

Key Considerations for Designing and Operating Clinically Successful and Solvent Lipid Clinic and Cardiometabolic Risk Reduction Programs

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Key Characteristics of Successful Lipid Clinic Programs

In recent years, particularly since the publication of the NCEP ATP III guideline update in 2004 and more recently the 2018 AHA/ACC Cholesterol Treatment Guidelines which was endorsed by the NLA, there continues to be growth of “lipid clinic” and cardiometabolic risk reduction (CMR) programs in a variety of health care settings. Many of these programs have come and gone with economic and referral challenges. This paper will discuss recommendations for inaugurating and sustaining a productive and cost-justified approach.

Although there has been no universally accepted definition of a “lipid clinic” in 2003 after having visited and consulted with scores of practices aiming to organize something more than just a generalized interest in “cholesterol control” for their patients it was necessary to qualify what would constitute a reasonable definition of a more focused clinic approach to managing more difficult dyslipidemia/dyslipoproteinemia cases: *A coordinated and systematic process whereby patients who have a lipid and/or lipoprotein disorder are identified, risk-triaged and expediently managed to acceptable lipid/lipoprotein and behavioral goals by a qualified and dedicated staff.* The assumption with this definition is that dedicated lipid clinics would address more uncommon and complex lipid disorders while health care providers in general would manage more straight-forward polygenic dyslipidemia in a usual care approach. Moreover, in contrast to usual care, such lipid clinic programs would employ defined treatment pathways grounded in currently published consensus diagnostic and treatment guidelines for lipid and lipoprotein disorders, e.g., AACE/ACE 2018, NLA 2018, IAS 2013, and ACC/AHA 2013/18.

Over the last 29 years having had the opportunity to help many health care institutions inaugurate more systematic approaches to managing lipid disorders and cardiometabolic risk primarily through the organization and implementation of a lipid or cardiometabolic/metabolic syndrome clinic service I have provided a short narrative synopsis of 13 key considerations when organizing operationally and clinically successful programs.

Please find this as an enduring document resulting from formally consulting with a wide variety of medical groups but also including 11 years as managing director of the Duke University Lipid Clinic Preceptorship Physician Education Program where we (Dr. John Guyton) “trained” over 220 various medical groups on designing and operating clinically and economically effective lipid clinics.

1. Understand the spectrum of staff and program delivery models

The issues and regulatory complexities of establishing lipid clinic and more comprehensive CMR programs will vary across the continuum of health care delivery system. In short, staffing, billing/reimbursement, and documentation of services depend on the program delivery model e.g., direct outpatient fee-for-service, government delivered (e.g., DOD, Indian Health Service, etc.), university-based, community clinics, ACO and medical home models. In outpatient office-based fee-for-service settings adherence to current federal coding and billing guidelines (e.g., “incident to” regulations) is paramount. Such regulations can affect the solvency of collaborative care models utilizing several therapeutic disciplines, e.g., dietary, pharmacy, clinical exercise physiology services. Contracted models of care are less regulated but require judicious attention to staff, laboratory, and therapeutic costs. Another consideration that will dictate the level of billing as well as the delivery of both therapeutic and patient counseling services is the staff model.

Fundamentally – from a fee-for-service billing perspective there are three delivery of services staff models: physician, nonphysician mid-level practitioner, and all other nonphysician staff. From a contracting perspective non fee-for-service lipidologists and clinical lipid specialists will be required to plan and propose select lipid and CMR services to employer, PCMH, ACO organizations, etc. In recent years there has been a growing interest in an integrated staff model particularly in CMR programs where all program staff are essentially “cross-trained” such that they can proficiently address diagnostic, lifestyle, dyslipidemia, and pharmacotherapeutic intervention (i.e., a cardiometabolic risk reduction practitioner) within the scope of a physician-authored and annually reviewed therapeutic care plan. All of these issues and regulations are addressed more thoroughly in separate documents and education programs, e.g., NLA’s Lipid Clinic and Cardiometabolic Risk Operations Course.

The issue of *Concurrent Care* when clinical lipidologists/specialists receive referrals from other physicians. The Center for Medicare Services has certain rules and requirements for physicians to claim that they provided concurrent care for a patient. Both physicians must be actively treating the patient at the same time. The diagnosis must show cause that the patient’s health required treatment from both physicians at the same time. Medicare has a policy definition of necessary and reasonable; and the physician’s treatments or services must meet this definition. Accurately meeting these requirements allows both doctors to file claims for concurrent care. That said, the practice of *clinical lipidology*, i.e., *clinical lipidologists*, unfortunately is a relatively new specialty which not yet recognized by but is in the enduring process of attaining recognition by the American Board of Medical Specialties. There are also variations in insurer and each state’s view on the necessity of ABCL-certified clinical lipidologists in concurrent care.

From the federal perspective, i.e., Medicare, in order to determine whether concurrent physicians’ services are reasonable and necessary, the carrier must decide the following:

1. Whether the patient’s condition warrants the services of more than one physician on an attending (rather than consultative) basis, and

2. Whether the individual services provided by each physician are reasonable and necessary.

2. Lipid Clinic Program Service: Clarify the level of lipid clinic service that you intend to offer.

Nearly all lipid clinics share common features particularly a dedicated staff and appointment schedule for dyslipidemic patients (Figure).

Essentially there are two levels of dyslipidemia management service: The first is *Practice Dyslipidemia Management* where a provider or all providers in a group practice have a working knowledge of and adherence to the most recent NLA and IAS dyslipidemia recommendations and at least a basic understanding of the ACC/AHA guidelines. These providers should be equally proficient at diagnosing and managing dyslipidemia with therapeutic lifestyle changes and both straight-forward mono- and combination therapy when necessary. The second level is a *Lipid Clinic Service* that is designed to employ more focused and systematic measures to treat patients with dyslipidemia particularly more complex dyslipidemias/dyslipoproteinemias. A lipid clinic service can be further categorized into a *general lipid clinic service (level 1)* or a *lipid clinic service (level 2)*. A level 1 service specifically assesses all patients with generalized dyslipidemia requiring relatively simple straight-forward therapy (e.g., diet and statin), several levels of complex dyslipidemia, and treats to target lipid and lipoprotein goals. Level 2 programs are referral programs and almost exclusively focus on difficult or complex cases and most frequently are local area if not regional referral centers. Complex lipid disorders most often require a higher level of diagnostic and therapeutic skill and proficiency at utilization of more advanced lipoprotein/biomarker tests. The knowledge and diagnostic skill level required of a lipid clinic practitioner is considerably more specialized especially when working with more complex dyslipidemias. Additionally, drug (e.g. statin) intolerance assessment and management is a new feature that either level of lipid service can offer and should be an attractive service to local providers.

