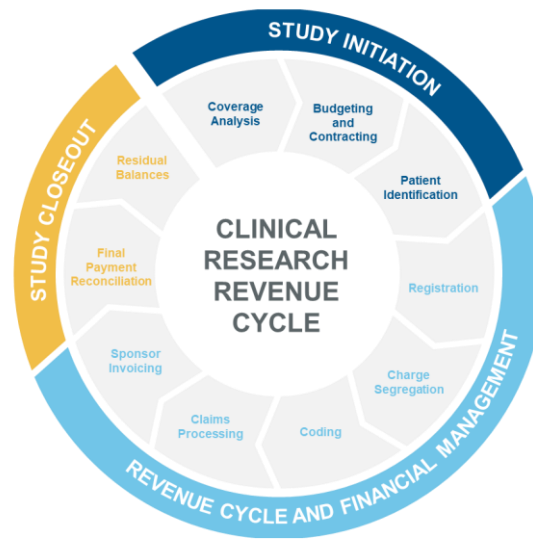


CLINICAL RESEARCH REVENUE CYCLE: APPLICABILITY OF GUIDANCE FROM CENTERS FOR MEDICARE & MEDICAID (CMS) AND OTHER INSURANCE COMPANIES RELATED TO COVID-19 REIMBURSEMENT

The confounding impacts of COVID-19 on healthcare systems, hospitals and academic health centers have resulted in responses from the Centers for Medicare & Medicaid Services (CMS) and other healthcare payors, including the exercise of regulatory and financial flexibility. To help institutions that conduct COVID-19 clinical trials keep up to date with the rapidly shifting landscape, Huron is collating a running list of guidance as it is released and highlighting the key takeaways from a clinical research revenue cycle perspective. The currently issued guidance are listed below. While these are broader than research, they do apply for trial services as well.



Study Initiation (or Re-Initiation)

1. [Reporting of COVID-19 Clinical Trial Data Through Quality Payment Program \(New Clinical Trials Improvement Activity\)](#)

Released 4/20/2020, updated 4/22/2020

Applicable Guidance: Clinicians who are contributing to scientific research and evidence to fight COVID-19 can participate in CMS' new program, the Quality Payment Program (QPP). Through this program, clinicians can earn credit in the Merit-Based Incentive Payment System (MIPS) to incentivize clinicians for participating in clinical trials and reporting clinical information by attesting to the new COVID-19 clinical trials improvement activity. QPP will provide vital data to help drive improvement in patient care and develop best practices to manage COVID-19. In order to receive credit, clinicians must attest that they participate in a COVID-19 clinical trial using a drug or biological product to treat and report their findings through a clinical data repository or registry for the duration of their study. Additional guidance may be found [here](#).

2. [CMS' Recommendations to Reopening Healthcare Systems in Areas With Low Incidence of COVID-19](#)

Released 4/19/2020

Applicable Guidance: CMS has issued guidance on providing essential non-COVID-19 care to patients without symptoms of COVID-19 in regions with low and stable incidence of COVID-19 as part of the administration's Guidelines for Opening Up American Again. The guidance recommends a gradual transition and encourages healthcare providers to coordinate with local and state public health officials, and to review the availability of their workforces, facility readiness and supplies when making the decision to restart or increase in-person care.

Revenue Cycle and Financial Management

Patient Registration

3. Major Commercial Insurance Companies Waive Patient Out-Of-Pocket Costs for Some or All Coronavirus Treatment and Testing

Applicable Guidance: CVS Health [announced](#) March 25 that it is waiving cost sharing and copays for inpatient hospital admissions for Aetna's commercially insured members effective immediately through June 1. Cigna and Humana [announced](#) March 29 that they are waiving cost sharing and copayments for all treatments related to COVID-19 through May 31 for Cigna customers. An end date for Humana has not yet been announced. UnitedHealthcare health insurance [announced](#) March 31 that it will waive member cost sharing for the treatment of COVID-19 through May 31 and cost sharing for in-network non-COVID-19 telehealth through June 18 for its fully-insured commercial, Medicare Advantage and Medicaid plans. The company also said it will work with its self-funded accounts to provide the same benefits. Blue Cross and Blue Shield (BCBS) [announced](#) April 2 that independent and locally operated BCBS across the country and the BCBS Federal Employee Program have decided to wave cost sharing for treatment of COVID-19 through May 31, which includes coverage for testing and treatment administered. Kaiser Permanente [announced](#) April 3 that it will waive all member out-of-pocket costs for the treatment of COVID-19-related inpatient and outpatient services effective April 1 through May 31.

