

AMCP Summary: *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*

Draft Released: *February 1, 2018*

Final Released: *April 2, 2018*

Effective Date: *January 1, 2019*

CMS Releases Final CY 2019 Call Letter, Finalizes New Strategies for Opioid Policy, Updates Standard Benefit Parameters to Account for New Coverage Gap Rules

On April 2, 2018 CMS released the [Final CY 2019 Call Letter for Medicare Advantage \(MA\) and Medicare Part D Plans](#). There were no substantial changes to the proposals included in the Draft Call Letter, which were finalized generally as proposed. However, the agency did have to update the Standard Benefit Parameters to reflect the changes to the coverage gap that were included in the Bipartisan Budget Act of 2018. CMS states that the updates made will continue to create more choices for Medicare beneficiaries that choose MA and Part D plans in 2019.

The provisions finalized in the Call Letter will apply to plans in the 2019 plan year.

New Strategies for Identifying Potential Opioid Abuse Finalized

For 2019, the following opioid overutilization policies will be in effect:

- Sponsors are expected to implement a hard safety edit at the point-of-sale (POS) that limits opioid naïve patients to an initial 7-day supply for the treatment of acute pain;
- Identify beneficiaries that use gabapentinoids in a dose greater than 2400 mg, in combination with prescription opioids (regardless of dose) for case management;
- Implement technical revisions to the Pharmacy Quality Alliance (PQA) measures used to evaluate plan sponsors' efforts to manage opioid abuse;
- Add the new PQA measure, Concurrent Use of Opioids and Benzodiazepines, to the Star Ratings system;
- Implement a real-time opioid care coordination safety edit, including documentation that the pharmacist had consulted with the prescriber, at the POS when a beneficiary's cumulative MME threshold exceeds 90 MME per day to engage patients and prescribers about overdose risk and prevention;
- Expect all sponsors to implement soft POS safety edits based on duplicative therapy of multiple long-acting opioids and request feedback on concurrent prescription opioid and benzodiazepine soft edits.

In response to comments from stakeholders, CMS will not finalize the proposal that all plan sponsors implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy at 90 morphine milligram-equivalent, with a 7-day supply allowance. Commenters raised concerns that a forcible/non-consensual dose reduction could negatively impact patients discontinuing a higher dose of opioids. Plan sponsors also raised concerns that the proposal would have little impact on overuse, as plans that had already implemented similar edits have seen an extremely high appeal approval rates. The proposed 7-day allowance was also opposed as potentially confusing and technically difficult to implement.

Additionally, CMS notes that plans will be required to follow the provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), including the ability to “lock in” beneficiaries to certain prescribers and pharmacies and apply beneficiary-specific edits at the POS.

Standard Benefit Parameters Altered to Account for Coverage Gap Changes, Biosimilar Manufacturers Expected to Pay Rebates in 2019

The Bipartisan Budget Act of 2018 changed the requirements for manufacturer rebates in the coverage gap for 2019. Under the Affordable Care Act, for 2019, manufacturers were scheduled to provide a 50% rebate while a beneficiary was in the coverage gap, with plan sponsors covering 20% of costs and beneficiaries responsible for the remaining 30%. Now, manufacturers will be required to provide a 70% rebate, while beneficiaries will be responsible for 25% of costs and plans will only be responsible for 5% of costs. For beneficiaries, this change “closes the donut hole” one year ahead of schedule; for manufacturers this change increases rebate liability, while plan sponsors will see cost relief.

Additionally, the Bipartisan Budget Act expanded the definition of drugs that were subject to the 70% manufacturer rebate to include biosimilars, which had previously been exempt (meaning that beneficiaries were responsible for 100% of costs of biosimilars in the coverage gap).

CMS notes that the agency plans to monitor the impact that these changes will have on plan costs overall, especially since plan sponsors will see a sharp reduction in cost liability. The agency plans to monitor drug utilization and the pace of progression of beneficiaries into the catastrophic phase of the benefit, which could include, but are not limited to: changes in generic drug uptake, formulary inclusion, tier composition, and substitutions.

Definition of Health-Related Supplemental Benefits for Medicare Advantage Plans Expanded

Currently, an item or service defined as a “supplemental health care benefit” is something that is not covered by Original Medicare, primarily health related, and something for which the MA plan must incur a non-zero direct medical cost. Beginning in 2019, MA plans may offer supplemental benefits covering a service or item that is “primarily health related.” In order to meet this new standard, the item or service must diagnose, prevent, or treat an illness or injury, compensate for physician impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. CMS believes this will give MA plans more flexibility in offering these supplemental benefits.