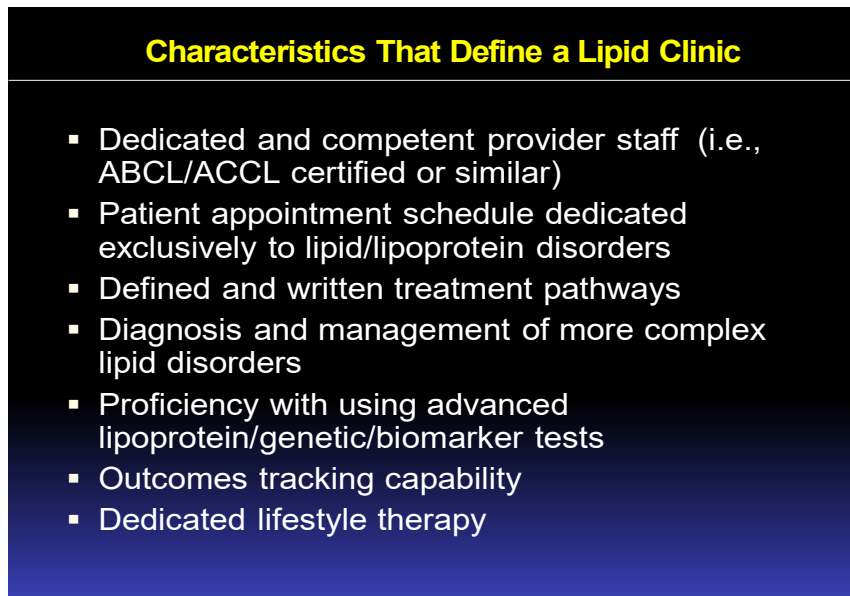
One opportunity for those who aspire to be medical directors of lipid clinic programs is certification in clinical lipidology. The National Lipid Association offers credentialing and board certification of clinical lipidologists through the American Board for the Certification of Lipid Specialists (ABCLS) (see NLA website: www.lipid.org and lipidboard.org). Preparation for board certification can also be provided by the NLA's Self Assessment Program and Masters in Lipidology board review course.

The ACCL (Accreditation Council for Clinical Lipidology) offers a clinical lipid specialist certification exam and credential for experienced qualified nonphysicians which is similar to the ABCL exam. Nurse practitioners, physician assistants, nurses, registered dietitians, CDE's, pharmacists, and clinical exercise physiologists are the principle focus of the ACCL. The credential for those who qualify for and pass the exam is *certified clinical lipid specialist*. Obtaining this credential for qualified nonphysician staff will improve local provider perception of your clinic's diagnostic and therapeutic proficiency and skill. More information is available at

www.lipidspecialist.org.

Finally, you may want to offer a *diagnostic only* service to local referral sources. Here your goal is to make a lipid disorder diagnosis based on, in many cases, more advanced lipoprotein, apoprotein, genetic, and other relevant assessments. In this case your service would include rendering a diagnosis, a probable etiology (genetic/lifestyle/drug) and a recommendation for therapy. This is a valuable service to many providers who want a lipidologist's opinion but not institute therapy.

Figure



3. Appropriate lipid clinic entry criteria and sufficient patient referral

It is paramount that consideration be given to formal establishment of written referral criteria. Most “lipid clinics” have no formalized or written referral criteria. Local providers should have some idea of what dyslipidemias/dyslipoproteinemias best suit your clinic’s clinical management skills and health care setting.

The first and primary source of patients with treatable lipid disorders are your own practice's higher-risk and/or more complex dyslipidemic patients. Patients who require relatively simple and straight-forward monotherapy and moderate dietary changes generally do not require a dedicated lipid clinic service except for perhaps a q6-month or annual follow-up to ensure compliance with lifestyle changes and/or drug therapy. Providers who see these patients should be strongly encouraged to manage these patients as per the NCEP ATP III/IAS 2013/NLA 2014 and ADA 2014 guidelines. Those who are higher risk (e.g., secondary prevention with two or

more CVD risk factors, i.e., >20-30+% 10-year CHD risk) and/or who require more advanced laboratory testing or multiple drug therapy are more appropriate for lipid clinic services. Complex dyslipidemias are perhaps the best candidates for specialized level 2 lipid clinic services (see examples below).

Many of these will require diagnostic proficiency and working knowledge of advanced genetic and lipoprotein assays (see #4 below). Patients requiring more complex therapy, e.g., two or more liver-metabolized drugs, are also good candidates for lipid clinic services. Special populations, e.g., PCOS, HIV, or pediatric dyslipidemia specialization, those who have historically been resistant or unresponsive to therapy including statin intolerance are also candidates for a lipid clinic service. Regardless of what criteria a provider chooses to refer a patient all new patients should be thoroughly evaluated to confirm type and origin of the dyslipidemia/dylipoproteinemia.

Example situations requiring a higher level of provider skill and systematic therapy:

- Complex dyslipidemias (including genetic forms)
e.g., Fredrickson type I, III, V, diabetic dyslipidemia, familial hypercholesterolemia and familial combined hypercholesterolemia, chylomicronemia, familial hypertriglyceridemia TG > 1000 mg/dL, elevated Lp (a), familial hypoalphalipoproteinemia, lysosomal, lipase and apolipoprotein deficiencies, etc.
- Complex therapy
e.g., Where two or more liver-metabolized drugs are needed
- Special populations
e.g. HIV, PCOS, renal dialysis, pediatric cases, diabetic dyslipidemia
- Patients who have been resistant or unresponsive to prior and/or current therapy
- Drug therapy resistance, e.g., statin intolerance
- Very high risk ASCVD patients where time-to-goal is paramount or lifetime ASCVD risk >45%
- Patients who require a differential diagnosis of a lipoprotein disorder and some determination of the genetic and lifestyle roles including recommended therapy

4. Familiarity with Advanced Lipoprotein Laboratory Measures

Utilization of more advanced laboratory measures are sometimes but not always required in assessing risk and response to therapy in every patient. Clinical lipid specialists should however be familiar with select more advanced lipoprotein and genetic laboratory assessments e.g., LDL-P, HDL-P, VLDL subspecies, Apo B & A, Lp(a), hsCRP, CAC, genetic markers (e.g., ApoB genotype, PCSK9, LIPA) with regard to if and when they may have meaningful clinical utility.

