## **CONCORD INTERNAL MEDICINE**

# PROTOCOL FOR SURVEILLANCE AND TREATMENT OF COMPLICATIONS OF DIABETES

Douglas G. Kelling, Jr., MD Carmella Gismondi-Eagan, MD, FACP J. Gregory Lyall, MD, FACP

Revised March 10, 2014

The information contained in this protocol should never be used as a substitute for clinical judgment.

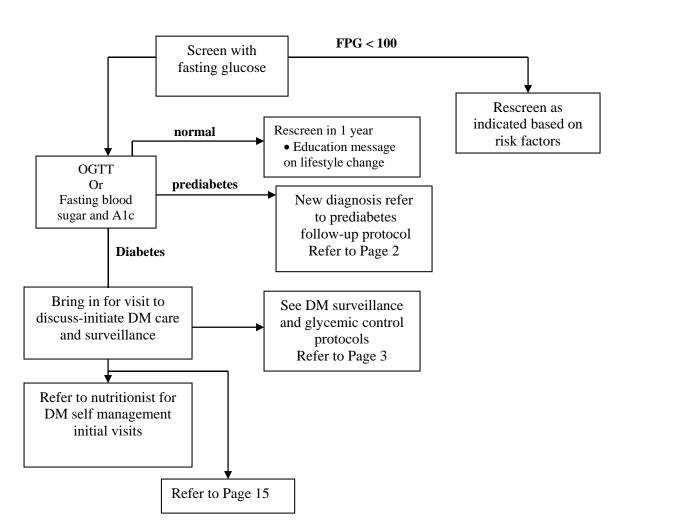
The clinician and the patient need to develop an individual treatment plan that is tailored to the specific needs and circumstances of the patient.

# SURVEILLANCE AND TREATMENT OF COMPLICATIONS OF DIABETES TABLE OF CONTENTS

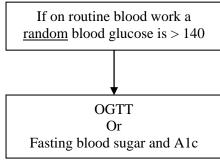
Screening for Diabetes and Predi	PAGE(S) 1-2
DIABETES SURVEILLANCE OVERVIEW	3
GLYCEMIC CONTROL	4
LIPID DISORDERS	REFER TO CIM LIPID DISORDERS PROTOCOL
RETINOPATHY	5
PERIPHERAL NEUROPATHY	6
AUTONOMIC NEUROPATHY	7
BIOMECHANICS OF THE FEET	8
PERIPHERAL ARTERIAL DISEASE (PAD	9
ULCERATION OF LOWER EXTREMITIES	10
Hypertension	REFER TO CIM HYPERTENSION PROTOCOL
NEPHROPATHY	11
Depression	12
TREATMENT OF COMPLICATIONS	13
INITIAL EVALUATION AND TREATMENT	OF DIABETES 14-17
GLYCEMIC CONTROL	18-40
LIPID DISORDERS	PLEASE REFER TO CIM LIPID DISORDERS PROTOCO
RETINOPATHY	41
PERIPHERAL NEUROPATHY	PLEASE REFER TO CIM PERIPHERAL NEUROPATHY PROTOCOL
AUTONOMIC NEUROPATHY	42
ABNORMAL BIOMECHANICS	43
PERIPHERAL ARTERIAL DISEASE (PAD	)) 44
ULCERATION OF LOWER EXTREMITIES	45
Hypertension	PLEASE REFER TO CIM HYPERTENSION PROTOCOL
NEPHROPATHY	46-47
Depression	PLEASE REFER TO CIM MENTAL HEALTH PROTOCOL

## **Screening for Diabetes and Prediabetes**

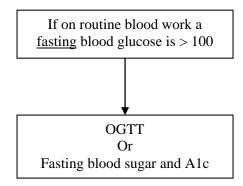
- Routine yearly screening on anyone overweight (BMI >25) or with CV risks
- Consider screening every 3 years on adults > 45 years old with BMI < 25 and no CV risk factors



