REVIEW OF PHARMACY QUALITY ALLIANCE (PQA) RECOMMENDATIONS FOR DIABETES MEDICATION DOSING AND UTILIZATION IN MS MEDICAID

BACKGROUND

Pharmacy Quality Alliance (PQA) is a multi-stakeholder, consensus-based membership organization established in 2006 to collaboratively promote appropriate medication use and develop strategies for measuring and reporting performance information related to medications. PQA has developed quality measures in areas such as medication safety, medication adherence and appropriateness. Various PQA measures are included in the Centers for Medicare and Medicaid Services (CMS) Medicare Part D Star Rating system and in the CMS Medicaid Adult Core Set and Child Core Set of quality measures.

One of the performance measures currently being developed by PQA addresses diabetes medication dosing. Type 2 diabetes mellitus is a chronic disease characterized by hyperglycemia resulting from the combination of resistance to insulin action, inadequate insulin secretion, and excessive or inappropriate glucagon secretion. According to the Centers for Disease Control and Prevention (CDC) National Diabetes Statistics Report, 9.4% of the U.S. population had diabetes in 2015.[1] Diabetes' progressive nature can lead to increased rates of heart disease, stroke, blindness, kidney disease, amputations and death.[2] Despite a plethora of pharmacologic agents available to treat diabetes, some patients are inadequately maintained on high doses of oral hypoglycemic agents rather than adding additional agents to their therapy. Excessive dosages of oral diabetes medications have not been shown to have better efficacy and may cause adverse effects.

The PQA Diabetes Medication Dosing (DOS) measure examines the percentage of individuals who were dispensed a dose higher than the daily recommended maximum dose for more than 90 (cumulative) days during the measurement year for the following categories of oral diabetes medications: alpha-glucosidase inhibitors, biguanides, dipeptidyl peptidase-4 (DPP-4) inhibitors, meglitinides, sodium-glucose cotransporter-2 (SGLT-2) inhibitors, sulfonylureas and thiazolidinediones.[3]

METHODS

A retrospective analysis was conducted using Division of Medicaid (DOM) administrative claims from January 1, 2017 through December 31, 2017. Claims for fee-for-service (FFS) and both coordinated care programs (United Healthcare and Magnolia) were included. The PQA DOS draft specifications were used for the analysis. For combination ingredient products the measure is calculated separately for each active ingredient in the target classes.

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[1] CDC National Diabetes Statistics Report, 2017

[2] CDC. Diabetes: Working to reverse the US epidemic at a glance 2016. July 25, 2016. Available at: https://www.cdc.gov/chronicdisease/resources/publications/aag/diabetes.htm

[3] PQA Measure Specifications: Diabetes Medication Dosing (DOS) – Revised 2017

Denominator for measure (inclusion criteria):

- Age 18 years and above at the beginning of the measurement year
- Continuously enrolled (11+ months) during the measurement year
- Two or more prescriptions fills for the same active ingredient.
- The index prescription start date (IPSD) for the active ingredient is at least 91 days prior to the end of the measurement year.

Numerator for measure (exceptions to standard):

- Individuals in denominator where the daily dose for the active ingredient exceeded the maximum recommended daily dose (see Table 1) for more than 90 days (cumulative).

TABLE 1: Maximum Recommended Daily Doses[a]	
Alpha-Glucosidase Inhibitors	
Acarbose	300 mg/day
Miglitol	300 mg/day
Biguanides	
Metformin[b]	2,550 mg/day
Dipeptidyl Peptidase 4 (DPP-4) Inhibitors	
Alogliptin	25 mg/day
Linagliptin	5 mg/day
Saxagliptin	5 mg/day
Sitagliptin	100 mg/day
Meglitinides	
Nateglinide	360 mg/day
Repaglinide	16 mg/day
Sulfonylureas	
Chlorpropamide	750 mg/day
Glimepiride	8 mg/day
Glipizide IR[c]	40 mg/day
Glipizide XL[c]	20 mg/day
Glyburide[d]	20 mg/day
Glyburide, micronized[d]	12 mg/day
Tolazamide	1,000 mg/day
Tolbutaminde	3,000 mg/day
Sodium-glucose Contransporter-2 (SGLT-2) Inhibitors	
Canagliflozin	300 mg/day
Dapagliflozin	10 mg/day
Empagliflozin	25 mg/day
Thiazolidinediones	
Pioglitazone	45 mg/day
Rosiglitazone	8 mg/day

[a] *Sources: American Diabetes Association. Pharmacologic approaches to glycemic treatment. Diabetes Care. 2017; 40(Suppl. 1):S64-S74. doi: 10.2337/dc17-S011.*
Facts & Comparison eAnswers Online, Hudson, OH, Wolters Kluwer Clinical Drug Information, Inc.; 2017. Accessed 05/31/2017.