Determine which patients/lipoprotein disorders will be evaluated with these measures. Six considerations should be addressed when employing more advanced laboratory measures: Is there a clear evidence base for using this laboratory measure for clinical and therapeutic decision making? What is the added cost of this laboratory measure(s) and who pays? Is this test measure an independent risk predictor and/or a target of therapy? Does it provide consistent and reproducible results? Is it well validated and standardized from a clinical chemistry standpoint? The question is frequently asked if insurers and health plans will reimburse these advanced tests instead of considering them “experimental”. The answer is that third parties generally look for the most conservative evidence-based justification for such assays – e.g., the USPSTF CHD screening guidelines which are not likely to paint broad support for the routine use of many of these tests. See the recent paper by MR Langlois to give an excellent overview and utility of some of the advanced tests: *Quantifying Atherogenic Lipoproteins: Current and Future Challenges in the Era of Personalized Medicine and Very Low Concentrations of LDL Cholesterol. A Consensus Statement from EAS and EFLM.*

5. Organized and current treatment plan

Clearly defined and written treatment pathways provide a vehicle that ensures consistency for all lipid clinic staff members. Lipid clinics should have a clear and ever-evolving treatment plan (i.e. algorithm) that specifies and prioritizes what class and choice of therapy for each magnitude/level of each lipid and lipoprotein (e.g., elevated LDL, elevated TG, elevated LDL & TG, and low HDL-C). There are many formats for dyslipidemia treatment plans but essentially there should be at least two choices of therapy for each level of dyslipidemia. Well-defined treatment plans authored, signed, and annually reviewed by a physician or physician-directed consensus panel also provide a therapy titration guide for nonphysician practitioners and should be reviewed and updated at least annually. In most health care settings a physician-authored treatment plan/pathway extends prescriptive “authority” to qualified and competent physician extenders. It is important to know that the NLA, EAS, IAS or ACC/AHA cholesterol recommendations/guidelines are not a defined treatment pathway but can be very helpful in the process of writing one. See *2018 Example Treatment Plan Template* provided during the LCMRP staff in-service.

6. Projecting income

Attaining solvency can be challenging particularly in outpatient physician office fee-for-service lipid clinic and CMR programs. With little increase, no increase, or even decreases in Medicare allowable payments for office visits over the next 3-5 years we will have to be creative in how we choose, staff and deliver lipid and CMR services. For now, the following are some key methods that can help ensure a productive business model.

Ensure that you include all lipid clinic service related income. This includes both billed visits and secondary revenue (e.g. laboratory testing income). For example, over the course of the first year of lipid management a relatively typical dyslipidemic patient in a lipid clinic service may

require 3 blood lipid profiles, at least one liver function test, a CK evaluations in addition to other labs. More complex dyslipidemias may require more advanced lipoprotein and/or apolipoprotein assays to make a definitive diagnosis and these should be included in your revenue projection. The income generated from these tests along with other tests which have been recommended on the basis of a lipid clinic visit, e.g., lipoprotein particle analysis, liver and kidney function, genetic tests, hsCRP, treadmill ECG's, etc. should be estimated and projected in the "benefit" side of your pro forma. Depending on what laboratory you use your clinic group may not actually "benefit" from this laboratory income. With such a burgeoning array of "advanced" testing assays it will be important to formulate a protocol for when such testing is clinically and economically justified as well as covered by the patient's health plan.

It is paramount that all direct and indirect costs be projected and tracked including staff, counseling space, patient education materials, continuing staff education, etc. Some lipid clinic settings, e.g., academic centers, find it very challenging to provide a break even service due to the multitude of institutional and facility costs associated with lipid clinic operations. A lipid clinic can clearly be solvent and can marginally contribute to bottom line revenue when specific procedures are followed and the clinic manager adopts reasonable business planning operational procedures. Perhaps the most important of these is keeping new and return patient visit times to no more than 25 and 15 minutes respectively. Cardiometabolic risk program visits may require slightly longer visit times in order to fully assess and manage lifestyle behavior.

When all of the operational expenses and space costs are considered, most lipid clinics operate at a small loss however this should not be a deterrent to inaugurating a service. When patients are chosen and managed appropriately significant improvements in health-related outcomes can be realized. Perhaps the biggest obstacle to solvent operations is unnecessary lengthy return visits, e.g., >15 minutes, and an inefficient nonproductive patient scheduling template. For example, 30-minute return visits take up excessive staff time for the billed level of service.

7. Billing and coding guidelines and adherence to federal regulations

2019 Medicare update:

Source: <https://www.cms.gov/About-CMS/Story-Page/2019-Medicare-PFS-proposed-rule-slides.pdf>

Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2019:

Streamlining Evaluation and Management Payment and Reducing Clinician Burden
CMS is finalizing a number of documentation, coding, and payment changes to reduce administrative burden and improve payment accuracy for office/outpatient evaluation and management (E/M) visits over several years. For CYs 2019 and 2020, we are implementing several documentation policies to provide immediate burden reduction, while other changes to documentation, coding, and payment would be implemented in CY 2021.

For CY 2019 and CY 2020, CMS will continue the current coding and payment structure for E/M office/outpatient visits and practitioners should continue to use either the 1995 or 1997 E/M documentation guidelines to document E/M office/outpatient visits billed to Medicare. For CY 2019 and beyond, CMS is finalizing the following policies:

Elimination of the requirement to document the medical necessity of a home visit in lieu of an office visit;

For established patient office/outpatient visits, when relevant information is already contained in the medical record, practitioners may choose to focus their documentation on what has changed since the last visit, or on pertinent items that have not changed, and need not re-record the defined list of required elements if there is evidence that the practitioner reviewed the previous information and updated it as needed. Practitioners should still review prior data, update as necessary, and indicate in the medical record that they have done so; Additionally, we are clarifying that for E/M office/outpatient visits, for new and established patients for visits, practitioners need not re-enter in the medical record information on the patient's chief complaint and history that has already been entered by ancillary staff or the beneficiary. The practitioner may simply indicate in the medical record that he or she reviewed and verified this information; and

Removal of potentially duplicative requirements for notations in medical records that may have previously been included in the medical records by residents or other members of the medical team for E/M visits furnished by teaching physicians.