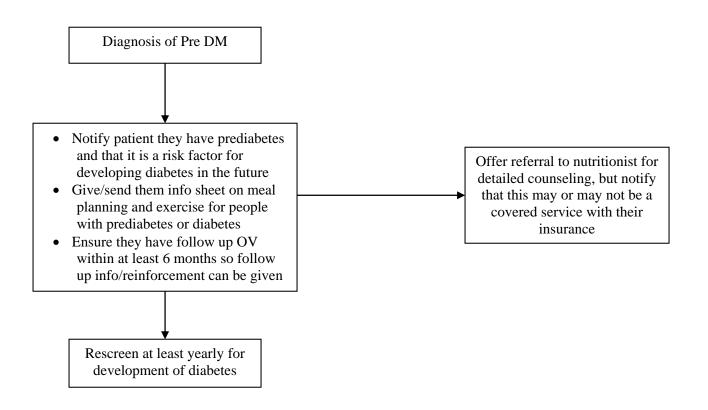
#### **Incidental:**



#### **Incidental:**



## New Diagnosis Prediabetes Follow Up



Glycemic Control

Lipid Disorders

Retinopathy

Peripheral Neuropathy

Autonomic Neuropathy

Biomechanics of the Feet

Peripheral Vascular Disease

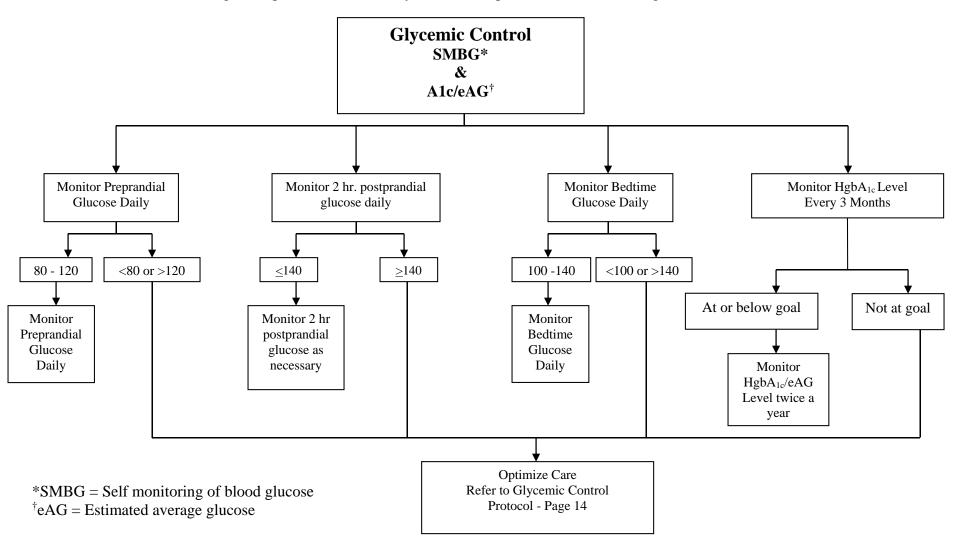
Ulceration of Lower Extremity

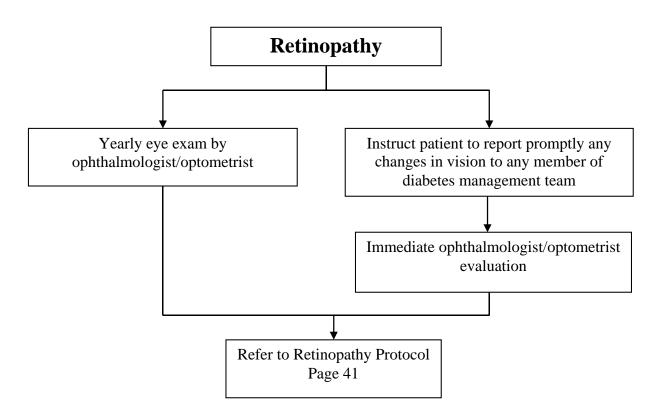
Hypertension

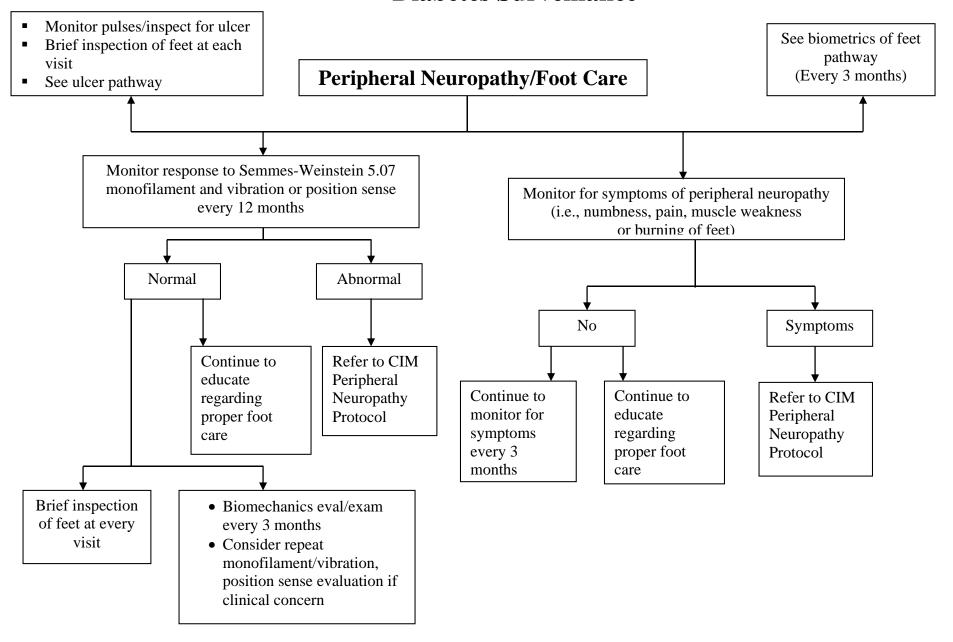
Nephropathy

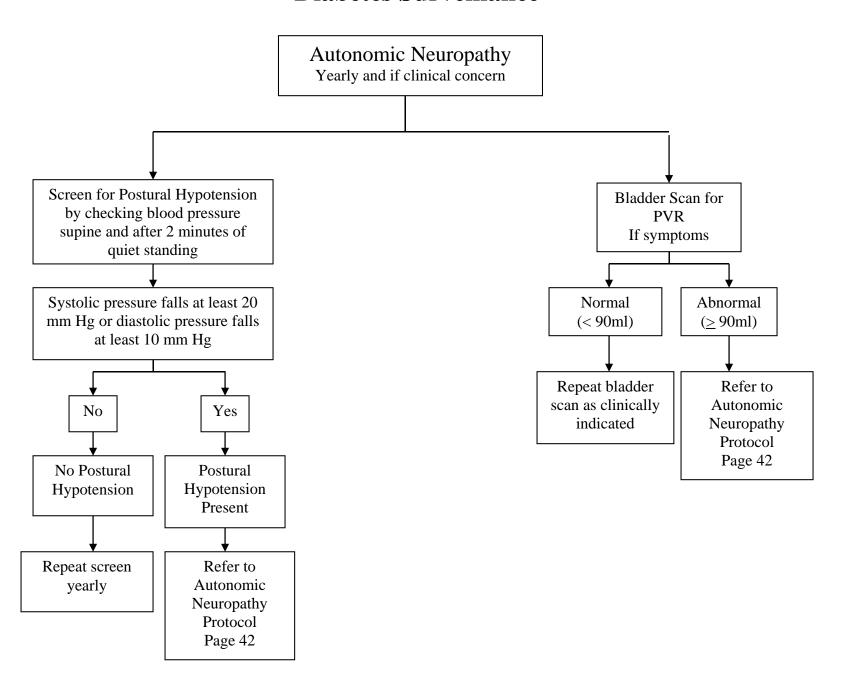
Depression

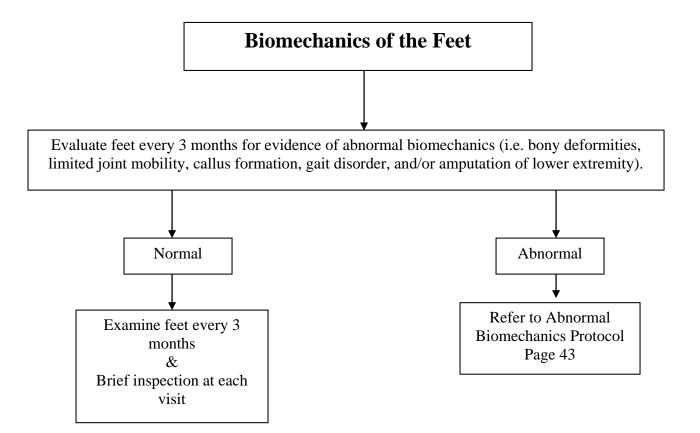
- Mandatory for patients using multiple injections or pump therapy
- For patients using less frequent insulin injections, non-insulin therapies or MNT alone SBMG should be recommended on an individual basis if deemed clinically appropriate to guide therapy or reinforce patient compliance
- Consider continuous glucose monitory one time in conjunction in patients with refractory diabetes, concern about fluctuations in blood sugar, or questions of reliability of SBMG report as a tool to achieve good A1c

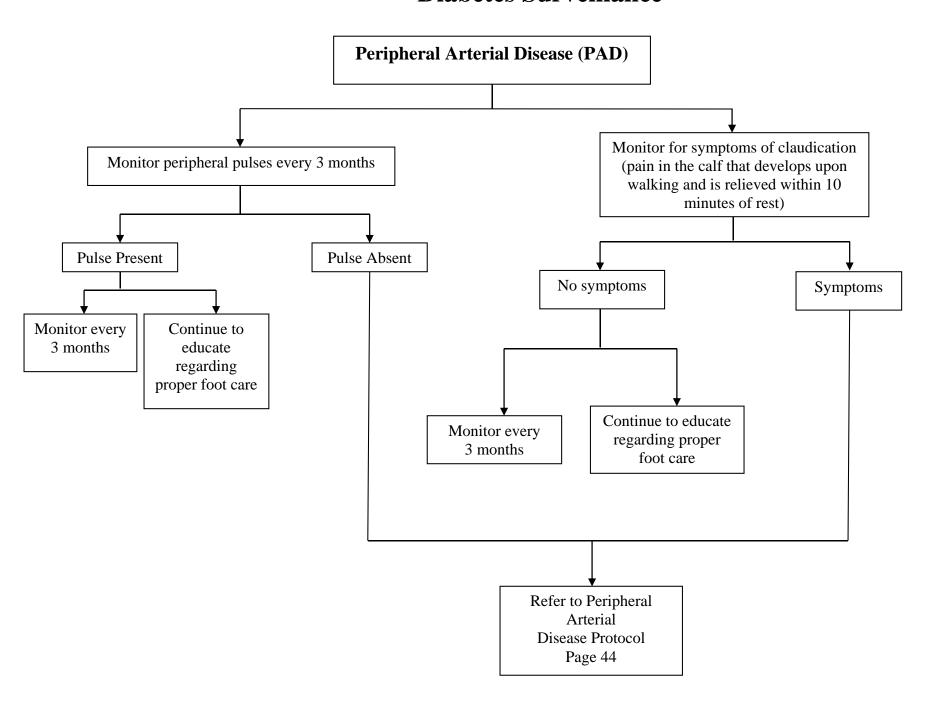


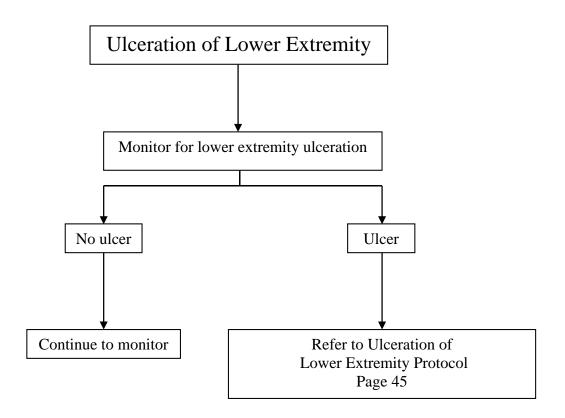


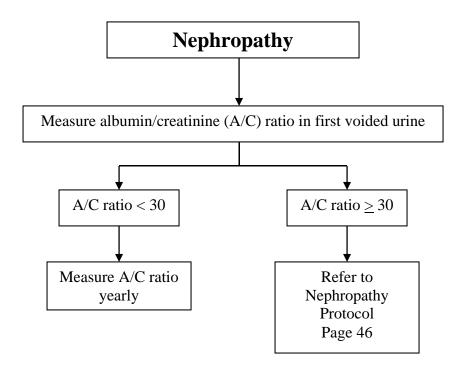


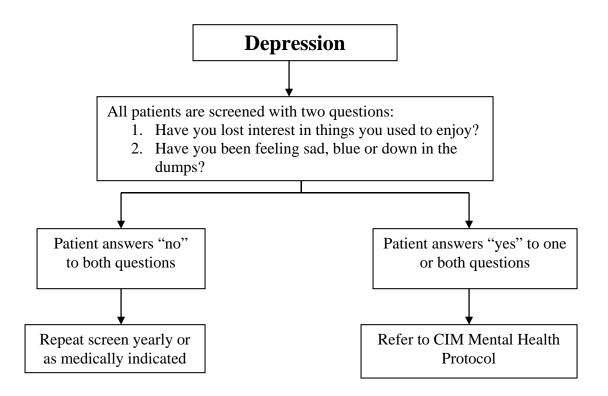












## **Treatment of Complications**

Glycemic Control

Lipid Disorders

Retinopathy

Peripheral Neuropathy

Autonomic Neuropathy

**Abnormal Biomechanics** 

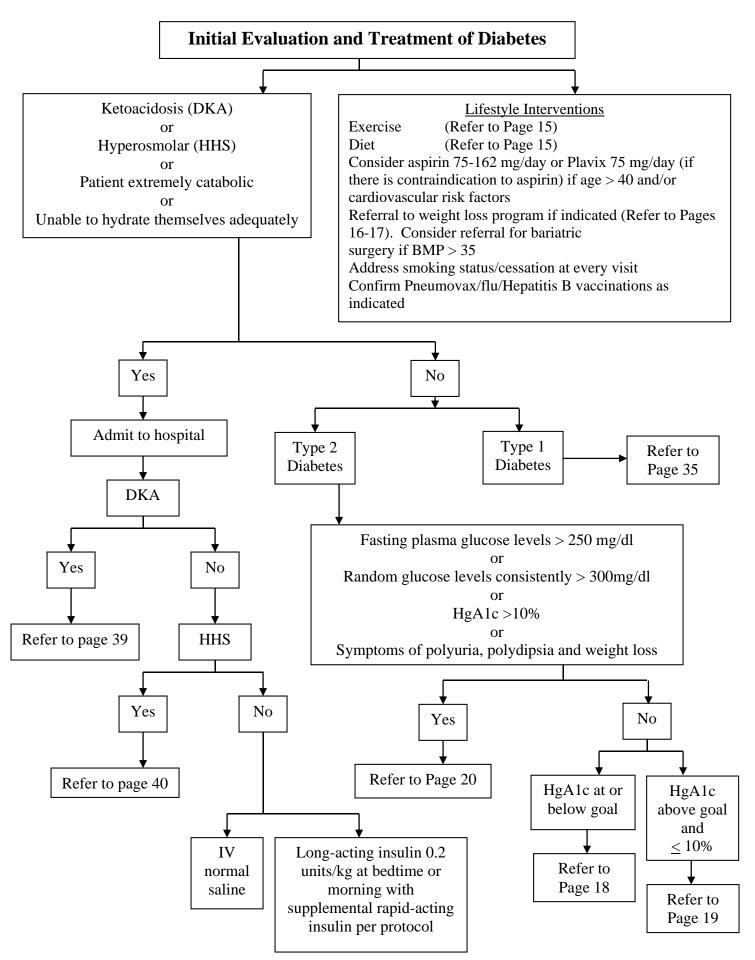
Peripheral Vascular Disease

Ulceration of Lower Extremity

Hypertension

Nephropathy

Depression



#### Concord Internal Medicine

#### STRATEGIES FOR WEIGHT LOSS

Healthy weight loss, and keeping the weight off requires changes for LIFE! Once you stop working at it, the weight will come back.

