The objective of the Joslin Diabetes Center & Joslin Clinic Clinical Guideline for Pharmacological Management of Type 2 Diabetes is to support clinical practice and influence clinical behavior to improve outcomes and assure quality of care according to accepted standards. The Guideline was established after careful review of current evidence, literature and clinical practice. This Guideline will be reviewed periodically and modified to reflect changes in clinical practice and available pharmacological information.

This Clinical Guideline is not intended to serve as a mandatory standard, but rather to provide a set of recommendations for patient care management. These recommendations are not a substitute for sound and reasonable clinical judgment or decision-making and do not exclude other options. Clinical care must be individualized to the specific needs of each patient and interventions must be tailored accordingly. The Guideline has been created to address initial presentations and treatment strategies in the adult non-pregnant patient population. The Guideline is not a substitution for full prescribing information. Refer to Joslin’s Clinical Guideline for Adults with Diabetes for additional, more comprehensive information on diabetes care and management.

### Diabetes Mellitus – Diagnostic Criteria (Non-Pregnant Adults)

- Random plasma glucose ≥ 200 mg/dl and symptoms of diabetes (polyuria, polydipsia, ketoacidosis, or unexplained weight loss) **OR**
- Fasting plasma glucose (FPG)* ≥ 126 mg/dl **OR**
- Results of a 2-hour 75-g Oral Glucose Tolerance Test (OGTT)* ≥ 200 mg/dl **OR**
- Glycated Hemoglobin (A1C) ≥ 6.5%**.

* These tests should be confirmed by a repeat test, on a different day, unless unequivocally high

** Only an A1C test that has been referenced to an accepted laboratory method (standardized) should be utilized for diagnostic purposes

### Goals of Glycemic Control for People with Diabetes

<table>
<thead>
<tr>
<th>Biochemical Index</th>
<th>Normal</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Plasma Glucose or Preprandial Glucose (mg/dl)</td>
<td>&lt; 100</td>
<td>70 – 130</td>
</tr>
<tr>
<td>2 hours Post-prandial (mg/dl)</td>
<td>&lt; 140</td>
<td>&lt; 180</td>
</tr>
<tr>
<td>Bedtime Glucose (mg/dl)</td>
<td>&lt; 120</td>
<td>90 – 150</td>
</tr>
<tr>
<td>A1C (%) sustained</td>
<td>&lt; 6%</td>
<td>&lt; 7%</td>
</tr>
</tbody>
</table>
INITIAL TREATMENT STRATEGY

Medical nutrition therapy (MNT), physical activity, blood glucose monitoring and patient education are the cornerstones of diabetes management for all patients. Pharmacological management should be used in combination with MNT and physical activity. Current weight status and lifestyle should be considered when choosing initial pharmacological therapy.

Initial Presentation (Based on characteristics listed within each box)

<table>
<thead>
<tr>
<th>Mild or no symptoms AND</th>
<th>FPG &gt; 150 mg/dl(^4) OR</th>
<th>Marked hyperglycemia OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative ketones AND</td>
<td>Random &gt; 250 mg/dl(^4) AND/OR</td>
<td>Significant weight loss OR</td>
</tr>
<tr>
<td>No acute concurrent illness AND</td>
<td>A1C &gt; 7.0%</td>
<td>Severe/significant symptoms OR</td>
</tr>
<tr>
<td>A1C ≤ 7.0%</td>
<td>Does not meet criteria for mild or severe</td>
<td>2+ or greater ketonuria OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DKA/ hyperosmolar state OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe intercurrent illness or surgery</td>
</tr>
</tbody>
</table>

- If after 6-8 weeks, target not met

Start MNT and physical activity and consider addition of metformin

See next page: CONSIDERATIONS FOR SELECTING NON-INSULIN GLUCOSE LOWERING MEDICATIONS

Start metformin. Choose alternate drug if metformin is contraindicated

Start insulin immediately\(^5\)