The call letter does state that the benefits offered under this broader interpretation must be medically appropriate and ordered by a licensed provider as part of a care plan if not directly provided by one. CMS says it will issue detailed guidance for MA organizations on this issue prior to the submission of 2019 bid submissions.

This expansion is in addition to a provision of the Bipartisan Budget Act of 2019, which expanded supplemental benefits for chronically ill beneficiaries beginning in 2020. The legislation allows coverage of items and services that are not “primarily health related,” but only for beneficiaries who are chronically ill. This expansion is separate from the expansion finalized above for 2019; CMS will provide additional guidance prior to the 2020 plan year bid submissions on defining the supplemental benefits eligible for coverage under this provision.

New Web Portal Launched to Help Plans Operationalize New Guidance on Coverage for Immunosuppressants

The Call Letter includes new guidance for Part D plan sponsors for performing due diligence when reviewing pharmacy claims for immunosuppressants. Immunosuppressants are one of several classes of drugs that are generally covered under Part D, but are covered under Part B when the patient has received an organ transplant paid for by Medicare. Sponsors have struggled with Part B/Part D coverage issues since the inception of the program; the new guidelines aim to resolve problems when Part D plan sponsors rely on prescribers for providing transplant coverage information.

- If the patient has no prior claims history with immunosuppressants, plans are expected to rely on information from CMS, or if the patient is covered under a Medicare Advantage plan, information from the patient’s health claims. If the plan cannot access information from CMS, or from the patient’s Medicare Advantage plan, the plan sponsor is expected to cover the prescription under Part D. The plan will no longer be required or expected to

reach out to prescribers for additional information, but if the plan already has received that information, they must use it when making a final coverage determination.

- If the patient has prior claims history for immunosuppressants, and CMS indicates that the patient received a transplant covered by Medicare, the plan must notify the patient that, going forward, their prescription will be covered under Part B. This is regardless of how the plan may have covered the prescription in the past.
- If the patient has prior claims history for immunosuppressants, and the plan does not have information from CMS or a MA plan regarding transplant coverage, but is made aware that Medicare covered the transplant during an audit, then going forward the plan will be required to cover the drugs under Part B, but no changes will be made to prior Part D claims.

In response to comments, CMS announced the launch of a new web portal, which will provide additional information to Part D plan sponsors on all Medicare-covered transplants, not just information on renal transplants. The portal, called Additional Beneficiary Information Initiatives (ABII) will be part of the web portal to which plan sponsors already have access.

Formulary Reference File to Drop Drugs Commonly Covered Under Part B and Drugs Rarely Covered Under Part D

In the draft Call Letter, CMS proposed to stop including drugs that are typically covered under Part B, and drugs that, based on historical claims data, are rarely covered under Part D (but are not statutorily excluded) on the Formulary Reference File (FRF). Because the FRF is used to populate information on the Medicare Plan Finder tool, it can cause confusion for beneficiaries when it is unclear whether a drug is covered under Part B or Part D.

On February 28, 2018, CMS released a draft FRF for 2019 that included a list of the drugs that were proposed for removal. A total of 375 drugs were proposed for deletion, with the largest category being antineoplastic drugs that are not usually self-administered. Commenters to the draft FRF noted that plan sponsors already use prior authorization to make sure that the drugs are covered under the correct benefit, and that deletion of the drugs from the FRF could negatively impact those utilization management edits. In response, CMS noted that plans are still able to cover drugs that are not on the FRF (provided they meet the definition of a Part D drug), and that formulary drugs that are not listed on the FRF may still be subject to utilization management.

Summer FRF Update Changes Delayed

Another administrative change proposed for the FRF was not finalized. CMS had proposed to shift the traditional mid-summer FRF update from July to August in order to give plans more time to add additional brand name or generic drugs (and change coverage of therapeutic alternatives). However, due to time constraints, the mid-summer update will remain unchanged. However, CMS will add an optional formulary submission window in the late Fall, prior to open enrollment, in order to address new product launches.

Expansion of Over-the-Counter Coverage Policy Shelved for Now

Currently, Part D plans are allowed to cover over-the-counter (OTC) drugs as part of a utilization management program that replaces a drug covered under Part D with the OTC drug. In the draft Call Letter, CMS noted that few plans offer OTC coverage and requested comments from stakeholders on ways that the agency could expand the benefit in the future to encourage broader coverage of OTC products when appropriate. Examples of products that could be included under such an expanded policy are dietary supplements or cough medicines.

Stakeholder comments were almost uniformly negative, with commenters citing increased program costs, the need for additional utilization management controls that could create access barrier for beneficiaries, and whether products such as dietary supplements were appropriate for coverage under Part D. In response, CMS has decided to table the issue for now.