**FIRST:** Stop all regular soda, sweetened teas and fruit juice. These are all basically liquid forms of sugar that have a lot of calories. This includes sports drinks, and any juices that say 100% natural or unsweetened. Alcoholic drinks should be avoided.

**SECOND:** Limit carbohydrates (see information on carbohydrates below), watch portion size of all food types.

**THIRD:** Exercise. Try to be active every day. Walking or any activity where you are moving without stopping will work. Start off slowly (10-15 min). Look to add 5 minutes to your time every week until you reach a goal of 45-60 minutes of exercise on most days of the week (yes, more than 30 min is needed if you want to have meaningful weight loss/maintenance). If you have a heart or lung problem or any concerns or problems with exercise talk to your medical provider more about exercise before you start.

**Carbohydrates** are foods that contain natural sugar or turn into sugar after we eat them. Because of this they are high in calories, and we often eat much larger amounts than we should

#### **Examples of carbohydrate foods**

Bread, rice, pasta, cereal, tortilla chips Milk, yogurt, ice cream Starchy veggies (potatoes, corn, beans) Candy, cakes, cookies, chocolate

#### **Examples of foods without carbohydrates**

Proteins, meats Non starchy veggies (broccoli, lettuce, green beans) Fats, oils, butter

How many carbohydrates can you eat? On average men should aim for about 60 grams of carbohydrate per meal, women should aim for about 45 grams of carbohydrate per meal. Examples of serving sizes

1/3 cup of rice (cooked) = 15 grams carbs	1 medium apple = 15 grams carbs
½ cup potatoes or corn = 15 grams carbs	1 slice of bread = 12 grams carbs
1 cup milk = 12 gram carbs	½ cup of pasta = 15 grams carbs

Limiting your serving size and balancing the foods you eat (carbs vs. non carbs) is the key to meeting your meal planning goals!

#### Other strategies that may work for you:

- 1) Get a pedometer and aim to get 10,000 steps a day.
- 2) Replace 1 meal 5 days a week with a shake or bar (slim fast etc.) very good strategy if you eat out a lot, will save money too.
- 3) Stick to a meal and exercise plan 6 days a week, and have one day a week be your free/splurge day.
- 4) Do not buy or store sodas/snack foods at home. Your family/kids do not need them either.

**Resources:** Weight watchers is proven and has been the support group many people need.

<u>www.weightwatchers.com</u>; Alli over the counter program and medication to block fat absorption is safe, and may be helpful. Check out <u>www.choosemyplate.org</u> for personalized information.

Feb 10, 2014 Proposal: CIM Physician Supervised Weight Loss Program C.Eagan, MD

<u>Note</u>: The American Society of Bariatric Physicians recommendations for overweight and obesity evaluation and management guidelines were reviewed and this proposal is consistent with their recommendations.

<u>Vision</u>: A comprehensive program that includes individually considered diet, exercise, behavior modification with anti-obesity medications and consideration of surgical options where appropriate to achieve a goal of a loss of 5-10% of body weight over 6 months and develop a long term plan for avoidance of weight gain.

Details: Monthly visits specifically to focus on bariatric issues for 6 months. Medications, if prescribed would only be prescribed on the 2<sup>nd</sup> visit, and refills given at the bariatric visits after that (i.e. pt must commit to and follow up with monthly visits in order to get meds). After 6 months long term f/u would be every 3 months (If controlled meds being used) or every 6 months if non-controlled meds.

Coordination of care with specified nutritionists, exercise specialists as well as CDE staff (diabetics) would be a main strategy of the program

30 min MD/40 min PA initial visit then 15/20 min subsequent visits would be time slots.

#### **Outline:**

#### VISIT 1

Focused History (see history/intake forms and screening tools)

- Readiness for change, med/surg hx, mental health hx, eating disorder screen, family/meal structure, fam hx as relates to obesity and cardiac risk factors, present physical activity level, food and drug intolerances and allergies, prior wt loss hx attempts, depression screening, sleep apnea screening.
- Consider referral to psych/counseling if concern eating disorder, thought disorder or severe mood disorder (Dr. Quinn)

Exam to include baseline weight and BMI, waist and hip measurements and ratio, general exam Diagnostic studies (order or compile results if done in last 6 months)

- CMP, TSH, free T4, A1c, Lipid panel
- Consider EKG AND cardiac stress test if comorbidities, clinical concern, vigorous exercise planned or sympathomimetic drug rx planned
- Consider sleep study if clinically indicated
- Consider 24 hr urine cortisol or dexamethasone suppression test if clinically indicated

Establish goal setting in writing (5-10% loss of body weight over 6 months)

Provide a nutritional plan and recommend a food diary

Refer and set up initial appt with team nutritionist Nurse Lifestyle/Nutrition Counselor (at Dr. Baumans office.)

Provide an initial exercise prescription

Refer and set up initial appt with exercise specialist (if no further cardiac testing needed)

- YMCA OR NE Health and Fitness OR individualized

Look to remove/change any meds that may be promoting weight gain Discuss and assess surgical options and if appropriate initiate referral Clarify and establish follow-up schedule.

Optional: every 2 week weigh in/nurse visit for patients who want that accountability.

#### VISIT 2

Interim history as it relates to weight loss and lifestyle change

- Review of diet and exercise diary info, motivational interviewing for behavioral progress, history regarding prior usage, readiness and issues related to anti-obesity medications.

Focused exam including vitals, weight/BMI and waist/hip measurements, CV exam

Review of any interim diagnostic studies ordered on 1st visit

Provide nutritional plan #2 and establish follow up plan with Lifestyle Rn Counselor

Provide exercise prescription #2 and establish follow up plan (w or w/o support)

Consider and if appropriate prescribe an anti-obesity medication and educate patient

\*informed consent document to include on/off label use as well as specific serious side effects and how pt should expect to receive refills (i.e. must show up for bariatric visits)

\*Rx info ed sheet / protocol available (patient/provider)

Document if surgical options being pursued and coordinate care

Reassess pts long term goals and objectives and clarify follow up schedule

#### Visits 3, 4 and 5

Interim history as it relates to weight loss and lifestyle change

Review of diet and exercise information, motivational interviewing for behavioral progress.

Medication eval for effect, tolerance issues etc.

Focused exam including vitals, weight/BMI, waist/hip measurements, CV exam

Consider reorder specific labs if baselines were abnormal (i.e. lipids, A1c)

Provide next step nutritional plan

Provide next step exercise prescription

Consider anti obesity medication management if being used

Maintain or adjust dose, consider add on therapy if appropriate and provide prescription

Evaluate for appropriate weight loss at least 3% body weight to justify continuation of meds.

Document if surgical options being considered and coordinate care

Reassess goals and objectives and clarify follow up schedule

#### Visit 6

Interim history as it relates to weight loss and lifestyle change

Review of diet and exercise information, motivational interviewing for behavioral progress.

Medication eval for effect, tolerance issues etc.

Focused exam including vitals, weight/BMI, waist/hip measurements, CV exam

Consider reorder specific labs if baselines were abnormal (i.e. lipids, A1c)

Provide maintenance nutritional plan

Provide maintenance exercise prescription

Consider anti obesity medication if to be used for maintenance

Establish dose, and provide prescription

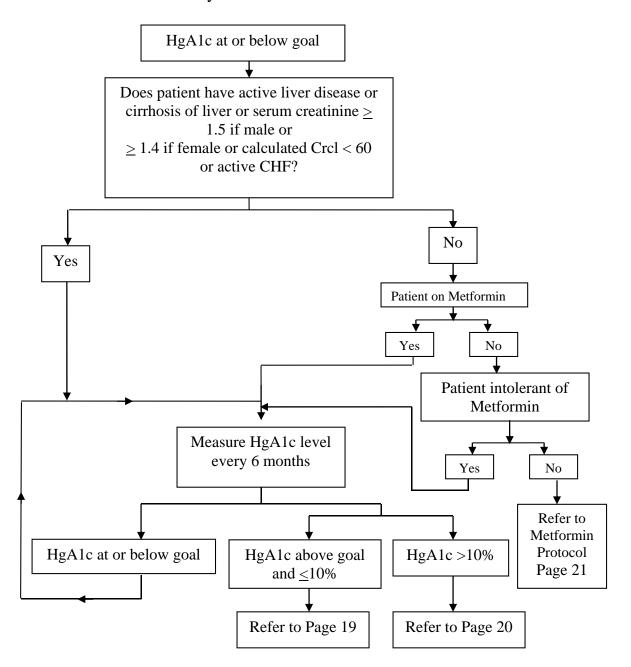
Reassess goals: maintenance goals are maintaining wt loss and avoiding the standard 1 kg/yr wt gain Document if surgical options being considered and coordinate care.