2021 Proposed Payment for Office/Outpatient Based E/M Visits:

Beginning in CY 2021, CMS will further reduce burden with the implementation of payment, coding, and other documentation changes. Payment for E/M office/outpatient visits will be simplified and payment would vary primarily based on attributes that do not require separate, complex documentation. Specifically for CY 2021, CMS is finalizing the following policies:

Reduction in the payment variation for E/M office/outpatient visit levels by paying a single rate for E/M office/outpatient visit levels 2 through 4 for established and new patients while maintaining the payment rate for E/M office/outpatient visit level 5 in order to better account for the care and needs of complex patients; Permitting practitioners to choose to document E/M office/outpatient level 2 through 5 visits using medical decision-making or time instead of applying the current 1995 or 1997 E/M documentation guidelines, or alternatively practitioners could continue using the current framework;

Beginning in CY 2021, for E/M office/outpatient levels 2 through 5 visits, we will allow for flexibility in how visit levels are documented— specifically a choice to use the current framework, MDM, or time. For E/M office/outpatient level 2 through 4 visits, when using MDM or current framework to document the visit, we will also apply a minimum supporting documentation standard associated with level 2 visits. For these cases, Medicare would require information to support a level 2 E/M office/outpatient visit code for history, exam and/or medical

decision-making;

When time is used to document, practitioners will document the medical necessity of the visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary;

Implementation of add-on codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care, though they would not be restricted by physician specialty. These codes would only be reportable with E/M office/outpatient level 2 through 4 visits, and their use generally would not impose new per-visit documentation requirements; and

Adoption of a new “extended visit” add-on code for use only with E/M office/outpatient level 2 through 4 visits to account for the additional resources required when practitioners need to spend extended time with the patient. CMS believes these policies will allow practitioners greater flexibility to exercise clinical judgment in documentation, so they can focus on what is clinically relevant and medically necessary for the beneficiary. CMS intends to engage in further discussions with the public to potentially further refine the policies for CY 2021.

Proposed Payment for Office/Outpatient Based E/M Visits

Level	Current Payment* (established patient)	Proposed Payment**	Level	Current Payment* (new patient)	Proposed Payment**
1	\$22	\$24	1	\$45	\$44
2	\$45		2	\$76	
3	\$74	\$93	3	\$110	\$135
4	\$109		4	\$167	
5	\$148		5	\$211	

* Current Payment for CY 2018

**Proposed Payment based on the CY2019 proposed relative value units and the CY2018 payment rate

Current 2019/20 Billing Guidelines

One key to reasonable revenue collection for lipid clinic services within a fee-for-service environment is efficient and productive use of allied health professionals (e.g. nurse, physician’s assistant, dietician, pharmacist, exercise physiologist). An important document which will help explain Medicare coverage for nonphysician practitioners from the Department of Health and

Human Services, Office of the Inspector General: Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services, August 2009 OEI-09-06-00430. Another helpful document on new rule changes is: Medicare Summary of Changes to the 2018 Physician Fee Schedule at: <https://www.cms.gov/PhysicianFeeSched/>. You can also search individual CPT codes and their current Medicare allowables for your specific U.S. locality at: <https://www.cms.gov/apps/physician-fee-schedule/search>. It is neither the purpose or responsibility of this document to fully discuss CPT coding but the following summarizes some of the essentials of nonphysician coding and billing.

Nonphysician billing. The **Medicare Incident-to regulations** provide that physicians may be reimbursed for services furnished by non-physicians "incident to" the physicians' professional services. Such non-physicians include: nurses, nurse practitioners, physician assistants, CDE's, clinical exercise specialists/physiologists, and dieticians. Nurse practitioners, physician assistants, and clinical nurse specialists may bill at the higher CPT established patient codes when the medical decision making and patient complexity for that visit warrants such billing (see second slide below). It is important to note that each prospective clinic should obtain competent local legal counsel regarding the precise application of the CMS "incident to" guidelines to your lipid clinic setting for your state and what fee codes non-physicians may bill. Timely billing and appropriate familiarity and use of billing codes are also required for respectable collections.

Some of the rules of "incident to" nonphysician billing: The provider must first see the patient and develop a plan of care and initiate the course of treatment. The "incident to" service provided by the auxiliary personnel is then an incidental part of the patient's treatment. The patient can see the auxiliary personnel for continued treatment of the initial problem that was presented to the provider. If a new problem is identified at a visit by the auxiliary personnel, the patient must be referred back to the provider for evaluation and development of a new plan of care. The provider must demonstrate an active participation in the ongoing care of the patient, such as providing services on a regular basis that reflects participation on an ongoing basis. Reimbursement is based on 100% of the provider's fee schedule amount. Note that some insurers do not allow any NPP "incident to" billing.

Settings Where "Incident to" May Be Considered

Physician/Providers Clinic

A physician/provider directed clinic is one where:

1. A physician or provider (or a number of physicians/providers) is present to perform medical (rather than administrative) services at all times the clinic is open;
2. Each patient is under the care of a clinic physician or provider; and
3. The nonphysician services are under medical supervision.

Nonphysician providers (NPPS) particularly mid-level providers, e.g., ARNPs and PA's, can create their own plan of treatment or change the dose of a medication started by the physician,

however the moment the NPP makes independent treatment decisions they are no longer following the physician’s treatment plan and services must now be billed to Medicare under the NPP’s name and NPI. A written *Collaborative Practice Agreement* enumerating the duties of the NPP and the duties of the physician (which shall include consultant and supervisory arrangements in case the physician is unavailable) and stating the management areas for which the NPP is responsible, including conditions for which therapies may be initiated by the NPP/ARNP and treatments that may be initiated can be very helpful.

In highly organized clinics, particularly those that are direct physician/provider supervision may be the responsibility of several providers as opposed to an individual provider. In this situation, medical management of all services provided in the clinic is assured. The physician ordering a particular service need not be the physician who is supervising the service. Therefore, services performed by auxiliary personnel and other aides are covered even though they are performed in another department of the clinic.

