Emergency Use Authorization (EUA)

In a national emergency, like the current COVID-19 pandemic, it may not be possible to have all the evidence that the FDA would usually have before approving a drug, device, or a test. When there is a declared national emergency (i.e. COVID pandemic), the FDA can make a judgment that it's worth releasing an investigational drug or device for use even without all the evidence that would fully establish its effectiveness and safety. If there's evidence that strongly suggests that patients affected by the national emergency have benefited from a treatment or test, the agency can issue an EUA to make it available to the public. Below is information on the difference between EUAs versus when an investigational drug is used as part of the expanded access/compassionate use program (to include use in an emergency setting outside a declared national emergency), clinical trial is being conducted using an IND/IDE, use of Convalescent Plasma during the COVID pandemic, and a list of all investigational products for which the FDA has issued EUAs during the COVID pandemic. If you have questions on any of the below submission requirements, feel free to contact the IRB office: IRB@uthscsa.edu or 210-567-8250.

EUA vs IND/IDE

Regulatory Requirement	EUA (Emergency Use Authorization)	Expanded Access/ Treatment Protocol (Compassionate Use)	Investigational Research Protocols (IND/IDE)
Purpose	Delivery of medical products for treatment/prophylaxis in a nationally declared emergency	Potential pathway for patients with a life-threatening/serious condition to gain access to an investigational product outside a clinical trial where no alternative treatment is available. May be approved for a single patient or an intermediate group.	Assessment of safety/efficacy of a drug or device
IRB Review	Not required (unless used to obtain research information, then IND/IDE required)	Required* (except in emergency use where there is not time to secure prospective approval, IRB must be notified within 5 working days of use)	Required
Documented informed consent	Not required	Required, including emergency use	Required
AE monitoring/ reporting to FDA	May be required	Required	Required
Recordkeeping/access by FDA	May be required	Required	Required
Duration	Determined by length of nationally declared emergency	Ends after clinical treatment is completed for either one subject or the intermediate group.	Length of clinical trial

**A licensed physician who submits a non-emergency individual patient expanded access IND may request a waiver from the requirement for full IRB review. FDA concludes that such a waiver is appropriate for individual patient expanded access INDs when the physician obtains concurrence from the IRB chairperson or another designated IRB member before treatment begins. The waiver would extend to any changes/amendments to the original treatment plan or for continuing review of the individual expanded access IND request.*

08.25.2021

COVID-19 Convalescent Plasma - FDA Guidance

Pathways for Use of Investigational COVID-19 Convalescent Plasma

Convalescent Plasma for treatment of COVID-19 has not yet been approved for use by the FDA, administration **MUST** be under the EUA **OR** an IND. Plasma must be obtained from an FDA-registered or licensed blood establishment.

Pathways	EUA (Emergency Use Authorization)	Expanded Access/ Treatment Protocol (Compassionate Use)	Investigational Research Protocols (IND/IDE)
FDA Approval	Not required, but use must be consistent with scope and conditions of Letter of Authorization*	Required, conducted under IND. The requesting physician may complete the Form FDA 3926 *(Emergency contact 1-866-300-4374 if IND needed before 8am ET the following morning)*	Required, conducted under IND submitted to the FDA under the traditional IND regulatory pathway (21 CFR Part 312).
IRB approval	Not required (unless used to obtain research information, then IND/IDE required)	Required (except in emergency use where there is not time to secure prospective approval, IRB must be notified within 5 working days of use)	Required
FDA reporting	Fatalities must be reported	Required	Required

Compliance and Enforcement Policy Regarding IND Requirements for Use of Convalescent Plasma (starting 08-23-20 and will remain effective until the declaration that circumstances exist justifying the authorization of the EUA of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.)

-*The updated EUA authorizes only the use of high titer COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19, early in the course of the disease. The use of low titer COVID-19 convalescent plasma is **NOT** authorized under this EUA.
-The EUA has been updated to include additional tests to be used in the manufacture of COVID-19 convalescent plasma: Approved tests link (pg. 9 Appendix A).

