHR documentation aids in charge capture and appointment scheduling [18]. Ensuring the procedure is documented in the patient's electronic health record (EHR) is crucial for accurate and timely reimbursement claims. Delayed documentation can lead to denials and penalties [18]. Figure 1 provides a visual representation of the sequential steps involved in implementing the buy-and-bill model for specialty pharmaceuticals, outlining key processes such as benefits investigation, prior authorization, medication procurement, administration, and reimbursement. Healthcare providers administering cardiovascular risk-modifying medications, such as inclisiran, should possess appropriate medical qualifications, including expertise in cardiology, internal medicine, or lipidology. They must be trained in lipid management guidelines, subcutaneous administration techniques, patient monitoring, and adherence strategies. Compliance with Medicare Part B regulations, buy-and-bill reimbursement procedures, and institutional credentialing are essential. Providers should have access to the necessary infrastructure for drug acquisition, storage, and administration, with integration into electronic health records for documentation and follow-up tracking.

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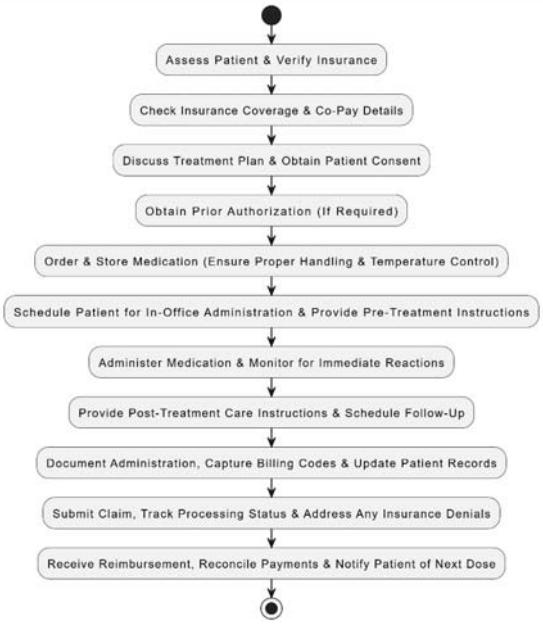

Figure 1: A flowchart illustrating the sequential method for implementing a buy-and-bill model for specialty pharmaceuticals.

Financial and access considerations

It is essential to ensure accurate coding in claims forms to receive timely reimbursement. National Drug Codes (NDC), Healthcare Common Procedure Coding System (HCPCS) codes, and Current Procedural Terminology (CPT) codes are utilized for the classification of drugs and procedures [21,22]. Common billing errors include the use of invalid codes or the omission of NDC numbers or modifiers. Claims are entered into the billing system and processed by the payer. Payment methods differ among payers, such as Medicare's Average Sales Price (ASP) plus 6% or Wholesale Acquisition Cost (WAC) plus 3%. Commercial insurance reimbursement models incorporate ASP or WAC plus a percentage or contract pricing [23]. Once the claim is approved, payment is disbursed to the healthcare provider, who then reviews and posts it for accuracy. Accounts receivable reports are then generated [24].

Conclusion

Provider-administered lipid-lowering therapies, such as inclisiran, present an innovative strategy for cardiovascular management by enhancing patient compliance, minimizing administrative obstacles, and improving overall health results. The buy-and-bill model serves as an effective solution for cardiology practices; however, its successful execution necessitates adequate infrastructure, specialized knowledge, and comprehensive patient education. As the availability of provider-administered medications increases, the process is expected to develop further, creating additional opportunities to enhance cardiovascular health outcomes.

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