

# COVID-19 Vaccine and Monoclonal Coverage: A Focus of the 2023 Medicare Physician Fee Schedule Proposed Rule

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The Centers for Medicare & Medicaid Services (CMS) recently issued the Medicare Physician Fee Schedule (PFS) proposed rule for calendar year (CY) 2023,[1] which clarified the timeline for increased COVID-19 vaccine administration fees and coverage of monoclonal antibody (mAb) products for the remainder of the public health emergency (PHE) and into the future.

The CY 2023 PFS proposed rule will become effective in 2023, and the deadline for public comment is September 6, 2022.

More broadly, CMS has reiterated that its goal for CY 2023 includes program expansions that create a more equitable health care system by providing “better accessibility, quality, affordability, and innovation.”[2] CMS’s CY 2023 PFS proposed rule highlights the federal agency’s goals to “promote broad and timely access” to both COVID-19 vaccines and mAb products.[3]

This *Insight* highlights four Medicare coverage and payment changes related to COVID-19 vaccines and mAb products in the CY 2023 PFS proposed rule and provides key takeaways for the commercialization of preventive vaccines and mAb products in the near future.

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## Focus Areas

### Services

Life Sciences  
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## Four Medicare Coverage and Payment Changes

### (1) Immunization Administration Fees Under Medicare Part B

Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, COVID-19 was added to the vaccine coverage benefit under Part B of the Medicare program.[4] In its CY 2022 PFS final rule,[5] CMS established payments under Part B for COVID-19 vaccine administration at \$40 per dose while existing preventive vaccines, such as pneumococcal, influenza, and Hepatitis B (HBV), remained at a payment rate of \$30.[6]

CMS continues its efforts to establish payment for vaccine administration for the long-term in the CY 2023 PFS proposed rule. Through 2021, vaccine administration payment rates for pneumococcal, influenza, or HBV vaccines were established using a crosswalk for similar services paid under the PFS. In its CY 2022 PFS final rule, CMS responded to commenter's concerns that the codes were improperly linked and did not reflect the unique costs of administering vaccines. Therefore, CMS finalized administration fees for non-COVID-19 vaccines (pneumococcal, influenza, and HBV) at \$30, while establishing a \$40 administration fee for COVID-19 vaccines.

CMS now proposes to update the payment for Part B vaccine administration by making adjustments to reflect cost differences for the geographic locality.[7]

CMS also proposes to continue the \$40 administration fee for COVID-19. The agency anticipates vaccinating providers will continue to experience rising costs associated with staffing, scheduling, and reporting requirements as the number of patients increases, especially as boosters remain an important tool in the COVID-19 response. While CMS previously intended to maintain increased payment for COVID-19 vaccine administration through the end of the PHE, it has determined this transition will occur on January 1 in the year following the termination of the March 27, 2020, Emergency Use Authorization Declaration ("EUA Declaration"). The payment rate for COVID-19 vaccine administration will then be set at a rate that aligns with other Part B preventive vaccine administration payment rates, which are currently at \$30.[8]

### (2) In-Home Administration Fees for COVID-19 Vaccines

In June 2021, CMS announced an add-on payment with a national rate of \$35 for COVID-19 vaccine in-home ("at-home") administration, bringing the national average for at-home COVID-19 vaccine administration payments to \$75 per dose (\$40 for the COVID-19 vaccine administration and an additional \$35 for administration in the home). By August 2021, CMS had expanded the circumstance for when the add-on payment was available, allowing providers and suppliers who administered the COVID-19 vaccine at a patient's home to bill Medicare. These policies were established to ensure beneficiaries received access to COVID-19 vaccines during the PHE.

After hearing multiple requests from commenters to extend the add-on payment past the PHE, CMS acknowledged in the CY 2022 PFS final rule that the costs of at-home COVID-19 vaccine administration would not diminish immediately after the PHE, thereby stating that it would allow the \$35 add-on payment to continue until the end of the calendar year of the PHE. CMS's CY 2023 PFS proposed rule suggests the continuation of the additional \$35 payment for at-home vaccination beyond the PHE, which allows the agency to maintain expanded COVID-19 vaccine access for vulnerable housebound beneficiaries. The CY 2023 PFS proposed rule also underscores the agency's need to better understand COVID-19 vaccine inaccessibility barriers in the Medicare population.[9]

While the CY 2023 PFS proposed rule provides a continuation of the additional \$35 payment for at-home COVID-19 vaccine administration, it does not include other preventive vaccines. CMS requests comments related to the inclusion of other Part B preventive vaccines (such as pneumococcal, influenza, and HBV).