See page 5 – Add Insulin
### INITIAL THERAPY

<table>
<thead>
<tr>
<th>Medication</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metformin</td>
<td>Use only if renal/liver function normal. <strong>Contraindicated with:</strong> Creatinine &gt; 1.4 (women) &gt; 1.5 (men), IV contrast use, dehydration, alcohol excess, &gt; 80 years age (unless creatinine clearance allows)</td>
</tr>
<tr>
<td>Insulin Secretagogue (sulfonylurea or meglitinide)</td>
<td>Repaglinide or nateglinide are useful for patients with postprandial hyperglycemia or with hypoglycemia on sulfonylurea. <strong>Contraindicated:</strong> Creatinine &gt; 1.4 (women) &gt; 1.5 (men), IV contrast use, dehydration, alcohol excess, &gt; 80 years age (unless creatinine clearance allows)</td>
</tr>
<tr>
<td>α-Glucosidase Inhibitor</td>
<td>Use if postprandial hyperglycemia is the predominant hyperglycemic pattern. <strong>Contraindicated:</strong> Chronic intestinal disorders, acarbose in cirrhosis, acarbose and miglitol in renal impairment (creatinine &gt; 2.0)</td>
</tr>
<tr>
<td>Thiazolidinediones (TZDs)</td>
<td>Use if postprandial hyperglycemia is the predominant hyperglycemic pattern. Follow LFT monitoring schedule. Can be used in renal impairment but may increase fluid retention. Consider risk for bone loss and fracture. <strong>Contraindicated:</strong> Class III or IV CHF, LFTs &gt; 2.5 times upper limit of normal. See footnotes 8, 9, 13 for CV and other risks</td>
</tr>
<tr>
<td>Dipeptidyl Peptidase IV Inhibitors (DPP-4 Inhibitors)</td>
<td>Use if postprandial hyperglycemia predominates. Follow LFT monitoring schedule. Can be used in renal impairment but may increase fluid retention. Consider risk for bone loss and fracture. <strong>Contraindicated:</strong> Class III or IV CHF, LFTs &gt; 2.5 times upper limit of normal. See footnotes 8, 9, 13 for CV and other risks</td>
</tr>
<tr>
<td>GLP-1 agonist</td>
<td>Use if postprandial hyperglycemia predominates. To avoid hypoglycemia if using with a sulfonylurea or insulin glargine, consider initially decreasing sulfonylurea or glargine dose. <strong>Contraindicated:</strong> hx of pancreatitis</td>
</tr>
</tbody>
</table>

**Titrate dose over 1-6 months**

**Reinforce MNT and physical activity**

**If A1C >7% OR**
- Fasting plasma glucose >130mg/dl OR
- 2 hour postprandial glucose >180mg/dl

**Add second oral glucose lowering medication OR GLP-1 agonist OR insulin**

### ADJUNCT THERAPY

<table>
<thead>
<tr>
<th>Medication</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bile Acid Sequestrant (colesevelam)</td>
<td>Use as monotherapy or combination therapy. Most effective when used in combination with other antihyperglycemic medications. Modest effect on A1C. <strong>Contraindicated:</strong> Bowel obstruction, Serum triglyceride &gt; 500mg/dl, hx of hypertriglyceridemia-induced pancreatitis</td>
</tr>
<tr>
<td>Centrally Acting Agent (bromocriptine mesylate)</td>
<td>Use as monotherapy or combination therapy. Most effective when used in combination with other antihyperglycemic medications. Modest effect on A1C. <strong>Contraindicated:</strong> Bowel obstruction, Serum triglyceride &gt; 500mg/dl, hx of hypertriglyceridemia-induced pancreatitis</td>
</tr>
</tbody>
</table>

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ADVANCING GLUCOSE LOWERING MEDICATION THERAPY

A1C > 7.0% OR
Fasting Plasma Glucose > 130 mg/dl OR
2 Hour Postprandial Plasma Glucose > 180 mg/dl

