PURPOSE
Administrative Policies are intended to provide further information about the administration of standard Cigna benefit plans. In the event of a conflict, a customer’s benefit plan document always supersedes the information in an Administrative Policy. Coverage determinations require consideration of 1) the terms of the applicable benefit plan document; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Administrative Policies and; 4) the specific facts of the particular situation. Administrative Policies relate exclusively to the administration of health benefit plans. Administrative Policies are not recommendations for treatment and should never be used as treatment guidelines.

Administrative Policy

Cigna covers COVID-19 convalescent plasma (CCP) for the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19) when administered in accordance with the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

General Background

COVID-19 is the respiratory illness caused by the most recently discovered coronavirus Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). This new virus and disease were unknown before the outbreak began in December 2019. The range in severity of symptoms of COVID-19 can be mild respiratory tract symptoms that are self-limiting to severe pneumonia with multiorgan failure resulting in death. Symptoms of COVID-19 infection may include fever, cough, shortness of breath or difficulty breathing, fatigue, body aches or muscle pain, headache, sore throat, new loss of taste or smell, congestion or runny nose, diarrhea, nausea or vomiting. Emergency warning signs for COVID-19 may include trouble breathing, persistent pain or pressure in chest, new confusion, inability to wake or stay awake, or bluish lips or face (Centers for Disease Control and Prevention ([CDC], 2021; Infectious Disease Society of America [IDSA], 2021). These symptoms typically appear 2–14 days after exposure. The virus is highly contagious and a global pandemic was declared by the World Health Organization on March 11, 2020.

COVID-19 convalescent plasma is human plasma collected from individuals whose plasma contains anti-SARS-CoV-2 antibodies. Convalescent plasma or serum has been used in the past in an effort to provide passive antibody transfer to treat infectious diseases that involve the respiratory system, and has recently been under investigation for the treatment of COVID-19.
On August 23, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for COVID-19 Convalescent Plasma (CCP) for the treatment of hospitalized patients with COVID-19. The EUA states that it is reasonable to believe that COVID-19 convalescent plasma may be effective in treating COVID-19 and that, when used under the conditions described in the authorization, the known and potential benefits of COVID-19 convalescent plasma when used to treat COVID-19 outweigh the known and potential risks. The EUA also states that there are no adequate, approved, and available alternative to the emergency use of COVID-19 convalescent plasma for the treatment of COVID-19.

The FDA scope and conditions of authorization also include the following:

- Authorized COVID-19 convalescent plasma will be obtained from registered or licensed blood establishments from donors in the United States or its territories in accordance with applicable regulations, policies, and procedures.
- Testing for relevant transfusion-transmitted infections must be performed and the donation must be found suitable.
- Plasma donations must be tested by registered or licensed blood establishments for anti-SARS-CoV-2 antibodies as a manufacturing step to determine suitability before release. Units tested by the Ortho VITROS SARS-CoV-2 IgG test and found to have a signal-to-cutoff (S/C) value of 12 or greater qualify as high titer COVID-19 convalescent plasma.
- Units containing anti-SARS-CoV-2 antibodies but not qualified as high titer by the test described above are considered low titer units and must be labeled accordingly. The health care provider may assess whether units with an S/C value of less than 12 are acceptable for use based on an individualized assessment of benefit-risk.
- Health care providers will administer CCP according to standard hospital procedures and institutional medical and nursing practices.

The EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated or the EUA is revoked. The fact sheet for health care providers accompanying the EUA states, “Given that the clinical evidence supporting this EUA was not obtained from prospective well-controlled randomized clinical trials (RCTs), additional RCTs are needed. Convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19.”

On September 2, 2020, the FDA issued new guidance to provide recommendations on the use of COVID-19 convalescent plasma under the EUA and investigational COVID-19 convalescent plasma under an IND (Investigational New Drug) process. For the purposes of the guidance, the term “COVID-19 convalescent plasma” refers to the convalescent plasma authorized under the emergency use authorization (EUA), while the term “investigational convalescent plasma” refers to convalescent plasma that does not meet all the conditions of the EUA and/or is being used under an IND. Convalescent plasma for the treatment of COVID-19 has not yet been approved for use by the FDA and is regulated as an investigational product. Administration therefore must be in accordance with the EUA or as an IND.

To administer COVID-19 convalescent plasma under the EUA, the use must be consistent with the terms of the Letter of Authorization, including the Scope of Authorization and Conditions of Authorization. Alternatively, investigational convalescent plasma may be administered under the traditional IND regulatory pathway; a single-patient IND for emergency use; or an intermediate-size population expanded access IND. The guidance document provides recommendations for pathways for use of investigational convalescent plasma, collection of plasma, record keeping, compliance and enforcement policy regarding IND requirements. The guidance further states that the FDA has received numerous inquiries following the issuance of the EUA on August 23, 2020 and understands that investigational convalescent plasma collected prior to the EUA may not meet the conditions of authorization, specifically the requirement for testing plasma donations using the OrthoVITROS SARS-CoV-2 IgG test to determine suitability as well as qualifying the unit as high titer or low titer. Considering this issue, and the fact that the National Expanded Access Treatment Protocol has been discontinued, the agency intends to exercise temporary enforcement discretion with respect to the IND requirements for the collection, shipment and administration of investigational convalescent plasma for a period of 90 days to allow blood establishments adequate time to develop the necessary procedures to manufacture COVID-19 convalescent plasma under the conditions of the EUA.
On February 4, 2021, the FDA issued a revision of the EUA in its entirety to: 
“(1) include updates based on data from additional clinical trials; (2) clarify that the authorization is limited to use of only high titer COVID-19 convalescent plasma in hospitalized patients early in the course of disease and those hospitalized with impaired humoral immunity; (3) add the Abbott SARS-CoV-2 IgG test (ARCHITECT and Alinity i platforms), Beckman Coulter Access SARS-CoV-2 IgG test, EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) test, GenScript cPass SARS-CoV-2 Neutralization Antibody Detection Kit test, Kantaro COVID-SeroKlir test, Roche Elecsys AntiSARS-CoV-2 S test, and Siemens ADVIA Centaur SARS-CoV-2 IgG (COV2G) test as acceptable tests to be used for the purpose of qualifying high titer COVID-19 convalescent plasma in the manufacture of COVID-19 convalescent plasma; and (4) change the cutoff of the Ortho VITROS Anti-SARS-CoV-2 IgG test from S/C≥12.0 to S/C≥9.5 for qualification of COVID-19 convalescent plasma as high titer.” The use of low titer COVID-19 convalescent plasma is no longer authorized under this EUA.

Definitions

Convalescent: Refers to anyone recovering from a disease.
Plasma: The yellow, liquid part of blood that contains antibodies.
Antibodies: Proteins made by the body in response to infections.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Eligible for Coverage:

<table>
<thead>
<tr>
<th>Revenue Codes*</th>
<th>Description</th>
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<tbody>
<tr>
<td>0383</td>
<td>Blood and Blood Components-Plasma</td>
</tr>
<tr>
<td>0391</td>
<td>Administration, Processing and Storage for Blood and Blood Components-Administration</td>
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<tr>
<th>ICD-10-CM Diagnosis Codes</th>
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<tr>
<td>B34.2</td>
<td>Coronavirus infection, unspecified</td>
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<tr>
<td>U07.1</td>
<td>COVID-19</td>
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<tr>
<th>ICD-10-PCS Procedure Codes</th>
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<td>XW13325</td>
<td>Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5</td>
</tr>
<tr>
<td>XW14325</td>
<td>Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5</td>
</tr>
</tbody>
</table>

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References


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