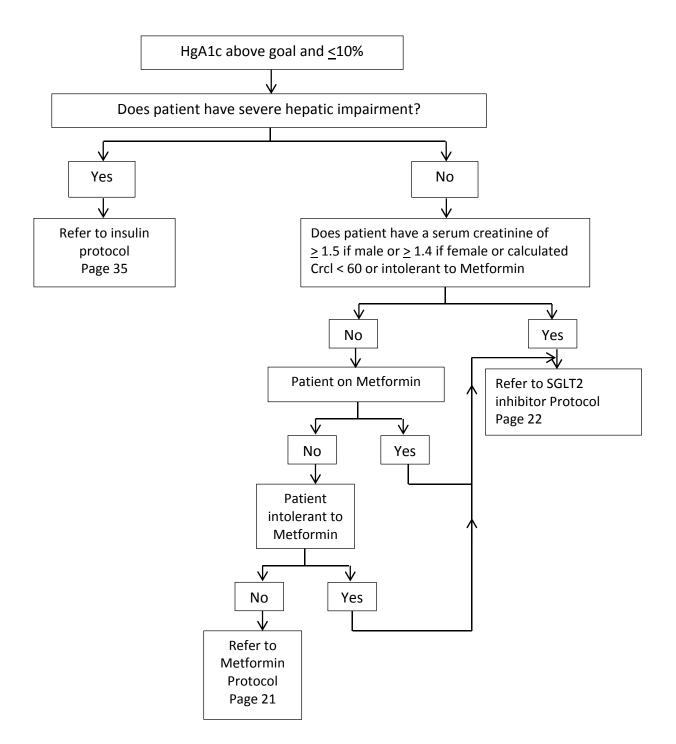
Clarify follow up schedule

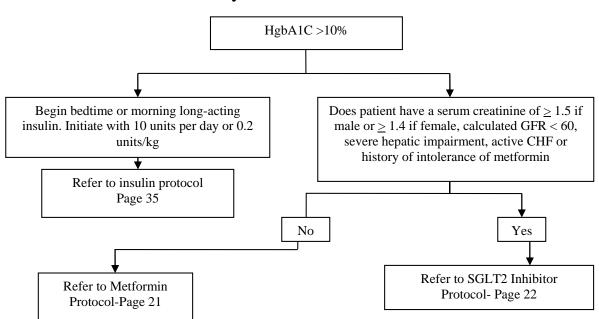
Every 3 months if controlled medication being prescribed

Every 6 months if uncontrolled medication being prescribed

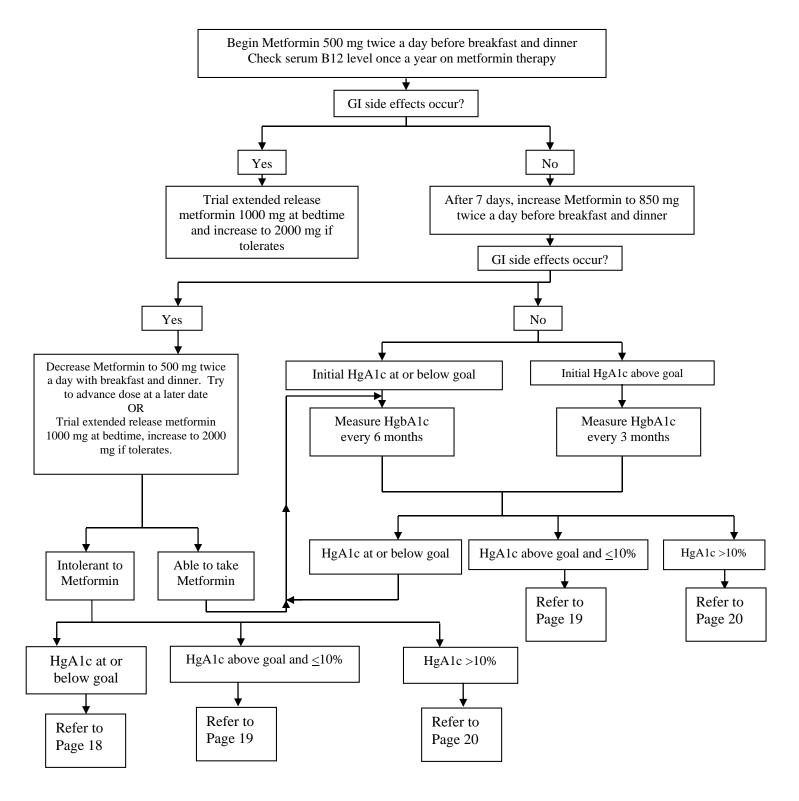
**Optional:** more frequent nurse weigh-ins or follow up visits for patients who desire support and accountability



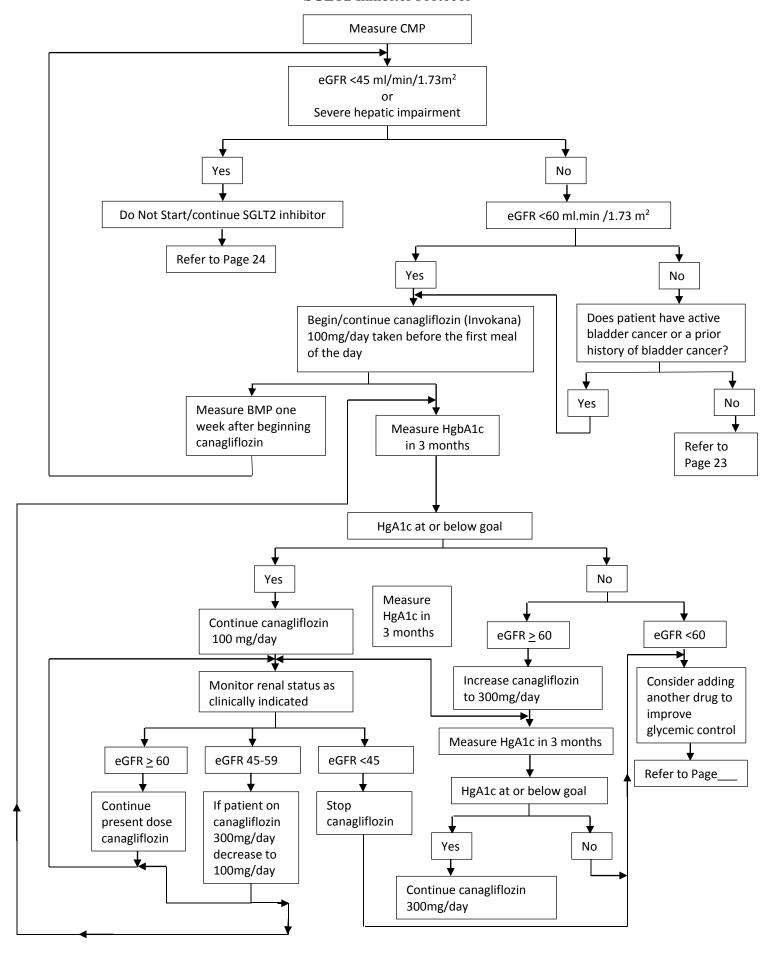




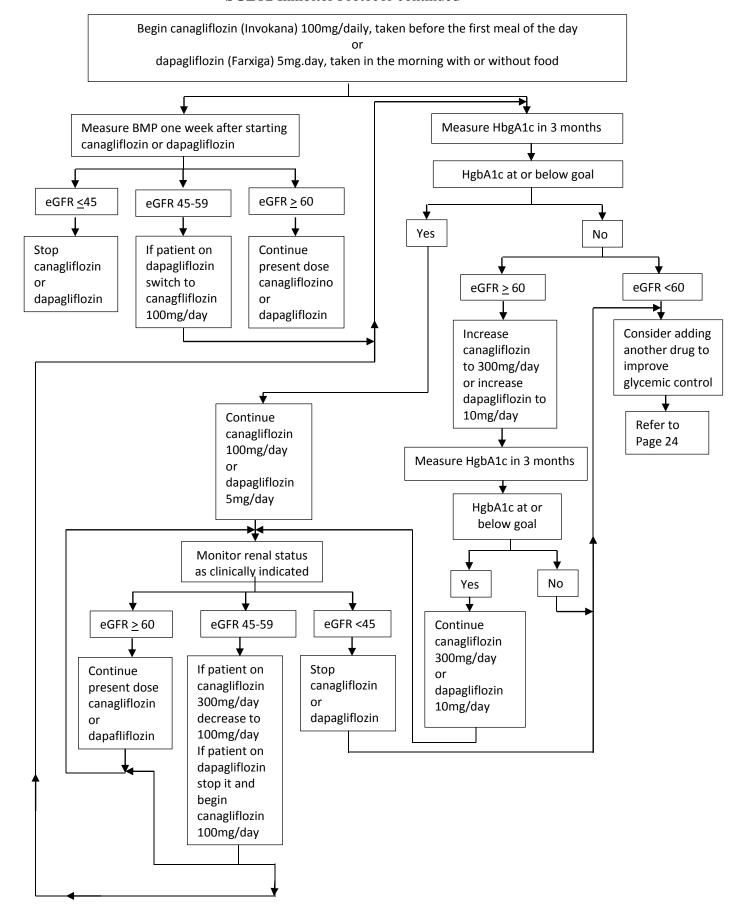
### **Metformin Protocol**



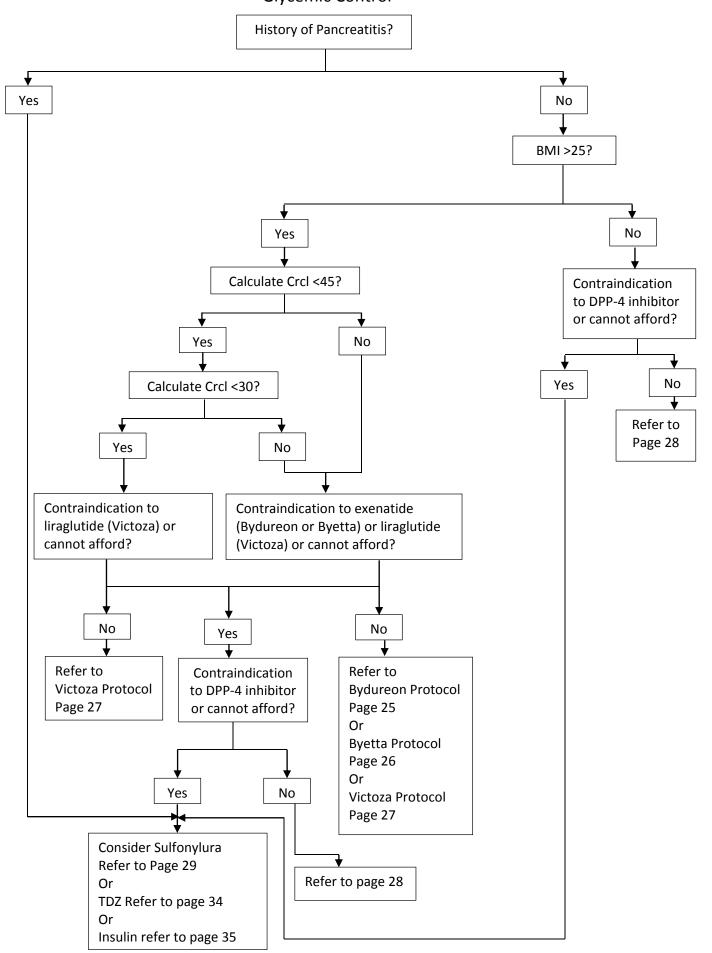
#### **SGLT2** Inhibitor Protocol



#### SGLT2 Inhibitor Protocol-continued



Glycemic Control



#### **Bydureon Protocol**

## Concord Internal Medicine Diabetes Clinic 704-403-1307

#### Goals

	HbA1c	LDL	HDL	Triglycerides	B/P
Goals	<6.5%	<100/70	>40/>50	<150	<130/80
<b>Current Values</b>					

