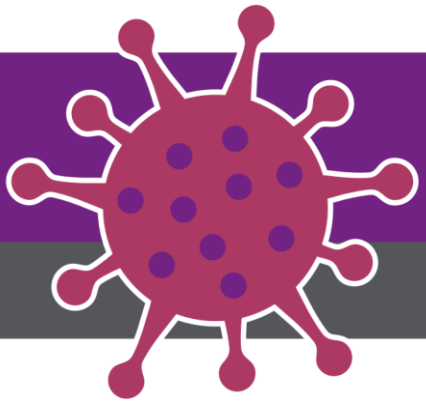
CORONAVIRUS DISEASE 2019
(COVID-19)

Veklury® (Remdesivir)
Charging & Billing Guidance



Trinity Health

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What's Changed: FDA approval was expanded to pediatric patients 28 days of age and older.

Veklury® (Remdesivir) Charging & Billing Guidance

Veklury (Remdesivir) by Gilead Sciences (Gilead) was approved by the Food & Drug Administration (FDA) on October 22, 2020. Veklury **is a drug approved for use in adults and pediatric patients** (12 years of age and older and weighing at least 40 kg/88 pounds) for the treatment of coronavirus disease 2019 (COVID-19) **requiring hospitalization** (acute inpatient status).

On January 21, 2022, the FDA **expanded its approval** of Veklury to include its use in adults and pediatric patients (12 years of age and older who weigh at least 40 kg / 88.2 pounds) with positive results of direct SARV-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death. These high-risk non-hospitalized patients may receive Veklury via intravenous infusion for a total of three (3) days for the treatment of mild-to-moderate COVID-19 disease.

Veklury **is authorized for use under an EUA** for treatment of hospitalized pediatric patients weighing 3.5 kg to less than 40 kg *or* hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg with suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) for whom use of an intravenous (IV) agent is clinically appropriate.

On January 21, 2022, the FDA **revised the EUA** for Veklury to additionally authorize the drug for treatment of pediatric patients weighing 3.5 kgs to less than 40 kgs or pediatric patients less than 12 years of age weighing at least 3.5 kgs, with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death. These high-risk non-hospitalized patients may receive Veklury via intravenous infusion for a total of three (3) days for the treatment of mild-to-moderate COVID-19 disease.

On April 25, 2022, the FDA expanded its approval of Veklury to include pediatric patients 28 days of age and older weighing at least 3 kilograms (about 7 pounds) with positive results of direct SARS-CoV-2 viral testing, who are either hospitalized, or, not hospitalized but have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. As a result of this FDA approval, the agency also revoked the emergency use authorization for Veklury that previously covered this pediatric population.

While Veklury is authorized to treat COVID-19, as indicated in the EUA's Section I, Criteria for Issuance of Authorization, it **is not available** through a retail pharmacy.

Clinical trials assessing the safe and effective use of Veklury in pediatric populations remain ongoing.

Clinical Trials

If a physician at your ministry is accepted to be an investigator in a clinical trial with Veklury as an investigational agent, contact Harriet Kinney, Director, Research Integrity & Compliance, Integrity & Audit Services Department (System Office) (kinneyh@trinity-health.org) to discuss how to apply and follow CMS coverage regulations and billing guidance for clinical trials.

Charging & Billing Guidance - Overview

- AmerisourceBergen (AB) is the exclusive distributor of Veklury (designated by the Department of Health & Human Services (HHS). AB provided it to states at no cost (donated product), and the states in turn provided it to hospitals at no cost. It is expected that AmerisourceBergen will continue to be the distributor until notice from HHS.
    - Some states still have a supply of donated product and will ship this donated product to hospitals at no cost upon request. This scenario is very uncommon; check with your local Supply Chain Management (SCM) Strategic Sourcing team if this scenario is applicable to your hospital.
    - Each hospital is to maintain a record of how much donated product they have on hand vs. how much of the purchased product. Some states may require hospitals to keep a percentage of donated product 'on hold' (retain in inventory) for potential use at a later date; check with your state's Department of Health for guidance. **Donated product is to be utilized first before using any purchased product**.
- For the sake of treatment expediency, it is recommended that ministries utilize the currently available "non-formulary" drug processes to get the drug into the various systems.
- **Donated Product**: When creating the new CDM/eRX, the price should be $0.01 or $1.01. *Do not* price as $0.00; doing so will trigger an edit on the claim.
- **Purchased Product**: When creating the CDM/eRX, price as your hospital normally prices a new product, with the appropriate Revenue Code.

