Partners Guidelines for the Treatment of Type 2 Diabetes
In the Non-Pregnant Adult

2012

This document contains the following:

Disclaimer: These guidelines were established after careful review of current evidence and sound clinical practice and are endorsed by the Partners Diabetes Council. The recommendations serve to assist clinicians in the treatment of diabetes and do not seek to supersede the judgment of healthcare providers. Modifications may be appropriate in a given setting; particular relevant influences may include a given individual's abilities, co-morbidities, overall health and anticipated lifespan. The responsibility for individual patient care decisions rests solely with healthcare providers.

Introduction

These guidelines represent the third writing of Partners' care guidelines for type 2 diabetes in the non-pregnant adult; the prior most recent update was prepared in 2009. While only three years have passed since that revision much of what follows has been updated. Our altered recommendations reflect changes in medical literature and the evolving roles and responsibilities in diabetes and medical care delivery generally, promoted in part by Partners' work to support diabetes care (Diabetes Care Redesign) and the Patient Centered Medical Home.

Major revisions in these guidelines include the following:

- Criteria for screening
- Revised BP targets
- Revised targets and medications for lipid management
- Increased emphasis on diet and exercise related content
- Recommended altered roles for Diabetes Self-Management Education services
- Specific recommendations for self-measurement of blood glucose (when and how often)
- A section is added regarding bariatric surgery
- A description of interventions to promote quality and value at Partners (Diabetes Care Redesign)
- Practical tools to support insulin initiation and dose titration (e.g. dose titration algorithms/handouts)

Many readers will find the insulin initiation and titration tools to be of practical value in daily clinical practice. To make these tools readily accessible, physicians may choose to print patient handouts and protocols to allow for ready access in their offices/clinics. Some providers may choose to cut and paste algorithms to become EMR templates for easy access, entry into patient charts and easy modification based on personal preference and individual patient requirements. You can access this material in a format that can be copied and/or edited via the following link: http://www.pchinet.com => click on Medical References => Diabetes Guidelines.

A new position paper by the ADA/EASD was issued in 2012. It reviews and updates the characteristics of currently available and approved diabetes medications. The new position paper provides a very similar, albeit updated, review of diabetes medications as the 2009 consensus algorithm, but notes that it has purposely adopted a non-prescriptive approach. Since one of the overarching goals of the Partners redesign initiative is to provide high quality, cost-effective treatment for diabetes, the Partners Diabetes Care Redesign group will continue to follow the 2009 algorithm which pays more attention to the relative costs of therapy, balanced against achieving metabolic targets, safety and patient tolerance-acceptability, than the 2012 position paper.

This document was prepared under the auspices of the Partners Diabetes Council and the Partners Diabetes Care Redesign Team. We would in particular like to acknowledge the work performed by Margo Hudson, M.D. (BWH) and Rita McCarthy, R.N., C.D.E. (BWH) in directing the writing of insulin titration protocols. We also appreciate additional expert assistance provided by Mason Freeman, M.D. (MGH), Sheila Partridge, M.D. (NWH), Edward Ryan, M.D. (MGH) and Randall Zusman, M.D. (MGH).

Alan Cole, M.D.
Elizabeth Savaria-Porter, R.N., C.D.E.
Partners Healthcare System
July, 2012

References:

1. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach. Diabetes Care 2012; 35:1-16

2. Nathan DM, Buse JB, Davidson MB, et al. ADA/EASD Consensus Statement and Algorithm for the Treatment of Type 2 Diabetes. Diabetes Care 2009; 32:193-203

Diagnosing Diabetes/Increased Diabetes Risk (Pre-diabetes) in the Non-Pregnant Adult

Diagnostic Criteria for Diabetes

- A1c ≥6.5%*, or
- Fasting plasma glucose (FPG) ≥126 mg/dl**, or
- ≥200 mg/dl random plasma glucose in a patient with classic symptoms of hyperglycemia, or
- 2-hour plasma glucose ≥200 mg/dl during an oral glucose tolerance test (OGTT)^

Test should be repeated to confirm diagnosis, unless symptoms of unequivocal hyperglycemia are present.

*A1c obtained by lab using a method that is NGSP certified and standardized to DCCT assay.
**Fasting is defined as no caloric intake for at least 8-hours.
^OGTT should be performed as described by WHO and should use a glucose load of the equivalent of 75 g anhydrous glucose dissolved in water. The OGTT is not generally recommended or required for the purpose of diagnosis outside of pregnancy.

Diagnostic Criteria for Increased Diabetes Risk (Pre-diabetes)

- A1c 5.7-6.4%, or
- FPG 100-125 mg/dl, or
- 2-hour plasma glucose 140-199 mg/dl during an OGTT

The individual who demonstrates increased diabetes risk based on modest hyperglycemia should undertake appropriate preventive interventions including dietary modification with weight loss when appropriate along with a program of regular exercise. The additional use of metformin, particularly among individuals under age 60, those with an elevated BMI (≥25 kg/m2) or with additional risk-related concerns (e.g. metabolic syndrome or vascular disease) should be considered.

Associated Complications and Conditions

In addition to the commonly recognized long-term microvascular and macrovascular complications of diabetes, i.e. retinopathy, nephropathy, and neuropathy, as well as several-fold increase in incidence of vascular disease, diabetes may increase the risk of the following:

Fatty liver disease with progression to cirrhosis
Hearing impairment
Cognitive impairment
Skin disorders
Obstructive sleep apnea
Cataracts
Low testosterone in men
Fractures
Certain cancers including that of the liver, pancreas, endometrium, colon/rectum, breast, and bladder

Screening for Diabetes in Asymptomatic Individuals

Screening for diabetes is recommended in asymptomatic adults. Initiation and frequency of routine screening is based on age as well as the presence of risk factors.

Screening is recommended in adults not known to have diabetes who are:

- Overweight or obese (BMI ≥25 kg/m2) and who have one or more additional risk factors for diabetes. Those risk factors include:
    - Physical inactivity
    - First-degree relatives with diabetes
    - High-risk race/ethnicity (African-American, Latino, Native American, Asian American, Pacific Islander)
    - Women who delivered a baby weighing >9 pounds or who are known to have had gestational diabetes mellitus
    - Hypertension (BP ≥140/90 mmHg or on therapy for HTN)
    - HDL cholesterol level <35 mg/dl and/or triglyceride level >250 mg/dl
    - Polycystic Ovarian Syndrome (PCOS)
    - A1c >5.7%
    - Other clinical conditions associated with insulin resistance (obesity, acanthosis nigricans)
    - History of cardiovascular disease
- Age 45 and older without risk factors

Frequency of Screening:
If studies are normal, recheck at three year intervals.

Note: Performance of OGTT is not generally recommended or required for the purpose of diagnosis outside of pregnancy.

Treatment Goals for Type 2 Diabetes in Non-Pregnant Adult

A. A1c ≤7%
Treatment targets which balance risk and benefit should be considered when determining individual glycemic targets. Less stringent A1c goals, e.g. an HbA1c target of 8% or at times higher, may be appropriate in those at particular risk of hypoglycemia, those with limited life expectancy, multiple co-morbidities, cardiovascular disease, or those for whom diabetes care may be challenging.

B. Blood Pressure ≤140/90 mmHg
Lower blood pressure target (e.g. 130/80 mmHg) may be preferred if diabetic nephropathy or microalbuminuria is present or if a lower target is reasonably achievable without medication-induced adverse effects.

C. Cholesterol (Lipids)

LDL Goals

- LDL <100 mg/dl in patients >40 years or in patients 30-40 years of age with additional risk factor for vascular disease
- LDL <70 mg/dl in patients with co-existing vascular disease (when reaching that goal is practical)

Other Considerations

Triglyceride elevations will often decline in parallel with improvement in glycemic control, limitation of dietary carbohydrates and/or alcohol ingestion. Pharmacological therapy is recommended when the fasting triglyceride levels remain >500 mg/dl despite initial efforts to manage with improved glycemic control or diet.

D. Diet

Even when weight loss is not desired, attention to diet is a necessary component of a successful diabetes treatment plan. Calorie content should be specific to the individual. Carbohydrate choices should be complex over simple carbohydrates and distributed fairly evenly over the course of the day rather than concentrated within a single large meal; doing so allows one with declining islet cell function to respond to ingested carbohydrates more effectively. Referral to a dietician is often of value.

E. Exercise

Regular exercise is another highly effective component of a successful diabetes treatment plan. Current exercise recommendations endorse at least

- 150 minutes per week of moderate intensity aerobic activity (i.e. brisk walking) with exercise performed at least three days each week
- 20 minute sessions at least two times per week of strength training directed toward multiple muscle groups

Regular exercise has been shown to improve blood glucose control, contribute to weight loss, reduce cardiovascular risk and promote well-being. Within the diabetes population, there are some conditions (e.g. peripheral vascular disease, more severe peripheral neuropathy or unstable proliferative retinopathy) that will at times place restrictions on exercise choices. The American Diabetes Association no longer recommends routine exercise tolerance testing in screening asymptomatic individuals prior to the start of an exercise program; providers should use clinical judgment based on individual circumstances. Consider use of exercise prescriptions.

Diabetes Self-Management Education (DSME)

Diabetes management is performed by patients in their home environment, sometimes with assistance and support from their social support system. As a result, it's particularly important that patients with diabetes engage in DSME beginning at around the time of diagnosis.

