



CENTER FOR MEDICARE

TO: Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Part D Patient Safety Measures-Updated NDC lists

DATE: July 16, 2010

This memo focuses on updates to the specifications for the two patient safety Part D Plan Ratings, the High Risk Medication (HRM) measure and the Diabetes Treatment (DT) measure. The National Drug Code (NDC) lists for these measures have been updated by the Pharmacy Quality Alliance (PQA), and CMS will immediately begin using these updated NDC lists to calculate the measures. Rates will be calculated using these updated NDC lists beginning with the July 2010 report release for the 2009 measurement period on the Patient Safety Analysis website and for the Part D Plan Ratings for the 2011 open enrollment period. The changes at the drug name level are highlighted in red in Attachment 1: Medication Lists.

Background

There are currently four Part D patient safety measures used by CMS. Two of the measures, the HRM measure and the DT measure, are published as part of Part D Plan Ratings each Fall on the Medicare Prescription Drug Plan Finder (Plan Finder). Two additional patient safety measures, the Drug-Drug Interaction (DDI) measure and the Diabetes Medication Dosing (DMD) measure, are part of the Part D Display measures on the CMS website (<http://www.cms.hhs.gov>). Patient Safety reports are also produced for each of the patient safety measures on a monthly basis and are posted on the Patient Safety Analysis website for each Part D contract to access. The reports allow sponsors to compare their status to overall averages and monitor their progress in improving measures over time.

The HRM measure was first developed by the National Committee for Quality Assurance (NCQA), through its Healthcare Effectiveness Data and Information Set (HEDIS), and then adapted and endorsed by the PQA. The DT measure was adapted from the Diabetes Suboptimal Treatment measure which was first developed and approved by the Pharmacy Quality Alliance (PQA). The National Quality Forum (NQF) Consensus Standards Committee also endorsed this measure. There was a significant lag between the time that the PQA Diabetes Suboptimal Treatment measure specifications and drug lists were first developed, tested, and endorsed. In the meantime, CMS proactively updated the NDC lists to calculate the current measure rates. PQA has since updated the NDC lists, and in an effort to be consistent with the NDC lists for the endorsed measures, CMS will use the updated NDC lists now available from the PQA.

Sponsors will have the ability to download updated HRM and DT reports calculated using the updated NDC lists on the Patient Safety Analysis website during the July 2010 report release for the 2009

measurement period. Prior to posting the Part D Plan Ratings on the Plan Finder for the 2011 open enrollment period this Fall, there will be one to two preview periods to allow sponsors to review calculations of the ratings at the measure, domain, and summary levels. Sponsors should closely review these data to identify data issues and alert CMS of questions or issues. Information will be forthcoming soon on the Plan Ratings previews.

PQA is currently considering updates to the DDI and DMD measure specifications and drug lists. CMS will consider updates to these Part D Display measure calculations when available and will communicate any changes to sponsors.

Access to the Patient Safety Analysis Website

In order to gain access, if you do not already have it, to the Patient Safety Analysis website to download reports, sponsors should complete the following steps.

1. CMS' contractor, Acumen, LLC, currently manages multiple websites for Medicare Part D contracts, including this Patient Safety Analysis website. In accordance with Federal Information Security Management Act (FISMA) regulations, only the Medicare Compliance Officer is authorized to give access to these websites for each contract. To streamline this process, Acumen has developed the User Security website – a web tool that allows Medicare Compliance Officers to manage their users on the Part D websites. The current Medicare Compliance Officer for your organization should already have access to the User Security website through existing work with Acumen. If you have any questions, please contact Acumen at PartD@AcumenLLC.com or (650) 558-8006.
2. To authorize users for the Patient Safety Analysis website, the Medicare Compliance Officer must log onto the User Security website (https://partd.programinfo.us/User_Security) to:
 - Submit an Available User Request Form for each user.
 - Authorize access permissions for each user.
 - For security purposes, each contract is allowed up to 5 users.
3. Acumen will send authorized Patient Safety Analysis website users:
 - An email with the website user guide
 - A letter with login credentials via USPS

Any general questions related to the patient safety measures should be sent via email to PartDMetrics@cms.hhs.gov. For technical questions, including the access process for the Patient Safety Analysis website, please contact Acumen at PatientSafety@AcumenLLC.com or by phone at (650) 558-8006.