Charging & Billing Guidance – Emergency Use Authorization (EUA) for Hospitalized and non-Hospitalized Pediatric Patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg.

The focus of the 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.

- Since the EUA is not a clinical trial, *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.
- Add Condition code 91 (to allow providers to report when the treatment is provided as part of the EUA).
- All charges related to the care and administration of Veklury to the patient are to be charged as normal, conventional, clinical care. In other words, the administration of the investigational agent (Veklury) and supplies are charged as usual and reported on the UB-04 claim in the covered column.

Charging & Billing Guidance – FDA Approved, Hospitalized Adults and Pediatric Patients (12 years of age and older and weighing at least 40 kg)

Inpatient Payment (CMS IPPS)

- ICD-10-PCS codes, effective August 1, 2020:
  - XW033E5 (Introduction of Remdesivir Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5)
  - XW043E5 (Introduction of Remdesivir Anti-infective into Central Vein, Percutaneous Approach, New Technology Group 5)

- Charge and bill with the appropriate Revenue Code for Veklury is as a hospital normally charges and bills for an approved drug that is purchased through SCM.

- All charges related to the care and administration of Veklury to the patient are to be charged as normal, conventional, clinical care. In other words, the administration of the approved drug (Veklury) and supplies are charged as usual and reported on the UB-04 claim in the covered column.

Outpatient Use, Charging and Billing

The National Institutes of Health (NIH) updated its guidance on therapies for high-risk, non-hospitalized patients with mild or moderate COVID-19 disease on December 30, 2021. NIH recommended the use of 1 of 4 therapeutics, in descending order; Veklury is one of the therapeutics listed. NIH acknowledged that its recommendation of Veklury in the outpatient setting is as an off-label drug.

Subsequently, on January 7, 2022, CMS issued a new HCPCS code J0248 (Injection, remdesivir, 1 mg) for the administration of Veklury, when administered in the hospital on-campus outpatient setting. The code is available for use by all payers and is effective for dates of service on or after December 23, 2021.

At this time, there is no national coverage determination (NCD) for Veklury in the outpatient setting. MACs determine Medicare coverage when there a no NCD, including in cases when provided use FDA-approved drugs for indications other than what is on the approved label. The MACs consider the major drug compendia, authoritative medical literature, and accepted standards of medical practice to determine medical necessity when considering coverage.

CMS COVID-19 Frequently Asked Questions document includes FAQ 30 under section BB. Drugs & Vaccines Under Part B which clarifies that when Remdesivir is provided to an outpatient this drug will reimburse in addition to any Comprehensive APC service.

During the weeks of January 10 and 17, 2022, all Trinity Health MACs posted the following claims submission guidance:

- VEKLURY™ (remdesivir) product code (J0248)
  - Refer to the Remdesivir FDA label for additional information about the product
- ICD-10 code U07.1 (COVID-19) or J12.82 (Pneumonia due to coronavirus disease 2019)
- In addition to the product code J0248, use the following CPT code for administration:
  - 96365 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour)
  - And if needed use:
    - 96366 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
- For Part A claims:
  - Appropriate type of bill (TOB)
  - Appropriate revenue codes
  - Condition Code DR
- For Part B claims:
  - Appropriate place of service (POS) code
  - Refer to the NIH COVID-19 Treatment Guidelines Panel for administration information
- Units administered for patient:

- J0248 represents 1mg and units should be adjusted to reflect dosage administered for each patient
- Price (payment) per unit set as $5.512 (effective from December 23, 2021, to March 31, 2022)

Claims submitted with dates of service on or after December 23, 2021, will be held until the claims processing systems are updated.

Summary

In summary for EUA and FDA-approved Veklury:

- **Donated Product**: Do not charge Veklury to the patient or the patient's insurance. The Veklury charge should be placed in the non-covered column on the UB-04.
- **Purchased Product**: Charge Veklury to the patient or the patient's insurance. The Veklury charge should be placed in the covered column on the UB-04.
- **Hospital OP billing**: Follow the coding and billing guidance from your MAC for Veklury provided in the hospital on-campus outpatient setting.
- 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.

