CORONAVIRUS DISEASE 2019
(COVID-19)

Convalescent Plasma Charging & Billing Guidance

Trinity Health

Audience: Revenue Cycle, Research, Compliance, Legal
Revision Date: 02/21/2022
Version : 5
COVID-19 Response Team Owner: Revenue Cycle
Date of Last Review: 02/22/2022

Convalescent Plasma Charging & Billing Guidance

What's New: Reissuance of the EUA letter by the FDA and creation of HCPCS code for billing of outpatient convalescent plasma.

On December 28, 2021 the Federal Drug Administration (FDA) reissued the Emergency Use Authorization (EUA) letter to authorize only the use of high titer COVID-19 convalescent plasma for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the inpatient or outpatient setting.

Convalescent Plasma Emergency Use Authorization (EUA) Charging, Coding & Billing Guidance

The focus of an EUA is to provide *treatment* to patients of an investigational agent outside of a clinical trial, whereas a clinical trial is focused on research. This means that the CMS coverage regulations and billing guidance for clinical trials do not apply.

- *Do not* add Z00.6 ICD-10-CM diagnosis code, Condition Code 30, modifiers Q1/Q0, or National Clinical Trial (NCT) number to the claim.
- For claims on or after February 1, 2021, add the Condition Code 91 to report when the convalescent plasma is provided as part of an EUA.
    - *Given that the intended use of COVID-19 convalescent plasma under the EUA is for treatment of hospitalized COVID-19 patients, the FDA expects to receive very few single patient Investigative New Drug (IND) or intermediate-sized population Expanded Access (EA) requests; if the physician determines that either IND or EA is appropriate for the patient, FDA approval must be granted prior to treatment. Also, the physician or the ministry's Research Department / Institutional Review Board Chair must notify PBS when the Condition Code 90 (to report when convalescent plasma is part of an IND or EA approved request) to be placed on the claim. This should be a very rare occurrence.*
- The ICD-10-PCS codes below were created for reporting convalescent plasma on inpatient claims. The convalescent plasma is considered a COVID New Technology Add-on Procedure which can trigger additional payment beyond the DRG so it is important to assign the ICD-10-PCS codes when the plasma is provided to COVID inpatients.

  - 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

- CMS created HCPCS code C9507 (Fresh frozen plasma, high titer COVID-19 convalescent, frozen within 8 hours of collection, each unit) for COVID-19 convalescent plasma for use in the outpatient setting, effective on or after December 28, 2021. CMS has established a payment of $750.50.

- All charges related to the care and administration of the convalescent plasma to the patient are to be charged as normal, conventional, clinical care. In other words, the type & screen blood test, thawing of the plasma (other blood product), administration of the plasma (other blood product) and supplies are charged as usual and reported on the UB-04 claim in the covered column.

- As of Friday, August 28, 2020, the Red Cross will be supplying the units of investigational convalescent plasma to a hospital or a patient for no charge. It is assumed that other blood bank suppliers will also not charge for investigational convalescent plasma provided to a hospital or a patient.
  - In February 2021, it was expected that hospitals will not be charged for the procurement and delivery of units of convalescent plasma through March 26, 2021.
  - Each HM should determine if they are receiving the convalescent plasma free or if they are paying for it.

- If the convalescent plasma is being obtained free of charge, use the CDM lines created for the investigational "study" convalescent plasma. These will have "Study" in the description. These should be priced at $0.01 or $1.01. *Do not* price as $0.00; doing so will trigger an edit on the claim.

EAST

Rev/Svc Dept	Department Description	CDM Code	Stmt/Bill Desc	UB Default	Bill Code 1
120	LAB	12004537	FFP COVID-19 CONV STUDY P/UNIT	390	~~P9059~~ C9507
120	LAB	12004549	FFP COVID-19 CONV P/UNIT	390	~~P9059~~ C9507