Signature requirements

Situation	Performed By	Signature Requirement
Incident to	Ancillary Staff	Must be signed by supervising provider (billing)
	NPP	May be signed by the NPP or the supervising physician
Split/Shared: Office/Clinic Setting	NPP and Physician	May be signed by the NPP or the supervising physician. If this service is billed under the physician’s NPI, the billing physician must sign the record. Additionally, the documentation must include a statement that the billing provider had face-to-face contact with the patient and performed a substantive portion of the E/M visit. (A substantive portion of the E/M visit includes at least one of the three key components (history, exam, or medical decision making.)

The **Medicare Learning Network** also recently published a new “Incident to” Services description for nonphysicians on 8/23/2018. See:

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0441.pdf>

Medicare-Information-for-APRNs-AAAs-PAs-Booklet-ICN-901623.pdf 2017

CPT Coding. Essentially, providers can use evaluation and management codes (CPT E&M coding for office lipid or CMR clinic visits) or specialty CPT codes (e.g., medical nutrition therapy, pharmacist medication therapy, e-visits) when coding for lipid clinic visits **HOWEVER**

there are federal, state, and third party regulations which govern who and with what visit criteria allow CPT codes and their billed allowables to be used. These rules and regulations change regularly and are beyond the scope of this paper but can be ascertained through individual medical group consultations, *Medicare Learning Network*, and the Federal Register. The following slide depicts the two categories (initial and established patient) of CPT coding most frequently used in lipid clinics. The second slide denotes which nonphysician practitioners can bill at higher E&M levels (but this can be State specific). 2018 Medicare estimates of allowables for established and initial patient visits are denoted in the last segment of this #7 section.

Primary CPT Codes for Evaluation and Management Services in Lipid and CMR Programs		
<u>Level</u>	<u>Initial visit</u>	<u>Established patient</u>
1	99201	99211
2	99202	99212
3	99203	99213
4	99204	99214
5	99205	99215

Non Physician Practitioners and E&M CPT Codes for Established Patients

Return Visits

Nurse practitioners	99211*
Nurse specialists	99212
Physician assistants	99213
PhCs (in some states)	99214
Nurses	99215
Pharmacists	
Dieticians	
Exercise specialists	
CDE's	
Other	

For contracted patient groups (e.g., employers, health plans) who are contracted to receive lipid or CMR/metabolic syndrome management services appropriate selection of high risk patients, tight adherence to the contracted number of patients, and efficient delivery of necessary clinic services (e.g. follow up visits, cost effective therapy, & education) will be paramount for a reasonable cost-benefit.

E-Visits. Telehealth services include office visits, psychotherapy, consultations, and certain other medical or health services that are provided by an eligible provider who isn't at your location using an interactive 2-way telecommunications system. Telehealth-delivered services under Medicare is limited in statute by 1834(m) of the Social Security Act which limits the use of telehealth to certain services, providers, technology (mainly live video) and patient locations (needing to be in certain types of healthcare facilities in rural areas where health professional shortage is prevalent, eg. Hawaii and Alaska. In 2020 Medicare will be expanding the requirements for electronic visits. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcs>.

2019 Physician Fee Schedule for Established and Initial Patient Office Visits (all areas but does not include new proposed E&M visit reimbursements as seen in 2019 Medicare Update table above)

<https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/>

<https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx>

Established Patients

HCPCS CODE ▲▼	MODIFIER ▲▼	SHORT DESCRIPTION ▲▼	PROC STAT ▲▼	MAC LOCALITY ▲▼	NON-FACILITY PRICE ▲▼	FACILITY PRICE ▲▼	NON-FACILITY LIMITING CHARGE ▲▼	FACILITY LIMITING CHARGE ▲▼
99211		Office/outpatient visit est	A	0000000	\$23.07	\$9.37	\$25.20	\$10.24
99212		Office/outpatient visit est	A	0000000	\$45.77	\$25.95	\$50.00	\$28.35
99213		Office/outpatient visit est	A	0000000	\$75.32	\$51.90	\$82.29	\$56.70
99214		Office/outpatient visit est	A	0000000	\$110.28	\$80.01	\$120.48	\$87.41
99215		Office/outpatient visit est	A	0000000	\$147.76	\$112.80	\$161.43	\$123.24

Initial Patient Visit

HCPCS CODE ▲▼	MODIFIER ▲▼	SHORT DESCRIPTION ▲▼	PROC STAT ▲▼	MAC LOCALITY ▲▼	NON-FACILITY PRICE ▲▼	FACILITY PRICE ▲▼	NON-FACILITY LIMITING CHARGE ▲▼	FACILITY LIMITING CHARGE ▲▼
99201		Office/outpatient visit new	A	0000000	\$46.49	\$27.39	\$50.79	\$29.92
99202		Office/outpatient visit new	A	0000000	\$77.48	\$51.54	\$84.65	\$56.30
99203		Office/outpatient visit new	A	0000000	\$109.92	\$77.48	\$120.09	\$84.65
99204		Office/outpatient visit new	A	0000000	\$166.86	\$131.18	\$182.30	\$143.32
99205		Office/outpatient visit new	A	0000000	\$209.75	\$171.19	\$229.15	\$187.02

8. Minimize unnecessary staff expenses

Minimize unnecessary staffing and long-return visits. Unnecessary staffing, lengthy return visits, and expensive educational materials are sure ways to reduce the probability of break-even.

Return visits should last no longer than 15 minutes (20 minutes with metabolic syndrome/CMR clinic patients where more dedicated lifestyle counseling is required) except in the most complex cases where medical decision making, evaluation and history taking are at a high complexity level. Team approaches to treating dyslipidemia and CMR patients are often extolled as the ideal staff model in larger medical centers however “team-approaches” can be difficult to cost-justify especially considering the visit fee limits and the fact that Medicare and most indemnity plans only allow one fee to be charged and documented per return visit day. Individual lipid specialist providers (e.g, physician, nurse practitioner, nurse specialist, pharmacist, dietitian, CDE, etc) with sufficient cross-training in clinical assessment, pharmacotherapy, dietary and lifestyle counseling skills are most likely to be your best staff model. Here, the lipid or “risk reduction” practitioner manages their own patients through the course of care but always with the physician seeing the patient and instituting inaugural therapy on the first (new) patient visit. When clearly necessary, referral to outside lifestyle therapy specialists, e.g., clinical dietitians, exercise specialists can be made. Finally and most importantly with regard to a lipid clinic service an experienced medical director competently skilled at diagnosis and management of a wide range lipid/lipoprotein disorders is paramount for a successful service.