DSME should include individualized lifestyle recommendations, education related to the character and complications of the disorder, risk reduction, monitoring, prescribed pharmacological interventions, acute and long-term complications as well as behavior change management and goal setting strategies. Diabetes education often requires reinforcement and revision as the character of one's diabetes-related circumstances change. As a result, the relationship between individuals with diabetes and diabetes educators should be an ongoing one.

Diabetes education may be provided in group or in individual settings, the choice for a given individual will be guided by one's needs and often by insurance coverage requirements. Insurance reimbursement for multiple individual sessions is usually restricted to selected situations as group sessions have been shown under many or most circumstances to be preferred when judged by outcomes and patient satisfaction. Diabetes education programs should be able to provide guidance for the appropriate education setting upon request.

Diabetes education services can act as partners in the provision of diabetes care; that role will undoubtedly increase as care transitions toward the Patient Centered Medical Home. Diabetes educators will increasingly partner with physicians in titrating insulin doses and performing additional clinical functions as medical home models develop.

A full listing of DSME programs available within Partners Healthcare service areas is attached.

Self-Monitoring of Blood Glucose (SMBG)

While the HbA1c serves as the most trusted measure for assessment of glycemic control, SMBG provides certain benefits that the HbA1c does not offer. As an example, SMBG is necessary to demonstrate hypoglycemia.

The HbA1c is an index of blood glucose over the prior 3 months while SMBG provides immediate and early feedback to patients and their providers. Examples of effective use of SMBG include time of insulin dose titration, dosing of prandial insulin that may vary as determined by a pre-meal glucose measure, and monitoring of the effect of exercise among insulin treated individuals. The functional value of SMBG among non-insulin

users is often less clear. The frequency and desirability of recommended BG monitoring should be individualized based at least in part on hypoglycemia risk. Frequency of testing may need to increase at times of medication changes, illness, dietary changes, alterations in exercise, change in work or sleep schedule, travel, and periods of increased stress.

Suggested Frequency/ Schedule for Home Blood Glucose Monitoring

Diabetes Treatment	**SMBG Schedule**
Diet, metformin, and/or other agents that do not promote hypoglycemia risk	Limited, if any, monitoring may be required, e.g. once or twice per week.
Sulfonylureas (SU)	Closer monitoring is required when SU is initiated or adjusted e.g. 2-3 times per week or more. Often frequency can be decreased once patterns are established.
Basal insulin	4-5 times per week. Fasting glucose is used to determine nighttime insulin dose. For patients on insulin and for others as well, it may be useful to monitor at differing times per day, e.g. related to meals and/or exercise.
Multiple daily insulin injections(MDI)	Pre-meals and/or bedtime. Times/frequency determined by one's treatment regimen.

SMBG data can be shared with providers in a number of ways, from simple handwritten log books to software that can organize data into easy to interpret formats. Such software, exclusive to each brand of meter, is available to patients and providers. Providers can often access the software without charge.

When used properly, home blood glucose meters offer an accuracy of +/- 10% as compared with laboratory blood glucose results of +/- 1-2%. Patients should be aware that while the imprecision of SMBG can lead to uncertainties, the rapid availability it offers provides unequaled value in properly defined circumstances.
Instruction in SMBG may have value in ensuring that technique is proper and equipment is up-to-date and properly used.

Surgical Treatment of Type 2 Diabetes

A diabetes treatment program incorporates dietary modification with weight loss often serving as the primary treatment target. Bariatric surgery may at times be the preferred treatment option toward effective weight loss and, in turn, toward effective management of the metabolic parameters of type 2 diabetes, e.g. glycemic control, management of lipids, blood pressure and cardiovascular risk. Less measurable benefits occur as a result of bariatric surgery as well. Roux-en-Y gastric bypass (RYGB), laparoscopic sleeve gastrectomy, adjustable gastric banding and biliopancreatic diversion with duodenal switch (BPD/DS) are among the surgical procedures that are currently offered. In terms of weight loss and metabolic changes, BPD/DS and RYGB, followed by sleeve gastrectomy are most effective. The lap adjustable gastric banding ("lap band") affords less weight loss and less resultant effect on diabetes related parameters but does not alter the physiology or have the same metabolic component as the other bariatric surgeries. Commonly, particularly following RYGB, improved blood glucose control occurs soon after surgery, prior to the occurrence of meaningful weight loss and not accounted for by low caloric intake alone. The surgical interventions' mechanisms are multifactorial and complex and, depending on the procedure performed, include alterations in anatomy, hormonal signaling, and factors that are not well defined.

The International Diabetes Federation (IDF), in a 2011 position statement, proposes the following indications for bariatric surgery in the setting of type 2 diabetes:

- Surgery should be an accepted option in people who have type 2 diabetes and a BMI of 35 or more
- Surgery should also be considered as an alternate treatment option in persons with a BMI of 30-35 when diabetes cannot be controlled by optimal medical regimen, especially in the presence of other major cardiovascular disease risk factors
- In Asian and some other ethnicities of increased risk, BMI action points may be lowered by $2.5\ \mathrm{kg/m^2}$

Two recent randomized controlled clinical trials published in the NEJM show that surgery appears superior to medical therapy when comparing diabetes care outcomes over one and two year intervals. Given that medical therapy of diabetes may promote weight gain, notably the use of insulin and sulfonylureas, bariatric surgery should be considered a viable option even early in the course of care in the appropriate population.

Criteria for insurance coverage for bariatric surgery may differ from the recommendations outlined by the IDF. Insurers will often base bariatric surgery approvals on 1991 NIH guidelines. These earlier guidelines recommend bariatric surgery

when a BMI is ≥35 with one major comorbidity or ≥40 without a major comorbidity. The lap band is the only surgical intervention covered by many insurers for individuals with a BMI ≥30 despite its lesser success in achieving desired weight loss and diabetes treatment targets.

References:

1. Mingrone G, Panunzi S, De Gaetano A, et al. Bariatric surgery versus conventional medical therapy for type 2 diabetes. N Engl J Med 2012; 366:1567-1576

2. Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. N Engl J Med 2012; 366:1577-1585

Recommended Frequency of Diabetes Care Components

Care Component	Frequency	Comments
BMI (weight)	At every visit	Provide weight management counseling and support regularly when BMI >25kg/m2.
Blood Pressure	At every visit	Reassess 1-4 weeks after treatment change. If self-monitoring BP, review results at diabetes care visits.
Foot Exam	Annually	Foot exam includes vibration perception or 10-g monofilament pressure sensation check for neuropathy along with circulation and inspection. Consider Ankle Brachial Index (ABI) since many patients with peripheral artery disease are asymptomatic.
Blood Glucose Logs	At every diabetes care visit	Review home results.
A1c	Every 3 months	When target not achieved or when there is a change in treatment plan. Also when insulin is in use.
	Every 6 months	When target is achieved and clinical/therapeutic conditions remain unchanged.
Urine Microalbumin/Creat	Annually	Annually unless microalbuminuria documented. Optimal time to check is early in the day. Exercise, infection, fever, CHF, marked hyperglycemia and marked HTN may falsely elevate. Elevation should be confirmed with a repeat measure. Continued monitoring once microalbuminuria is established is performed by some providers to titrate doses of ACEI/ARB.
Serum Creatinine and eGFR	Annually	
Lipid Profile	Annually	Repeat lipid profile within 3 months of medication change.
Dilated Eye Exam	Annually	Initial dilated eye exam should occur around the time of diagnosis, generally after control is achieved. Subsequent frequency may be decreased at the discretion of the eye care professional.
Smoking Cessation Education	At every visit	Unless non-use is assured.
Influenza Vaccine	Annually	
Hepatitis B Vaccine	See comments	Recommend if <age 60, discretionary if ≥age 60.
Pneumococcal Vaccine	See comments	Once before age 65, with follow-up immunization after age 65 with at least a five-year interval between doses.
Assess Aspirin (ASA) Therapy Indication (81 mg)	As needed	Secondary prevention for individuals with diabetes and a history of CVD. Primary prevention is generally appropriate men >age 50 and women >age 60 who have at least one additional risk factor.
Depression screening	As needed	Depression may be present in upwards of 20% of the diabetes population.
Assessment of self-management behaviors and skills, knowledge deficits related to diabetes care	Annually	Refer to DSME and MNT at time of diagnosis, change in treatment plan or knowledge deficit.

Diabetes Care Redesign

Partners' *Care Redesign* initiative seeks to provide **increased value** for patients, families and the entire medical enterprise by **improving outcomes** and/or efficiencies by **lowering unnecessary or excessive costs**. Recommendations have been developed through the collaborative efforts of providers and staff that touch a number of selected conditions, diabetes being one. Due to the enduring nature of diabetes care, our focus has been to address the character of care over an extended interval. Patient input has been solicited during the planning phase of the care redesign process. A review of the medical literature, practice patterns and costs led to the following recommendations for the treatment of type 2 diabetes in the non-pregnant adult:

- Use of generic oral medications are preferred over brand name alternatives in most settings
- Avoid most oral agents in the setting of insulin use
- Encourage and support use of insulin when clinically indicated

The management of hyperglycemia in this population, along with other components of diabetes care, is reflected in the treatment recommendations outlined in this document.