Add:

- Consider starting with:
  - Intermediate-acting insulin (NPH) once or twice daily as part of a conventional program
  - Long-acting insulin (detemir or glargine) once or twice daily for basal therapy
  - Pre-supper insulin mixture (75/25 lispro, 50/50 lispro, 50/50 aspart, 70/30 aspart, or 70/30 human insulin)
- Suggested starting dose for insulin: 0.1-0.2 units/kg ideal body weight
- Titrate/adjust insulin dosage to achieve glucose goals

If target glucose not met after 2-4 months, consider:
- Combining exenatide with glargine
- Adding pre-meal rapid or short-acting insulin (e.g. aspart, glulisine, lispro or regular) to bedtime intermediate or long-acting insulin
- Adding basal insulin and adjusting the rapid or short-acting insulin as needed if taking pre-meal insulin and postprandial glucose targets are met, but fasting glucose is elevated
- Changing to multidose insulin therapy using combination of rapid, short, intermediate, or long-acting insulin
- Adding oral glucose lowering medication to improve glycemic control if already on insulin (metformin, TZDs, sulfonylureas or meglitinides, sitagliptin, α-glucosidase inhibitors, and Colesevelam are approved for use in combination with insulin)

- If post-prandial excursions predominate, refer to endocrinologist for intensification of therapy or for consideration of pramlintide use
GLUCOSE LOWERING MEDICATION COMBINATIONS

Suggested well-studied combinations based on results of clinical studies.
These do not preclude other combinations:

- metformin and insulin secretagogue **
- metformin and dipeptidyl peptidase IV inhibitors **
- metformin and GLP-1 agonists
- metformin and thiazolidinediones **, 9
- metformin and colesvelam

- sulfonylurea and α-glucosidase inhibitor
- sulfonylurea and dipeptidyl peptidase IV inhibitors
- sulfonylurea and GLP-1 agonists
- sulfonylurea and colesvelam

- dipeptidyl peptidase IV inhibitors and pioglitazone
- pioglitazone and sulfonylurea**, 9
- pioglitazone and repaglinide 9
- pioglitazone and GLP-1 agonists 9

- glargine and exenatide

* Also available in fixed combinations

Continued on next page
### ORAL GLUCOSE LOWERING MEDICATIONS AVAILABLE IN THE USA

<table>
<thead>
<tr>
<th>Biguanides</th>
<th>TZDs (Thiazolidinediones)</th>
<th>α-Glucosidase Inhibitors</th>
<th>Insulin Secretagogues</th>
<th>Dipeptidyl Peptidase IV Inhibitors (DPP-4 Inhibitors)</th>
<th>Bile Acid Sequestrant</th>
<th>Centrally Acting</th>
<th>Fixed Combinations</th>
</tr>
</thead>
</table>
| - liquid metformin* (Riomet)  
- metformin (Glucophage)  
- metformin extended release (Glucophage XR, Fortamet, Glumetza) (metformin and metformin ER available as generic medication)  
* Liquid formulation for patients unable to swallow pills | - pioglitazone (Actos)  
- rosiglitazone (Avandia)  
(glimepiride, glipizide and glyburide are available as generic medications) | - acarbose (Precose)  
- miglitol (Glyset)  
| Sulfonylureas  
- glimepiride (Amaryl)  
- glipizide (Glucotrol)  
- glipizide extended release (Glucotrol XL)  
- glyburide (Micronase, Diabeta)  
- micronized glyburide (Glynase)  
| - sitagliptin (Januvia)  
- Saxagliptin (Onglyza)  
- Linagliptin (Tradjenta)  
| - colesevelam (Welchol)  
| bromocriptine (Cycloset)  
| - metformin and glipizide (Metaglip)  
- metformin and glyburide (Glucovan)  
- metformin and pioglitazone (Actoplus met)  
- pioglitazone and glimepiride (Duetact)  
- rosiglitazone and glimepiride (Avandaryl)  
- rosiglitazone and metformin (Avandamet)  
| - sitagliptin and metformin (Janumet)  
- saxagliptin and metformin ER (Kombiglyze XR)  
- repaglinide and metformin (PrandiMet)  
- sitagliptin and simvastatin (Juvisync)  

