***Template*: Nursing Standardized Procedure for Use of Statins in Management of Patients at High Risk for Cardiovascular Events**

Clinical Protocol: Nurse co-management of patients receiving treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk

Effective date:

Policy & Procedure:

Revision date:

Last reviewed:

**Policy**

It is the policy of \_\_\_\_\_\_\_\_ Health Center to allow qualified RNs to co-manage patients ages 21-75 years at high risk for cardiovascular events with statins (HMG-CoA reductase inhibitors).

I. Procedure

A. Functions the RN may perform: collect subjective data (patient history), collect objective data (perform physical examinations), assess patient status, order and interpret labs, develop and implement treatment and educational plan of care

B. Scope - under the following circumstances the RN may function:

1. Setting – within the clinic site

2. Supervision – the RN may operate independently within the constraints and criteria of this policy in partnership with mentoring physician(s) and the designated primary care provider to administer care under the protocol.

3. Treatment criteria are based on 2013 ACC/AHA treatment benefit groups: a) patients with clinical ASCVD; b) diabetics age 40-75y with LDL >70mg/dL; c) patients >21y with LDL >190mg/dL; and d) patients with a 10-year ASCVD risk >7.5%.

4. Additionally, the following criteria must be met:

a. Patient must have a designated primary care provider;

b. Patient does not have contraindications for statin medication use (Appendix II);

c. Patient does not have secondary causes of hyperlipidemia: hypothyroidism, hyperglycemia, renal disease, excessive alcohol intake, &/or cholestatic liver disease;

d. The patient’s baseline labs are within normal limits: creatinine (Cr) or estimated Glomerular Filtration Rate (eGFR) and transaminase (ALT);

e. The nurse has introduced her/himself utilizing correct title and explain role and the patient accepts RN co-management.

C. Definitions:

Atherosclerotic cardiovascular disease (ASCVD) – defined as previous heart attack, stroke (CVA), transient ischemic attack (TIA), previous abdominal aortic aneurysm (AAA or ‘triple A’) repair, known coronary artery disease (CAD), peripheral arterial disease (PAD)

Subclinical ASCVD includes asymptomatic coronary artery disease or peripheral artery disease, abnormal ankle brachial index (ABI) detected on screening

*Champion –* primary care mentoring physician

D. Procedure for Nurse Practice

1. Subjective assessment
* Review relevant health history reported by the patient and documented in the EMR for possible contraindications to statin use
* Conducted review of systems and evaluate current medications for contraindications to statin use
* Assess health habits: diet, exercise, alcohol intake, and tobacco use.
1. Objective assessment
2. BP measurement
3. Lab review: Low Density Lipid (LDL), baseline Complete Metabolic Panel (CMP-14) with Cr or eGFR and ALT, hemoglobin A1c. Consult with provider if:
	* 1. ALT or AST >3 times upper limits of normal.
		2. LDL-C >190mg/dL or TG >mg/dL to evaluate for secondary causes of hyperlipidemia.
4. Assessment – increased risk for cardiovascular event by history, laboratory and/or Heart Risk Calculator (<http://www.cvriskcalculator.com>)
5. Plan
* Treatment goal is 30-50% reduction in LDL; no specific targets indicated.
* Base treatment:determine if moderate or high intensity statin is indicated then begin medication using protocol (Appendix I):
	+ High intensity
		- if 40-75 years and:
			* ASCVD
			* DM with LDL>190mg/dL
	+ Moderate intensity
		- > 75 years
		- Diabetes with LDL 70-189 mg/dL
* Consult with physician for:
	+ Possible contraindications or medication side effects (Appendix II)
	+ Evaluating benefits, risks and patient preferences in treating individuals <40y and >75y
	+ Diabetic patients with LDL 70-189mg/dL and a ASCVD risk >7.5% using Heart Risk Calculator (<http://www.cvriskcalculator.com>)
* Dispense 3-month supply and instruct on once at night
* If recommended dose is not tolerated, reduce to highest tolerated dose or change to another statin. (Appendix I)
* Patient education:
	+ Potential risk of a CVD event
	+ Medication – risks/benefits, side effects, administration (timing, cautions)
	+ Lifestyle modifications should be addressed at every encounter:
* physical activity (30 minutes per day or 150 minutes a week)
* weight management (goal < 25 kg/m2)
* dietary choices – select foods low in saturated fats, high in mono and polyunsaturated fats and fiber
* Limiting alcohol consumption (<1 drink/day for women; <2 drinks for men)
* Smoking cessation
1. Patient follow-up
* LDL monitoring is optional to assist with adherence assessment
	+ Check lipid panel 6 weeks after initiation of statin therapy; then every 12 months
	+ Consider lower statin dose if LDL<40 on two consecutive occasions.
	+ In individuals with less than anticipated therapeutic response or intolerant of recommended intensity, evaluate and reinforce lifestyle changes, medication adherence; exclude secondary causes of hyperlipidemia
* If patient assessed to have possible side effects from statin use, nurse will consult with a provider in order to treat with the maximum tolerated intensity. (Appendix III)
* Order CMP and Lipid panel if not done in last 12 months
1. Record keeping of patient encounters – all patient care (medications, lab work, and education) and verbal or telephone communications with the clinician, or patient/family shall be documented in the EMR.

II. Requirements for Registered Nurse

A. Preparation

1. Education/Licensure: nurse must be licensed as Registered Nurse in California and be in good standing with the Board of Registered Nursing (BRN).
2. Experience: a minimum of one year’s experience (full-time or 2080 hours) as an RN is required.
3. Training: nurse must successfully complete advanced training on subjective and objective evaluation of patients including statin medications, patient education and implementation of the protocol.
4. Nurse must demonstrate knowledge of cardiovascular risk assessment and interpreting lipid test results.