Medication Recommendations: Bydureon weekly injection

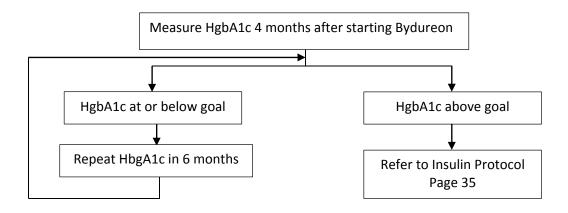
#### Patient information on Bydureon©:

- Incretin Mimetic,
- Byetta © is supplied as a one-time injection set.
- Each set contains one does to be administered once weekly.
- Throw away Bydureon after administered or if beyond expiration date on label.
- Inject your dose of Bydureon© under the skin of your stomach (abdomen).
- **Do not** take an extra dose to make up for a missed dose.
- Common Side Effects: nausea, vomiting, low blood sugar.
- Store Bydureon© sets in the original carton in the refrigerator (36°F to 46°F) protected from light. Do not freeze. Throw away if it has been frozen.
- Discard pens needles in an appropriate sharps container.

#### **Pharmacist Recommendations:**

- Check blood sugars at least 1-2 times per day.
- Call one weeks worth of blood sugars in to the diabetic clinic.

#### Bydureon © Hotline (24 hrs , 7 days a week): 1-800-868-1190

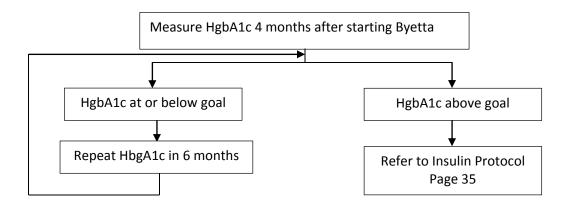


#### **Byetta Protocol**

This medication is for diabetics to assist them in weight loss and control sugars

- 1. When patient starting Byetta it is your choice as to whether or not you choose to show the video first or if you just want to flip to the back of the patient instruction booklet and read from there.
- 2. Even if you show the video it is good to reinforce the back of the info sheet.
- 3. Byetta always starts at 5mcg sc twice daily within 1 hour of 2 largest meals= ≥ 6 hours apart. Best results are if you take Byetta then wait 40 minutes to eat. (More weight loss if taken this way). After one month patient should be brought back for follow up. At this time they will be evaluated as to whether or not they will go up to 10mct. (Usually if they are doing really well at 5mcg they will stay at that dose).
- 4. You must show how to use the Byetta pen.
  - a. The first time any of these pens are used they must do an "air shot". Once that is done, it will not need it for the remainder of the pen use.
  - b. The pen will have enough doses for 1-month supply.
  - c. Then the patient will pull off the cover cap.
  - d. Screw the needle on the end.
  - e. Follow the arrows on the pen to load it for injection. Be sure the patient knows that they must turn the pen until it completely locks into place before trying to turn it to the next arrow.
  - f. Clean site (abdomen, thigh or arm –rotate sites) with alcohol.
  - g. Pinch skin up and give injection.
  - h. Remove needle and place in sharps container or laundry detergent bottle (something hard plastic).
- 5. If you miss a dose of Byetta and start eating, skip that dose and wait until the next dose is due. If you do not eat, do not take Byetta dose.
- 6. They should be aware the biggest side effect is nausea and usually lasts for a couple of hours after each injection for the 1<sup>st</sup> week only. It will subside. If we increase them to 10mch at 1 month they may have nausea for another week.
- 7. After first use, Byetta can be kept at room temperature not to exceed 77°F (25°celsius)
- 8. If patient travels frequently, there is a free travel kit they can send off for. The card containing ordering info is in the Byetta start kit.
- 9. Byetta is only good for 30 days from opening even if you have missed doses and still have a lot left. Still throw out if it has been 30 days.
- 10. Do not store Byetta pen with needle attached as it may leak the medication out.

\*\*This medication is FDA approved only for people not on insulin. Be aware Dr.'s Kelling and Eagan are trying it on some patients who are only on Lantus and also overweight, off label.



#### Victoza Protocol

Concord Internal Medicine Diabetes Clinic 704-403-1307

Name:	Date:
-------	-------

#### Goals

	HbA1c	LDL	HDL	Triglycerides	B/P
Goals	<6.5%	<100/70	>40/>50	<150	<130/80
<b>Current Values</b>					

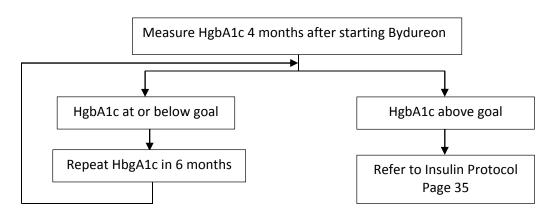
**Medication Recommendations:** Victoza© 0.6mg injected into abdomen once daily x1 week, ten increase to Victoza© 1.2mg injected into abdomen once daily.

#### Patient information on Victoza©:

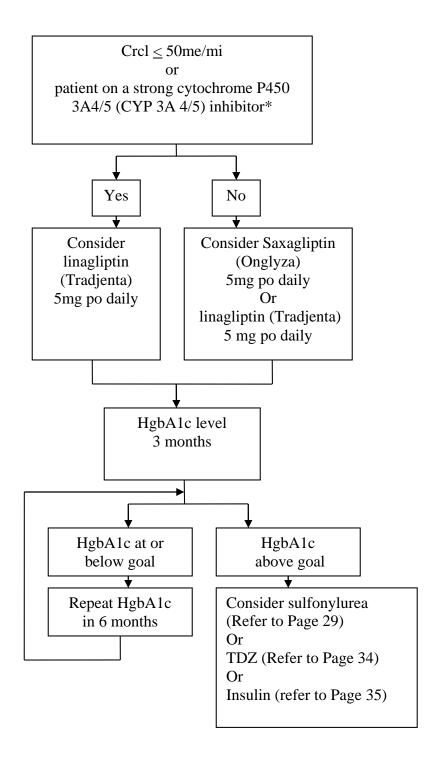
- Incretin Mimetic.
- Throw away Victoza© pen after 30 days of use or if beyond expiration date on the label.
- You must prime your Victoza© pen only once when starting a new pen.
- Inject your dose of Victoza© under the skin of your stomach (abdomen) once daily (any time of day regardless of meals).
- Rotate injection sites.
- **Do not** take an extra dose to make up for a missed dose.
- Common Side Effects: headache, nausea, diarrhea and low blood sugar. Nausea is the most common and will decrease over time in most patients.
- Store Victoza© pens in the original carton in the refrigerator (36°F to 46°F) protected from light. Do not freeze. Throw away if it has been frozen.
- Use each pen needle only once and Discard pens needles in an appropriate sharps container.
- Do not store Victoza© pen with needle attached (medication may leak out or air bubble may form in the cartridge).

#### **Pharmacist Recommendations:**

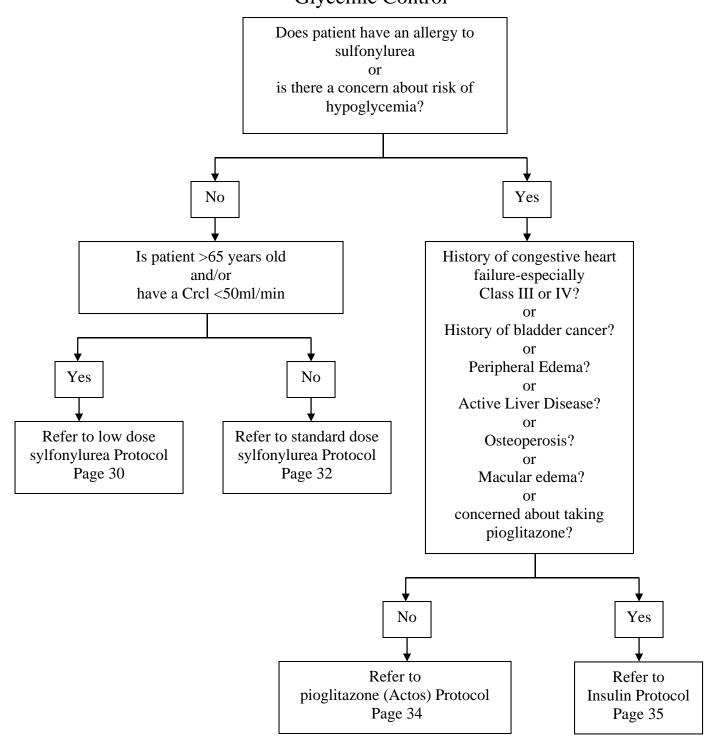
- Check blood sugars at least 1-2 times per day.
- Call 1 weeks worth of blood sugars in to the diabetic clinic after switching to Victoza©
   1.2mg dose.
- Call the diabetes clinic sooner if you have any questions or concerns.