Continued on next page
# Injectable Diabetes Medications Available in the USA

## Insulins

<table>
<thead>
<tr>
<th>Insulin Type</th>
<th>Product</th>
<th>Onset</th>
<th>Peak</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rapid-Acting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin aspart analog</td>
<td>NovoLog</td>
<td>10 – 30 minutes</td>
<td>30 minutes – 3 hours</td>
<td>3 – 5 hours</td>
</tr>
<tr>
<td>Insulin glulisine analog</td>
<td>Apidra</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin lispro analog</td>
<td>Humalog</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Short-Acting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Regular</td>
<td>Humulin R Novolin R</td>
<td>30-60 minutes</td>
<td>2 – 5 hours</td>
<td>up to 12 hours*</td>
</tr>
<tr>
<td><strong>Intermediate-Acting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human NPH insulin</td>
<td>Humulin N Novolin N</td>
<td>90 minutes – 4 hours</td>
<td>4 – 12 hours</td>
<td>up to 24 hours**</td>
</tr>
<tr>
<td><strong>Long-Acting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin detemir</td>
<td>Levemir</td>
<td>45 minutes -4 hours</td>
<td>Minimal peak</td>
<td>up to 24 hours ***</td>
</tr>
<tr>
<td>Insulin glargine</td>
<td>Lantus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Usual clinical relevance can be less than 12 hours
** Usual clinical relevance can be less than 24 hours. Often requires twice daily dosing
*** Individual response may require twice daily dosing

## Premixed Insulin Combinations

<table>
<thead>
<tr>
<th>Insulin Type</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>70% NPH; 30% Regular</td>
<td>Humulin 70/30</td>
</tr>
<tr>
<td>70% NPH; 30% Regular</td>
<td>Novolin 70/30</td>
</tr>
<tr>
<td>50% lispro protamine suspension, 50% lispro</td>
<td>Humalog Mix 50/50</td>
</tr>
<tr>
<td>75% lispro protamine suspension, 25% lispro</td>
<td>Humalog Mix 75/25</td>
</tr>
<tr>
<td>70% aspart protamine suspension, 30% aspart</td>
<td>Novolog Mix 70/30</td>
</tr>
</tbody>
</table>

## Incretin Mimetics and Non-Insulin Synthetic Analogs

<table>
<thead>
<tr>
<th>Product</th>
<th>Mechanism of Action</th>
<th>Type of Diabetes</th>
<th># of Injections Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exenatide (Byetta)</td>
<td>Incretin mimic that enhances glucose-dependent insulin secretion and several other antihyperglycemic actions of incretins.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Liraglutide (Victoza)</td>
<td>Incretin mimic that enhances glucose-dependent insulin secretion and several other antihyperglycemic actions of incretins</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Pramlintide (Symlin)</td>
<td>Synthetic analog of human amylin, a naturally occurring hormone made in the beta cells, which slows gastric emptying, suppresses glucagon secretion, and regulates food intake. A significant reduction in insulin dose may be required when insulin is used in conjunction with pramlintide.</td>
<td>1 and 2</td>
<td>1–4 (with meals)</td>
</tr>
</tbody>
</table>
Footnotes:

1Laboratory methods measure plasma glucose. Most glucose monitors approved for home use calibrate whole blood glucose readings to plasma values. Plasma glucose values are 10-15% higher than whole blood glucose values. It is important for people with diabetes to know whether their meters and strips record whole blood or plasma results.

2 Goals should be individualized based on the following, including: co-morbidity, age, duration of diabetes, hypoglycemic awareness.

