Policy Number	**RX501.173**
Policy Effective Date	**10/15/2025**

Pemivibart

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Related Policies (if applicable)
None

Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Pemivibart (Pemgarda) **is considered experimental, investigational and/or unproven** for all indications as it has not received approval from the U.S. Food and Drug Administration (FDA), including use for pre-exposure prophylaxis of COVID-19.

NOTE 1: Pemivibart (Pemgarda) has been issued an emergency use authorization (EUA) from the U.S. Food and Drug Administration for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents. **The use of pemivibart (Pemgarda) under the EUA is outside the scope of this policy**.

Policy Guidelines

According to the EUA, pemivibart (Pemgarda) may only be used by healthcare providers for pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2; **AND**
- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. (1)

The Fact Sheet for Healthcare Providers: Emergency Use Authorization of pemivibart (Pemgarda) includes the following limitations of authorized use:
Pemgarda is not authorized for use:

- For treatment of COVID-19; or
- For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2. (1)

Description

SARs-CoV-2 Novel Coronavirus (COVID-19)
The SARS-CoV-2 coronavirus, or COVID-19, first appeared in Wuhan, China, in December 2019. It quickly spread throughout the world, causing a world-wide pandemic. A novel coronavirus is a new coronavirus that has not been previously identified. The virus causing COVID-19 is not the same as the coronaviruses that commonly circulate among humans and cause mild illness, such as the common cold. The World Health Organization (WHO) announced the official name for the disease causing the 2019 novel coronavirus outbreak. The new name of this disease is coronavirus disease 2019, abbreviated as COVID-19. In COVID-19, 'CO' stands for 'corona,' 'VI' for 'virus,' and 'D' for disease. Formerly, this disease was referred to as "2019 novel coronavirus" or "2019-nCoV." (2)

Symptoms
The virus causing COVID-19 is thought to spread from person to person, mainly through respiratory droplets produced when an infected person talks, coughs or sneezes. A wide range of symptoms have been reported, including fever, cough, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, shortness of breath or difficulty breathing. The clinical spectrum of SARS-COV-2 infection ranges from asymptomatic infection to critical and fatal illness. The prevalence of asymptomatic infection has increased over the years as more people received vaccinations and developed post-infection immunity to the infection, with estimates suggesting that about 20 to 40 percent of infections are now asymptomatic. The incubation period for COVID-19 is generally within 14 days following exposure with most cases occurring approximately four to five days after

exposure. The median incubation period for the newer SARS-CoV-2 variants appears to be slightly shorter, with symptoms first appearing at around three days. (2)

Pemivibart (Pemgarda)
Pemivibart (Pemgarda) (Invivyd, Inc.) is an IgG1λ antibody that works by targeting the SARS-CoV-2 spike protein receptor binding domain (RBD), inhibiting the attachment of the SARS-CoV-2 virus to human ACE2 receptors (the entry points of the virus into human cells). (1)

Regulatory Status
The U.S. Food and Drug Administration (FDA) has not approved pemivibart (Pemgarda) for use outside the Emergency Use Authorization (EUA) issued March 22, 2024. The FDA considers it to be investigational and it is not currently approved for any indication. (1)

Rationale

This medical policy was developed in May 2024 and is based on information retrieved from the U.S. Food and Drug Administration (FDA) website.

Pemivibart (Pemgarda) has been issued an emergency use authorization (EUA) from the FDA for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents. **The use of pemivibart (Pemgarda) under the EUA is outside the scope of this policy**.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	M0224, Q0224

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

1. FDA. Fact Sheet for Healthcare providers: Emergency Use Authorization of Pemgarda (Pemivibart). Highlights of Emergency Use Authorization (EUA). (5/2025). Available at: <https://www.fda.gov> (accessed July 24, 2025).
2. Gandhi RT. COVID-19: Clinical features. In UpToDate, Hirsch MS (Ed), UpToDate, Waltham, MA. Available at <https://www.uptodate.com> (accessed July 29, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2025	Document updated with literature review. Coverage unchanged. No new references added; one updated.
09/15/2024	New medical document. Pemivibart (Pemgarda) is considered experimental, investigational and/or unproven for all indications as it has not received approval from the U.S. Food and Drug Administration, including use for pre-exposure prophylaxis of COVID-19. The use of Pemivibart (Pemgarda) under the Emergency Use Authorization (EUA) is outside the scope of this policy.