**9/14/2017 V14.1**

~~Change bicarb<=21 to bicarb<24 to be consistent with VA lab limits~~

**9/21/2017 V14.2**

Added more absolute contra ADR reactions to Glipizide; added absolute contra ADR rx to Biguanide, Pio

**9/22/2017 V14.3mkg**

Additional word choice corrections (tracked)

**10/2/2017 V14.4withComments**

Changes in response to v 14.3mkg

**10/2/2017 V14.5**

Same content as v14.4, but comments removed, changes accepted, tracking off; added “absolute contraindication” instead of simply “contraindicated/contraindication”; correction to Table 1; added text to distinguish One Drug Scenario cases (alphabetic) from Two Drug Scenario Cases (numeric) and link from Two Drug Scenario Cases to Two Drug Scenario Examples in Appendix.

**10/5/2017 v14.5**

Change, “In the event there are patients with **HbA1c < 6** or **glycosylated hemoglobin < 8**, they will receive an alert that these values are low.” To In the event there are patients with **HbA1c < 7** or **glycosylated hemoglobin < 9**, they will receive an alert that these values are low.” To be consistent with QA measures and other Medsafe project.

**10/17/2017 v14.5**

Replace SGOT with AST and replace SGPT with ALT

**10/19/2017 v15.0**

Additional messages for Metformin, Blocked add & blocked Increase dose; now there are 3 for each; one when no eGFR ever; one when eGFR>=45; one when eGFR<45

**11/7/2017 v15.1**

Update to Rules doc wrt input from Mary Goldstein; added to Rules doc additional text about ADR’s to sulfa and wish list item to consult with allergist/pharmacy;

Update to Rules doc wrt input from Stephen Ku; added footnote about keeping creatinine criteria for biguanide; added to Rules and encoded 2 primary messages when adding or increasing biguanide and eGFR<=45<60; added osteoporosis as relative contra to Pio, as well as cirrhosis

**11/9/2017 v15.1**

Continue Update to Rules doc wrt input from Stephen Ku: added GLP-1 agonist as bad drug partner of saxagliptin

**11/14/2017 v15.1**

Added, to existing ALERT when patient has active prescription of metformin and 30<=eGFR<45, to monitor eGFR every 3-4 months

**11.20/2017 v15.1**

Minor re-wording

**11/21/2017 v15.1**

Added message about sax and dose adjustment per Ku.

**1/9/2018 v16**

Add definition/clarification of “active prescription”

**1/16/2018 v16**

Clarification of start date of prescription.

**1/30/2018 v17**

Added Absolute contra = ADR anaphylaxis to biguanide; ADR anaphylaxis to pio or rosi; ADR anaphylaxis to SGLT2 inhibitors

**2/15/2018 v 17**

Added new message: "The CDS is display all possible therapeutic drug options. Please select one that is the most appropriate for the patient."

**3/19/2018 v17**

Changed out of scope line from: Patient has an active prescription for 3 or more oral hypoglycemic drugs

To: Patient has an active prescription for 3 or more **encoded** DM medications

**3/21/2018 v17**

Changes wrt bad drug partner

Out of scope condition #3 was:

Patient has an active prescription for two drugs, at least one of which is a DM medication, that are normally not prescribed together (these are “Bad drug partners,” described in the previous section)

Now

Patient has an active prescription for two drugs, at least one of which is a DM **encoded** medication, that are normally not prescribed together (these are “Bad drug partners,” described in the previous section) **and the DM encoded medication is not contraindicated**.

Definition of Bad Drug Partners was:

List of drugs that change, interfere with, or otherwise negatively affect the action of the listed DM drug. This may be a drug in the same class, a DM drug in a different class, or a drug in a different therapeutic area. Some action needs to be taken. In the evaluation of drugs to add, if a patient already has an active prescription of a bad drug partner, the candidate drug will be ruled out and will not appear as a therapeutic option. If a patient has active prescriptions for two drugs in the same class, there will be a message to stop one of the drugs, and no drugs will be recommended.

