

Date: October 16, 2008

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D. Chairman DRC

At its 10/16/08 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected anti-diabetic agents.

**Non-insulin anti-diabetic agents under consideration**

First generation oral sulfonylureas

Chlorpropamide

Tolazamide

Tolbutamide

Second generation oral sulfonylureas

Glimepiride

Glipizide

Glyburide

Glyburide-micronized

Non-sulfonylurea secretagogues (meglitinides)

Nateglinide (Starlix)

Repaglinide (Prandin)

Thiazoladinediones

Pioglitazone (Actos)

Rosiglitazone (Avandia)

Newer agents

Exenatide (Byetta)

Pramlintide (Symlin)

Sitagliptin (Januvia)

**Indications under consideration in adults and children**

Diabetes mellitus

Pre-diabetes or metabolic syndrome

**Discussion**

The Committee concluded the following based upon its perception of the bulk of the best available evidence utilizing comparable doses where appropriate:

1. None of the captioned agents is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration.
2. At least one first generation sulfonylurea should be available.

3. At least one second generation sulfonylurea should be available, and if only one, then glyburide.

4. At least one meglitinide should be available.

5. At least one thiazolidinedione should be available, and if only one, then pioglitazone.

6. Relative to insulin, sulfonylureas, meglitinides, and thiazolidinediones there is relatively little data regarding the efficacy and toxicity of exenatide, pramlintide and sitagliptin. At this time, these three agents should not be considered as routine first or second line therapy and they should be used only after documented failure of optimal established treatments.

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