WEST

Home Dept Number	Dept. Description	CDM Code	CDM Claim Description	ICC	HCPCS	UB Code
~~2100~~	~~Blood Bank~~	~~21035845~~	~~FFP COVID-19 Conv Study P/Unit~~	~~100~~	~~P9059~~	~~390~~
2100	Blood Bank	21037165	COVID-19 FFP Conv Study P/Unit	100	C9507	390
~~2100~~	~~Blood Bank~~	~~21036177~~	~~FFP COVID-19 Conv P/Unit~~	~~39~~	~~P9509~~	~~390~~
2100	Blood Bank	21037159	Cov-19 FFP H Titer Conv P/Unit	39	C9507	390

TogetherCare

EPIC EAP	EPIC Description	UB DEFAULT	Bill Codes 1-5
~~390P9059002~~	~~HC FRESH FROZEN PLASMA 8-24 HOURS COLLECTION CONVALESCENT STUDY EACH UNIT~~	~~390~~	~~P9059~~
390C9507002	HC COV-19 FRESH FROZEN PLASMA HIGH TITER 8HR COLL CONVALESCENT STUDY P/UNIT	390	C9507
~~390P9059003~~	~~HC FRESH FROZEN PLASMA 8-24 HOURS COLLECTION CONVALESCENT EACH UNIT~~	~~390~~	~~P9059~~
390C9507001	HC COVID-19 FRESH FROZEN PLASMA HIGH TITER 8 HOURS COLL CONVALESCENT P/UNIT	390	C9507

In summary:

- If the plasma product is provided free of charge, the token charge should be placed in the non-covered column on the UB-04.
- The account is billed as normal. Please find additional guidance on co-pays and deductibles here. In addition, uninsured patients *will not* be responsible for the co-pay / deductible balance. Please see additional guidance here on registration protocols.
- Use condition code 91 on these accounts unless otherwise notified by the Research Department that condition code 90 is appropriate for that case.
- Use condition code DR on these accounts.
- If you have a patient who is a participant in a clinical trial of convalescent plasma, continue to follow the clinical trial coding and billing processes.

NOTE: Charging and billing instructions for clinical trials are different from what is described above for the Convalescent Plasma Emergency Use Authorization. If your site plans to participate in a convalescent plasma clinical trial, contact Harriet Kinney, Director, Research Integrity & Compliance, Integrity & Audit Services Department.

NOTE: For information on appropriate billing under the Expanded Access Program (EAP), prior to August 28, 2020, see the Archive Guidance section at the end of this document (after References and Other Materials).

References and Other Materials:

American Association of Blood Banks (AABB): http://www.aabb.org/Pages/default.aspx

COVID-19 website: https://covidplasma.org/

Summary: Donation of CCP, Blood Components and HCT/Ps Following COVID-19 Vaccines or Treatment with CCP or Monoclonals, updated February 3, 2021: https://www.aabb.org/docs/default-source/default-document-library/regulatory/summary-of-blood-donor-deferral-following-covid-19-vaccine-and-ccp-transfusion.pdf?sfvrsn=91eddb5d_2

Toolkit for CCP under EUA: http://www.aabb.org/advocacy/regulatorygovernment/Documents/Toolkit-for-CCP-under-EUA.pdf#search=eua%20plasma

FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID–19 Treatment, Another Achievement in Administration's Fight Against Pandemic, August 23, 2020 https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment

FDA Updates Emergency Use Authorization for COVID-19 Convalescent Plasma to Reflect New Data (Revised Letter)

December 28, 2021 Revised Letter of Authorization: Convalescent Plasma EUA Letter of Authorization 12282021 (fda.gov)

February 4, 2021 https://www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data

February 4, 2021 Revised Letter of Authorization: https://www.fda.gov/media/141477/download

February 4, 2021 Revised Fact Sheet for Health Care Providers: https://www.fda.gov/media/141478/download

February 4, 2021 Revised Fact Sheet for Patients/Caregivers: https://www.fda.gov/media/141479/download

FDA Final Guidance: Investigational COVID-19 Convalescent Plasma Guidance for Industry, April 2020, Updated September 2, 2020, November 16, 2020, January 15, 2021 https://www.fda.gov/media/136798/download

FDA Final Guidance: Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers for Industry, June 2016, Updated October 2017. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expanded-access-investigational-drugs-treatment-use-questions-and-answers

21 CFR 312 Subpart I — *Expanded Access to Investigational Drugs for Treatment Use*

ARCHIVED GUIDANCE

Convalescent Plasma EAP Charging & Billing Guidance – Discontinued as of August 28, 2020

The Convalescent Plasma National Expanded Access Program (EAP), sponsored by Mayo Clinic and the federal government, discontinued new physician and new patient enrollment effective 11:59 pm Eastern Daylight Time August 28, 2020.