[b] *Metformin: The maximum daily dose used for this measure is the highest maximum daily dose across all metformin products.*

[c] *Glipizide: If an individual is receiving glipizide IR and glipizide XL concurrently, the maximum daily dose for days of concurrent use is 20 mg/day.*

[d] *Glyburide: If an individual is receiving glyburide and glyburide, micronized concurrently, the maximum daily dose for days of concurrent use is 12 mg/day.*

The number of exceptions to the measure were identified using the proposed PQA quality measure criteria. As with most quality measures, the standard for not meeting the measure (90 days or more above the recommended dose and continuous enrollment for observation year) are set fairly high to minimize false positives due to clinical situations that could occur and to assure that all people included in the denominator have an equal chance of being in the numerator. Conservative specifications like these are needed when comparing health plans to assure a fair comparison. MS-DUR also ran the analysis using less stringent criteria of 30 or more days exceeding the recommended daily dose and 2 or more months of eligibility. More than 30 days exceeding the recommended daily dose is sufficient to rule out false positives resulting from changing medication strengths shortly after a prescription refill and having what would appear to be two overlapping prescriptions for the same medication. Dropping the enrollment criteria to 2 months or more includes the maximum number of beneficiaries that could potentially be exceptions to the clinical rule. The less stringent criteria are more in line with what would be used for drug utilization management interventions and quality improvement initiatives and provide a better estimate of the potential impact of potential drug utilization management strategies.

RESULTS

Table 2 shows the number of beneficiaries taking each active ingredient and the number exceeding the recommended maximum daily dose for more than 90 days (highlighted columns) using the proposed PQA criteria. Using the 90-day criteria, few exceptions were identified.

TABLE 2: Number Beneficiaries Taking Medication and Exceeding Maximum Daily Dose for PQA Criteria of More Than 90 Days*

	FFS		UHC		MAG	
	Taking Medication	Exceeding Max Dose 91+ Days	Taking Medication	Exceeding Max Dose 91+ Days	Taking Medication	Exceeding Max Dose 91+ Days
Alpha-Glucosidase Inhibitors						
Acarbose	2	0	1	0	0	0
Biguanides						
Metformin	1,022	2	1,590	2	2,480	1
Dipeptidyl Peptidase 4 (DPP-4) Inhibitors						
Alogliptin	1	1	0	0	0	0
Linagliptin	28	1	38	1	113	2
Saxagliptin	15	1	42	0	79	0
Sitagliptin	90	0	134	0	182	0
Meglitinides						
Repaglinide	1	0	0	0	0	0
Sulfonylureas						
Chlorpropamide	0	0	1	0	0	0
Glimepiride	64	0	112	0	195	0
Glipizide IR	69	0	86	0	178	0
Glipizide XL	25	0	37	0	65	0
Glipizide IR/XL	1	0	7	0	12	1
Glyburide	75	0	139	0	188	0
Glyburide, micronized	1	0	1	0	3	0
Sodium-Glucose Contransporter-2 (SGLT-2) Inhibitors						
Canagliflozin	4	0	4	0	14	0
Dapagliflozin	1	0	2	0	10	0
Empagliflozin	25	0	55	0	82	0
Thiaxolidinediones						
Pioglitazone	26	1	40	0	66	0

** Includes beneficiaries 18 and older, enrolled at least 11 months during year, filling 2+ prescriptions for medication ingredient, and having first fill for active ingredient at least 91 days before end of year.*

Table 3 shows the number of beneficiaries taking each ingredient and exceeding the recommended daily dose when a 30-day limit and 2-month enrollment criteria are used. Using the alternate criteria, a small percentage of beneficiaries taking metformin are identified as exceeding the recommended dose. Only 54 beneficiaries were identified as exceeding the maximum daily dose when a 30-day limit and 2-month enrollment criteria were utilized.

TABLE 3: Number Beneficiaries Taking Medication and Exceeding Maximum Daily Dose for More Than 30 Days*

	FFS		UHC		MAG	
	Taking Medication	Exceeding Max Dose 30+ Days	Taking Medication	Exceeding Max Dose 30+ Days	Taking Medication	Exceeding Max Dose 30+ Days
Alpha-Glucosidase Inhibitors						
Acarbose	3	0	2	0	0	0
Biguanides						
Metformin	1,630	11	2,555	12	3,817	13
Dipeptidyl Peptidase 4 (DPP-4) Inhibitors						
Alogliptin	1	1	0	0	0	0
Linagliptin	46	1	56	1	153	4
Saxagliptin	22	1	48	0	100	0
Sitagliptin	137	0	212	0	261	4
Meglitinides						
Repaglinide	1	0	1	0	0	0
Sulfonylureas						
Chlorpropamide	0	0	1	0	0	0
Glimepiride	95	0	179	0	292	0
Glipizide IR	114	0	140	0	269	0
Glipizide XL	34	0	60	0	94	1
Glipizide IR/XL	2	0	10	0	14	1
Glyburide	102	0	181	0	264	2
Glyburide, micronized	1	0	1	0	3	0
Glyburide and miconized	0	0	0	0	0	0
Sodium-Glucose Contransporter-2 (SGLT-2) Inhibitors						
Canagliflozin	9	0	8	0	18	0
Dapagliflozin	2	0	4	0	17	1
Empagliflozin	51	0	111	0	154	0
Thiaxolidinediones						
Pioglitazone	39	1	53	0	93	0

** Includes beneficiaries 18 and older, enrolled at least 2 months during year, filling 2+ prescriptions for medication ingredient, and having 30+ days supply of active ingredient.*

CONCLUSIONS AND RECOMMENDATIONS

After applying both the PQA criteria and the modified lower criteria, very few exceptions were captured. Both FFS and the CCOs appear to have maximum daily dosage limits mirroring the PQA criteria currently in place in Mississippi Medicaid. MS-DUR recommends no additional changes be made at this time.