In an Effort to Increase Vaccination Rates, CMS Urges \$0 Co-Pays

Noting that vaccination rates for some vaccines, especially herpes zoster, remain low, CMS reiterates that plans are “encouraged” to cover Part D vaccines at \$0 or the lowest co-payment tier for each plan.

CMS Finalizes Proposed Changes to Measures in Star Ratings

The following drug-related measures will be added for the 2019 Star Ratings:

- **Statin Use in Persons with Diabetes (SUPD) (Part D):** This measure is the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period.
- **Statin Therapy for Patients with Cardiovascular Disease (Part C):** This measure, currently included as a display measure, focuses on the percentage of males ages 21 to 75 and females ages 40 to 75 who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year.

The following includes changes to existing display measures:

- **High Risk Medication (Part D):** this measure will remain on the display page for 2019. However, as noted in the 2018 call letter, CMS is proposing to use the updated PQA High Risk Medication (HRM) drug list for that display.
- **Drug-Drug Interactions (DDI) (Part D):** the PQA updated the drug-drug interactions (DDI) so CMS is proposing to implement the revised list for the 2019 display measure, as discussed in the 2018 call letter.
- **Antipsychotic Use in Persons with Dementia (APD) (Part D):** CMS is proposing to display the rates for the two population breakouts (community-only residents and long-term nursing home residents) on the 2019 display page and state that they will assess adding this measure to the Star Ratings in the future.
- **Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP) (Part D):** this measure will be added to the 2019 Part D display page.

The following measure is being retired:

- **Appropriate Monitoring of Patients Taking Long-term Medications and Asthma Medication Ratio (Part C)**

CMS Maintains Increased Specialty Cost Threshold, Drops Concerns Over Number of High-Cost Drugs

CMS is proposing to maintain the specialty cost threshold at \$670 per month for 2018. Noting that ~1% of all prescription drug claims exceed the threshold, the agency stated that it will continue to review data to determine if additional increases are necessary.

2019 Part D Benefit Parameters – Standard Benefit

The majority of the Part D benefit parameters are indexed to an annual percentage increase (API) in average expenditures for Part D drugs. For 2019, this increase will be 1.94 percent. Maximum copayments and out of pocket thresholds are instead based on the consumer price index, and for 2019 will see increases of 1.78 - 1.83 percent.

For 2019, the standard benefit parameters are as follows. CMS notes that, due to changes in beneficiary cost-sharing requirements during the coverage gap, the estimated total drug spend when a beneficiary enters catastrophic coverage for non-LIS beneficiaries will drop \$767 from an estimated \$8,907 to \$8,140.

	2018	2019
Deductible <i>Beneficiary responsible for 100% of costs</i>	\$405	\$415
Initial Coverage Limit <i>Beneficiary responsible for 25% of costs; plan responsible for 75%</i>	\$3,750	\$3,820
Out-of-Pocket Threshold <i>Beneficiary liability during deductible, initial coverage limit, and coverage gap</i> <i>Manufacturer rebates during coverage gap</i>	\$5,000	\$5,100
Estimated Total Drug Spend When Beneficiary Enters Catastrophic Coverage – LIS beneficiaries*	\$7,509	\$7,654
Estimated Total Drug Spend When Beneficiary Enters Catastrophic Coverage – non-LIS beneficiaries*	\$8,418	\$8,140

Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit – Generic	\$3.35	\$3.40
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit – Other	\$8.35	\$8.50

**When a beneficiary's true out-of-pocket (TrOOP) costs reach the Out-of-Pocket Threshold (OOPT), the beneficiary enters catastrophic coverage. The total drug costs at the point when the beneficiary hits the OOPT (and enters catastrophic coverage) will vary for each beneficiary. The numbers presented here represent estimates calculated by CMS of the total drug costs (including OOP costs, manufacturer rebates, and plan-covered costs) the average beneficiary will spend before qualifying for the catastrophic coverage portion of the benefit.*

Part D Benefit Parameters – Non-Standard Benefit

Maximum copayments for both generic drugs and brands stay stable.

	2018	2019
Maximum Copayments (3 or more Tiers)		
Preferred Generic	<\$20	<\$20
Generic Tier	\$20	\$20
Preferred Brand/Brand Tier	\$47	\$47
Non-Preferred Drug Tier	\$100	\$100
Non-Preferred Brand Tier	\$100	\$100
Injectable Tier	\$100	\$100
Select Care/Diabetic Tiers	\$11	\$11
Maximum Co-Insurance (3 or More Tiers)		
Preferred Generic Tier	25%	25%
Generic Tier	25%	25%
Preferred Brand Tier/Brand Tier	25%	25%
Non-Preferred Drug Tier	50%	50%
Non-Preferred Brand Tier	50%	50%
Injectable Tier	33%	33%
Select Care/Diabetes Tier	15%	15%