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

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• 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				

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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