Now:

List of drugs that change, interfere with, or otherwise negatively affect the action of the listed DM drug. This may be a drug in the same class, a DM drug in a different class, or a drug in a different therapeutic area. Some action needs to be taken. In the evaluation of drugs to add, if a patient already has an active prescription of a bad drug partner, the candidate drug will be ruled out and will not appear as a therapeutic option. If a patient has active prescriptions for two **encoded** drugs in the same class, **and the drugs are not contraindicated,** there will be a message to stop one of the drugs, and no drugs will be recommended **(out of scope, described previously).  If a patient has active prescriptions for two encoded drugs in the same class and the drugs are contraindicated, then both drugs will be substituted.  If a patient has an active prescription for one encoded drug that is contraindicated and one drug that is used for a different therapeutic treatment (and is not a DM medication), the encoded drug will be substituted. If a patient has an active prescription of one encoded drug and a second prescription for a non-encoded drug, the patient is out of scope, as described previously, and we do not actually check that the encoded drug is contraindicated.**

**4/3/2018 v18 many changes; no 3 drug scenario**

Definition of bad drug partner now reads

List of drugs that change, interfere with, or otherwise negatively affect the action of the listed DM drug. This may be a drug in the same class, a DM drug in a different class, or a drug in a different therapeutic area. Some action needs to be taken. In the evaluation of candidate drugs to add, if a patient already has an active prescription of a bad drug partner of that candidate drug, the candidate drug will be ruled out and will not appear as a therapeutic option. The behavior of the CDS when the patient has active prescriptions of bad drug partners is described in the section ‘Two Drug Scenario”

~~Bicarb changes~~

* + ~~Bicarbonate < 24 or Bicarbonate<22 or Bicarbonate<23 in past year (cutoff value dependent upon actual laboratory measurement used)~~

Out of scope changes

* 1. Unchanged
  2. Unchanged.
  3. Patient has an active prescription for two drugs, only one of which is a DM encoded medication, that are normally not prescribed together (these are “Bad drug partners,” described in the previous section) and the DM encoded medication is not contraindicated
  4. unchanged

Addition to Two drug Scenario, include actions with bad drug partners

* Actions in the presence of bad drug partners:
  + As mentioned [Section 3.0](#_Drugs_Therapies), there will be no drug recommendations if the patient has active prescriptions of two drugs that are normally not taken together (“bad drug partners”), one of which is a DM medications and the other is not. Instead, there will be a primary message stating that the patient has active prescriptions for two drugs that are not normally taken together, and to please stop one. (Specific example: presence of pioglitazone and gemfibrozil).
  + If one of bad drug partners is a DM medication, and the other is not, and the DM medication is contraindicated, then there will be a substitution for the DM medication. (Specific example: presence of pioglitazone contraindicated and gemfibrozil).
  + If the bad drug partners are from the same DM medication class and are not contraindicated, there will be a message to stop one. In addition,
    - If one or both of the drugs are not at maximum dose, and its dose can be increased, we will recommend increasing dose (or blocked increase dose)
    - If one of the drugs is not at maximum dose, but it’s dose cannot be increased because of a “do not intensify uncontrollable” criteria, then we will recommend adding a drug
  + If the bad drug partners are from the same DM medication class and are contraindicated, we will recommend substituting both drugs

**4/10/2018 v18**

Change relative contraindication bicarb back to bicarb<24

Update Wish list (Appendix L)

Fix Reformatting issues with Appendix and Table of Contents; enable links in Reference section

**4/16/2018 v18**

Now using “first line drug, second line drug” rather than “compelling” and “relative” indications for drug evaluation/recommendations. (neglected to update earlier)

Include nph Insulin as out of scope, along with insulin and insulin syringe.

Now first line and second line drug are Presence of DM-2 OR Absence of DM-2 and Presence of DM-meds, to be consistent with eligibility of “pres of DM-2 or DM-meds”

Added definition of messages

**4/30/2018 v18.1**

Added to wish list order of displaying “add drug” before “increase dose”

Removed references to consultation action messages before definition of consultation action messages.

**5/1/2018 v18.1**

Added footnote that we used 24 as cutoff for bicarbonate for simplicity

**5/3/2018 v18.1**

Added 249.40, SECONDARY DIABETES MELLITUS WITH RENAL MANIFESTATIONS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED, to appendix icd9 code for DM-2

**5/31/2018 v19**

Updated eligibility section, no longer uses “exclusion”; filter of eligible patients to receive rec’s now in fixed order (change in KB); added Figure 1 to display order

**6/4/2018 v19.1**

Updated description of collateral messages, added message type; updated collateral messages for metformin, glipizide, pio but NOT sax and empa. Did not update Additional messages section.