9. Efficient and aggressive patient scheduling

Efficient and aggressive patient scheduling is very important for financial solvency. An example of an initial patient scheduling template: on two half days a week (e.g., two mornings) a lipid specialist should be capable of seeing 4-5 new patient visits and 7-8 return visits, or some combination of both. The figure below is an example of an **initial** four-morning per week lipid clinic schedule. In time, this patient throughput can increase by reducing visit and charting time such that the return visit intervals are ~10-15-minutes and the new patient visits are 20-25 minutes. Since lipid clinic staff resources are usually limited it will be smarter to use intensive one-on-one follow-up with only high CMR risk or complex therapy dyslipidemic patients and use an informed usual-care approach or a group and/or telemanagement follow-up protocol with those who are relatively low CVD risk or who may require relatively simple straight-forward therapy. Implementing a once or twice monthly self-pay (e.g., \$10) 75-minute provider-facilitated group education and problem solving session will help address patient issues and questions and help provide additional lifestyle instruction. Deferring to a regular standing self-pay group education program will help keep office-visit time to a minimum as well as provide more meaningful dietary and physical activity instruction. Third parties generally do not reimburse for group education support outside of diabetes education and group psychological therapy.

Example LC Weekly Pt Schedule (16-20 hrs/wk) INAUGURAL SCHEDULE				
Monday	Tuesday	Wednesday	Thursday	Friday
8:00	8:00	8:00	8:00	
8:30	8:45	8:30	8:45	
9:00		9:00		
9:30	9:30	9:30	9:30	
10:00	10:15	10:00	10:15	
10:30	11:00	10:30	11:00	
11:00		11:00		

14 returns
10 news
(4 half days)

*note that these visit times in the figure above are purposely elongated for start-up clinics and should shorten considerably within 2-3 months, i.e., 10-15 minutes for return visits.

10. Establishing Outcome and Quality Performance Measures via Data Management

Regardless of the level of clinical service you are planning it will be important to establish or integrate your service with an outcomes assessment platform either through an electronic medical records (EMR) tool or a separate functional relational database management system (e.g., dBase, CSQL). This capability is a necessity because of outcomes reporting requirements for contractual agreements, NCQA accreditation, PQRS, CMS EMR meaningful use incentive programs, internal quality monitoring, and/or research purposes. Performance measures need not be prolific in number but should be concordant with 2018

AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guidelines on the Management of Blood Cholesterol guidelines and/or ADA clinical measures and goals. Lipid clinic performance measures should include at least the central NLA/AHA/ACC lipid and lipoprotein targets and goal attainment (LDL, HDL, TG, nonHDL) for all lipid clinic patients. CMR program measures should include waist circumference, blood pressure, fasting glucose and/or HbA1C, triglycerides, and HDL. Objective measures of behavior change should also be recorded, e.g, dietary nutrient choices, minutes of moderate exercise per week, weekly changes in pedometer step-count. Some measure of compliance with pharmacotherapy and lifestyle therapy can also be helpful even if such a measure is serially scored on a 0-10 likert scale. Advanced lipoprotein measures, other biomarkers, advanced anthropometric measures are optional.

✓ Historically the 2013 ACC/AHA Cholesterol Guidelines de-emphasized LDL-C target performance measures and instead advised statin intensity allocation to one of four statin-benefit groups. This recommendation has generated confusion on whether to use LDL-C as a reporting measure. Indeed the NCQA has for now abandoned LDL-C as a goal or reporting measure. That said, my strong recommendation is for dedicated lipid clinics to keep LDL-C as a reporting measure and target. It would be wise to view the NLA perspective on the 2018 Guideline on the Management of Blood Cholesterol - NLA Perspective: <https://www.lipid.org/2018-guidelines-nla-perspective>. Drs. Orringer and Brown attempt to differentiate lipid targets, goals, thresholds, and “triggers” which in my opinion begets confusion and leaves much interpretation.

Medicare Shared Savings Program Quality Measure Benchmarks for 2018-19 may include LDL-C goals of <100 mg/dL for coronary artery disease and diabetes quality performance benchmarks for ACO’s but it remains to be seen if this LDL benchmark will be formalized in the future.

11. Internal and external program promotional strategies

Demonstrating the value of your services to your own practice partners is always the first and most important step in promoting lipid clinic services. Clear demonstration of your diagnostic and management skill, including ABLS and ACCL certification, is a good way to garner local provider support. It is important to not be perceived as a replacement for simple straight-forward therapy for which the majority of providers should be implementing and following themselves. Your certified expertise in special, more difficult cases should be evident with time. This characteristic is even more true for outside referrals. A number of programs have had remarkable success with offering quarterly lipid tutorials to community physicians on practical management of dyslipidemia where each attending provider brings at least one difficult patient case for discussion. I strongly recommend that you encourage local providers to diagnose and manage their own patient’s lipid disorders that require relatively simple straight-forward therapy (mono and combination drug therapy). Illustrating such straight-forward cases will be important as well as defining the more complex cases that are your particular expertise. Ensure that you show examples of such complex cases categorically and by example cases. Remember also that you can offer a very helpful and productive service: **diagnostic only service** with recommendations for therapy. Opportunities to contract with employee benefits managers, PCMH’s, ACO’s, and community care centers will also depend on your ability to illustrate the clinical value of clinical lipidology services particularly calling attention to your skill with diagnosing and managing more complex lipid disorders.

12. Recommendations for Improving Solvency of Your Program

Regarding lipid clinic profitability and solvency of lipid programs approximately two-thirds of the 2011 NLA Lipid Pulse Survey respondents indicated they operate at break-even or better. Did these respondents actually do an objective cost-benefit analysis or was this a subjective response? This in actuality may or may not be true depending on if this response was based on results of a valid cost/benefit analysis. *2019 NLA Lipid Clinic cost-benefit survey Results should*

be inserted here. Because of the current fiscal climate for looming large Medicare physician fee cuts and increasing staff costs – lipid specialists would benefit from performing a thorough analysis of lipid clinic costs and projected revenue. One of the issues inherent in performing health care-related cost-benefit analysis is that the computation of many components of benefits and costs is intuitively obvious but that there are others for which intuition fails to suggest methods of measurement and sources of benefit for example your impact on system revenue.

