Table 2e. Characteristics of Antiviral Agents That Are Approved or Under Evaluation for the Treatment of COVID-19

Last Updated: July 08, 2021

Dosing Regimens *The doses listed here are for approved indications or from reported experiences or clinical trials.*	**Adverse Events**	**Monitoring Parameters**	**Drug-Drug Interaction Potential**	**Comments and Links to Clinical Trials**
Remdesivir				
The doses and indications listed below come from the FDA product information. Please see Therapeutic Management of Hospitalized Adults With COVID-19 for the Panel's recommendations on when to use RDV. **For Hospitalized Adults and Children (Aged ≥12 Years and Weighing ≥40 kg)** *For Patients Who Are Not Mechanically Ventilated and/or on ECMO:* • RDV 200 mg IV[a] on Day 1, then RDV 100 mg IV on Days 2–5 • For patients who do not show clinical improvement after 5 days of therapy, treatment may be extended to up to 10 days. *For Mechanically Ventilated Patients and/or Patients on ECMO:* • RDV 200 mg IV[a] on Day 1, then RDV 100 mg IV on Days 2–10 **Suggested Dose in EUA[b] for Hospitalized Children** *For Patients Weighing 3.5 kg to <40 kg:* • RDV 5 mg/kg IV[a] on Day 1, then RDV 2.5 mg/kg IV once daily starting on Day 2	• Nausea • ALT and AST elevations • Hypersensitivity • Increases in prothrombin time • Drug vehicle is SBECD, which has been associated with renal and liver toxicity. SBECD accumulation may occur in patients with moderate or severe renal impairment. • Each 100 mg vial of RDV lyophilized powder contains 3 g of SBECD, and each 100 mg/20 mL vial of RDV solution contains 6 g of SBECD. • Clinicians may consider preferentially using the lyophilized powder formulation (which contains less SBECD) in patients with renal impairment.	• Infusion reactions • Renal function and hepatic function should be monitored before and during treatment as clinically indicated. • In the FDA product information, RDV **is not recommended** when eGFR is <30 mL/min. See the Remdesivir section for a discussion on using RDV in people with renal insufficiency. • RDV may need to be discontinued if ALT level increases to >10 times ULN and should be discontinued if there is an increase in ALT level and signs or symptoms of liver inflammation are observed.[1]	• Clinical drug-drug interaction studies of RDV have not been conducted. • In vitro, RDV is a substrate of CYP3A4, OATP1B1, and P-gp and an inhibitor of CYP3A4, OATP1B1, OATP1B3, and MATE1.[1] • Minimal to no reduction in RDV exposure is expected when RDV is coadministered with dexamethasone (Gilead Sciences, written communication, July 2020). • CQ or HCQ may decrease the antiviral activity of RDV; coadministration of these drugs **is not recommended.**[1] • No significant interaction is expected between RDV and oseltamivir or baloxavir (Gilead Sciences, personal and written communications, August and September 2020).	• RDV should be administered in a hospital or a health care setting that can provide a similar level of care to an inpatient hospital. • RDV is approved by the FDA for the treatment of COVID-19 in hospitalized adult and pediatric patients (aged ≥12 years and weighing ≥40 kg). • An EUA[b] is available for hospitalized pediatric patients weighing 3.5 kg to <40 kg or aged <12 years and weighing ≥3.5 kg. • A list of clinical trials is available here: Remdesivir

Dosing Regimens *The doses listed here are for approved indications or from reported experiences or clinical trials.*	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
• For patients who are not mechanically ventilated and/or on ECMO, the duration is 5 days. If patients have not shown clinical improvement after 5 days, treatment may be extended to up to 10 days. • For mechanically ventilated patients and/or patients on ECMO, the recommended treatment duration is 10 days. *For Patients Aged <12 Years and Weighing ≥40 kg:* • Same dose as for adults				
Ivermectin				
Adults: • The dose most commonly used in clinical trials is IVM 0.2–0.6 mg/kg PO given as a single dose or as a once-daily dose for up to 5 days.	• Generally well tolerated • Dizziness • Pruritis • GI effects (e.g., nausea, diarrhea) • Neurological AEs have been reported when IVM has been used to treat parasitic diseases, but it is not clear whether these AEs were caused by IVM or the underlying conditions.	• Monitor for potential AEs.	• Minor CYP3A4 substrate • P-gp substrate	• Generally given on an empty stomach with water; however, administering IVM with food increases its bioavailability.[2] • A list of clinical trials is available here: Ivermectin
Nitazoxanide				