**6/5/2018 v19.2a (ignore v19.2)**

Update messages for sax and empa. Changes from v18. 1 highlighted .

**6/7/2018 v19.2b**

Same as 19.2a, but removed highlight.

**6/12/2018 v19.3**

Section 3.3

The KB and execution engine evaluates patients on a fixed date. All diagnoses recorded before that date are considered and all laboratory values recorded *two years* before that date are used. This fixed date is referred to as the “session time.”

[no changes on next two paragraphs]

Update 6/12/2018: Fixing the session date alone, unfortunately, does not freeze the input medication data. As mentioned in section 3.1, Definitions, active prescriptions are those medications that have an RxStatus=”Active”, “Hold”, “Provider Hold” or “Suspended”, and the Issue date of the prescription (date prescription was written) is less than a year old. If a patient receives a new prescription after the session date, the old prescription is discontinued (because he/she has a new prescription). The new prescription is ignored because the issue date is after the session date, and the old prescription is also ignored because the RxStatus=Discontinued. In order to freeze all data, all data must be extracted and not be modified.

**6/19/2018 v19.3**

Added to wish list: Decrease dose of metformin at max dose and eGFR<45 (and >30) (from 6/19/2018 clinical meeting)

Was on wish list, but not added to this update list: Decrease dose of Sax if >2.5 and eGFR<45 in past year

New message type=”No drug recommendations”

**6/26/2018 v19.4**

Added another Limitation (section 2.3) Issue date of DM drug vs date of CDS recommendations

For the current CDS, we assumed that the patient had had his DM medication for a “reasonable” period of time, but was still not at goal. More specifically, we did not consider the issue date of a patient’s DM prescription relative to the date that we provided recommendations. That means that a patient could have received his/her new prescription (or medications) within the last few days. Any recommendations we provide would be, in such a situation, premature. Inclusion of the an issue date, or a consideration of an appropriate cut off date of “reasonable” period of time, is a wish list item, and listed in the Appendix.

Also added to wishlist

**7/3/2018 v19.4-UsedForOffline**

**7/3/2018 v19.5**

Changes based upon offline testing:

Section 2.2 Goals now reads:

* Glycemic Control: HbA1c <= 9 or glycosylated hemoglobin <= 11 in the past year

These goals were set to be consistent with PBM dashboard goals, which are based upon the goals set by the VHA Office of Reporting, Analytics, Performance, Improvement, and Deployment (RAPID) Performance Measurements. ~~Because the CDS is triggered only when the patient is not at goal, we would normally not evaluate the patient. For testing purposes, we included checks for patients who are at goal. In this case, and in the event that HbA1c < 7 or glycosylated hemoglobin < 9, these patients will receive an alert that these values are low.~~

Changed 2.2; see below

Section 4.0 Behavior CDS, on med, change “or” to “and” for clarity

* If the drug does not have an absolute contraindication, is not at maximum dose, and its dose cannot be increased because of a “do not intensify uncontrollable criteria”:
  + Then recommend adding metformin and other second line drugs
* If the drug does not have an absolute contraindication, and is at maximum dose:
  + Then recommend adding metformin and other second line drugs
* If the drug has an absolute contraindication:
  + Then substitute with metformin and other second line therapy

Section 4.0 Behaviour of CDS, RE: out of scope messages,

Multiple out of scope messages can be displayed, if multiple out of scope conditions are present~~. For example, a patient may have active prescriptions of both insulin and non-encoded drugs; two out of scope messages are issued.~~

Changed; see below

**7/9/2018 v19.5**

Changed all AST or ALT to AST and ALT for blocked conditions

Added eligibility HbA1c>9 or GlycHem>11

Need to fix Figure 1.

**7/10/2018 v19.5**

Section 2.2 Goals

Now reads:

## 2,2 Goals

* Glycemic Control: HbA1c <= 9 or glycosylated hemoglobin <= 11 in the past year

These goals were set to be consistent with PBM dashboard goals, which are based upon the goals set by the VHA Office of Reporting, Analytics, Performance, Improvement, and Deployment (RAPID) Performance Measurements. Because the CDS is triggered only when the patient is not at goal, the eligibility criteria, “HbA1c>9 or glycosylated hemoglobin>11” (See above) was selected to be consistent with this goal.