Direct costs include staff, materials, and in some cases laboratory costs. Indirect costs, which should be included in your analysis (and pro forma), include lipid clinic assigned space costs, facility fees, administrative and medical supervision costs. Revenue benefit includes your collectibles (not billables) but should also include what revenue you generate for your institution or health care system in terms of what laboratory services you order (e.g., blood assays) and special diagnostic procedures (e.g., treadmill tests, imaging). In my experience when these considerations are included in the cost-benefit evaluation most lipid clinics operate close to or at break-even.

The following are several suggestions for improving the operational and fiscal health of your program:

- 1) A lipid clinic service should not be perceived as a mechanism to ciphen off straight-forward dyslipidemia cases which can be managed by most local providers. Lipid clinics best function when they focus and demonstrate proficiency at addressing more complex cases of dyslipidemia and dyslipoproteinemia and special populations such as PCOS, HIV, or pediatric dyslipidemia and/or those who are high risk but have historically been resistant or unresponsive to therapy including statin intolerance. Lipid clinic visits should warrant separate dedicated visit time to more challenging cases requiring a higher level of clinical and laboratory evaluation and medical decision making that clearly justifying greater than 99211 or even 99212 CPT codes.

*Remember also that you can offer a very helpful and productive service: **diagnostic only service** with recommendations for therapy (see example referral form - Figure below). Clinic referral forms should not be overly complex but should be simple and straight forward.

- 2) Be judicious with new patient and return visit time. i.e., new patient visits should not last longer than 20-25 minutes and return visits no more than 10-15 minutes. This would allow at least 2 new patient visits an hour or 3-6 return visits an hour.
- 3) One way to improve on patient throughput (i.e., increasing the number of return patients seen in an hour) is to have a standing monthly (or more frequent) 75-minute patient group education meeting facilitated by a lipid-specialist staff person whereby patients can get more practical therapeutic lifestyle instruction as well as problem solving. This process can defer many of the lesser issues and questions patients have from the exam room to the classroom and decrease return visit time.

Relatively small “co-payments” of ~\$10 per patient can be generated from each of these meetings.

- 4) Be knowledgeable of the current and forthcoming Medicare allowable payments specific for your geographic area for each of the CPT codes you bill with (new and return patient visits). See CMS website referenced earlier.

*As important as CPT familiarity is familiarity with ICD-10 coding system. The U.S. Department of Health and Human Services has mandated the replacement of the ICD-9-CM code sets used by medical coders and billers to report health care diagnoses and procedures with ICD-10 code sets. These relatively new codes are somewhat more discriminating than previous ICD versions on the specificity of lipid/lipoprotein disorders.

- 5) Consider a concierge or cash-only delivery approach to lipid and cardiometabolic risk management programming, i.e., annual cash fee for services. For this to work you will clearly have to offer meaningful value (clinic visits, labs, education). This approach is growing in popularity but requires judicious pricing and service packaging. There are rules and regulations governing concierge-level programs.
- 6) Become familiar with patient centered medical homes (PCMH's) and accountable care organizations (ACOs) and become proactive in working with these groups to advise and demonstrate complex lipid disorder and high cardiometabolic risk referral criteria. It is paramount that you understand that these organizations are very sensitive to costs, e.g., excessive laboratory testing, quality of care, and objectively measured outcomes. Note that the NCQA quality measures for dyslipidemia, BMI, etc. are not difficult to achieve for well-organized lipid and CMR programs. See: <http://www.ncqa.org/tabid/59/default.aspx>.
- 7) Consider enrolling in *Medicare's Chronic Condition Management program*. CPT Code 99490. The new program will pay physicians for managing Medicare patients with two or more chronic conditions, even when contacts are made by phone or email rather than face to face. Providers, including midlevel practitioners, will be paid \$44 per patient per month for providing at least 20 minutes of care. To qualify for the program, physicians need to have EHR systems and be able to exchange information on the patient with other caregivers. Also, they or their staff must be available to patients around the clock. To accommodate this, Medicare has loosened its "incident to" rule, which requires doctors to directly supervise staff. All medical specialties are eligible for this program. Source: <https://www.medicare.gov/coverage/chronic-care-management-services>
- 8) Consider re-engineering your lipid clinic staff to provide alternate day cardiometabolic risk (CMR) reduction services (with focus on high risk primary prevention metabolic syndrome patients, especially your own system's employees) with your lipid clinic visit days. There are growing financial incentives for CMR

programming particularly when they focus on deferring diabetes risk. Such programs can be contracted for reasonable per-patient per-year rates (see #13 below)

Although there are going to be financial challenges ahead (there here already with impending decisions in 2020 by congress and the Medicare Payment Advisory Commission!!) the more your lipid clinic prepares for very real opportunities to improve care and improve solvency by considering programs such as *pay-for-performance* adherence to quality measures initiatives and improved skill and proficiency at discounted fee-for-service contracting with at-risk employee groups, particularly those at high risk for cardiometabolic disease, will clearly help contribute to your clinic's improved solvency and success.

13. Growing your program beyond your group's walls: Integrated preventive endocrinology and cardiology service (e.g., high risk metabolic syndrome or cardiometabolic risk reduction program)

After several years of successful clinic operations some programs will find it more productive and opportunistic to expand their services beyond lipid management and the walls of their provider group. Oftentimes this service can be directed to high cardiometabolic risk patient/employee populations, e.g., discounted fee-for-service contracting with employee benefits managers including your own clinic or hospital employee group. These programs are best directed at high diabetes and CVD risk employee groups. These individuals represent high health care claims and costs for most employer groups. Screening and systematically managing those with impaired fasting glucose (prediabetes) and high-risk metabolic syndrome (prediabetes + metabolic syndrome + at least one additional risk factor) will be far more productive than offering a dyslipidemia management service alone. Few employer groups will be receptive to contracting for dyslipidemia services alone but may be more interested in a cost-efficient *multi-risk factor* management model, e.g., high risk metabolic syndrome/cardiometabolic risk management program. Price competitive outcomes-based *cardiometabolic risk management programs* which emphasize adiposity reduction are new models of care and appear to be well positioned for employer groups, medical homes, and health plans who have an abundance of at-risk members.