## Glycemic Control DPP-4 Inhibitor Protocol

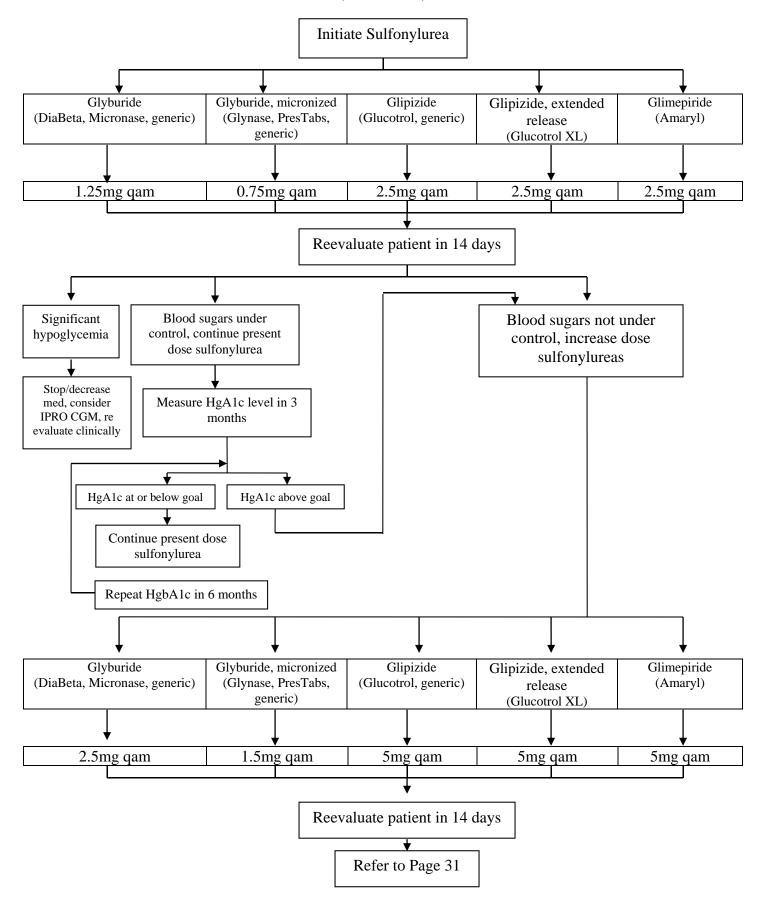


<sup>\*</sup>ketoconazole,atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinvir and telithromycin



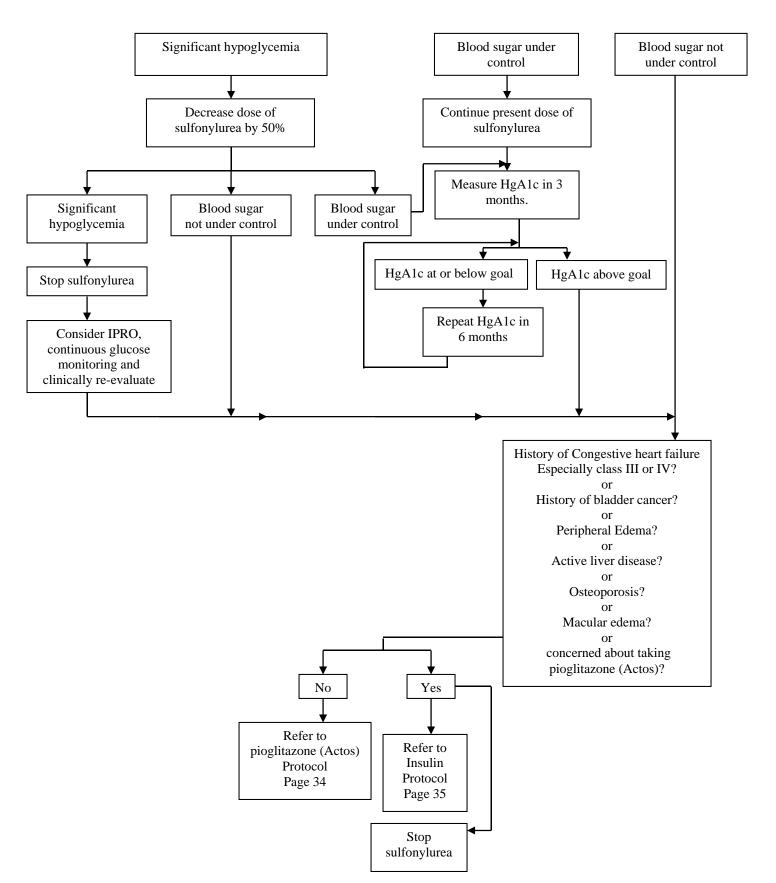
## **Sulfonylurea Protocol**

(Low Dose)



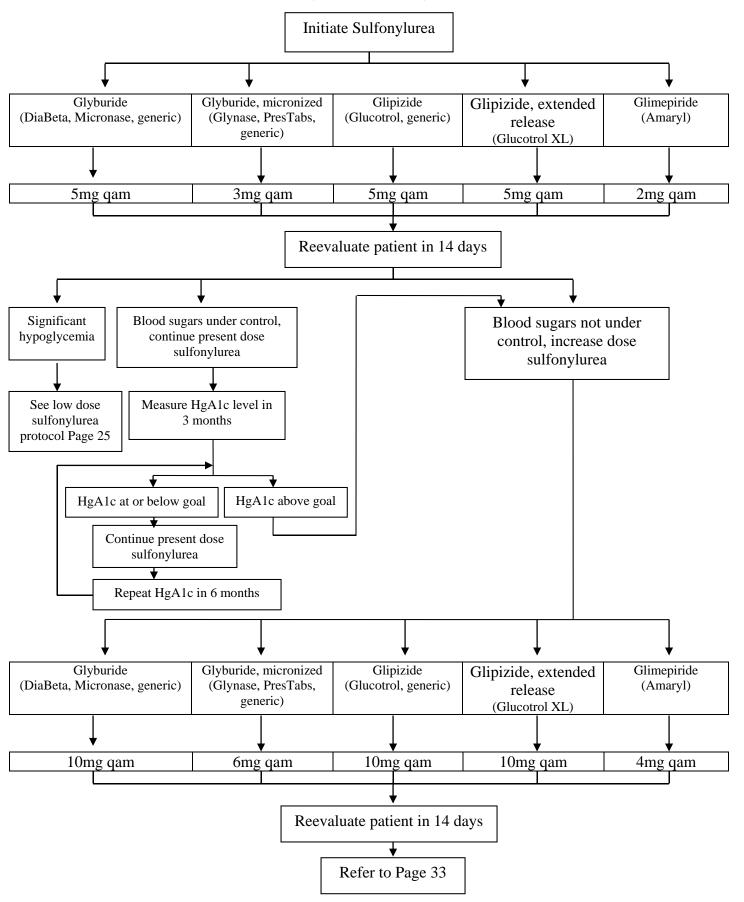
## Sulfonylurea Protocol – continued

(Low Dose)



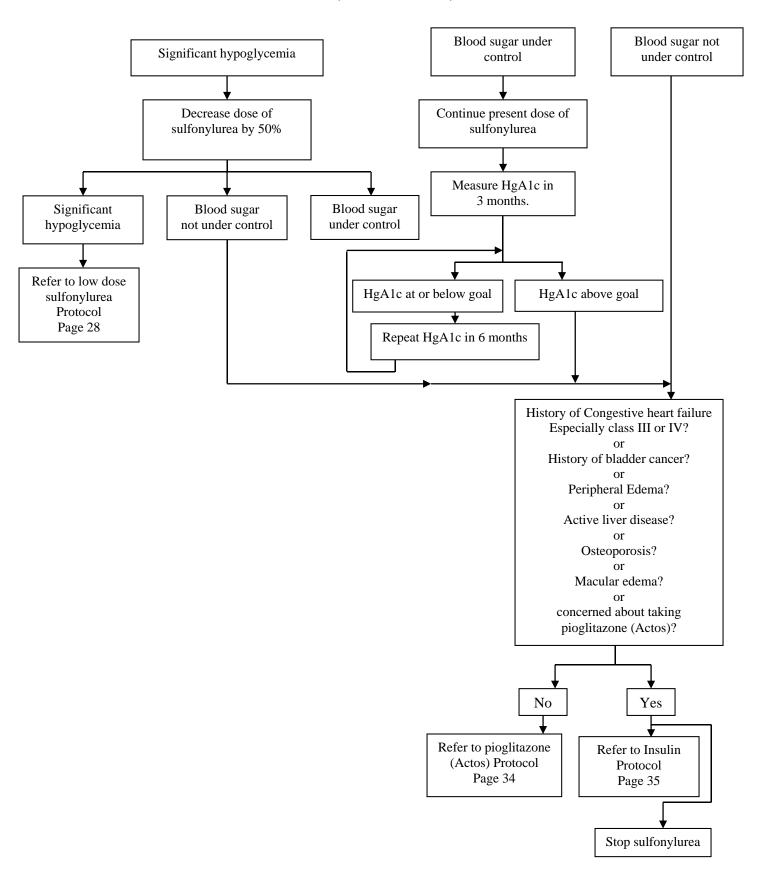
## **Sulfonylurea Protocol**

(Standard Dose)