References and Other Materials:

Veklury (remdesivir) website: https://www.vekluryhcp.com/

Gilead Sciences press release, 10.22.2020: https://www.gilead.com/news-and-press/press-room/press-releases/2020/10/us-food-and-drug-administration-approves-gileads-antiviral-veklury-remdesivir-for-treatment-of-covid19

Fact Sheet for Healthcare Providers, pediatric patients (EUA): https://www.gilead.com/-/media/files/pdfs/remdesivir/eua-fact-sheet-for-hcps.pdf

Fact Sheet for Patients and Caregivers of pediatric patients (EUA): https://www.gilead.com/-/media/files/pdfs/remdesivir%20/eua-fact-sheet-for-patients-and-caregivers.pdf

AmerisourceBergen website: https://www.amerisourcebergen.com/coronavirus-covid-19-information

FDA approves for pediatric use 28 days of age: Coronavirus (COVID-19) Update: FDA Approves First COVID-19 Treatment for Young Children | FDA

FDA Takes Actions to Expand Use of Treatment for Outpatients with Mild-to-Moderate COVID-19 news release, January 21, 2022 FDA Takes Actions to Expand Use of Treatment for Outpatients with Mild-to-Moderate COVID-19 | FDA

Reissued Letter of Authorization and EUA by the FDA:

FDA Letter to Gilead, revised 01.21.2022: EUA 046 Gilead Remdesivir LOA Outpatients (01212022) (fda.gov)

FDA Fact Sheet to Healthcare Providers, EUA for pediatric patients, revised 01.21.2022: EUA 046 Veklury (remdesivir) FS for HCPs (01212022) (fda.gov)

FDA Fact Sheet to Parents & Caregivers, EUA for pediatric patients, revised 01.21.2022: EUA 046 (remdesivir) FS for Parents Caregivers (01212022) (fda.gov)

FDA Frequently Asked Questions for Veklury, updated 01.21.2022: Frequently Asked Questions for Veklury January 21, 2022 (fda.gov)

FDA Dear Healthcare Provider Letter, updated 01.21.2022:
EUA 46 Veklury (remdesivir) DHCP (01212022) (fda.gov)

FDA Prescribing Information Sheet, revised 01.2022:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214787Orig1s000lbl.pdf
label (fda.gov)

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*

CMS - Fourth COVID-19 Interim Final Rule with Comment Period (IFC-4), 10.22.2020

Fact Sheet: https://www.cms.gov/newsroom/fact-sheets/fourth-covid-19-interim-final-rule-comment-period-ifc-4

HHS-Approved document: https://www.cms.gov/files/document/covid-vax-ifc-4.pdf

CMS ICD-10-PCS update: https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-PCS

National Institutes of Health (NIH): *The COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19*, updated December 30, 2021 Statement on Therapies for High-Risk, Nonhospitalized Patients | COVID-19 Treatment Guidelines (nih.gov)

New York City, NY Department of Health announcement: *2021 Health Advisory #39 COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products*, December 27, 2021 covid-19-oral-treatments-authorized-shortage.pdf (nyc.gov)

CMS MLN Matters Number 12049, Implementation Date February 22, 2021, *Implementation of Two (2) New NUBC Condition Codes. Condition Code "90", "Service Provided as Part of an Expanded Access Approval (EA)" and Condition Code "91", "Service Provided as Part of an Emergency Use Authorization (EUA)"* MM12049 (cms.gov)

CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 50 Drugs and Biologicals
- Section 50.2 Determining Self-Administration of Drug or Biological
- Section 50.4.1 Approved Use of Drug
- Section 50.4.2 Unlabeled Use of Drug
- Section 50.4.5 Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17
- Section 10 Payment Rules for Drugs and Biologicals
- Section 40 Discarded Drugs and Biologicals
- Section 80 Claims Processing for Special Drug Categories

CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 38
- Section 10, Emergency Preparedness Fee-for-Service Guidance

CMS IOM Publication 100-08, *Medicare Program Integrity Manual,* Chapter 13
- Section 13.5.4 Reasonable and Necessary Provision in an LCD

Veklury Outpatient Coding/Billing Guidance links:
- CGS: Billing VEKLURY™ (Remdesivir) Antiviral Medication in Outpatient Settings (cgsmedicare.com)
- First Coast: Billing VEKLURY (remdesivir) antiviral medication in outpatient settings (fcso.com)
- NGS: Search Details - NGSMEDICARE
- Noridian: Article Detail - JF Part A - Noridian (noridianmedicare.com)

- Novitas: Billing VEKLURY™ (remdesivir) antiviral medication in outpatient settings (novitas-solutions.com)
- Palmetto: Jurisdiction J Part A - Billing VEKLURY (Remdesivir) antiviral medication in outpatient settings (palmettogba.com)
- WPS: Billing VEKLURY™ (Remdesivir) Antiviral Medication in Outpatient Settings (wpsgha.com)

CMS Frequently Asked Questions for FFS Providers: COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing (cms.gov)