The EAP was discontinued because the FDA announced on August 23, 2020 that the COVID-19 Convalescent Plasma EAP meets the eligibility criteria for Emergency Use Authorization (EUA) under Section 564 of the Food, Drug & Cosmetics Act. Treating patients with investigational convalescent plasma under the EUA is considered part of the practice of medicine in a temporary emergency situation as long as the declaration of the public health emergency exists. Use of investigational convalescent plasma under the EUA is not considered use in a clinical trial/study.

New patient enrollment under the EAP **is not authorized after August 28, 2020**. Placing an order for COVID-19 convalescent plasma under the EAP **is not authorized after August 31, 2020**.

All patients enrolled in the EAP as of 11:59 pm Eastern Daylight Time August 28, 2020 will be able to receive convalescent plasma under the EAP, and ministries are required to complete all of the reporting (e.g., significant adverse event) and other forms that are associated with the EAP. This is a Federal requirement.

The focus of an EAP is to provide *treatment* to patients of an investigational agent outside of a clinical trial, whereas a clinical trial is focused on research. This means that the CMS coverage regulations and billing guidance for clinical trials do not apply.

- *Do not* add Z00.6 ICD-10-CM diagnosis code, Condition Code 30, modifiers Q1/Q0, or National Clinical Trial (NCT) number to the claim.
- All of the charges related to the care and administration of the plasma to the patient are to be charged as normal, conventional, clinical care. In other words, the type & screen blood test, thawing of the plasma (other blood product), administration of the plasma (other blood product) and supplies are charged as usual and reported on the UB-04 claim in the covered column.
- There is no charge from the supplier associated with the unit of convalescent plasma provided to a hospital or a patient. The Expanded Access Program will reimburse the supplier for the plasma collection costs (e.g., procurement, recovery, and delivery fees) regardless of the supplier (e.g., American Red Cross, Vitalant, OneBlood, ABC, New York Blood Center, or other local supplier).
- The following new CDMs have been created for the investigational convalescent plasma. These should be priced at $0.01 or $1.01. *Do not* price as $0.00; doing so will trigger an edit on the claim.

EAST

East Corp Dept Name	East Corp Dept #	Corp CDM	Description	Medcr Rev Code	Medcr CPT	NonMedcr CPT
LAB	120	12004537	FFP COVID-19 CONV STUDY P/UNIT	390	P9059	P9059

WEST

Rev/Svc Dept	Department Description	Legacy CDM Code	CDM Description	UB Default	Bill Codes 1-5
2100	BLOOD BANK	21035845	FFP COVID-19 CONV STUDY P/UNIT	390	P9059

TogetherCare

EPIC EAP	EPIC Description	UB DEFAULT	Bill Codes 1-5
390P9059002	HC FRESH FROZEN PLASMA 8-24 HOURS COLLECTION CONVALESCENT STUDY EACH UNIT	390	P9059

In summary:

- The hospital will not charge the unit of convalescent plasma to the patient or the patient's insurance. The plasma charge should be placed in the non-covered column on the UB-04.
- The account is billed as normal. Please find additional guidance on co-pays and deductibles here. In addition, uninsured patients *will not* be responsible for the co-pay / deductible balance. Please see additional guidance here on registration protocols.
- Due to the program closure, these charging and billing instructions are invalid after August 31, 2020.

COVID-19 Expanded Access Program – Mayo Clinic web site: https://www.uscovidplasma.org/

Comparing EAP vs. EUA: What you need to know: https://www.uscovidplasma.org/pdf/EAP%20vs%20EUA.pdf

Frequently Asked Questions: EAP to EUA Transition: https://www.uscovidplasma.org/pdf/FAQ%20on%20EAP%20to%20EUA.pdf