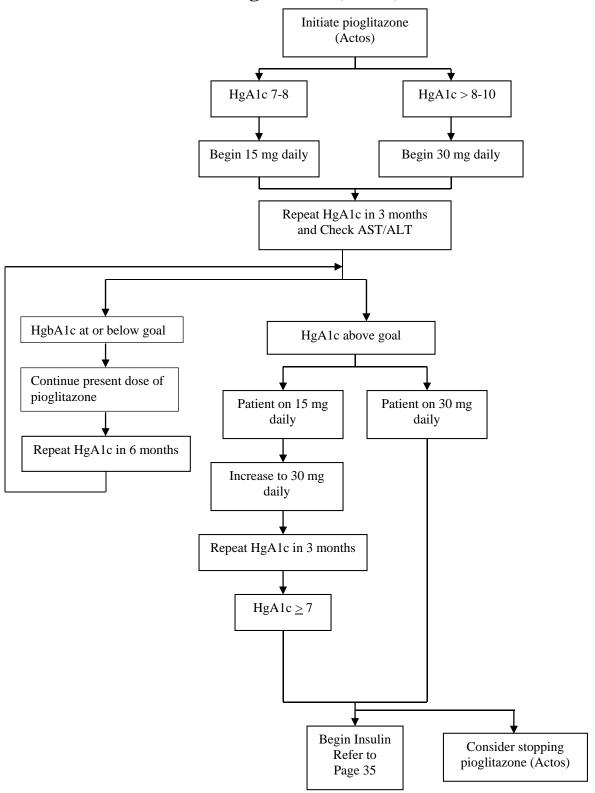


## Sulfonylurea Protocol – continued

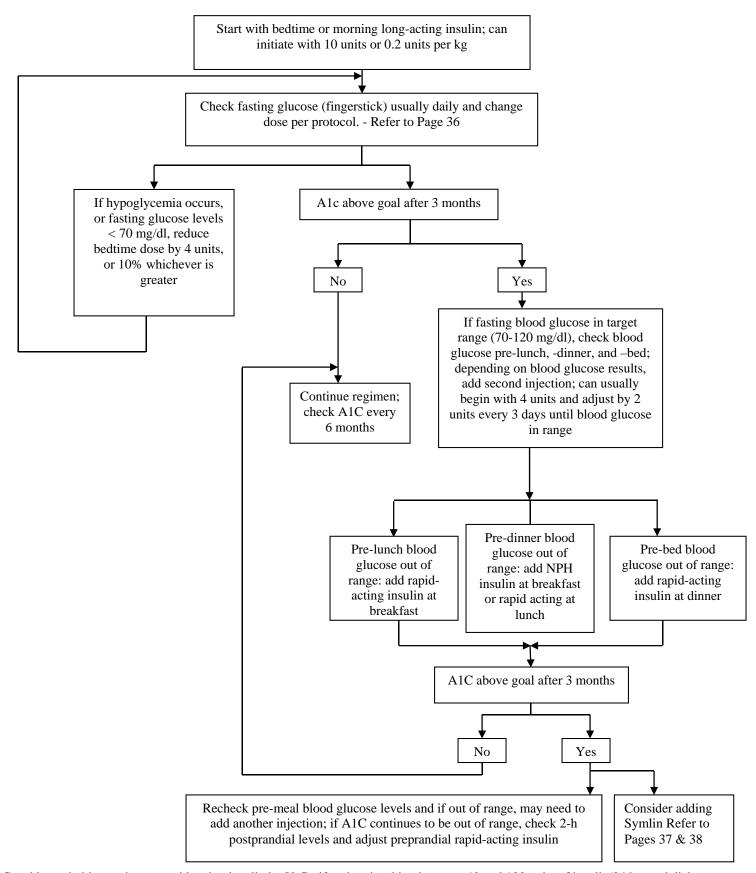
(Standard Dose)



## Pioglitazone (Actos) Protocol



#### **Insulin Protocol**



Consider switching patient to rapid acting insulin by V-Go if patient is taking between 40 and 120 units of insulin/24 hrs and diabetes not under control and/or patient does not want to take more than one shot of insulin/24 hrs

### Patient instructions for beginning Lantus or Levemir

Start with \_\_\_\_\_ units at bedtime

Check morning fasting glucose daily

Increase the dose by 2 units every 3 days if blood sugars 121-140 mg/dl on the 3<sup>rd</sup> day.

Increase the dose by 4 units every 3 days if blood sugar > 141-160 mg/dl on the 3<sup>rd</sup> day.

Increase the dose by 6 units every 3 days if blood sugar > 161-180 mg/dl on the 3<sup>rd</sup> day.

Increase the dose by 8 units every 3 days if blood sugar > 181 mg/dl on the 3<sup>rd</sup> day.

If hypoglycemia occurs, or fasting glucose level < 70 mg/dl reduce dose by 4 units or 10%, whichever is greater

### **Symlin Protocol**

- 1. Once provider gives order to start Symlin, pull out patient instruction sheet.
- 2. Fill out patient name and SSN.
- 3. Cut all scheduled insulin (Lantus, Levemir, 70/30, 75/25, or schedule NovoLog TID) by half the dose currently on (i.e. if on Lantus 25 units, and NovoLog 10 units with each meal, they will now be on 12 units Lantus and 5 units of NovoLog with meals). (Since ½ of 25 fell at 12.5, round down to 12).
- 4. Dosing:

**Type I DM** – Sub Q: initial: 15 mcg immediately prior to meals; titrate in 15 mcg increments every 3 days (if no significant nausea occurs) to target dose of 30-60 mcg.

**Type II DM** – Sub Q: initial: 60 mcg immediately prior to meals; increase to 120 mcg prior to meals if no significant nausea occurs.

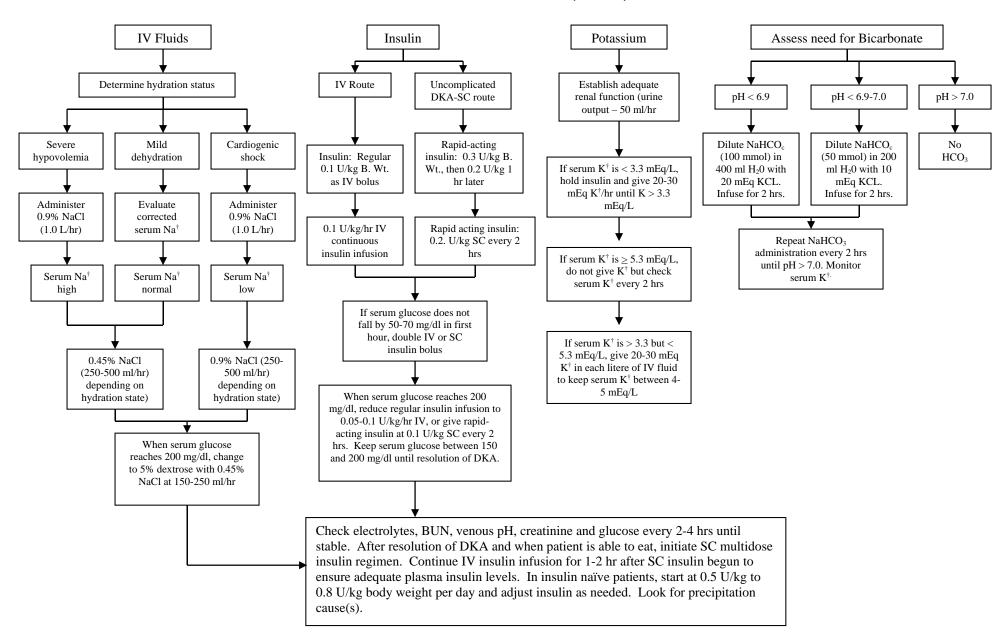
- 5. Patient will continue to use their sliding scale for elevated blood sugars.
- 6. They must take Symlin within 15 minutes before eating.
- 7. They should be instructed that it might cause nausea, but usually only for a few hours after taking each dose and usually goes away. If the nausea is too great they can back the dose up a step for an additional week then try to increase again.
- 8. They must continue to check blood sugars preferably TID when starting med to be sure they are at proper doses of all meds to be effective.
- 9. They also can call our office if they still have questions.

# **Symlin Protocol**

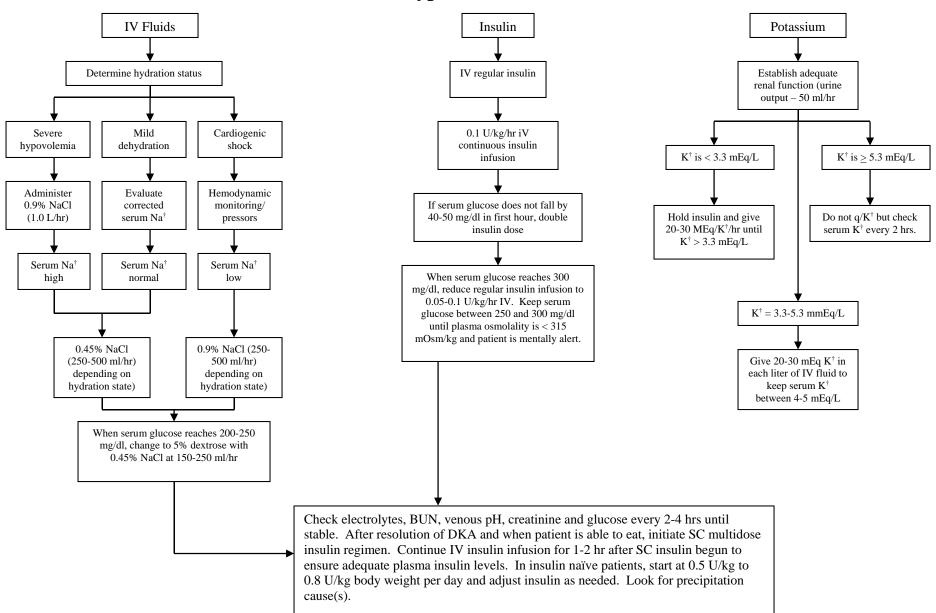
Patient	ID		
Date			
	Insulin, decrease to	units	
	Insulin, decrease to	units	
Continue	Insulin for slidir	ng scale if blood sugar 240 and al	bove
Start Symlin BEFORE	each meal as follows:		
units before	re each meal for 7 days, then ore each meal for 7 days, then ore each meal for 7 days, then ore each meal for 7 days nits before each meal.	n increase to:	
Do not mix in same syri	nge with any insulin.		
Do not take after a meal calories at a meal or 30 g		take only when eating at least 25	50
May cause nausea. <b>Do 1</b>	not stop Symlin, decrease to	lower dose if needed.	
Call our office with any	y questions at 704-403-1307	7.	

Continue to check blood sugars.

