ATRIO HEALTH PLANS

COVID-19 Agents
Veklury (remdesivir) J0248, bebtelovimab Q0222, Pemgarda (pemivibart) Q0224
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Pemgarda (Q0224)**

☐ Patient 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

☐ Patient has moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and are unlikely to mount an adequate response to COVID-19 vaccination.

☐ Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Covid-19 Agents PA

Drug Name(s):

VEKLURY **REMDESIVIR**
BEBTELOVIMAB **PEMGARDA**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member's Covid-19 Diagnosis determined by positive results of direct SARS-CoV-2 viral testing
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Bebtolovimab

- Patient is hospitalized due to COVID-19
- Patient requires oxygen therapy and/or respiratory support due to COVID19
- Patient requires an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID19 related comorbidity.

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Veklury

- Adults and pediatric patients (aged 12 years or older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization.

Off-Label Uses:

Veklury

- **CMS Emergency Authorization**: Non-hospitalized patients with mild to moderate COVID-19 who are at high risk of clinical progression

Bebtelovimab, Pemgarda

- **CMS Emergency Authorization**: Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients:
  - With positive results of direct SARS-CoV-2 viral testing, and
  - Who are at high risk for progression to severe COVID-19, including hospitalization or death AND
  - For whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

Age Restrictions:

- Aged 12 years or older

Weight Restrictions:

- Weighing at least 40 kg

Other Clinical Considerations:

- Bebtelovimab is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of bebtelovimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Bebtelovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to this drug and regional variant frequency.

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/F57625/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/B916B1/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932927&contentSetId=100&title=Remdesivir&servicesTitle=Remdesivir&brandName=Veklury&UserMdxSearchTerm=Veklury&=null#

https://www.micromedexsolutions.com/micromedex2/librarian/CS/CE365C/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/B5B958/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Bebtelovimab&UserSearchTerm=Bebtelovimab&SearchFilter=filterNone&navitem=searchGlobal#

https://www.micromedexsolutions.com/micromedex2/librarian/CS/6396D2/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/CC6F3D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=pemgarda&UserSearchTerm=pemgarda&SearchFilter=filterNone&navitem=searchGlobal#

https://www.coronavirus.in.gov/files/Remdesivir-Treatment-Criteria-Final.pdf

https://www.fda.gov/media/156152/download