### **(3) mAb Products Used for Treatment, and Post-Exposure Prophylaxis of COVID-19**

Once COVID-19 mAb products for treatment and post-exposure prophylaxis were granted EUAs, CMS's CY 2022 PFS final rule finalized coverage and payment for COVID-19 mAb products under the Part B vaccine benefit. Notably, this determination absolved beneficiaries of cost-sharing responsibility for both the mAb product and its administration.

The payment for administration of mAb products for treatment or post-exposure prophylaxis under Part B ranges between \$150.50 and \$750.00. CMS intends to continue coverage under the Part B vaccine benefit at these reimbursement levels until the EUA Declaration is terminated. In the year following termination of the EUA Declaration, CMS intends to then transition coverage of these products to ordinary system coverage for complex biological products under Part B.

### **(4) mAb Products Used for Pre-Exposure Prophylaxis for Prevention of COVID-19**

Following the CY 2022 PFS final rule, a mAb product was granted an EUA for use as pre-exposure prophylaxis prevention of COVID-19. Although the CMS policies regarding coverage of COVID-19 mAb products did not address mAb products used for prevention of COVID-19, the agency covered and paid for them without subjecting patients to out-of-pocket costs.

CMS proposes to continue coverage of preventive mAb products under the Part B vaccine benefit beyond the termination of the EUA Declaration, so long as a product has market authorization. CMS also proposes to maintain the current payment amounts for administration for pre-exposure

prophylaxis mAb products under Part B of either \$150.50 or \$250.50, depending on a product's administration setting.

## Key Takeaways

While the Biden administration has yet to detail plans for a full market transition for COVID-19 vaccines and therapeutics,<sup>[10]</sup> CMS's articulation of timelines for coverage of vaccines and monoclonals provides a degree of future payment clarity for these products under Medicare.

CMS's decision to cover mAb products the same as vaccines under the Part B benefit is potentially precedent setting as future prophylactic monoclonals are licensed.<sup>[11]</sup> The agency's decision to shift coverage of mAb products for treatment to ordinary biological product coverage under Part B means that patients will begin to bear out-of-pocket costs for these products once the EUA Declaration is terminated.

CMS's continued consideration of its methods for setting vaccine administration fees and intent to extend at-home administration add-ons provides opportunities for commenters to encourage policies that promote better access to vaccines for Medicare beneficiaries.

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## ENDNOTES

[1] CMS Proposed Rule, "CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies," 87 Fed. Reg. 45860 (July 29, 2022), available at <https://www.govinfo.gov/content/pkg/FR-2022-07-29/pdf/2022-14562.pdf> (hereinafter "CMS CY 2023 PFS Proposed Rule").

[2] CMS Fact Sheet, "Calendar Year (CY) 2023 Medicare Physician Fee Schedule Proposed Rule" (July 7, 2022), available at <https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-proposed-rule>.

[3] CMS CY 2023 PFS Proposed Rule, *supra* note 1, at 46225-46226.

[4] *Id.* at 46218.

[5] CMS Final Rule, “Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies” (Nov. 19, 2021), *available at* <https://www.federalregister.gov/documents/2021/11/19/2021-23972/medicare-program-cy-2022-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part>.

[6] CMS CY 2023 PFS Proposed Rule, *supra* note 1, at 46219.

[7] *Id.* at 46222.

[8] *Id.*; CMS uses this example: “[I]f the COVID-19 PHE ends in CY 2022, the payment amount for COVID-19 vaccine administration would change from \$40 to \$30 effective January 1, 2023, and would apply the proposed geographic adjustments and the proposed annual update as proposed for the other preventive vaccine administration services . . . .”

[9] Inaccessibility barriers include patients having a condition due to illness or injury that limits their ability to leave home without a device or help from a caregiver, a condition that makes the patient more likely to contract COVID-19, or the patient is generally unable to leave the home and if they do, they consider it “a considerable and taxing effort.” CMS CY 2023 PFS Proposed Rule, *supra* note 1, at 46223.

[10] See Richard Hughes, “As Congress, Biden administration squabble over COVID-19 funds, an ongoing pandemic response posture strains public health,” *HealthCareDive* (July 14, 2022), *available at* <https://www.healthcaredive.com/news/biden-administration-covid-19-funds-oped/627105/>.

[11] Sara Rosenbaum, “A Twenty-First Century Vaccines for Children Program,” *Health Affairs* (July 12, 2022), *available at* <https://www.healthaffairs.org/content/forefront/twenty-first-century-vaccines-children-program>.