**Brigham and Women's Hospital**
**Type 2 Diabetes Management Program**
Physician – Pharmacist Collaborative Drug Therapy Management Protocol

***Please note that this guideline may not be appropriate for all patients and does not replace clinical judgment***
Treatment goals and algorithms will follow the most current disease state guidelines, as well as other BWH-approved protocols that may exist.

1. Referral
    a. Patients will be referred to the Type 2 Diabetes Management Program by their primary care provider (PCP)
    b. The PCP will communicate the official diagnosis and associated patient-specific therapeutic goals to the pharmacist upon referral

2. Treatment Goals
    a. Treatment goals to be determined based on current general guidelines with input from the referring PCP

| Parameter | Goal |
|---|---|
| HbA1C | < 7%* |
| Fasting blood glucose | 80-130 mg/dL |
| 2-hr Post-prandial blood glucose | < 180 mg/dL |

*Individual patient goal should be as close to normal (HbA1c <7%) without significant hypoglycemia. Less stringent treatment goals (i.e. HbA1c 7-8%) may be appropriate for older adults, people with severe hypoglycemia, limited life expectancy and co-morbid conditions.

    b. Determining HbA1c goal
        i. Target < 7% for most patients
        ii. Consider < 6.5% in patients who can achieve this goal without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with
            1. A long life expectancy
            2. Short duration of diabetes
            3. No established vascular complications
            4. Few potential risks associated with hypoglycemia and other medication adverse effects
            5. No significant comorbidities
            6. Excellent self-care capabilities and highly motivated attitude
            7. Readily available resources and support systems
        iii. Consider <8% in patient with
            1. History of severe hypoglycemia
            2. Limited life expectancy
            3. Advanced microvascular or macrovascular complications
            4. Extensive comorbid conditions
            5. Longstanding diabetes in whom the general goals are difficult to attain despite appropriate education, blood glucose monitoring and effective doses of multiple glucose lowering agents including insulin
            6. Poor self-care capacities and limited motivation

7. Limited resources and support systems

c. Framework for considering treatment goals in older adults with diabetes

| Patient Health Status | Patient Health Characteristics | Reasonable HbA1c Goal | Fasting or preprandial glucose (mg/dL) | Bedtime Glucose (mg/dL) |
|---|---|---|---|---|
| Healthy | Few chronic illnesses, intact cognitive/functional status | <7.5% | 90-130 | 90-150 |
| Complex/intermediate | Multiple chronic illnesses, 2+ instrumental ADL impairments or mild-to-moderate cognitive impairment | <8.0% | 90-150 | 100-180 |
| Very complex/poor health | Long-term care or end-stage chronic illnesses or moderate-to-severe cognitive impairment or 2+ ADL dependencies | <8.5% | 100-180 | 110-200 |

3. Treatment Algorithm
    a. See Appendix 1
    b. Drug Selection Table (See Appendix 2):
        i. The pharmacist will optimize pharmacotherapy including initiation, modification and discontinuation of medications listed.
        ii. Therapy will be initiated with the preferred drug within the class. A secondary agent may be used instead of a preferred agent if a contraindication exists, the patient is already on another appropriate regimen, or for patient financial consideration
        iii. Patient-centered approach will be used to guide choice of pharmacologic agents. Considerations will include efficacy, safety, cost, potential side effects, weight, comorbidities, risk of hypoglycemia, and patient preferences.
    c. Drug Titration (See Appendix 3)
        i. Metformin
        ii. Liraglutide
        iii. Basal insulin
        iv. Prandial insulin
        v. Pre-mixed insulin
    d. Special considerations in which treatment algorithm may not be followed and use of clinical judgment and/or consult with provider may be necessary
        i. Patient financial consideration
        ii. Patient has frequent episodes of hypoglycemia
        iii. Pharmacist does not feel algorithm is appropriate for patient for any reason
    e. Pharmacists will contact PCP in instances where patient's blood glucose is reported to be inexplicably> 400 mg/dL.