Attachment 1: Medication Lists

Part D drugs do not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) of the Act, except for smoking cessation agents. As such, these drugs were excluded from the analyses.

High Risk Medication Measure Medication List

Table A: High Risk Medications

| Description | Prescription | | |
|--|---|---|---|
| Antianxiety (includes combination medications) | • aspirin-meprobamate | • meprobamate | |
| Antiemetics | • scopolamine | • trimethobenzamide | |
| Analgesics (includes combination medications) | • | | • ketorolac |
| Antihistamines (includes combination medications) | <ul style="list-style-type: none"> • acetaminophen-diphenhydramine • diphenhydramine-magnesium salicylate • APAP/dextromethorphan/diphenhydramine • APAP/diphenhydramine/phenylephrine • APAP/diphenhydramine/pseudoephedrine • acetaminophen-diphenhydramine • carbetapentane/diphenhydramine/phenylephrine • codeine/phenylephrine/promethazine • codeine-promethazine • cyproheptadine • dexchlorpheniramine • dexchlorpheniramine/dextromethorphan/PSE • dexchlorpheniramine/guaifenesin/PSE • dexchlorpheniramine/hydrocodone/phenylephrine • dexchlorpheniramine/methscopolamine/PSE | | <ul style="list-style-type: none"> • dexchlorpheniramine-pseudoephedrine • dextromethorphan-promethazine • diphenhydramine • diphenhydramine/hydrocodone/phenylephrine • diphenhydramine-magnesium salicylate • diphenhydramine-phenylephrine • diphenhydramine-pseudoephedrine • hydroxyzine hydrochloride • hydroxyzine pamoate • phenylephrine-promethazine • promethazine • |
| Antipsychotic, typical | • | • thioridazine | |
| Amphetamines | <ul style="list-style-type: none"> • amphetamine-dextroamphetamine • benzphetamine • dexmethylphenidate | <ul style="list-style-type: none"> • dextroamphetamine • diethylpropion • methamphetamine • methylphenidate | <ul style="list-style-type: none"> • phendimetrazine • phentermine |
| Barbiturates | • butabarbital | <ul style="list-style-type: none"> • mephobarbital • pentobarbital • phenobarbital | • secobarbital |
| Long-acting benzodiazepines (includes combination medications) | <ul style="list-style-type: none"> • amitriptyline-chlordiazepoxide • chlordiazepoxide | <ul style="list-style-type: none"> • chlordiazepoxide-clidinium • diazepam | • flurazepam |
| Calcium channel blockers | • nifedipine—short-acting only | | |
| Gastrointestinal antispasmodics | • dicyclomine | • propantheline | |

Table A: High Risk Medications (continued)