Use of Generic Oral Agents Are Preferred in Most Settings
Metformin and sulfonylureas (SUs) will lower HbA1c by an estimated 1 - 1.5% in most settings. Metformin is inexpensive, well tolerated and will not promote weight gain unlike most alternatives. Likewise, SUs are inexpensive and lower HbA1c with a comparable glucose-lowering effect to that of metformin. SUs may promote hypoglycemia, however, particularly among the elderly. The risk of hypoglycemia may be limited with proper choice of agent (glipizide and glimepiride are preferred), timing, dose and education.

Newer alternatives are available at notably higher cost and/or may promote a greater incidence of adverse effects than the older alternatives. Januvia® (sitagliptin) and other DPP-IV inhibitors offer lower efficacy than metformin and SUs, i.e. will lower HbA1c by an estimated 0.6 - 0.8%. Thiazolidiones (TZDs), such as Actos® (pioglitazone) will lower glucose comparably to metformin and SUs, but may promote significant weight gain, fluid retention, osteoporosis and as recently reported, a higher incidence of bladder cancer. Injectable GLP-1 receptor agonists, such as Byetta® (exenatide), Bydureon® (extended release exenatide), and Victoza® (liraglutide) will lower HbA1c by up to 1%. Use of these agents is commonly encouraged for their potential weight loss benefit, although the average weight loss is only 4 - 6 pounds after 30 weeks of use. There is a relatively high incidence of GI intolerance with use of GLP-1 receptor agonists.

Under most circumstances, metformin, SUs and insulin are preferred for the purpose of glucose control.

Avoid Most Oral Agents with Insulin Use
Use of metformin along with insulin administration in the setting of type 2 diabetes can limit insulin dose requirements and may in turn limit weight gain, a commonly cited result of insulin use. Other oral agents, including SUs, have limited or no complimentary effect when insulin is in use and may only add to cost/co-pays for affected patients.

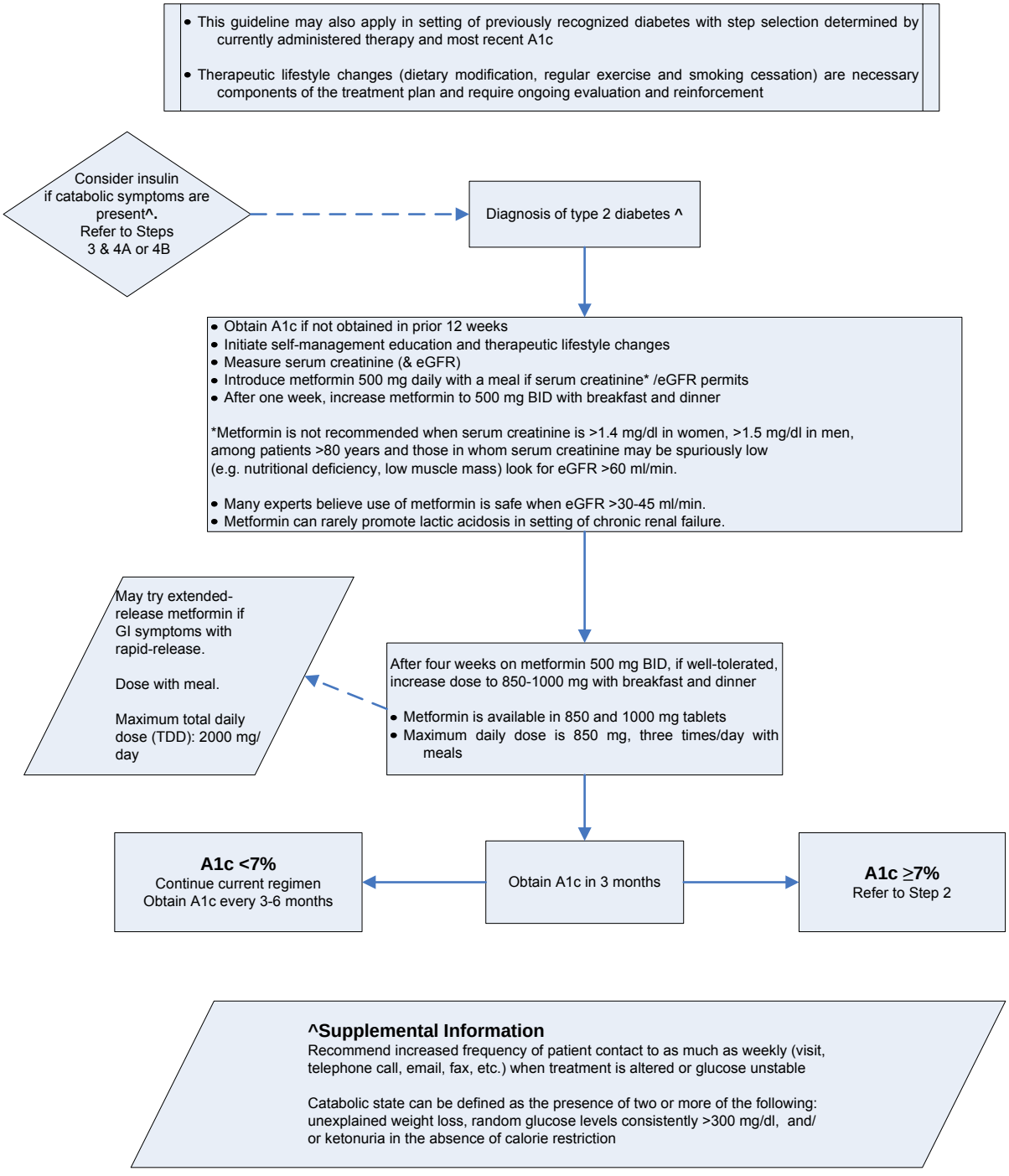
Encourage and Support Use of Insulin
Insulin is the only agent that has the potential to lower HbA1c by >2%. Having said that, there are obvious obstacles to insulin initiation. Obstacles include:

- Psychological insulin resistance (among patients and providers)
- Clinical inertia
- The resources required to successfully teach, initiate and titrate insulin
- Provider access to and awareness of recommendations and tools to support providers and patients

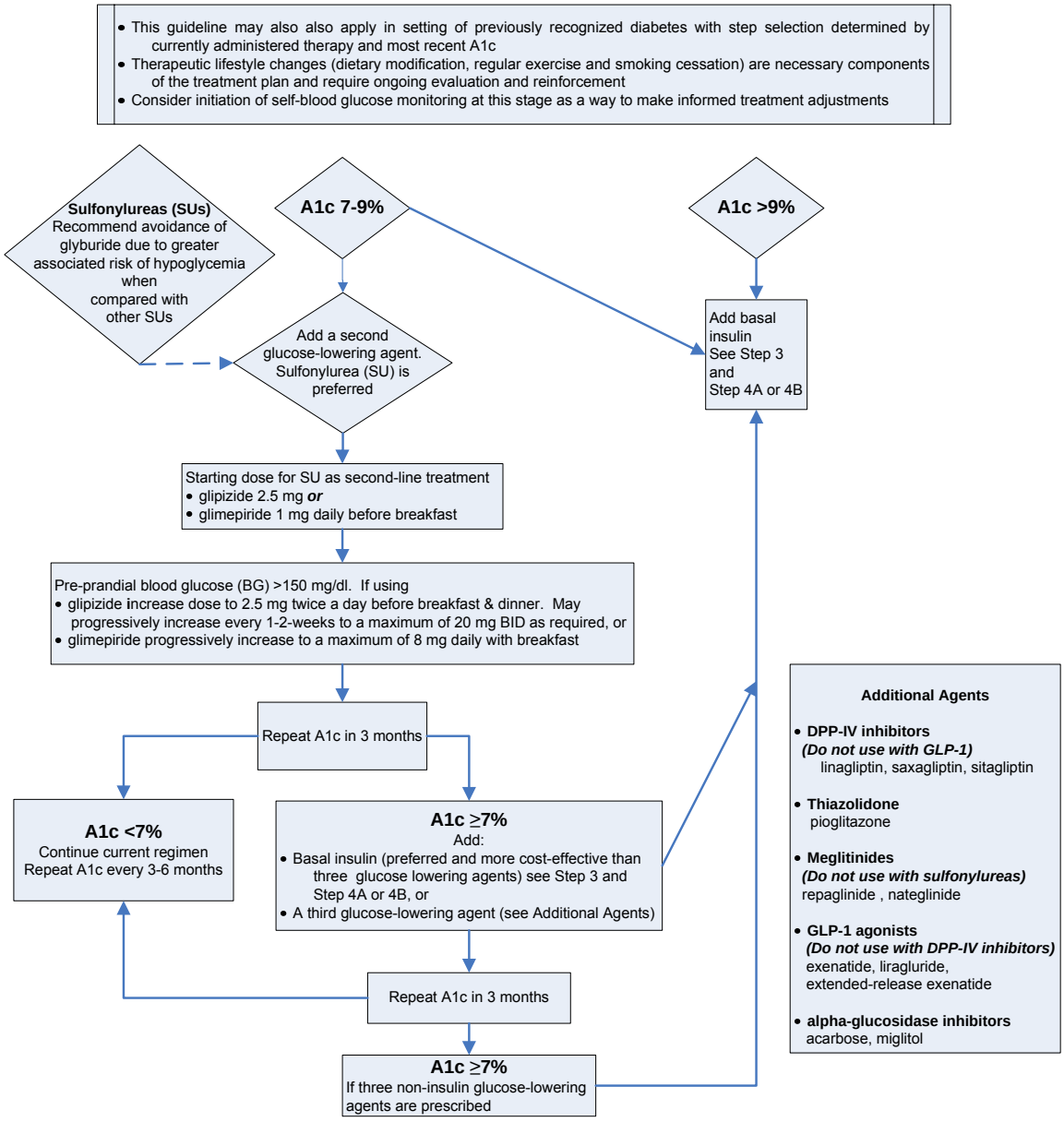
Interventions to support the implement *Diabetes Care Redesign* recommendations include the following:

- Creation of LMR decision support to encourage
    - Use of generic medications when appropriate
    - Proper use of oral agents when insulin is prescribed
    - Insulin initiation (development of order sets and protocols)
- Development of tools for provider and patient use to support initiation and titration of insulin (see attached protocols which users can use as EMR templates)
- Development of metrics to measure progress toward Diabetes Care Redesign recommendations
- Support local medical directors in providing education within their communities

Management of Hyperglycemia: Step 1- At the Time of Diagnosis, Initiation, and Titration of Metformin



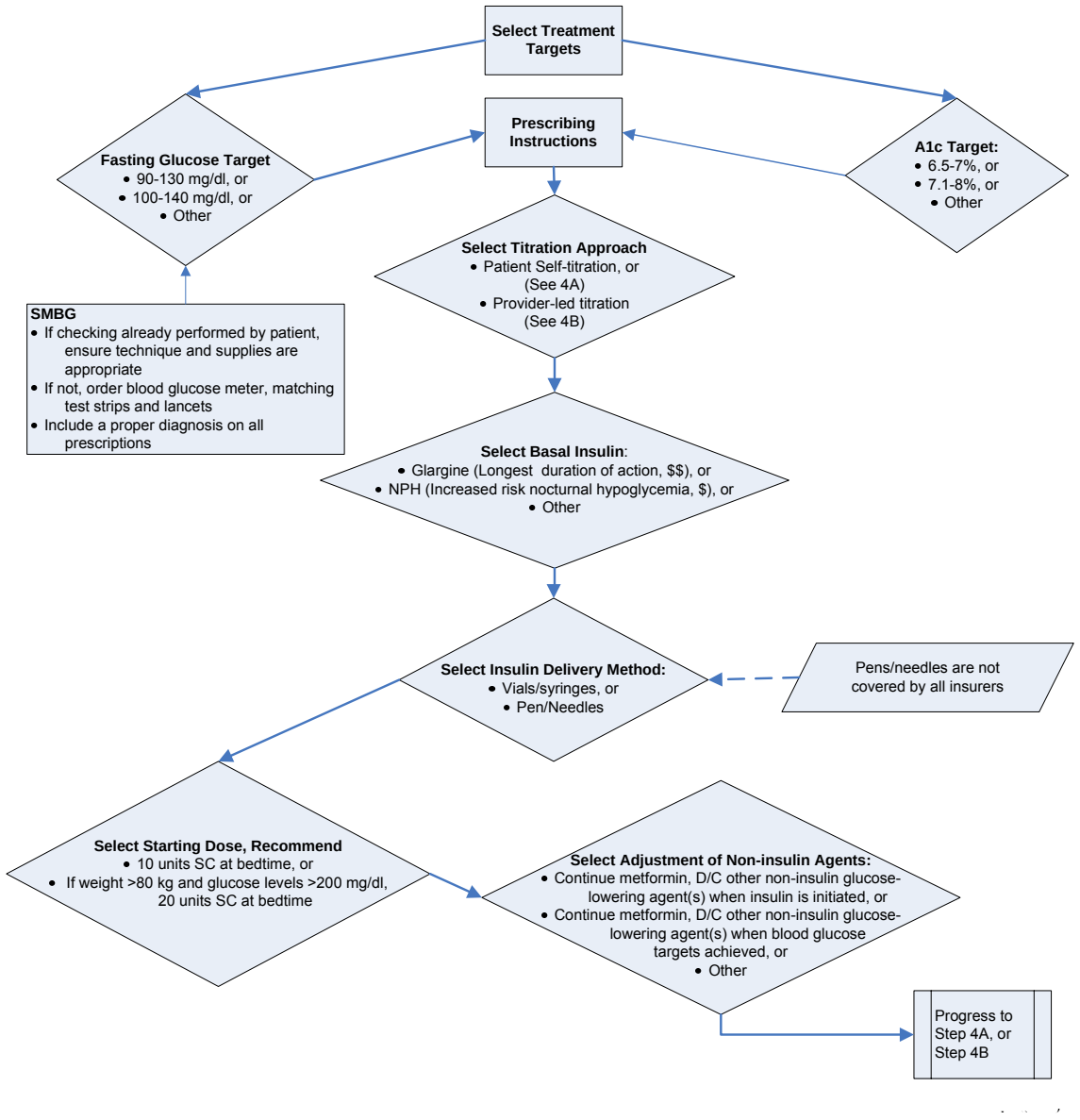
Management of Hyperglycemia: Step 2
Addition of a Second Glucose-lowering Agent



- The use of metformin, SU's and insulin are generally recommended for glycemic management in most settings.
- When desire for weight loss or avoidance of hypoglycemia is a consideration, use of alternative glucose-lowering agent may be appropriate.
- Medications listed in this document as additional agents are considered to be second-tier due to lower relative effectiveness directed toward glycemic control, higher cost and associated adverse effects.

Management of Hyperglycemia: Step 3
Initiation of Basal Insulin

- A usual fasting glucose target should be 90-130 mg/dl and an A1c target should be 6.5-7.0%
- Targets should be relaxed for individuals who are compromised based on their state of health (comorbidities, anticipated lifespan) or hypoglycemia risk (ability level, motivation, etc.)
- Teaching should be provided that addresses blood glucose checking and schedule, insulin use (injection preparation and technique, site rotation, care of insulin and disposal of sharps, insulin action) as well as glucose management in the setting of insulin use (integration of food and exercise, recognition and approved response to hypoglycemia)
- Teaching is generally performed by non-physician providers (e.g. certified diabetes educators) or alternatively properly selected teaching materials



Management of Hyperglycemia: Step 4A
Basal Insulin Adjustment, Self-Titration Protocol

- Therapeutic lifestyle changes (dietary modification and exercise) as well as ongoing self-monitoring blood glucose (SMBG) are components of the insulin treatment plan
- Prescribing Provider designates Insulin Adjustment Provider
- Recommend intervals between patient and insulin adjustment provider contact should not exceed two weeks during active phase of titration
- Provide each patient with self-administration verbal guidance and written instructions (Insulin Adjustment Guide 1, 2 or 3)

Titration Directions

1. Patient obtains daily fasting blood glucose

2. If fasting levels are above goal range for 2 consecutive days, basal insulin dose is increased by 2 units

3. Insulin dose is increased by 2 units whenever 2 consecutive fasting blood glucose readings are above goal range until a dose of 40 units has been reached **or** a fasting blood glucose has been achieved.

4. If a patient reaches a total daily dose (TDD) of 40 units **and** fasting blood glucose levels have not reached goal, patient may increase titration of insulin dose to 4 units every 2 days **after confirming dose adjustment with insulin adjustment provider**.

5. When fasting blood glucose target is reached, do not increase insulin dose. Continue to monitor blood glucose levels and continue with routine contact with insulin adjustment provider.

Patient to contact Insulin Adjustment Provider for the Following:

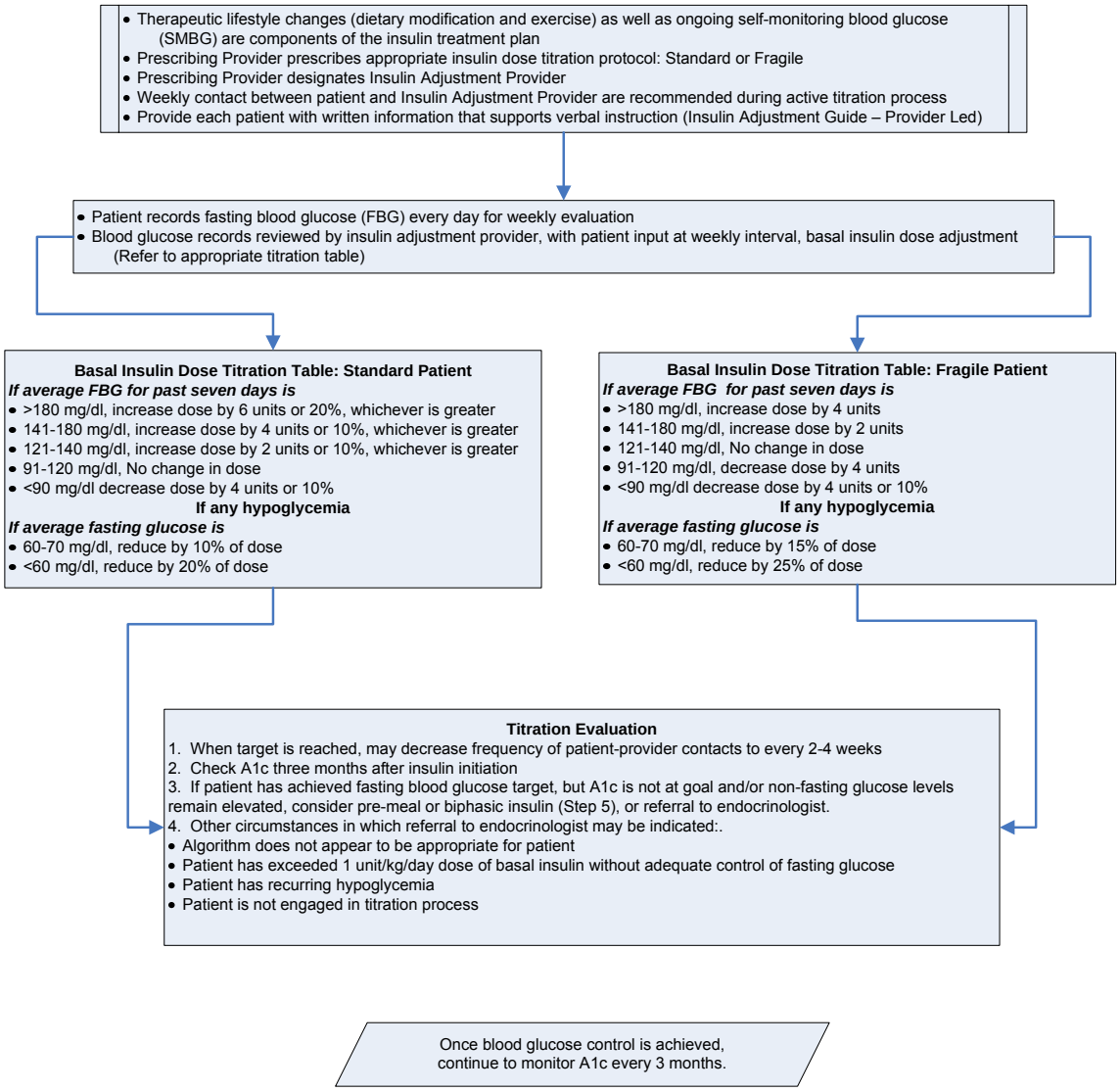
- Per Insulin Adjustment Provider-Patient Agreement
- If dose has exceeded 1 unit/kg or _____units (determined by Prescribing Provider)
- If patient experiences any fasting glucose level below goal, contact insulin adjustment provider on next business day
- If patient experiences any glucose below 80 mg/dl or symptomatic hypoglycemia, contact insulin adjustment provider within 24-hours for further instruction **and** decrease basal insulin dose by 10% until further instruction received

Titration Evaluation

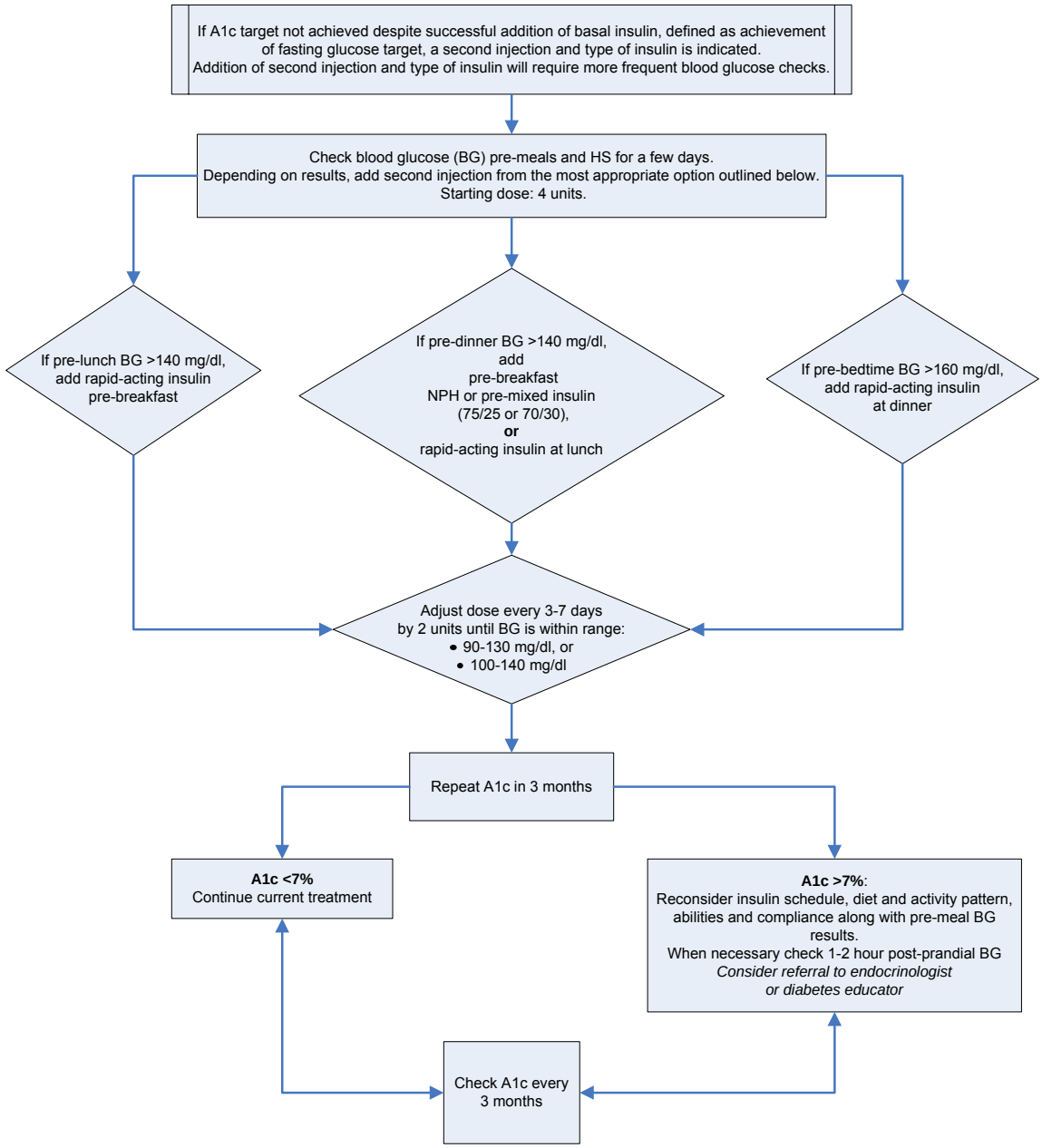
1. Assess A1c three months after insulin initiation/active titration period
2. If patient has achieved fasting blood glucose target, but A1c is not at goal and/or non-fasting glucose levels remain elevated, consider pre-meal or biphasic insulin (Step 5), or referral to endocrinologist.
3. Other circumstances in which referral to endocrinologist may be indicated:
   - Algorithm does not appear to be appropriate for patient
   - Patient has exceeded 1 unit/kg/day dose of basal insulin without adequate control of fasting blood glucose
   - Patient has recurring hypoglycemia
   - Patient is not engaged in titration process

Once blood glucose control achieved,
continue to monitor A1c every 3 months

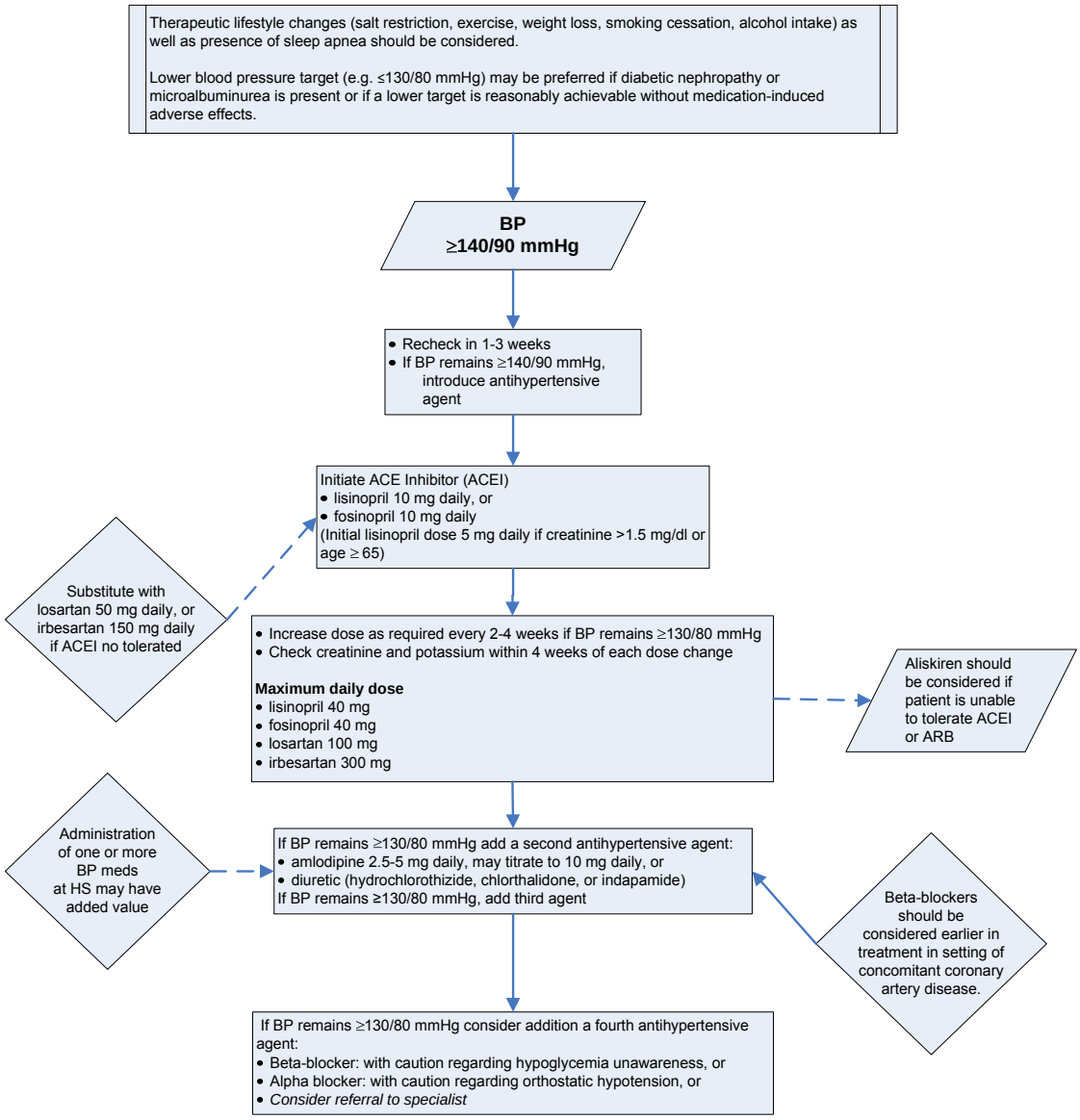
Management of Hyperglycemia: Step 4B
Basal Insulin Adjustment, Provider Led Protocol