4. Monitoring
    a. Most patients should return for follow-up and adjustment of medications at monthly intervals or until the glycemic goals are reached
    b. More frequent contact will be necessary for patients with frequent episodes of hypoglycemia, or with complicating comorbid conditions, or for accelerated insulin titration
    c. After blood glucose is at goal and stable, follow-up visits can usually be at 3 to 6-month intervals
    d. Monitor self-reported blood glucose values at every visit to assess effects of therapy; monitor blood pressure, lipids, and weight as appropriate to assess changes in cardiovascular risk
    e. Assess patient for signs and symptoms of adverse drug events
    f. Monitor laboratory markers to assess for toxicity, cardiovascular risk, and for selection of appropriate therapy
        i. HbA1c at 3 or 6-month intervals
        ii. Microalbumin/Cr at least annually
        iii. Fasting lipid panel at least annually

5. Additional Resources
    a. Partners Guidelines for the Treatment of Type 2 Diabetes in the Non-Pregnant Adult. *Partners Diabetes Council*. July 2012. http://vdc.partners.org/guidelines/Guidelines_7-10-12.pdf
    b. Brigham and Women's Hospital Basal Insulin Initiation and Titration Protocol. Policy # 1.13.5. BWH Diabetes Leadership Committee. November 2014.

6. References

    a. American Diabetes Association. Standards of Medical Care in Diabetes – 2015 (Position Statement). Diabetes Care. 2015;38: S4-S69.
    b. Nathan DM, Buse JB, Davidson MB, et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. Diabetes Care 2009; 32: 193-203.
    c. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach. Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2015; 38: 140-149.
    d. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach. Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2012; 35: 1364-1379.
    e. Mooradian, AD, Bernbaum M, Albert SG. Narrative review: a rational approach to starting insulin therapy. Annals of Internal Medicine 2006; 145: 125-134.
    f. Riddle MC, Rosenstock J, Gerich J. The Treat-to-Target Trial: Randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. Diabetes Care. 2003;26:3080–3086.


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|---|---|
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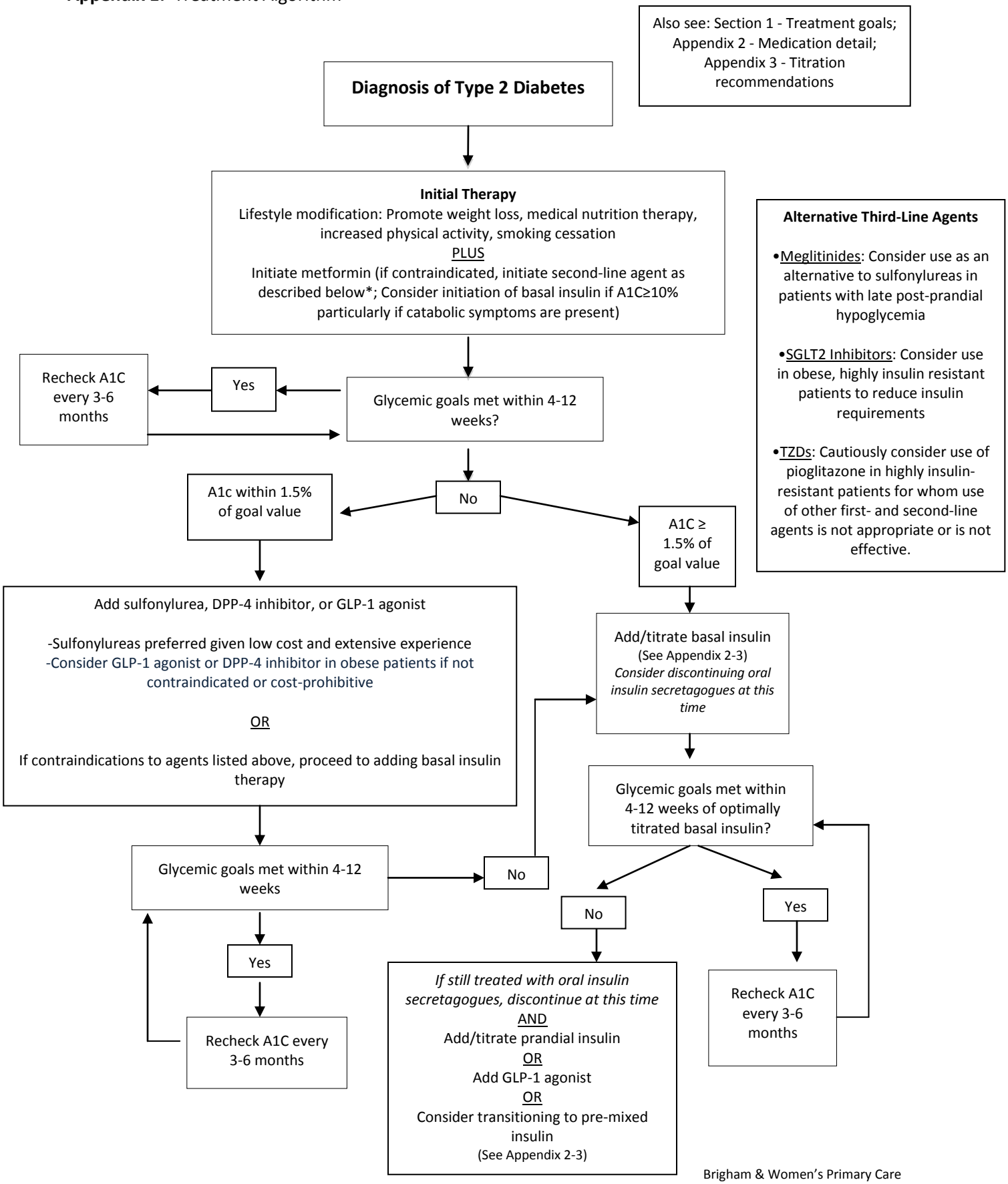
**Appendix 1:** Treatment Algorithm




