**DEPARTAMENTO DE SALUD DE PUERTO RICO**

**Remdesivir Request Form**

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| Hospital Name |  | | | | | | | | | |
| Date |  | | | | | Pharmacy License | | | |  |
| Patient ID (HIPAA compliant) |  | | | | |  | Adult | |  | Pediatric |
| Director of Pharmacy Name |  | | | | | # License | | | |  |
| Phone Num. | Email: | | | | | | | | | |
| Infectious Disease/Pulmonologist Name |  | | | | | # License | | | |  |
| Sign |  | | | | | | | | | |
| Quantity Requested |  | **11 *VIALS*** |  | **6 *VIALS*** |  | **5 *vials*** | | *only to complete therapy for pts with previous 6 vials dispensed* | | |

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| **PHYSICIAN GUIDANCE AND DRUG USE CRITERIA (DUC)**  Remdesivir use for the treatment of COVID-19 |
| **GUIDANCE FOR USE ARE BASED ON CLINICAL EVIDENCE AND EXPERT OPINION. THIS INFORMATION CAN CHANGE ON A DAILY BASE DURING THIS PANDEMIC AND WILL BE REVISED AS NEW INFORMATION BECOMES AVAILABLE. PRODUCT INFORMATION SHOULD BE CONSULTED.**   * FDA approved use of Remdesivir under Emergency Use Authorization (EUA), to permit the emergency use of the unapproved product for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in adults and children hospitalized with severe disease, according to the preliminary results of clinical trials included in the last section. * MOA: Is a nucleotide analog antiviral, has activity against Ebola virus, MERS- CoV, SARS – CoV and SARS – CoV-2. * **SHOULD BE MANAGE IN CONJUCTION WITH INFECTIOUS DISEASE AND/OR PULMONOLOGY SPECIALIST** * Providers are required to review The Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734). * As the health care provider, you must communicate to your patient or parent/caregiver information consistent with the “Fact Sheet for Patients and Parents/Caregivers” (and provide a copy of the Fact Sheet) prior to the patient receiving Remdesivir.   + Provider Fact Sheet: <https://www.fda.gov/media/137566/download>   + Patient Fact Sheet: <https://www.fda.gov/media/137565/download> |

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| **PRECAUTIONS** |
| * ALT levels > 5 X ULN   *Do not start treatment or D/C treatment if ALT levels > 5 X ULN.*   * Cr Clearance < 30 mL/min or dialysis   *The pharmacokinetics of remdesivir have not been evaluated in patients with renal impairment. Use in patients with renal impairment are based on potential risk and potential benefit considerations* |

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| **INCLUSION CRITERIA** |
| Patient should meet the following criteria   * Patient is hospitalized due to COVID-19 (confirmed or highly suspected based on clinical presentation and physician clinical judgement) with severe disease, define as:   + oxygen saturation **(SpO2) ≤ 94% on room air** or   + requiring supplemental oxygen or   + requiring mechanical ventilation or   + requiring extracorporeal membrane oxygenation (ECMO) * Case discussed with Infectious Disease Specialist and/or Pulmonologist   Prescriber should discuss and must document in the patient’s medical record that the patient/caregiver has been:   * Informed that remdesivir is an unapproved drug that is authorized for use under EUA. * Informed on risks, benefits and alternatives treatments * Given Fact Sheet for Patients and Parent/Caregivers: Emergency Use Authorization (EUA) of Remdesivir for Coronavirus Disease 2019 (COVID-19). Available in Pharmacy Department |

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| **MONITORING** |
| Prior to administration and then daily:   |  |  |  |  | | --- | --- | --- | --- | |  | CBC |  | CMP |   Prior to administration and then every 48 hours to monitor the progress of the condition.   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  | Ferritin |  | D-Dimer |  | CRP |  | LDH |   Document patient clinical status daily |

