



COVID-19 Agents
Veklury (remdesivir) J0248,
bebtelovimab Q0222
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.*

<input type="checkbox"/>	NEW START - Start Date: _____	<input type="checkbox"/>	Continuation (within 365 days): Date of last treatment _____
<input type="checkbox"/>	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

HCCP Code	Name of Drug <input type="checkbox"/> Self-administered	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

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)
 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

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:

Bebtelovimab

- 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 (remdesivir)

- 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 (remdesivir)

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

Bebtelovimab

- **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 (**Veklury AND Bebtelovimab**)

Weight Restrictions:

- Weighing at least 40 kg (**Veklury AND Bebtelovimab**)

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/DOPLICATI/ONSHIELDSYNC/B916B1/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActio/nId/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/DOPLICATI/ONSHIELDSYNC/B5B958/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActio/nId/evidencexpert.DoIntegratedSearch?SearchTerm=Bebtelovimab&UserSearchTerm=Bebtelovimab&SearchFilter=filterNone&navitem=searchGlobal#

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

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

CLINICAL USE ONLY