B. Evaluation

Initial: Three cases must be documented and reviewed with *Champion* each week for one month; followed by 3 cases per month for 3 months; then 6 cases per year. Nurse must demonstrate appropriate management of patients on statins. If primary care provider disagrees with management plan, cases will be reviewed with *Champion*. Evidence of successful completion will be documented and included in the nurse’s personnel file

Ongoing Evaluation: Annual competency evaluations will be conducted documenting the RNs ability to function appropriately under the protocol including clinical knowledge, skills/ procedures, appropriate consultation and documentation.

C. Supervision and Review

Roles and responsibilities of Registered Nurses working under the protocol:

1. RN must verify that patients have a designated primary care provider and that the patient meets the criteria for standardized procedure.
2. RN will collaborate and work in partnership with mentoring physician(s) and individual patient’s primary care physician to provide care under the protocol.
3. RN will introduce her/himself utilizing correct title and explain role.
4. RN will collect subjective data (patient history), collect objective data (perform physical examinations), assess patient status, order and interpret labs, develop and implement treatment and educational plan of care
5. Documentation - RN will maintain record of patient encounters (in person, group, telephone) patient ID, complaints, assessment of adherence to meds, diet, exercise, pertinent lab results, plan for med changes, follow-up labs and visits; physician notification if needed

Roles and responsibilities of the *Champion* & the primary care physician:

1. *Champions* should be identified for each site and meet with PHASE consultant prior to implementation.
2. The *Champion* will assure a physician will be available when the nurse consultation or for the physician to see the patient, the patient requests to see the physician, and/or there is an onsite emergency.
3. Primary care physician is responsible for patient management. He/she will be available for consultation and collaboration with RN.
4. The physician will see the patient or review the care of each patient at least once a year and renew the patient specific medication order on an annual basis.

III. Development and Approval of the Standardized Procedure

A. Method – this procedure was developed using the most current guidance from the Board of Registered Nursing, American Academy of Family Practice and technical references from the PHASE program.

B. Review schedule – the procedure shall be assessed at 3 and 6 months following implementation and then annually.

**References**

Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH, Goldberg AC, Gordon D, Levy D, Lloyd-Jones DM, McBride P, Schwartz JS, Shero ST, Smith SC Jr, Watson K, Wilson PWF. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013;00:000-000.

U.S. Preventive Services Task Force. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults. *JAMA*. 2016; November 15, Vol.316, No.19; 1997-2007.

**Appendix I:**

Statin Algorithm

Source: RCHC, September 2017

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*Related Footnotes:*

*2 Reproductive potential alert -> verify effective contraception: ACE-I & ARBs (contraindicated in pregnancy), Calcium Channel Blockers & Spironolactone (Risk Category C); Beta-Blockers (Risk Category D); Statins (Risk Category X).*

*5 Evaluate for 2ndary causes of hyperlipidemia.*

*6 Consider high-intensity statin If ASCVD risk >7.5%* ***(www.cvriskcalculator.com)***

*7 Treating individuals <40y & >75y in with statins is optional; clinicians should evaluate potential ASCVD benefits, risks and patient preferences.*

*⁸ LDL monitoring is an option to assist with adherence assessment; consider lower statin dose if LDL<40 x 2.*

Medication Table

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | **Medication** | **Preferred Dosage Forms** | **Optimal Titration Interval** | **Labs** | **Caution\*** |
| Moderate Intensity | **First line** | **Atorvastatin (Lipitor®)** | 10-20mg | 4 weeks | Baseline: Cr or eGFR, ALTFollow-up: Cr, ALT, CK or CMP 1-2 months after initiating new medications, raising dose or clinically indicatedAnnual:HgA1C, CMP, Lipid Panel | **Pregnancy alert: verify contraception** |
|  | Pravastatin | 20-40 mg |  |
|  | Lovastatin | 40 mg |  |
|  | Rosuvastatin | 5-10 mg |  |
|  | Simvastatin | 20-40 mg |  |
| High intensity | **First line** | **Atorvastatin (Lipitor®)** | 40-80mg | 4 weeks |
|  | Rosuvastatin | 20-40 mg |  |

**Appendix II:**

Contraindications

* History of rhabdomyolysis with prior use or intolerance
* Pregnancy or intended pregnancy
* Lactation

Relative contraindication- consult with physician prior to medication start; may modify decision to use higher statin intensities:

* Multiple or serious comorbiditites including impaired renal or hepatic function
* Amyelotropic Lateral Sclerosis (Lou Gehrig’s Disease), other myositis such as polymyositis, inclusion body myositis, dermatomyositis, or uncontrolled hypothyroidism
* Childbearing age without effective contraception
* Asian ancestry

Drug interactions – consult with provider before prescribing if:

* Currently taking anti-viral or antifungal medications fibrate (e.g. gemfibrozil, fenofibrate)
* Avoid simvastatin with SSRI, amlodipine

Medication side effects - if patient assessed to have possible side effects from statin use, nurse is to consult with provider

* Myopathy and myalgias: symptoms include muscle ache, muscle weakness, muscle inflammation; very rarely rhabdomyolysis
	+ markedly elevated creatine kinase (CK) and renal failure)
* Hepatic dysfunction: Jaundice, nausea, fatigue, loss of appetite
* Repeat CMP only if signs of liver toxicity
* Transaminitis – elevation in AST and ALT over 3-4 times upper limits of normal
* If LFT’s >3x ULN but no symptoms
* decrease dose to moderate intensity and repeat CMP in 2-3 months and consult with a provider