| Description | Prescription | |
|--|--|--|
| Belladonna alkaloids (includes combination medications) | <ul style="list-style-type: none"> • atropine • atropine/hyoscyamine/PB/scopolamine • atropine/CPM/hyoscyamine/PE/scopolamine • atropine-difenoxin • atropine-diphenoxylate • atropine-edrophonium • belladonna | <ul style="list-style-type: none"> • belladonna/ergotamine/phenobarbital • butabarbital/hyoscyamine/phenazopyridine • digestive enzymes/hyoscyamine/ phenyltoloxamine • hyoscyamine • hyoscyamine/methenam/m-blue/phenyl salicyl • |
| Skeletal muscle relaxants (includes combination medications) | <ul style="list-style-type: none"> • ASA/caffeine/orphenadrine • ASA/carisoprodol/codeine • aspirin-carisoprodol • | <ul style="list-style-type: none"> • aspirin-methocarbamol • carisoprodol • chlorzoxazone • cyclobenzaprine • metaxalone • methocarbamol • orphenadrine |
| Oral estrogens (includes combination medications) | <ul style="list-style-type: none"> • conjugated estrogen • conjugated estrogen-medroxyprogesterone | <ul style="list-style-type: none"> • esterified estrogen • esterified estrogen-methyltestosterone • estropipate |
| Oral hypoglycemics | <ul style="list-style-type: none"> • chlorpropamide | <ul style="list-style-type: none"> • |
| Narcotics (includes combination medications) | <ul style="list-style-type: none"> • ASA/caffeine/propoxyphene • acetaminophen-pentazocine • acetaminophen-propoxyphene • belladonna-opium • meperidine | <ul style="list-style-type: none"> • meperidine-promethazine • naloxone-pentazocine • pentazocine • propoxyphene hydrochloride • propoxyphene napsylate |
| Vasodilators | <ul style="list-style-type: none"> • dipyridamole—short-acting only | <ul style="list-style-type: none"> • ergot mesyloid • isoxsuprine |
| Others (including androgens and anabolic steroids, thyroid medications, urinary anti-infectives) | <ul style="list-style-type: none"> • methyltestosterone • nitrofurantoin • nitrofurantoin macrocrystals | <ul style="list-style-type: none"> • nitrofurantoin macrocrystals-monohydrate • thyroid desiccated |

Note: Includes all dosage forms. Medication list updated based on NCQA/Hedis Table DAE-A (Hedis 2010) list; available at: <http://www.ncqa.org/tabid/1091/Default.aspx>.

Diabetes Treatment Measure Medication List

Table B: Oral Hypoglycemic, Insulin, Incretin Mimetics

| Biguanides and Biguanide Combination Products | | | |
|---|--|---|---|
| <ul style="list-style-type: none"> metformin pioglitazone & metformin rosiglitazone & metformin | <ul style="list-style-type: none"> repaglinide & metformin sitagliptin & metformin | <ul style="list-style-type: none"> glyburide & metformin glipizide & metformin | |
| Sulfonylureas and Sulfonylurea Combination Products | | | |
| <ul style="list-style-type: none"> acetohexamide chlorpropamide glipizide & metformin | <ul style="list-style-type: none"> glimepiride glipizide glyburide & metformin | <ul style="list-style-type: none"> glyburide rosiglitazone & glimepiride pioglitazone & glimepiride | <ul style="list-style-type: none"> tolazamide tolbutamide |
| Meglitinides and Meglitinide Combination Products | | | |
| <ul style="list-style-type: none"> nateglinide | <ul style="list-style-type: none"> repaglinide | <ul style="list-style-type: none"> repaglinide & metformin | |
| Alpha- Glucosidase Inhibitors | | | |
| <ul style="list-style-type: none"> acarbose | <ul style="list-style-type: none"> miglitol | | |
| Thiazolidinediones and Thiazolidinedione Combination Products | | | |
| <ul style="list-style-type: none"> pioglitazone pioglitazone & glimepiride | <ul style="list-style-type: none"> pioglitazone & metformin rosiglitazone | <ul style="list-style-type: none"> rosiglitazone & glimepiride rosiglitazon & metformin | |
| Incretin Mimetic Agents | | | |
| <ul style="list-style-type: none"> exenatide | | | |
| Amylin Analogs | | | |
| <ul style="list-style-type: none"> pramlintide | | | |
| DPP-IV Inhibitors and DPP-IV Inhibitor Combination Products | | | |
| <ul style="list-style-type: none"> sitagliptin | <ul style="list-style-type: none"> saxagliptin | <ul style="list-style-type: none"> sitagliptin & metformin | |
| Insulins | | | |
| <ul style="list-style-type: none"> insulin aspart insulin aspart Protamine & Aspart insulin detemir insulin glargine insulin glulisine | <ul style="list-style-type: none"> insulin isophane & regular human insulin insulin isophane (human N) insulin lispro insulin lispro Protamine & Insulin lispro insulin regular (human R) | <ul style="list-style-type: none"> insulin regular (human) buffered insulin regular inhalation powder insulin zinc (Lente) insulin zinc extended (human Ultralente) | |

Note: The active ingredients are limited to oral and injectable formulations only (includes all dosage forms).