Management of Hyperglycemia: Step 5
Insulin Titration Beyond Basal Insulin



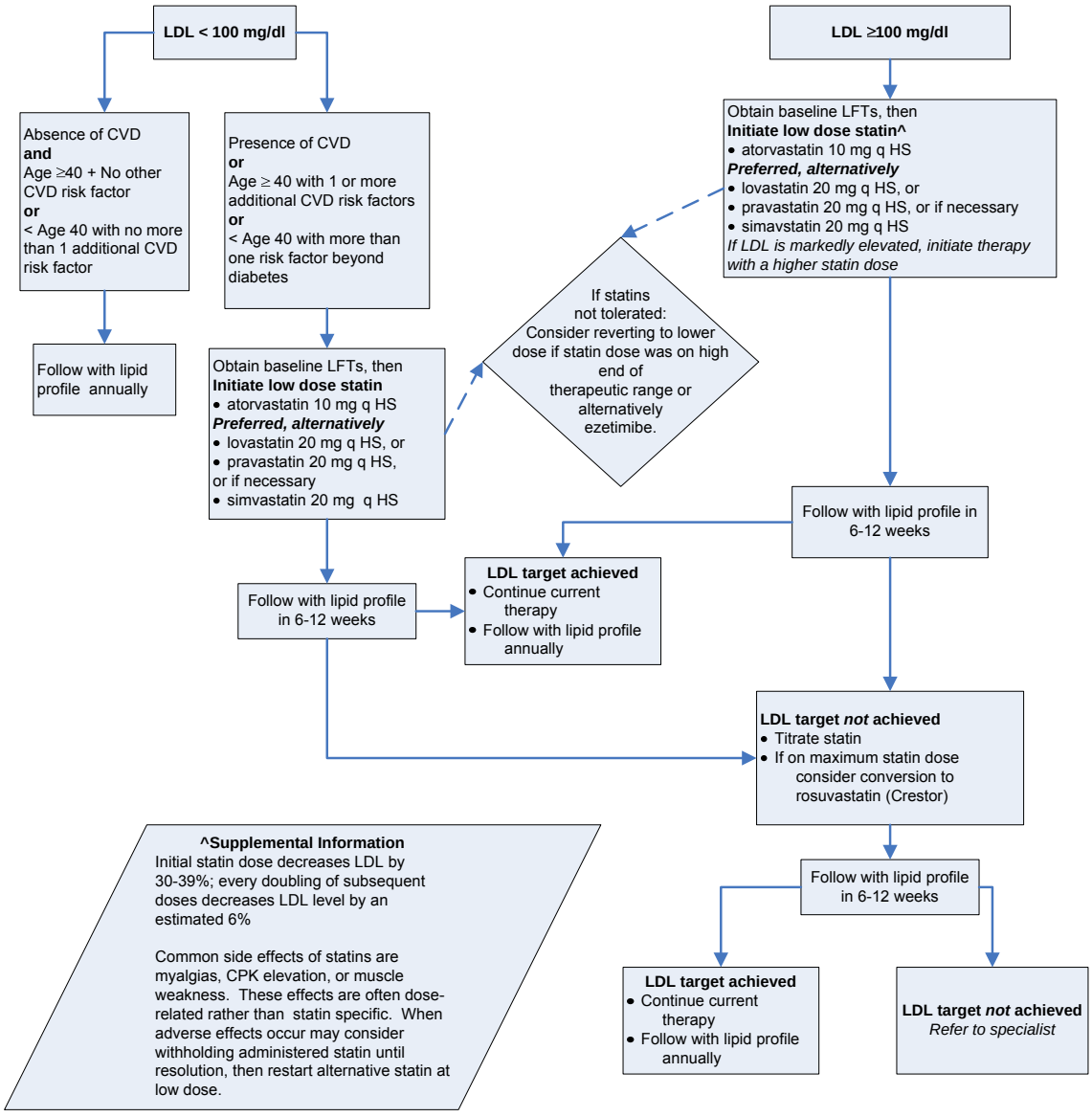
Blood Pressure (BP) Management



Lipid Management

- LDL level to <100 mg/dl (<70 mg/dl with co-existing or cardiovascular disease [CVD] when reaching that goal is practical)
- Treatment target in setting of diabetes is more aggressive than in the population-at-large and may not be achievable in all individuals

- Treatment of hyperlipidemia includes therapeutic lifestyle changes (weight management, regular exercise, smoking cessation, etc.)
- Treatment of hypothyroidism when present can lower cholesterol level
- Refer to page 6 for guidance related to management of triglycerides



Basal Insulin Initiation Template for Physicians
Partners Healthcare System

Criteria:

a. Patient with type 2 diabetes on 2 oral diabetes medications and HbA1c >8% *or*
b. Patient felt to be appropriate for insulin initiation for any other reason *and*
c. Patient performs self-monitoring of glucose with a glucose meter

Determine targets:

A1C target:

a. 6.5-7%
b. 7.1-8%
c. Other (specify) _____

Fasting Glucose Targets:

a. 90-130 mg/dl for most patients
b. 100-140 mg/dl for older patients and those with significant co-morbidities
c. Other (specify) _____

Prescribing Instructions

1. Choose titration approach and who will be primarily responsible for titration: based on assessment of ability and interest of patient to self-titrate

a. Patient self-titration under guidance of _____ (specify provider)
b. Provider-led titration: Usual patient
c. Provider-led titration: Fragile patient (e.g.> age 80, creatinine > 2.0 mg/dl, moderate to severe hepatic insufficiency)

2. Choose oral regimen

a. Continue metformin and discontinue all other non-insulin glucose lowering medications
b. Continue metformin and sulfonylurea, discontinue all other non-insulin glucose lowering medications and plan to taper or stop sulfonylurea as glucose control is achieved
c. Other (specify) _____

3. Choose basal insulin

a. NPH (less expensive, some potential for nocturnal hypoglycemia)
b. Glargine (Lantus, longer duration of action, more expensive)
c. Other (specify) _____

4. **Choose an insulin delivery method and prescribe**

a. Vials/Syringes

- **Vials** (contain 1000 units per vial)
  1. Instructions: "increase by 2 units every 2 days to a max of 40 units then as directed"
- **Syringes** (#100 per box)
  1. 0.50 cc with 31 gauge needle

2. 1.0 cc with 31 gauge needle for anticipated dose > 50 units
3. Instructions: "for use with insulin vials"

b. Pen/Needles

- **Pen** (contain 300 units each and are packaged 5 to a box, may be restricted by some insurers)
  1. Lantus Solostar
  2. Humulin N pen
  3. Instructions: "increase by 2 units every 2 days to a max of 40 units then as directed"
- **Needles** (#100 needles per box)
  1. 31 gauge short pen needles
  2. Instructions: "for use with insulin pens"

5. Choose an insulin starting dose

a. Recommend starting 10 units sc qhs
b. If weight >80 kg and glucose levels >200 start at 20 units sc qhs

6. Choose a maximum dose before considering referral to endocrinologist

a. 80 units (maximum for single injection with glargine pen)
b. 1 unit/kg/day

7. Blood Glucose Testing Supplies (Must match brand of test strips and lancets to meter)

a. Blood glucose meter
b. Test Strips
c. Lancets
d. Include a diagnosis code on all prescriptions for glucose testing supplies
- 250.00 (type 2)
- 250.02 (type 2 uncontrolled)

Insulin Management Plan

1. Pre-insulin initiation patient education (Consider referral to CDE)

a. Review home blood glucose monitoring:
i. Meter is functional
ii. Patient demonstrates ability to use meter
iii. Patient has adequate supplies
iv. Patient verbalizes target blood glucose range
v. Patient verbalizes when to check glucose:
- Check fasting blood glucose daily
- Check pre-largest meal blood glucose (e.g. daily, 3x/week)
- Other _____

b. Patient verbalizes knowledge of symptoms of hypoglycemia
c. Patient verbalizes hypoglycemia treatment options (15 gm CHO, e.g. 3 glucose tabs, ½ cup juice, 1cup low fat milk) and importance of carrying carbohydrate source at all times
d. Discuss insulin
i. Action of insulin and relationship to meals

ii. Demonstrate injection with appropriate device and confirm competence with insulin delivery system

2. Patient titration algorithm – give patient one of the insulin titration guides that follows. Patient Insulin Adjustment Guide 1 and 2 are found on page 26 and 27 – 8, (Guide No. 2 is for lower-literacy situations). The higher dose algorithm on page 29 (Guide 3) is intended for patients on 40 or more units as a starting dose.

