#### Exhibit 361

# **New COVID-19 Treatments Add-On Payment (NCTAP)**

https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap



# New COVID-19 Treatments Add-On Payment (NCTAP)

CMS is planning for the end of the COVID-19 public health emergency (PHE), which is expected to occur on May 11, 2023. Review this page for information about Medicare payment during and after the PHE.

CMS issued an Interim Final Rule with Comment Period that established the New COVID-19 Treatments Add-on Payment (NCTAP) under the Medicare Inpatient Prospective Payment System (IPPS). The NCTAP, designed to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments, is effective from November 2, 2020, until September 30, 2023 (the end of the fiscal year in which the COVID-19 public health emergency (PHE) ends).

Through the NCTAP, Medicare will provide an enhanced payment through September 30, 2023, for eligible inpatient cases that use certain new products with current FDA approval or emergency use authorization (EUA) to treat COVID-19, including the following:

- Convalescent plasma: On August 23, 2020, the FDA issued (reissued on November 30, 2020, and revised on March 9, 2021) an <u>EUA for the use of</u> <u>COVID-19 convalescent plasma</u> for treating COVID-19 in hospitalized patients.
- VEKLURY® (remdesivir): On January 21, 2022, the FDA approved a supplemental New Drug Application (NDA) for VEKLURY, which expanded its use from adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization to certain non-hospitalized adults and pediatric patients for the treatment of mild-to-moderate COVID-19 disease. See the Federal Register announcement for more information about the revoked EUA and NDA approval.

- Olumiant® (baricitinib): On November 19, 2020, the FDA issued (and amended on December 20, 2021) an <u>EUA for the use of Olumiant</u> for the treatment of suspected or laboratory confirmed COVID-19 in certain hospitalized patients.
- Molnupiravir: On December 22, 2021, the FDA issued an EUA for molnupiravir for the treatment of mild-to-moderate COVID-19 in certain adults who are at high-risk for progression to severe COVID-19, including hospitalization or death.
- PAXLOVID<sup>TM</sup> (nirmatrelvir co-packaged with ritonavir): On December 23, 2021, the FDA issued an <u>EUA for PAXLOVID</u> for the treatment of mild-to-moderate COVID-19 in certain adults and pediatric patients at high risk for progression to severe COVID-19, including hospitalization or death. On July 6, 2022, the <u>FDA revised the EUA</u> to let pharmacists prescribe and dispense PAXLOVID to eligible patients without seeing a doctor or other clinician. Review the <u>Fact Sheet for Health Care Providers: EUA for PAXLOVID</u> for more information about the limits and conditions for pharmacists prescribing PAXLOVID.
- Kineret® (anakinra): On November 8, 2022, the FDA issued an EUA for Kineret injection for the treatment of COVID-19 in hospitalized adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low-or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR). Review the Fact Sheet for Healthcare Providers: EUA for Kineret for more information about the limits and conditions for pharmacists prescribing Kineret.

For eligible cases, the NCTAP is equal to the lesser of these:

- 65% of the operating outlier threshold for the claim
- 65% of the amount by which the costs of the case exceed the standard Diagnosis-Related Group (DRG) payment (including the adjustment to the relative weight under <u>Section 3710 of the Coronavirus Aid, Relief, and</u> <u>Economic Security Act (CARES Act)</u>

#### **Coding for NCTAP**

NCTAP claims are those that are eligible for the 20% add-on payment under Section 3710 of the CARES Act. Eligible claims have an ICD-10-CM diagnosis code U07.1 (COVID-19) and one of the following:

- ICD-10-PCS codes for VEKLURY (remdesivir), COVID-19 convalescent plasma, or Olumiant (baricitinib)
- National Drug Codes (NDC) for PAXLOVID (nirmatrelvir co-packaged with ritonavir) and molnupiravir

### Codes for VEKLURY or COVID-19 Convalescent Plasma for Hospital Discharges on or after November 2, 2020

ICD-10-PCS Code	Description
XW033E5	Introduction of VEKLURY anti-infective into peripheral vein, percutaneous approach, new technology group 5
XW043E5	Introduction of VEKLURY anti-infective into central vein, percutaneous approach, new technology group 5
XW13325	Transfusion of convalescent plasma (nonautologous) into peripheral vein, percutaneous approach, new technology group 5
XW14325	Transfusion of convalescent plasma (nonautologous) into central vein, percutaneous approach, new technology group 5

#### Codes for Olumiant for Hospital Discharges between November 19, 2020 and December 31, 2020

ICD-10-PCS Code	Description
XW0DXF5	Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5
3E0G7GC	Introduction of other therapeutic substance into upper G.I. via natural or artificial opening
3E0H7GC	Introduction of other therapeutic substance into lower G.I. via natural or artificial opening

## Codes for Olumiant for Hospital Discharges on or after January 1, 2021

ICD-10-PCS Code	Description
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6

#### Codes for PAXLOVID for Hospital Discharges on or after December 23, 2021

National Drug Code	Description
00069108506	PAXLOVID (nirmatrelvir co-packaged with ritonavir)
00069108530	PAXLOVID (nirmatrelvir co-packaged with ritonavir)

NDCs are listed as 11-digit codes for hospital institutional billing

### Codes for Molnupiravir for Hospital Discharges on or after December 22, 2021

National Drug Code	Description
00006505506	molnupiravir
00006505507	molnupiravir

NDCs are listed as 11-digit codes for hospital institutional billing

### Codes for Kineret for Hospital Discharges on or after November 8, 2022

National Drug Code	Description
06665823407	Kineret (anakinra)

NDCs are listed as 11-digit codes for hospital institutional billing

Hospitals should report the ICD-10-PCS code(s) or NDC(s) for all products administered during the stay, even if the hospital got the product for free. Hospitals shouldn't report charges for products they got for free.

#### Note:

A hospital shouldn't seek additional payment on the claim for drugs or biologicals to treat patients with known or suspected COVID-19 that the government purchased or provided for free. See the CMS Medicare Claims Processing Manual, Pub. 100-04, Chapter 32, Section 67 (PDF).

For more information on COVID-19 diagnosis and procedure codes, visit the "Latest News" section of the MS-DRG Classifications and Software webpage.

You can also review our <u>COVID-19 FAQs (PDF)</u>, which include information on NCTAP and our implementation of <u>Section 3710 of the CARES Act</u>.



#### **Related Links**

CMS COVID-19 webpage

CMS COVID-19 FAQs

CMS COVID-19 toolkits

CDC COVID-19 website

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