Hospital or clinic employees, affiliated health plans, accountable care organizations, law-enforcement personnel, and public service employee groups are generally good targets for contracting these diabetes and CVD prevention services. Contracting with employer groups with *higher-risk* employees will require that patient clinical information is kept on a secure patient database for periodic group outcome trend-reporting which will be required by the employer group risk or benefits manager. Note that this reporting process does not in any way identify individual patients – just *group* laboratory, anthropometric, therapeutic, and compliance trends. Finally, and perhaps most importantly, the best method of justifying CMR programs is estimating the cost savings of delaying or preventing metabolic disease, e.g., type 2 diabetes. There is a rich source of diabetes cost justification information from numerous sources. For

example, a November 2010 ADA report disclosed that the average annual health care costs in 2009 for a person with known diabetes were about \$11,700 compared with about \$4,400 for non-diabetics, according to new data in the report drawn from 10 million UnitedHealthcare members (a \$7,300 difference). **In 2018 the ADA estimated that people with diagnosed diabetes, on average, have medical expenditures that are approximately 2.3 times higher than the expenditures would be in the absence of diabetes.** As of 2018 people with diagnosed diabetes incur average medical expenditures of \$16,752 per year. Clearly, becoming familiar with publications and claims-data projecting diabetes costs will be helpful.

Overview of the Metabolic Syndrome/Cardiometabolic Risk Clinic Model (CMR program)

For existing cardiovascular risk reduction and lipid clinic programs, especially those in multispecialty medical group settings where family practice and perhaps endocrinology is well represented, this program represents an opportunity to reorganize and combine therapeutic protocols and staff resources. Such program integration will provide additional opportunities to partner with employee benefits managers and health plans who have members at high metabolic and CVD risk, and the community at large.

Predetermined clinical pathways, i.e., a defined treatment pathway (see *2018 Metabolic Syndrome Patient Treatment Visit/Protocol Summary – R. La Forge* – CMRP staff in-service program), can be adapted and implemented for the systematic management of the features of the metabolic syndrome dyslipidemia, obesity, hypertension, and/or impaired fasting glucose (primary prevention model). Dietary and exercise instruction as per the current guidelines as set forth by the 2014 NLA Patient Centered Lifestyle Recommendations and the 2018 Tenth Edition - American College of Sports Medicine Guidelines on Exercise Testing and Prescription will be helpful.

Establishing a **standard cardiometabolic laboratory panel** will be helpful in making objective assessments and serial changes in cardiometabolic risk. Such a panel should be a stand-alone laboratory panel that includes: *fasting glucose, A1C, HDL-C, triglycerides, nonHDL-C, and LDL-C, blood pressure, waist circumference and optional baseline subscapular and/or tricep skinfold measure*. The advantage of a single visit panel here is that all of the metabolic measures are measured on the same day which ensures more valid interpretation and risk triage. Objective and skillful measurement of adiposity is also important to assess at first visit and serially track. One example here would be skillful skinfold assessment with Lange calipers of select skinfold sites to evaluate serial changes in adiposity versus only using BMI and body weight. When measured proficiently skinfolds more precisely reflect changes in adiposity compared to body weight changes. A copy of the *2018 Office-based Anthropometric Assessment Guidelines* are available as part of the 6-hour intensive staff LCMRP in-service (email: rlaforge@nc.rr.com for more information).

Patient visit procedures should consist of individual office and/or telephonic follow-up visits. High risk metabolic syndrome (CMR) patients will require individual follow-up, e.g., *initial office visit: 25-30 minutes, return office visits: (4-8 week intervals) 20 minutes*. The frequency of

return visits are based on the patient's level of motivational readiness. One CMR programming model focuses on the metabolic syndrome. Patients who meet the entry criteria for the metabolic syndrome, i.e., at least 3 metabolic syndrome risk factors, can be classified or risk-triaged as *high or intermediate risk* metabolic syndrome based on the number and magnitude of risk factors. Those who have *high risk metabolic syndrome* (those with NLA 2018 criteria plus additional risk factors such as NASH, stage I hypertension, very high triglycerides, PCOS, etc.) should be prioritized for intensive therapy and more frequent follow-up. Traditional Framingham risk factors exclusive of those of the metabolic syndrome, e.g., elevated TC and LDL-C should also be addressed. All metabolic syndrome patients should have access to a once-monthly education support group which will be helpful with problem solving, lifestyle education, and reinforcement of the therapeutic plan. Compliance management tools (motivational interviewing-brief negotiations) can also be productively employed in this program.

*As an option to metabolic syndrome risk factors for program entry criteria those programs specifically focusing on *diabetes prevention* can use **prediabetes** (i.e., impaired fasting glucose and/or impaired glucose tolerance or A1C of 5.7–6.4%) plus a measure of obesity (waist circumference or BMI) as program entry criteria. They can also require prediabetes and any two other metabolic syndrome risk factors. These programs do not exclude LDL-C or nonHDL management but prioritize management of glucose tolerance and adiposity.

Choosing clear objective outcomes measures will be important for CMR programs to establish their value both for patients and payers. Besides standard laboratory derived outcomes behavioral outcomes measures will be key to measure and record, for example: objective dietary changes as measured by the STC (Starting the Conversation) dietary score, weekly/monthly pedometer step totals, fast food encounters/wk, fruits/vegetable servings/wk, Mediterranean dietary score, physical activity encounters/wk, etc. Clinical pedometry prescription guidelines for CMR programs are available as part of the Lipid and CMRP staff in-service (*Clinical Application of Pedometers: Recommendations for Health Care Providers. La Forge, 2019*). Another resource for physical activity incentivization is *The Gym Inside Your Door* (<https://www.facebook.com/search/top/?q=the%20gym%20inside%20your%20door>) LaForge 2019.

A detailed operational description of the metabolic syndrome/cardiometabolic risk clinic is described elsewhere (see *Operational and Clinical Framework Essentials for Developing Metabolic Syndrome/CMR Management Programs, 6th Edition*). La Forge, 2018.

10/30/2019