Figure 1 updated.

Section 4.0 Behaviour of CDS

Now

Therapeutic recommendations are NOT provided:

1. If a patient’s HbA1c or glycosylated hemoglobin is older than 1 year. Instead, we recommend that a new HbA1c is ordered.
2. If a patient has an active prescription of insulin or insulin syringe and therefore is “out of scope.”
3. If a patient has other out of scope conditions, a situation that occurs in one of the following possible conditions:
   1. Patient has active prescriptions for 3 or more encoded DM medications (encoded DM medications described above, under Limitations).
   2. Patient has an active prescription for one or more DM medications that are “non-encoded drugs”, described above, under Limitations (to clarify, even if the patient also has an active prescription for an encoded drug, the patient is considered “out of scope”[[1]](#footnote-1). )
4. Or if the following criterion is true:
   1. If a patient has active prescriptions of the following bad drug partners, a thiazolidinedione (pioglitazone) and gemfibrozil, and pioglitazone is not contraindicated.

When a patient is eligible but is “out of scope,” the health professional using the CDS will receive an “out of scope” message. This contrasts with patients who are ineligible (described in Section 2.1). There is no message issued explaining why the patient is not eligible.

The order of the listing of the criteria above is significant. The CDS processes to first find patients who are eligible. If a patient is eligible, then it checks to see if the HbA1c or Glycosylated Hemoglobin is present within the past year (#1 above). If *not*, then only an order for an HbA1c is issued. If an HbA1c within the past year is present, then the CDS checks for the presence of insulin or insulin syringe. (#2). If there is an active prescription of insulin or insulin syringe, then the “insulin out of scope” message is issued and there is no more processing. If insulin is not present, but, one or more of the other “out of scope” conditions are present (#3), then out of scope messages are issued and there is no more processing. Multiple out of scope messages can be displayed, if multiple out of scope conditions are present. For example, a patient may have active prescriptions of 3+ encoded drugs as well as an active prescription of non-encoded drugs; two out of scope messages are issued. If none of the “out of scope” conditions are present, then the CDS checks the other criteria (#4) i.e., whether or not pioglitazone and gemfibrozil are present. If pioglitazone and gemfibrozil are not present (#3), then the patient is evaluated for drug recommendations. See Figure 1.

More items to wish list, from offline testing

**7/16/2018 v19.6**

Removed from Biguanide absolute contra; to remove PALQuery

* + - Male and creatinine > 2.5 in the past 30 days or female and creatinine > 2.3 in the past 30 days[[2]](#footnote-2)

**7/17/2018 v19.6**

More changes from offline testing: now count 3+ encoded drugs from different drug classes as out of scope; not including metformin and metformin er and glipizide and glipizide er

**8/16/2018 v19.6**

If a patient does *not* have an active prescription of insulin, but *does* have a diagnosis of “Long term use of insulin” (icd9=V58.67, icd10=Z79.4), then we issue a message:

“Warning: recommendations do not apply to patients taking insulin.”

**8/21/2018 v19.7**

Decision from clinical meeting offline testing round 2:

Change for Glipizide, ADR renal failure or renal impairment to sulfonylurea or sulfa drug from Absolute Contraindication to Do not start condition

8/23/2018 v19.7

Email from Mike after change of glip ADR renal impairment or renal failure

Change, for Biguanide, ADR renal failure or renal impairment to MF from Absolute Contraindication to Do not start condition

**9/17/2018 v19.7**

Changed “not at goal” from eligibility criteria to “no drug rec” criteria. Changes in Fgiure 1.

**9/17/2018 v19.8**

Starts same as v19.7, but want to close 19.7.

**9/20/2018 v19.9**

Converted mkg version to v19.9; did a compare mkg and v19.8 and there were no differences BUT via inspect, MKG removed hidden text and xml.

Added to do: dorzolamide

**10/4/2018 v19.9**

Added caveat to start:

Note: text of messages in KB have been revised and are not exactly the same as written here

1. [↑](#footnote-ref-1)
2. [↑](#footnote-ref-2)