INFORMATION FOR PAYER AND TRADE ORGANIZATIONS

# Emergency Use Authorization of remdesivir (GS-5734™)

**The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of remdesivir to treat coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 infection. In response, the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the unapproved product, remdesivir, for the treatment of COVID-19.**

Remdesivir is an investigational drug that has not been approved by the FDA for any use. It is not yet known if remdesivir is safe and effective for the treatment of COVID-19.

Remdesivir is authorized for use under an EUA only for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. Severe disease is defined as patients with an oxygen saturation (SpO2) ≤94% on room air or requiring supplemental oxygen, mechanical ventilation, and/or extracorporeal membrane oxygenation (ECMO). Remdesivir is authorized for adult or pediatric patients who are admitted to a hospital and for whom use of an intravenous (IV) agent is clinically appropriate. Remdesivir must be administered intravenously.

For information on the authorized use of remdesivir and mandatory requirements of the EUA, please review the Fact Sheet for Healthcare Providers (HCPs) available at www.gilead.com/remdesivir.

**Remdesivir is being supplied through an agreement between Gilead Sciences, Inc., and the United States government. There is no charge to hospitals acquiring remdesivir through this agreement.**

- The U.S. government will coordinate the donation and distribution of remdesivir to hospitals in regions most heavily impacted by COVID-19. Given the severity of illness of patients appropriate for remdesivir treatment and the limited availability of drug supply, hospitals with intensive care units and other hospitals that the government deems most in need will receive priority in the distribution of remdesivir. At this time, the U.S. government will work through the product distribution capabilities of AmerisourceBergen as the exclusive distributor for remdesivir. Gilead and AmerisourceBergen are not deciding which hospitals will receive remdesivir.
- Remdesivir will be distributed based on urgent need as determined by health, government, and regulatory agencies and used for individuals as directed by a patient's HCP, with appropriate guidance by the FDA. More information on how to access remdesivir under the EUA is available at www.remdesivir.com/us or by calling 1-877-987-4987.
- This use is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use, unless the authorization is terminated or revoked sooner.
- The distribution of remdesivir has been authorized only for the treatment of hospitalized patients with severe COVID-19. It is not authorized for the treatment of any other viruses or pathogens.

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## AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of HHS has declared a public health emergency that justifies the emergency use of remdesivir to treat COVID-19 caused by SARS-CoV-2. In response, the FDA has issued an EUA for the unapproved product, remdesivir, for the treatment of COVID-19.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that remdesivir may be effective for the treatment of COVID-19 in patients as specified in the Fact Sheet for HCPs available at www.gilead.com/remdesivir.

The FDA issued this EUA, requested by Gilead Sciences, Inc., and based on their submitted data. The FDA Letter of Authorization for the EUA is available at www.gilead.com/remdesivir.

## IMPORTANT INFORMATION

**This section provides a brief introduction to selected information on use of remdesivir under the EUA.**

- Remdesivir, a nucleoside ribonucleic acid (RNA) polymerase inhibitor, is authorized for use under an EUA only for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. Severe disease is defined as patients with an oxygen saturation (SpO2) ≤94% on room air or requiring supplemental oxygen, mechanical ventilation, and/or ECMO.
- Remdesivir is authorized for adult or pediatric patients who are admitted to a hospital and for whom use of an IV agent is clinically appropriate.

**This is not all of the important information for remdesivir. Since remdesivir is an investigational drug, full Prescribing Information is not available. The FDA has authorized distribution of this medicine with accompanying Fact Sheets, which can be accessed at www.gilead.com/remdesivir.**

## HOW SUPPLIED

**Remdesivir is manufactured in two ways:**

- Remdesivir for injection (100 mg) lyophilized powder in single-dose vials. Unopened vials of lyophilized powder can be stored below 30°C (86°F). The lyophilized powder must be reconstituted and diluted prior to use.
- Remdesivir injection (5 mg/mL) concentrated solution in single-dose vials. Unopened vials of the concentrated solution must be refrigerated (at 2°C to 8°C [36°F to 46°F]). The concentrated solution must be diluted prior to use.
- Once opened, do not reuse or save unused remdesivir lyophilized powder or solution for future use. This product contains no preservative.
- Remdesivir must be administered intravenously. See the Fact Sheet for HCPs for additional information on the storage, handling, preparation, and administration of remdesivir IV solution.