Additional COVID-19 Drugs

COVID-19 Vaccines approved by the FDA

- Pfizer-Comirnaty ® COVID-19 Vaccine
  1. To prevent COVID-19 in in individuals ≥ 16 yrs

COVID-19 Medications approved by the FDA

- Gilead Veklury® (Remdesivir)
  1. COVID-19 treatment requiring hospitalization for adults and pediatric patients (≥12 yrs and at least 40kg/~88lb)

COVID-19 Vaccines Authorized for Emergency Use

- Pfizer-BioNTech COVID-19 Vaccine
  2. To prevent COVID-19 in in individuals 12 yrs – 15 yrs

3. To provide a third dose to individuals ≥ 12 yrs who have been determined to have certain kinds of immunocompromise.

- *COMIRNATY (COVID-19 Vaccine, mRNA)
    1. To prevent COVID-19 in individuals 12-15 yrs
    2. To provide a third dose to individuals ≥ 12 yrs who have been determined to have certain kinds of immunocompromise.
- Moderna COVID-19 Vaccine
- Johnson & Johnson Janssen COVID-19 Vaccine

**FDA-approved COVID-19 vaccine made by Pfizer for BioNTech (marketed under the name Comirnaty) for a 2-dose series for prevention of COVID-19 in individuals ≥ 16 yrs. Both the Pfizer-BioNTech and Comirnaty (although legally distinct from each other) have the same formulation and can be used interchangeably without any safety or effectiveness concerns.*

Drug and Biological Therapeutic Products

Date EUA first issued	Letter of Authorization (most recent)	Authorized use
6/24/21	Actemra (Tocilizumab)-Human monoclonal antibody	Treatment of COVID-19 in hospitalized adults and pediatric patients (≥2yrs) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or Extracorporeal Membrane Oxygenation (ECMO).
5/26/21	Sotrovimab	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (≥12yrs weighing at least 40 kg(~88lb) with positive results of direct SARS-CoV-2 viral testing and at high risk for progression to severe COVID-19, including hospitalization or death.
3/12/21	Propofol-Lipuro 1%	To maintain sedation via continuous infusion in patients > 16 years with suspected or confirmed COVID-19 who require mechanical ventilation in an ICU setting.
2/09/21	Bamlanivimab and Etesevimab Pause in distribution 6/25/21	Treatment of mild-to-moderate COVID-19 in adult and pediatric patients with +ve test SARS-CoV-2, ≥12 yrs weighing at least 40 kg(~88lb), and who are at high risk of progressing to severe COVID-19 and/or hospitalization.
11/21/20	REGEN-COV (Casirivimab and Imdevimab in combination)	1)Treatment of mild-to-moderate COVID-19 in adults and pediatrics (≥12 yrs weighing at least 40 kg(~88lb)) with +ve SARS-CoV2 viral testing, and who are at risk for progressing to severe COVID-19 and/or hospitalization. 2)Use post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19 including hospitalization or death.
11/19/20	Baricitinib (Olumiant)	Treatment of hospitalized COVID-19 adult and pediatric (≥2yrs), requiring supplemental oxygen, non-invasive or invasive mechanical ventilation or ECMO.
8/13/20	Regiocit replacement solution containing citrate for regional citrate anticoagulation	Replacement solution in adults treated with continuous renal replacement therapy (CRRT)
5/8/20	Fresnius Kabi Propoven 2%	Maintenance of sedation via continuous infusion in patients older than age 16 with suspected or confirmed COVID-19 who require mechanical ventilation in ICU

5/1/20	Remdesivir for Certain Hospitalized COVID-19 Patients**	Emergency use by licensed healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5kg to less than 40kg (~8lb to less than ~88lb) or hospitalized pediatric patients <12 yrs weighing at least 3.5kg (~8lb).
4/30/20	Fresnius Medical, multiFiltrate PRO System and multiBic/multiPlus Solutions *[also listed under Medical Device EUAs]*	To provide continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during COVID-19 pandemic

***(Remdesivir is approved by FDA for COVID-19 treatment requiring hospitalization for adults and pediatric patients (≥12 yrs and at least 40kg/~88lb)*

COVID-19 EUA Authorizations for Medical Devices

Blood Purification Devices

Continuous Renal Replacement Therapy and Hemodialysis Devices

Decontamination Systems for PPE

In Vitro Diagnostics

Infusion Pumps

Personal protective equipment (PPE)

Remote or Wearable Patient Monitoring Devices

Respiratory Assist Devices

Ventilators and Ventilator Accessories

Other Medical Device EUAs