- **a.** Patient obtains fasting glucose daily
- **b.** If fasting glucose levels are above goal range for 2 consecutive days, basal insulin dose is increased by 2 units
- **c.** Dose is increased by 2 units whenever 2 consecutive fasting blood glucose readings are above goal range until a dose of 40 units has been reached or fasting blood glucose has been achieved
- **d.** If patient reaches a total daily dose of 40 units and fasting glucose levels have not reached goal, patient may increase titration to 4 units every 2 days after confirming dose adjustment with provider
- **e.** For any blood sugar below 80 mg/dl patient should decrease insulin dose by 4 units or _____ and contact provider for further instructions

3. Provider–led titration algorithm – is available when close supervision is preferred. The Provider-led insulin titration guide for patients is available on page 30.

- **a.** Patient records fasting glucose every day for weekly evaluation
- **b.** Adjust basal insulin dose according to dose titration table

Basal Insulin : Dose Titration Table		
Average Fasting Blood Glucose level for the past 7 mornings	**Usual Patient**	**Fragile Patient**
> 180 mg/dl	6 Units or 20%, whichever is greater	4 units
141 – 180 mg/dl	4 Units or 10%, whichever is greater	2 units
121 – 140 mg/dl	2 Units or 10%, whichever is greater	No change
91 – 120 mg/dl	0 Units	Decrease dose by 4 units
< 90 mg/dl	Decrease dose by 4 units	Decrease dose by 4 units or 10%, whichever is greater
Any Hypoglycemia	**Dose Reduction**	**Dose Reduction**
Fasting glucose 60-70 mg/dl	Reduce by 10% of dose	Reduce by 15% of dose
Fasting glucose less than 60 mg/dl	Reduce by 20% of dose	Reduce by 25% of dose

4. Patient will contact identified provider for the following (for both provider titration and for patient self-titration):

- **a**. Patients will report blood glucose readings and self-titrated insulin dose to provider as determined mutually by patient and provider (not to exceed 2 week intervals during initial titration)
- **b**. Maximum dose achieved by either protocol should not exceed pre-determined amount of 1 unit/kg or 80 units without contacting provider
- **c.** If patient experiences any glucose below 80 mg/dl or any symptomatic hypoglycemia, patient should decrease dose by 4 units and contact provider within 24 hours

5. Evaluation of titration

- **a.** Consider referral to an endocrinologist for the following after discussion with referring provider:
    i. Insulin titration provider does not feel algorithm is appropriate for patient **for any reason**
    ii. Patient has exceeded 1 unit/kg/day or 80 units of basal insulin without adequate control of fasting glucose
    iii. Patient has frequent episodes of hypoglycemia
    iv. Patient is not engaged in the titration process
    v. Patient has achieved fasting blood sugar goal, but A1C is not at goal and/or non-fasting glucose levels remain elevated (consider pre-meal or bi-phasic insulin – Refer to Step 5)
- **b.** When target is reached, do not increase insulin dose further. Decrease frequency of patient-provider contact to every 2-4 weeks
- **c.** HbA1c is checked at 3 months after insulin initiation
    i. If A1C is at predetermined goal without significant hypoglycemia, and stable insulin dose has been achieved, patient may return to PCP for ongoing care
    ii. If patient is not at goal and not at maximum insulin dose, patient will continue with titration for another 3 months

Insulin Adjustment Guide 1

Name _____ Insulin Adjustment Provider _____

Preferred Contact Method with adjustment provider (check one)

___ Patient Gateway

___ Phone _____

Date _____ ___ Other _____

Your fasting (before breakfast) blood sugar TARGET RANGE is _____

Starting Dose

- Please start taking (Lantus/NPH) _____ units at 10 PM or at _____. It is important that you take your insulin at about the same time every day
- Check your blood sugar every morning before breakfast (fasting)

Adjusting Insulin

- Look over your fasting blood sugar readings from the last 2 days
- If both readings are above your target range (as noted above), increase your dose by 2 or _____ units
- Take the new dose for the next two nights
- If your fasting blood sugar is above your target for 2 mornings in a row, increase the number of units of insulin you are taking by 2 or _____ units until your fasting blood sugar is in your target range
- If you have required no insulin dose adjustment for 2 weeks, a scheduled visit or message to your provider is advised
- Contact your insulin adjustment provider if you have reached an insulin dose of 40 units or _____ units and your target has not yet been met

Low Blood Sugar

- If you feel symptoms of low blood sugar such as sweating and shaking, ***test your blood sugar right away***
- If your blood sugar is below 80 mg/dl and you have having low blood sugar symptoms:
    1. Treat with 15 grams of a simple carbohydrate:
       ½ cup (4 ounces) of fruit juice ***or*** 1 cup (8 ounces) skim or 1% milk ***or*** 3 packets regular sugar, ***or*** 3 – 4 commercially available glucose tablets
    2. Wait 15 minutes and check your blood sugar again
    3. If it is still low (below 80 mg/dl), treat again with 15 grams of simple carbohydrates
    4. Stop increasing your insulin dose and call the office on that same day for instructions
    5. If unable to reach your provider that day, decrease your next insulin dose by 4 or _____ units until you receive further instructions

Insulin Adjustment Guide 2

Name _____
Date: _____
Insulin Adjustment Provider _____
Preferred contact method with Insulin Adjustment Provider (check one)
___ Patient Gateway
___ Phone _____
___ Other _____

Your fasting (before breakfast) blood sugar TARGET RANGE is _____

- Your starting dose of _____insulin is _____ units
- Take your insulin at _____
- Take your insulin at about the same time every day
- For any questions, contact your Insulin Adjustment Provider _____
- You will increase your insulin dose by _____units at a time as explained below
- Do not increase dose above _____units a day without contacting your Insulin Adjustment Provider

---

Your glucose result

Day 1 ☐

Day 2 ☐

→ If both of your blood sugars are are greater than _____, add _____ units to your daily insulin dose.

If either of your blood sugars is less than _____, continue with same dose of insulin.
Your daily dose of insulin for the next two days is____ units.

Day 3 ☐

Day 4 ☐

→ If both of your blood sugars are greater than _____, add _____ units to your daily insulin dose.

If either of your blood sugars is less than _____, continue with same dose of insulin.
Your daily dose of insulin for the next two days is____ units.

Day 5 ☐

Day 6 ☐

→ If both of your blood sugars are greater than _____, add _____ units to your daily insulin dose.

If either of your blood sugars is less than _____, continue with same dose of insulin.
Your daily dose of insulin for the next two days is____ units.

Day 7 and beyond: continue with similar pattern and record daily doses in log book.

Low Blood Sugar

- If you feel symptoms of low blood sugar such as sweating and shaking, ***test your blood sugar right away***
- If your blood sugar is <u>below 80 mg/dl and you have having low blood sugar symptoms</u>:
    - Treat with 15 grams of a simple carbohydrate, such as one of the following:
        - 1/2 cup (4 ounces) of fruit juice
        - 1 cup (8 ounces) of skim or 1% milk
        - 3 - 4 commercially available glucose tablets
        - 3 small packets of regular sugar
    - Wait 15 minutes and check your blood sugar again
        - If it is still low (less than 80 mg/dl), treat again with 15 grams of simple carbohydrates
    - Stop increasing your insulin dose and call the office on the same day for instructions
    - If unable to reach your provider that day, decrease your next insulin dose by 4 or ___ units until you receive further instructions

Insulin Adjustment Guide 3 – High Dose

Name _____ Insulin Adjustment Provider _____

Preferred Contact Method with adjustment provider (check one)

___ Patient Gateway

___ Phone _____

Date _____ ___ Other _____

Your fasting (before breakfast) blood sugar TARGET RANGE is _____

Starting Dose

- Please start taking (Lantus/NPH) _____ units at 10 PM or at _____. It is important that you take your insulin at about the same time every day
- Check your blood sugar every morning before breakfast (fasting)

Adjusting Insulin

- Check your blood sugar every morning before breakfast (fasting)
- Look over your fasting blood sugar readings from the last 2 days
- If both readings are above your target range (as noted above), increase your dose by 4 or _____ units
- Take the new dose for the next two nights
- Every 2 nights, increase the number of units you are taking by 4 or _____ units until your fasting blood sugar is in your target range
- If you have required no insulin dose adjustment for 2 weeks, a scheduled visit or message to your provider is advised
- Contact your insulin adjustment provider if you have reached an insulin dose of 80 or _____ units and your target has not yet been met