## DOSAGE AND ADMINISTRATION

Adult and pediatric patients ≥40 kg:
- For patients requiring invasive mechanical ventilation and/or ECMO, the suggested dose is a single loading dose of remdesivir 200 mg on Day 1 followed by once-daily maintenance doses of remdesivir 100 mg for 9 days.
- For patients not requiring invasive mechanical ventilation and/or ECMO, the suggested dose is a single dose of remdesivir 200 mg on Day 1 followed by once-daily maintenance doses of remdesivir 100 mg for 4 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days (up to 10 days total).
- Remdesivir is to be administered via intravenous infusion in a total volume of up to 250 mL 0.9% saline over 30 to 120 minutes.

Pediatric patients 3.5 kg to <40 kg:
For pediatric patients with body weight between 3.5 kg and <40 kg, use remdesivir for injection, 100 mg, lyophilized powder only. Refer to the Fact Sheet for HCPs for dosage and dose duration information for patients weighing <40 kg.

Pregnancy:
Remdesivir should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

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## DOSAGE AND ADMINISTRATION (CONT.)

Renal impairment:
Remdesivir is not recommended in adults and pediatric patients (>28 days old) with an estimated glomerular filtration rate (eGFR) <30 mL/min and in full-term neonates (≥7 days and ≤28 days old) with serum creatinine ≥1 mg/dL unless the potential benefit outweighs the potential risk. All adult and pediatric patients (>28 days old) must have an eGFR determined before dosing; full-term neonates (≥7 days to ≤28 days old) must have serum creatinine determined before dosing. Monitor renal function prior to initiating and daily during treatment with remdesivir.

Hepatic impairment:
It is not known if dose adjustment is needed in patients with hepatic impairment, and remdesivir should only be used in patients with hepatic impairment if the potential benefit outweighs the potential risk. Do not initiate remdesivir in patients with alanine aminotransferase (ALT) ≥5x the upper limit of normal (ULN); discontinue therapy in patients who develop ALT ≥5x ULN or ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or international normalized ratio (INR). Monitor hepatic function prior to initiating and daily during treatment with remdesivir.

Drug interactions:
Drug interaction trials of remdesivir and other concomitant medications have not been conducted in humans.

## OVERALL SAFETY SUMMARY

- Remdesivir is an unapproved investigational product, and there are limited clinical data available. Serious and unexpected adverse events may occur that have not been previously reported with remdesivir use.
- **Warnings:** In clinical studies with remdesivir, infusion-related reactions and liver transaminase elevations have been observed. Remdesivir should not be used in patients who are hypersensitive to any ingredient of remdesivir. If signs and symptoms of a clinically significant infusion reaction occur, immediately discontinue administration of remdesivir and initiate appropriate treatment. Do not initiate remdesivir in patients with ALT ≥5x ULN; discontinue therapy in patients who develop ALT ≥5x ULN or ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR.
- Patients should have appropriate clinical and laboratory monitoring to aid in early detection of any potential adverse events. Monitor renal and hepatic function prior to initiating and daily during therapy with remdesivir; additionally monitor serum chemistries and hematology daily during therapy. The decision to continue or discontinue remdesivir therapy after development of an adverse event should be made based on the clinical risk/benefit assessment for the individual patient. For additional information and mandatory adverse event reporting, please see the Fact Sheet for HCPs.

## ADVERSE EVENT REPORTING

HCPs and/or their designee are responsible for mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths occurring during remdesivir treatment and considered to be potentially attributable to remdesivir. These events must be reported within 7 calendar days from the onset of the event. MedWatch adverse event reports can be submitted to the FDA online at www.fda.gov/medwatch or by calling 1-800-FDA-1088.

## OUR COMMITMENT

Gilead is working closely with global health authorities and is focused on contributing our antiviral expertise and resources to help patients and communities impacted by COVID-19. Whenever possible, HCPs are encouraged to enroll patients in ongoing clinical trials for remdesivir. We have initiated two Phase 3 clinical trials of remdesivir and will continue working to evaluate its safety and efficacy in adults diagnosed with COVID-19.

FDA-approved Fact Sheets for HCPs and patients are available at www.gilead.com/remdesivir.

Additional information is also available at www.remdesivir.com/us.

**The most up-to-date information on COVID-19 can be found on the CDC webpage: www.cdc.gov/COVID19.**

**Reference:** 1. Remdesivir [EUA Fact Sheet]. Foster City, CA: Gilead Sciences, Inc.; 2020.



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