3The true goal of care is to bring the A1C as close to normal as safely possible. A goal of < 7% is chosen as a practical level for most patients using medications that may cause hypoglycemia to avoid the risk of that complication. Achieving normal blood glucose is recommended if it can be done practically and safely.

4If diet history reveals markedly excessive carbohydrate intake, may consider initial trial of MNT and physical activity before initiating oral agent therapy even though glucose levels are above the thresholds listed.

5Some patients with type 2 diabetes initially stabilized on insulin may be considered for transition to non-insulin anti-hyperglycemic therapy as blood glucose control permits.

6A combination of two drugs of different classes may be used as initial pharmacotherapy when there is marked hyperglycemia or when MNT and physical activity alone have not resulted in an A1C of < 7.0%.

7FDA Requirements for LFT monitoring for thiazolidinediones (TZDs):
If initial ALT is > 2.5 times normal, do not start this medication
Once TZD is started, monitor ALT periodically thereafter according to clinical judgement.
If ALT is > 2.5 times normal during treatment, check weekly. If rise persists or becomes 3 times > normal, discontinue TZD.

8 Thiazolidinediones cause or exacerbate congestive heart failure in some patients. After initiation of TZDs and after dose increases, observe patients carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of the TZD must be considered. TZDs are not recommended in patients with symptomatic heart failure or in patients with established NYHA Class III or IV heart failure.

9 On September 23, 2010, the Food and Drug Administration (FDA) announced regulatory actions with respect to products containing rosiglitazone: Avandia® (rosiglitazone maleate) Tablets, Avandamet® (rosiglitazone maleate and metformin hydrochloride) Tablets and Avandaryl® (rosiglitazone maleate and glimepiride) Tablets. The FDA is requiring GlaxoSmithKline (GSK) to implement restrictions on the use of these products through a program to assure their safe use (i.e., Risk Evaluation and Mitigation Strategy or REMS) and additional safety labeling changes in response to the agency’s review of data that suggest an elevated risk of cardiovascular events. GSK will be working with the FDA to implement the agency’s requirement for a REMS and additional labeling changes. Additional information will be communicated when these measures are finalized. It will take several months to put the REMS program in place. Until the REMS program is in place, the FDA's decision allows current or potential users of rosiglitazone to continue or start using the medication after consultation with their health care provider about treatment options. Once the REMS program is in place a) Health care providers will need to be enrolled in the program in order to prescribe rosiglitazone containing products. b) Pharmacists will need to be enrolled in order to dispense rosiglitazone containing products. c) Patients will need to be enrolled in the program by their physician in order for them to begin or continue receiving rosiglitazone. d) Health care providers will have to attest to and document their patient's eligibility if they believe that their patient is a candidate for rosiglitazone. e) Patients will have to review statements describing the cardiovascular safety concerns with rosiglitazone and sign an acknowledgment of their understanding of the information. f) Current users of rosiglitazone will only be able to continue using the medication if they acknowledge and document that they understand the risks associated with the drug. g) Patients not already taking rosiglitazone can receive the medicine only if they are unable to achieve glycemic control on other medications and, in consultation with their health care provider, decide not to take pioglitazone for medical reasons.


10 If therapeutic goals are not met, consider starting insulin. Stop exenatide when starting insulin other than glargine.

11 May need to taper and discontinue some or all oral antihyperglycemic medications as insulin is initiated and adjusted, particularly if using short or rapid-acting and basal insulins.
Pre- and postprandial blood glucose should be checked. Frequency of checking may vary between 1-4 times/day depending on individual patient and status of glycemic control.

There is an increased risk for edema when insulin and a thiazolidinedione are used together. Rosiglitazone should not be used in combination with insulin.