Brigham & Women's Primary Care
Rev. 3.20.15 by S. Freitas, PharmD, A. Bilodeau, PharmD, and J. Allen, PharmD

**Appendix 2: Drug Titration Schedules**

**Metformin Titration Schedule**

a. The dose of metformin should be increased no more frequently than weekly.
b. If metformin is not tolerated due to gastric disturbances (i.e. diarrhea, abdominal pain), switch to Metformin ER tablets and counsel patient to take with food

| Week | Metformin Dose |
|---|---|
| **1** | 500mg once daily |
| **2** | 500mg twice daily |
| **3** | 500mg in the morning, 1000mg (2x500mg tablets) in the evening |
| **4** | 1000mg twice daily |

**Liraglutide (Victoza©) Titration Schedule**

| Week | Liraglutide Dose |
|---|---|
| **1** | 0.6 mg SC once daily |
| **2** | 1.2 mg SC once daily |
| **3** | 1.8 mg SC once daily |

**Basal Insulin Titration Schedule**

a. Initial basal insulin dose for most patients will be 10 units/day given at bedtime.
b. Initial basal insulin dose for patients weighing more than 80 kg and with fasting glucose levels consistently over 200 mg/dL will be up to 20 units/day given at bedtime.
c. Pharmacists may educate certain patients to self-titrate their insulin dose upon request from the referring physician

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

**Prandial Insulin Titration**

a. Consider initiating when FBG target is reached but A1c remains above goal or when total daily basal insulin dose exceeds 0.5 units/kg/day
b. Initial prandial insulin dose for most patients will be 4 units once daily before the largest meal of the day
    i. If A1c < 8%, consider reducing basal insulin dose by same amount
c. Additional doses of prandial insulin will be added before other daily meals as needed for post-prandial hyperglycemia

| **Prandial Insulin: Dose Titration Table** | |
|---|---|
| **Average 2-hour post-prandial blood glucose level for the past 7 days (mg/dL)** | **Dose Adjustment** |
| Greater than 180 | +2 units |
| Less than 180 | No Change |
| Lower than 80 or unexplained hypoglycemic episode | -2 to 4 units or 10 to 20% of dose, whichever is greater |

**Pre-Mixed Insulin Titration**

a. Initial pre-mixed insulin dose for most patients will be 10 units administered twice daily prior to morning and evening meals
b. If transitioning from basal insulin, divide current basal insulin dose into 2/3 AM, 1/3 PM or 1/2 AM, 1/2 PM

| **Pre-Mixed Insulin : Dose Titration Table** | | | |
|---|---|---|---|
| **Average fasting glucose level for the past 7 days (mg/dL)** | **Dose Adjustment (Pre-dinner dose)** | **Average pre-dinner glucose level for the past 7 days (mg/dL)** | **Dose Adjustment (Pre-breakfast dose)** |
| Greater than 180 | +6 units | Greater than 180 | +6 units |
| 141-180 | +4 units | 141-180 | +4 units |
| 111-140 | +2 units | 111-140 | +2 units |
| 80-110 | No Change | 80-110 | No Change |
| <80 | -4 units | <80 | -4 units |