4. Coronavirus Waivers and Flexibilities

Released 3/22/2020, updated 3/30/2020

Applicable Guidance: CMS announced it was approving Medicaid Section 1135 waivers to over 13 states in response to COVID-19. Examples of waivers under 1135 include suspending prior authorization requirements and extending existing authorizations for services.

5. High Deductible Health Plans and Expenses

Released 3/11/2020

Applicable Guidance: On March 11, the Internal Revenue Service advised that high-deductible health plans (HDHPs) can pay for COVID-19-related testing and treatment, without jeopardizing their status. This also means that an individual with an HDHP that covers these costs may continue to contribute to a health savings account (HSA). Furthermore, the IRS said that health plans that otherwise qualify as HDHPs will not lose that status merely because they cover the cost of testing for or treatment of COVID-19 before plan deductibles have been met. The IRS also noted that, as in the past, any vaccination costs continue to count as preventive care and can be paid for by an HDHP.

6. Families First Coronavirus Response Act

Released 1/3/2020

Applicable Guidance: Congress passed a bill eliminating the need for Medicare beneficiaries to pay their Part B deductible or coinsurance associated with COVID-19 testing and treatments, including the physician visit or other outpatient visit. The law also eliminates cost sharing for Medicare Advantage enrollees for both the

COVID-19 test and testing-related services and prohibits the use of prior authorization or other utilization management for these services.

Billing and Coding

[7. Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge](#)

Released 3/30/2020

Applicable Guidance: CMS is temporarily eliminating paperwork requirements to allow physicians to spend more time with their patients. Hospitals will not be required to have written policies on processes and visitation of patients who are in COVID-19 isolation. Medicare is also allowing payment coverage for respiratory devices and equipment for any medical reason determined by physicians.

[8. CMS Develops Additional Code for Coronavirus Lab Tests](#)

Released 3/5/2020

Applicable Guidance: CMS issued two Healthcare Common Procedure Coding System (HCPCS) codes for certain COVID-19 laboratory tests (HCPCS U0001 and U0002) in response to an urgent need to bill for these services. Both codes are effective February 4, 2020 and will be available in the Medicare claims processing system April 1, 2020.

Local Medicare administrative contractors (MACs) are responsible for developing the payment amount for claims they receive until Medicare has established national rates.

Claims Processing

[9. CMS Fact Sheet: Expansion of the Accelerated and Advance Payments Program for Providers and Suppliers During COVID-19 Emergency](#)

Released 3/31/2020

Applicable Guidance: To address cash flow issues caused by COVID-19, healthcare providers and suppliers will start to receive accelerated and advance payments from Medicare. Most providers will be able to request up to 100% of the Medicare payment amount for a three-month period. Inpatient acute care hospitals, children's hospitals and certain cancer hospitals can request up to 100% and critical access hospitals can request up to 125% of the Medicare payment amount for a six-month period. Medicare has also reduced the processing time for reimbursement to a maximum of seven days as opposed to the typical timeframe of three to four weeks. A step-by-step guide on how to request accelerated or advance payment is described in the fact sheet.

[10. Coverage and Payment Fact Sheet Related to COVID-19 Medicare](#)

Released 3/23/2020

Applicable Guidance: Regarding Medicare payment for laboratory tests and other services related to COVID-19, CMS clarifies topics such as the following: There is no special diagnosis-related group (DRG) for COVID-19, payment will be made for medically necessary extensions due to COVID-19, coverage will be allowed once a COVID-19 vaccine is available, etc. The fact sheet states Medicare Advantage is required to cover all Part A and B services related to COVID-19.

[11. Medicare Telemedicine Health Care Provider Fact Sheet](#)

Released 3/17/2020, updated 3/30/2020

Applicable Guidance: Starting March 6, 2020, and for the duration of COVID-19, Medicare will provide payments for telehealth services. These visits are considered the same as in-person visits and are paid at the same rate as regular in-person visits.

Furthermore, CMS will now pay for more than [80 additional services](#) when furnished via telehealth, which includes emergency department visits and discharge visits. CMS is also now allowing for visits to be done via telephone only and will cover these types of visits as they typically would for an in-person visit.

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Access other educational resources on our [COVID-19 resource page](#). For more information, [contact us](#).