Low Blood Sugar

- If you feel symptoms of low blood sugar such as sweating and shaking, ***test your blood sugar right away***
- If your blood sugar is below 80 mg/dl and you have having low blood sugar symptoms:
    - Treat with 15 grams of a simple carbohydrate, such as one of the following:
        - ½ cup (4 ounces) of fruit juice
        - 1 cup (8 ounces) skim or 1% milk
        - 3 – 4 commercially available glucose tablets
        - 3 small packets of regular sugar
    - Wait 15 minutes and check your blood sugar again
    - If it is still low (below 80 mg/dl), treat again with 15 grams of simple carbohydrates
- Stop increasing your insulin dose and call the office on that same day for instructions
- If unable to reach your provider that day, decrease your next insulin dose by 8 or _____ units until you receive further instructions

Insulin Adjustment Guide – Provider-led

Name _____
Date _____
Insulin Adjustment Provider _____
How to reach me (check one)
___ Patient Gateway
___ Phone _____
___ Other _____

Insulin information

- **Your starting dose of _____insulin is _____ units**
- **Take your insulin at _____**
- It is important to take your insulin at about the same time every day
- For any questions, contact your Insulin Adjustment Provider

Blood sugar information

- **Your fasting (before breakfast) blood sugar target range is _____**
- **Check your blood sugar before breakfast every morning**
- Write your blood sugar results in your log book every day
- Report those results every week on _____ to your Insulin Adjustment Provider
- If you have a blood sugar **below** your target range, call your Insulin Adjustment Provider **the next business day**

Low Blood Sugar

- If you feel symptoms of low blood sugar such as sweating and shaking, **test your blood sugar right away**
- If your blood sugar is below 80 mg/dl and you have having low blood sugar symptoms
    - Treat with 15 grams of a simple carbohydrate, such as one of the following:
        - 3-4 commercially available glucose tablets
        - ½ cup (4 ounces) fruit juice
        - 1 cup (8 ounces) skim or 1% milk
        - 3 packets of regular sugar
    - Wait 15 minutes and check your blood sugar again
    - If it is still low (less than 80 mg/dl), treat with another 15 grams of simple carbohydrate

If you cannot to reach your provider that day, decrease your next insulin dose by 4 or _____ units until you receive further instructions.

Diabetes Self-Management Education Programs
July 2012

Referral is required for participation

RSO	Diabetes Education Program	Accredited by	Program Telephone Number	Point of Contact Information
BWPO	Brigham Ambulatory Care 850 Boylston Street Chestnut Hill, MA 02467	ADA	617-732-9300	Samira Sheth PHS Directory
BWPO	221 Longwood Avenue Boston, MA .2115	ADA	617-732-5666	Samira Sheth PHS Directory
BWPO	Brookside Community Health Center 3297 Washington Street Jamaica Plain, MA 02130	ADA	617-522-4700	Samira Sheth PHS Directory
BWPO	Southern Jamaica Plain Health Center 640 Centre Street Jamaica Plain, MA 02130	ADA	617-983-4100	Samira Sheth PHS Directory
CAMC	Cape Ann Medical Center 1 Blackburn Drive Gloucester, MA 01930	ADA	781-477-3409	Anne Abramo, PT, DPT PHS Directory
CHA	Cambridge Hospital 1493 Cambridge Street Cambridge, MA 02139	ADA	617-665-1552 (Appointments)	Ann Lindsay, RN, CDE alindsay@challiance.org 617-665-2788 (Office/Voicemail)
CHA	Somerville Hospital 236 Highland Avenue Somerville, MA 02143	ADA	617-591-4350 (Appointments)	Ann Lindsay, RN, CDE alindsay@challiance.org 617-665-2788 (Office/Voicemail)
CRMA	CRMA Framingham 600 Worcester Road Suite 404 Framingham, MA 01720	ADA	508-848-2190	Sandra Krafsig, RN, MS, CDE PHS Directory
CRMA	CRMA Marlborough 246 Maple Street Marlborough, MA 01752	ADA	508-848-2190	Sandra Krafsig, RN, MS, CDE PHS Directory
CRMA	CRMA Natick 67 Union Street Suite 410 Natick, MA 01760	ADA	508-848-2190	Sandra Krafsig, RN, MS, CDE PHS Directory
EPHO	Elizabeth Smith Agarwal Diabetes Center 54 Baker Avenue Suite 104B Concord, MA 01742 www.emersonhospital.org/MedServicesAndCenters/Centers/AgarwalDiabetes.aspx		978-287-8590	Cheryl Laundry, RN, BS, CDE claundry@emersonhosp.org
HHS	Joslin Diabetes Center @ Hallmark Health Lawrence Memorial Hospital 170 Governor's Avenue Medford, MA 02155	ADA	781-306-63707	Alice DiCenzo, RN, BSN, CDE adicenzo@hallmarkhealth.org
HHS	Joslin Diabetes Center @ Hallmark Health Melrose Wakefield Hospital 22 Corey Street Melrose, MA 02176	ADA	781-979-3165 (Appointments) 781-979-3173 (Coordinator)	Alice DiCenzo, RN, BSN, CDE adicenzo@hallmarkhealth.org
HMA	Hawthorn Medical Associates 535 Faunce Corner Road North Dartmouth, MA 02747	ADA	508-996-3991	Janet Morgado, RN, BSN, CDE jmorgado@hawthornmed.com

RSO	Diabetes Education Program	Accredited by	Program Telephone Number	Point of Contact Information
MGPO	Bulfinch Medical Group Wang Building Suite 555 15 Parkman Street Boston, MA 02114	ADA	617-726-3370	Colleen Larkin PHS Directory
MGPO	Charlestown Community HealthCare Center 73 High Street Charlestown, MA 02129 mghCharlestownDiabetes@partners.org	ADA	617-724-8311	Eileen McAdams, NP, CDE PHS Directory
MGPO	Chelsea Health Center 151 Everett Avenue Chelsea, MA 02150 mghChelseadiabetes@partners.org	ADA	617-884-8300	Barbara Chase, NP, CDE PHS Directory
MGPO	Chelsea Health Center 100 Everett Avenue Chelsea, MA 02150 mghChelseadiabetes@partners.org	ADA	617-887-4600	Barbara Chase, NP, CDE PHS Directory
MGPO	Diabetes Center 50 Staniford Street 3rd Floor Boston, MA 02114 mghDiabetesCenter@partners.org	ADA	617-726-8722	Craig Cochrane PHS Directory
MGPO	Endocrine and Pediatric Center Yawkey Center for Outpatient Care 55 Fruit Street, Suite 6C Boston, MA 02114	ADA	617-726-2909	Leah Berthold, RN, CDE PHS Directory
MGPO	Internal Medicine Associates 15 Parkman Street WACC 645 Boston, MA 02114 mghIMAdiabetes@partners.org	ADA	617-726-7944	Debra Hollon, RD, CDE Kathleen Walsh, RN, CDE PHS Directory
MGPO	Revere Health Center 300 Ocean Avenue Revere, MA 02151 mghReverediabetes@partners.org	ADA	781-485-6350	Christine Goscila, NP PHS Directory
NWPHO	Newton-Wellesley Hospital 2014 Washington Street Newton, MA 02462	ADA	617-243-6144	Kathleen Casper, RN, CDE, M.Ed PHS Directory
NSHS	Union Hospital 500 Lynnfield Street Lynn, MA 01904 Email:NSMCdiabetes@partners.org http://nsmc.partners.org/diabetes management	ADA	781-477-3409	Anne Abramo, PT, DPT PHS Directory
PMA	PMA One Parkway Haverhill, MA 01830 www.pmaonline.com	ADA	978-521-3250	Joan Hultgren, RD, LDN, CDE jhultgren@pmaonline.com
PMA	PMA 500 Merrimac Street Lawrence, MA 01843 www.pmaonline.com	ADA	978-557-8700	Joan Hultgren, RD, LDN, CDE jhultgren@pmaonline.com
PMA	PMA 260 Merrimac Street Newburyport, MA 01950 www.pmaonline.com	ADA	978-499-7200	Joan Hultgren, RD, LDN, CDE jhultgren@pmaonline.com

RSO	Diabetes Education Program	Accredited by	Program Telephone Number	Point of Contact Information
PMG	Jordan Hospital Diabetes Education Center 36 Cordage Park Circle Suite 314 Plymouth, MA 02360 www.jordanhospital.org (Classes & Support Groups)	ADA	508-830-2446	Kay Grosberg, RN, BSN, MA, CDE kgrosberg@jordanhospital.org
PrimaCARE	Southcoast Health System Durfee Union Building 283 Pleasant Street Fall River, MA 02720	ADA	508-324-3260	Geraldine Santos, RN, MSN, CDE santosg@southcoast.org
PrimaCARE	Southcoast Health System Dartmouth Place 49 State Road, Mashpee Building Dartmouth, MA 02747	ADA	508-910-3434-	Geraldine Santos, RN, MSN, CDE santosg@southcoast.org
PrimaCARE	Southcoast Heath System Tobey Hospital 43 High Street Wareham, MA 02571	ADA	508-295-0880	Geraldine Santos, RN, MSN, CDE santosg@southcoast.org
TCMA	Milford Regional Hospital 14 Prospect Street Milford, MA 01757 www.milfordregional.org	ADA	P: 508 422-2396 F: 508 634-4382	Jo Fleming, RN, CDE jfleming@milreg.org