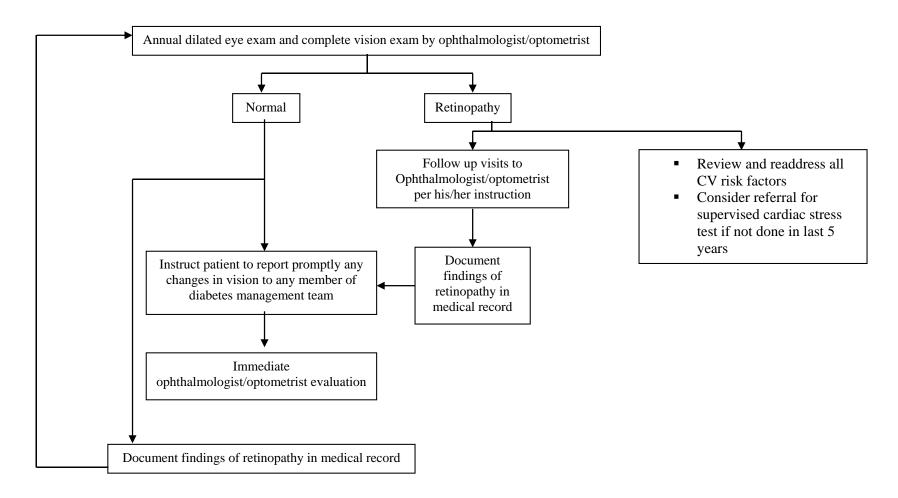
### **Diabetic Ketoacidosis (DKA)**



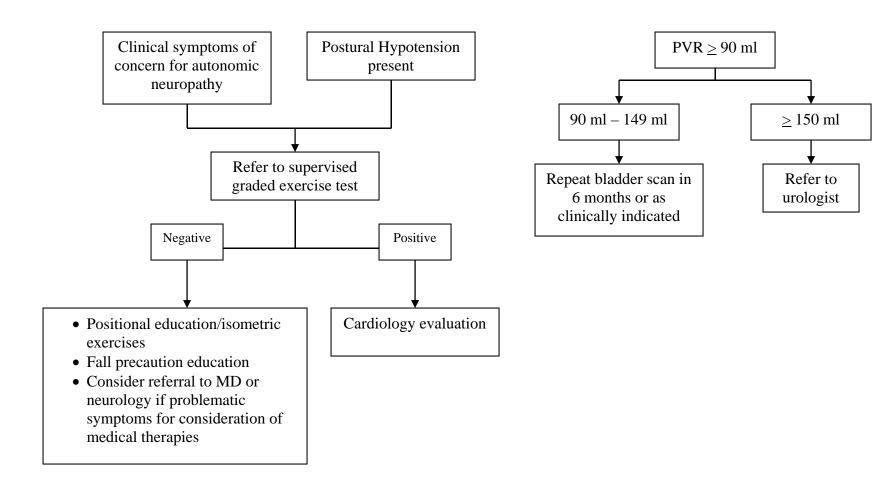
### **Hyperosmolar (HHS)**



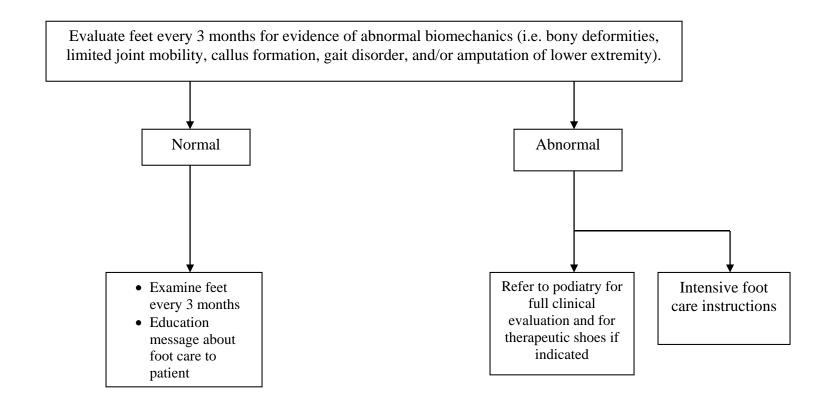
# **Retinopathy Protocol**



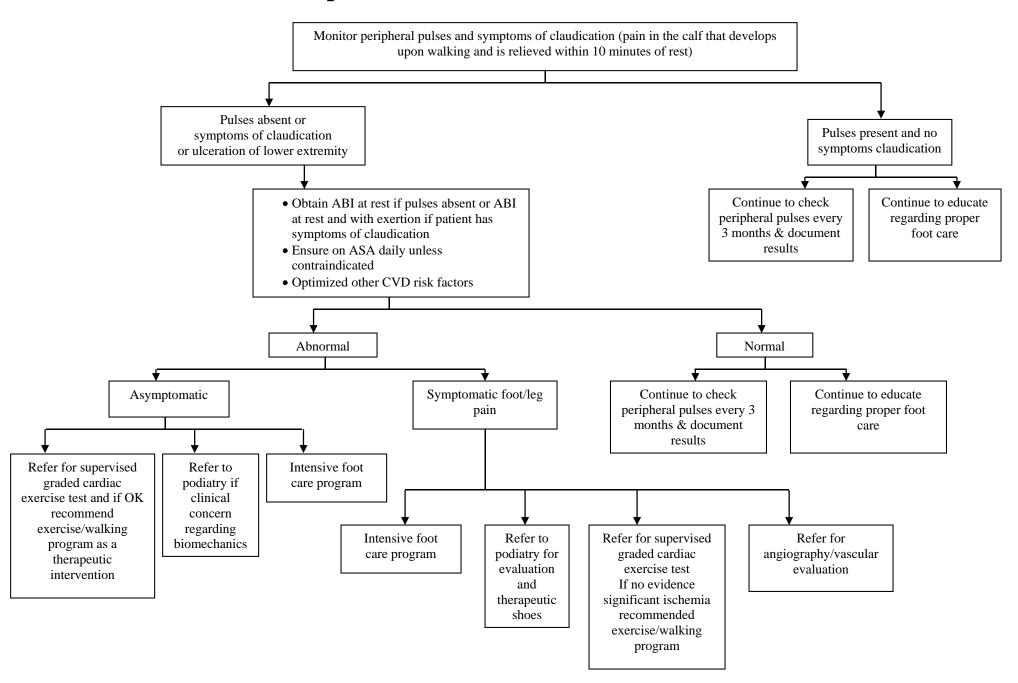
# **Autonomic Neuropathy Protocol**



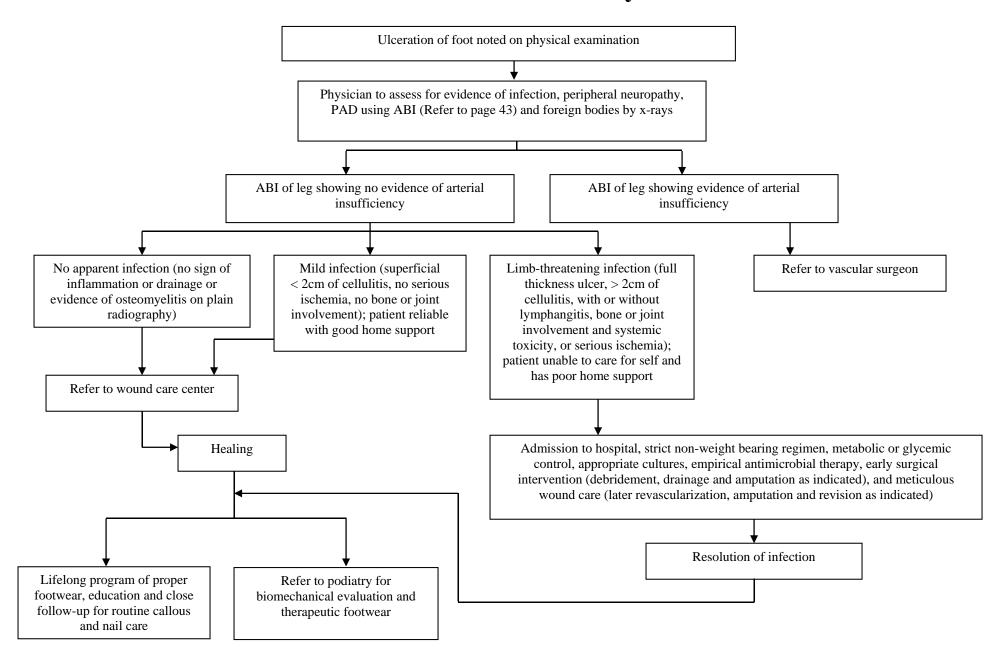
### **Biomechanics of the Feet Protocol**



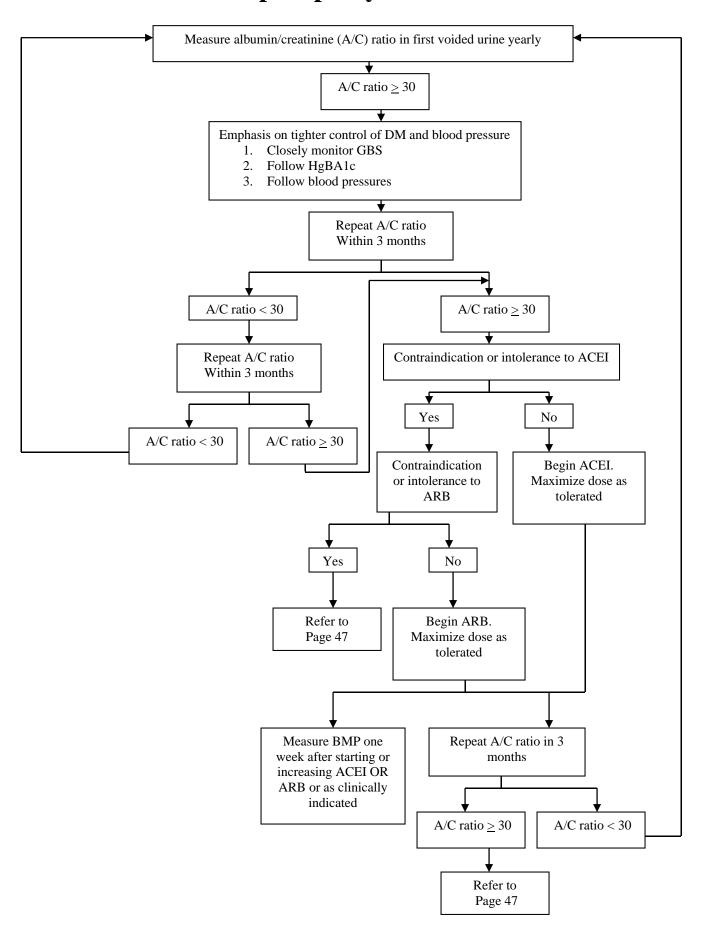
# Peripheral Arterial Disease (PAD) Protocol



### **Ulceration of Lower Extremity Protocol**



# **Nephropathy Protocol**



# **Nephropathy Protocol - continued**