Guideline Authors: Om Ganda, MD, Martin Abrahamson, MD, Jason Gaglia, MD, Richard Beaser, MD, Elizabeth Blair, ANP-BC, CDE, Alissa Segal Pharm D, CDE

Approved by Joslin Clinical Oversight Committee on 10/27/2011

Glossary and Common Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C</td>
<td>glycohemoglobin (hemoglobin A1C)</td>
</tr>
<tr>
<td>ALT</td>
<td>alanine aminotransferase</td>
</tr>
<tr>
<td>CHF</td>
<td>congestive heart failure</td>
</tr>
<tr>
<td>CV</td>
<td>cardiovascular</td>
</tr>
<tr>
<td>DPP-4</td>
<td>Dipeptidyl Peptidase IV Inhibitors</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FPG</td>
<td>fasting plasma glucose</td>
</tr>
<tr>
<td>G</td>
<td>gram</td>
</tr>
<tr>
<td>GLP-1</td>
<td>Glucagon-like peptide-1s secreted by the intestinal L cell in response to food intake, impacting glucose regulation.</td>
</tr>
<tr>
<td>HS</td>
<td>bedtime</td>
</tr>
<tr>
<td>Incretin</td>
<td>hormone produced by the gastrointestinal tract in response to food intake and necessary for glucose homeostasis</td>
</tr>
<tr>
<td>Incretin mimetics</td>
<td>a class of agents used for managing type 2 diabetes that mimics the enhancement of glucose-dependent insulin secretion and other glucoregulatory actions of naturally occurring incretins</td>
</tr>
<tr>
<td>Kg</td>
<td>kilogram</td>
</tr>
<tr>
<td>LDL-C</td>
<td>low density lipoprotein, cholesterol</td>
</tr>
<tr>
<td>LFT</td>
<td>liver function tests</td>
</tr>
<tr>
<td>MEN2</td>
<td>Multiple endocrine neoplasia type 2</td>
</tr>
<tr>
<td>Mg</td>
<td>milligram</td>
</tr>
<tr>
<td>Mg/dl</td>
<td>milligram per deciliter</td>
</tr>
<tr>
<td>MNT (Medical Nutrition Therapy)</td>
<td>Begins with assessment of overall nutrition status, followed by individualized prescription for treatment. Registered dietitian considers food intake, physical activity, course of any medical therapy, individual preferences and other factors.</td>
</tr>
<tr>
<td>Rx</td>
<td>treatment</td>
</tr>
<tr>
<td>TZDs</td>
<td>thiazolidinediones</td>
</tr>
</tbody>
</table>

Joslin Clinical Oversight Committee

<table>
<thead>
<tr>
<th>Chairperson</th>
<th>Ex officio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Om Ganda</td>
<td>Martin J. Abrahamson</td>
</tr>
<tr>
<td>Richard Beaser</td>
<td>Richard Jackson</td>
</tr>
<tr>
<td>Elizabeth Blair</td>
<td>William Sullivan</td>
</tr>
<tr>
<td>Amy Campbell</td>
<td>Howard Wolpert</td>
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<tr>
<td>Cathy Carver</td>
<td>John Zrebiec</td>
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<td>Martin J. Abrahamson</td>
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<td>David Feinbloom</td>
<td>Melinda Maryniuk</td>
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<td>William Hsu</td>
<td>Medha Munshi</td>
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References for Joslin’s Pharmacological Management of Type 2 Diabetes Guideline

Diagnosis


Goals of Glycemic Control and Pharmacotherapy


Oral Antihyperglycemic Therapy


**Metformin**


**Thiazolidinediones**


13. FDA Drug Safety Communication: Update to ongoing safety review of Actos (pioglitazone) and increased risk of bladder cancer; June 15, 2011

**Insulin Secretagogues**


**Alpha-Glucosidase Inhibitors**


**GLP-1 receptor agonists**


DPP-IV Inhibitors


Bile Acid Sequestrants


Combination Therapy with insulin


**Insulin**


**Pramlintide**


**Bromocriptine**