Table C: Antihypertensive Agents

| Beta-Blocker Medications | | | |
|--|--|--|--|
| <ul style="list-style-type: none"> • acebutolol HCL • atenolol • betaxolol HCL • | <ul style="list-style-type: none"> • bisoprolol fumarate • carteolol HCL • carvedilol • labetalol HCL • | <ul style="list-style-type: none"> • metoprolol succinate • metoprolol tartrate • nadolol • nebivolol | <ul style="list-style-type: none"> • penbutolol sulfate • pindolol • propranolol HCL • timolol maleate |
| Beta-Blocker Combination Products | | | |
| <ul style="list-style-type: none"> • atenolol & chlorthalidone • bisoprolol & HCTZ | <ul style="list-style-type: none"> • metoprolol & HCTZ | <ul style="list-style-type: none"> • nadolol & bendroflumethiazide | <ul style="list-style-type: none"> • propranolol & HCTZ • timolol & HCTZ |
| Calcium-Channel Blocker Medications | | | |
| <ul style="list-style-type: none"> • amlodipine besylate • diltiazem HCL | <ul style="list-style-type: none"> • felodipine • isradipine | <ul style="list-style-type: none"> • nicardipine HCL • nifedipine (long acting only) | <ul style="list-style-type: none"> • nisoldipine • verapamil HCL |
| CCB Combination Products | | | |
| <ul style="list-style-type: none"> • amlodipine besylate & benazepril HCL • amlodipine & valsartan • | <ul style="list-style-type: none"> • enalapril maleate & felodipine • amlodipine & valsartan & HCTZ | <ul style="list-style-type: none"> • trandolopril & verapamil HCL • amlodipine & olmesartan • amlodipine & atorvastatin | <ul style="list-style-type: none"> • telmisartan & amlodipine |

Note: Active ingredients are limited to oral formulations only. Excludes the BB sotalol because it is indicated for the treatment of ventricular arrhythmias (and not for hypertension). Excludes CCB nimodipine since it has a limited indication for use following a subarachnoid hemorrhage.

Table D: ACE/ARB Medications

| ARB Medications | | | |
|--|--|---|---|
| <ul style="list-style-type: none"> • candesartan • eprosartan | <ul style="list-style-type: none"> • irbesartan • losartan | <ul style="list-style-type: none"> • olmesartan • telmisartan | <ul style="list-style-type: none"> • valsartan |
| ACE Inhibitor Medications | | | |
| <ul style="list-style-type: none"> • benazepril • captopril | <ul style="list-style-type: none"> • enalapril • fosinopril | <ul style="list-style-type: none"> • lisinopril • moexipril | <ul style="list-style-type: none"> • perindopril • quinapril • ramipril • trandolopril |
| ACE Inhibitor Combination Products | | | |
| <ul style="list-style-type: none"> • amlodipine & benazepril • benazepril & HCTZ • captopril & HCTZ | <ul style="list-style-type: none"> • enalapril & HCTZ • enalapril & felodipine • fosinopril & HCTZ | <ul style="list-style-type: none"> • lisinopril & HCTZ • moexipril & HCTZ • lisinopril & nutritional supplement | <ul style="list-style-type: none"> • quinapril & HCTZ • trandolopril-verapamil HCL |
| ARB Combination Products | | | |
| <ul style="list-style-type: none"> • candesartan & HCTZ • eprosartan & HCTZ • telmisartan & amlodipine | <ul style="list-style-type: none"> • irbesartan & HCTZ • losartan & HCTZ • amlodipine & olmesartan | <ul style="list-style-type: none"> • olmesartan & HCTZ • telmisartan & HCTZ • aliskiren & valsartan | <ul style="list-style-type: none"> • valsartan & HCTZ • amlodipine & valsartan • amlodipine & valsartan & HCTZ |

Note: Active ingredients are limited to oral formulations only.