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| **DOSING** |
| **Note: The optimal duration of treatment for COVID-19 is unknown, suggestion according FDA EUA.**  **Adults**  Requiring invasive mechanical ventilation and/or ECMO   * ≥40 kg: 200 mg IV loading dose on **day 1**, then 100 mg IV daily for **9 days**.   Not requiring invasive mechanical ventilation and/or ECMO   * 200 mg IV loading dose on **day 1**, then 100 mg IV daily for **4 days.**   \*\* If a patient does not demonstrate clinical improvement, treatment **may be extended for up to 5 additional days** (i.e., up to a total of 10 days).  **SPECIAL POPULATION**: Remdesivir should be used during pregnancy only if potential benefits justify the potential risk for the mother and the fetus.  **Pediatric (Only use lyophilized powder only)**  Requiring invasive mechanical ventilation and/or ECMO   * 3.5 kg ≤ 40 kg: 5 mg/kg IV loading dose on day 1, then 2.5 mg/kg IV daily for 9 days * ≥40 kg: 200 mg IV loading dose on day 1, then 100 mg IV daily for 9 days   Not requiring invasive mechanical ventilation and/or ECMO   * 3.5 kg ≤ 40 kg: 5 mg/kg IV loading dose on day 1, then 2.5 mg/kg IV daily for 4 days * ≥40 kg: 200 mg IV loading dose on day 1, then 100 mg IV daily for 4 days   \*\* If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days (i.e., up to a total of 10 days).  Dosing administration IV   * Dilute in 100 - 250 mL 0.9% Sodium Chloride   + Lyophilized Powder in 100-250 ml 0.9 Sodium Chloride   + Remdesivir Solution (5mg/ml) in 250 ml 0.9% Sodium Chloride * Use a dedicated IV line (do not infuse with other medication) * Infuse solution over 120 minutes * After administration flush the line with 30 ml NSS |

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| **STORAGE AND STABILITY** |
| ***Lyophilized Powder***  Store remdesivir for injection, 100 mg, vials below 30°C (below 86°F) until required for use. Do not use after expiration date.  After reconstitution, vials can be stored up to 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) prior to administration or 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]). Dilute in 100 – 250 ml within the same day as administration.  ***Injection Solution***  Store remdesivir injection, 5 mg/mL, vials at refrigerated temperature (2°C to 8°C [36°F to 46°F]) until required for use. Do not use after expiration date. Dilute in 250 ml within the same day as administration.  **Prior to dilution, equilibrate remdesivir injection to room temperature (20°C to 25°C [68°F to 77°F]). Sealed vials can be stored up to 12 hours at room temperature prior to dilution.** |

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| **ADVERSE DRUG EVENTS** |
| **Note: Health care providers must submit a report on all medication errors and ALL SERIOUS ADVERSE EVENTS related to remdesivir, required by FDA.**  May include, but are not limited to:   * Infusion related reactions; signs and symptoms may include hypotension, nausea, vomiting, diaphoresis, and shivering   In this case stop the infusion and give supportive treatment.   * Phlebitis * Elevated liver function tests (ALT) Monitor daily * Headache * Constipation * Potential to have drug interactions with medications trough cytochrome system   Healthcare facilities and healthcare providers receiving remdesivir will track serious adverse events that are considered to be potentially attributable to remdesivir use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm), or Complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports should state, “use of remdesivir was under an EUA” at the beginning of the question “Describe Event” for further analysis. |

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| **REFERENCES** |
| Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment. Available at [https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment Accessed on 5/13/2020](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment%20Accessed%20on%205/13/2020)  Provider Fact Sheet. Available at <https://www.fda.gov/media/137566/download> Accessed on 5/13/2020  Patient Fact Sheet. Available at <https://www.fda.gov/media/137565/download> Accessed on 5/13/2020  Authorization use letter. Available at <https://www.fda.gov/media/137564/download> Accessed on 5/13/2020  Wang Y, Zhang D, Du G et al. [Remdesivir in adults with severe COVID-19: A randomised, double-blind, placebo, controlled, multicentre trial.](https://marlin-prod.literatumonline.com/pb-assets/Lancet/pdfs/S0140673620310229.pdf) The Lancet 2020; doi: https://doi.org/10.1016/ S0140-6736(20)31022-9.  Grein J, Ohmagari N, Shin D, et al. [Compassionate use of remdesivir for patients with severe Covid-19.](https://www.nejm.org/doi/pdf/10.1056/NEJMoa2007016?articleTools=true) N Engl J Med. doi: 10.1056/NEJMoa2007016. |