Dosing Regimens ***The doses listed here are for approved indications or from reported experiences or clinical trials.***	**Adverse Events**	**Monitoring Parameters**	**Drug-Drug Interaction Potential**	**Comments and Links to Clinical Trials**
Adults: • Doses reported in COVID-19 studies range from NTZ 500 mg PO 3 times daily to 4 times daily.[3,4] Higher doses are being studied (*ClinicalTrials.gov* Identifier NCT04746183). • Doses used for antiprotozoal indications range from NTZ 500 mg to 1 g PO twice daily.	• Generally well tolerated • Abdominal pain • Diarrhea • Headache • Nausea • Vomiting • Urine discoloration • Ocular discoloration (rare)	• Monitor for potential AEs.	• Drug-drug interactions may occur if NTZ is administered concurrently with other highly plasma protein-bound drugs due to competition for binding sites.[5] • If NTZ is coadministered with other highly protein-bound drugs with narrow therapeutic indices, monitor the patient for AEs.	• NTZ should be taken with food. • The oral suspension is not bioequivalent to the tablet formulation. • A list of clinical trials is available here: Nitazoxanide

[a] Infuse over 30–120 minutes.

[b] The FDA EUA permits the emergency use of RDV for the treatment of suspected COVID-19 or laboratory-confirmed SARS-CoV-2 infection in hospitalized pediatric patients weighing 3.5 kg to <40 kg or aged <12 years and weighing ≥3.5 kg.[6]

Key: AE = adverse event; ALT = alanine transaminase; AST = aspartate aminotransferase; CQ = chloroquine; CYP = cytochrome P450; ECMO = extracorporeal membrane oxygenation; eGFR = estimated glomerular filtration rate; EUA = Emergency Use Authorization; FDA = Food and Drug Administration; GI = gastrointestinal; HCQ = hydroxychloroquine; IV = intravenous; IVM = ivermectin; LPV/RTV = lopinavir/ritonavir; MATE = multidrug and toxin extrusion protein; NTZ = nitazoxanide; OATP = organic anion transporter polypeptide; the Panel = the COVID-19 Treatment Guidelines Panel; P-gp = P-glycoprotein; PO = orally; RDV = remdesivir; SBECD = sulfobutylether-beta-cyclodextrin; ULN = upper limit of normal

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

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 the end of the COVID-19 public health emergency (PHE).

Through the NCTAP, the Medicare Program will provide an enhanced payment 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:

- On August 23, 2020, the FDA issued (reissued on November 30, 2020, and revised on March 9, 2021) an EUA for the use of COVID-19 convalescent plasma for treating COVID-19 in hospitalized patients
- On October 22, 2020, the FDA approved remdesivir (Veklury) for the treatment of COVID-19 for adults and certain pediatric patients requiring hospitalization
- On November 19, 2020, the FDA issued an EUA for the use of baricitinib (Olumiant), in combination with remdesivir (Veklury), for the treatment of suspected or laboratory confirmed COVID-19 in certain hospitalized patients

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 Section 3710 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

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 both of the following:

- ICD-10-CM diagnosis code U07.1 (COVID-19)
- ICD-10-PCS codes for remdesivir (Veklury), COVID-19 convalescent plasma, or baricitinib (Olumiant) in combination with remdesivir, as described below

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

ICD-10-PCS Code	Description
XW033E5	Introduction of remdesivir anti-infective into peripheral vein, percutaneous approach, new technology group 5
XW043E5	Introduction of remdesivir 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 Baricitinib 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

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ICD-10-PCS Code	Description
3E0H7GC	Introduction of other therapeutic substance into lower G.I. via natural or artificial opening

*In accordance with the EUA, providers should administer baricitinib with remdesivir. Claims should also include the code for remdesivir (XW033E5 or XW043E5).

Codes for Baricitinib for Hospital Discharges on or after January 01, 2021 through the End of the COVID-19 PHE*

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

*In accordance with the EUA, providers should administer baricitinib with remdesivir. Claims should also include the code for remdesivir (XW033E5 or XW043E5).

Hospitals should report the ICD-10-PCS code(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 COVID-19 FAQs (PDF), which include information on NCTAP and our implementation of Section 3710 of the CARES Act.

Related Links

- CMS COVID-19 webpage
- CMS COVID-19 FAQs
- CMS COVID-19 toolkits
- CDC COVID-19 website

Page Last Modified: 04/21/2021 03:17 PM

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