

Reimbursement for Emergency Use Authorization of Baricitinib for COVID-19 Treatment in the Inpatient Setting

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Individual coding decisions should be based upon diagnosis and treatment of individual patients. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies. Please consult with your legal counsel or reimbursement specialist for any reimbursement or billing questions.



Access to coronavirus disease 2019 (COVID-19) therapies administered in the hospital setting will follow existing site-of-care policies for inpatient reimbursement, along with COVID-19-specific enhancements in some cases. For Medicare patients, hospitals will receive an additional payment when treatment includes baricitinib to treat those diagnosed with COVID-19.¹

Baricitinib is authorized for use under an Emergency Use Authorization (EUA) for treatment of COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Please see Important Safety Information on page 6, and click to access the [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents and Caregivers](#).



Baricitinib for COVID-19

Baricitinib received an [Emergency Use Authorization \(EUA\)](#)

- ✓ Baricitinib is authorized for use under an Emergency Use Authorization (EUA) for treatment of COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
- ✓ Baricitinib has not been approved for the treatment of COVID-19, but has been authorized for emergency use by the FDA.
- ✓ Baricitinib is authorized under an EUA only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of baricitinib under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.
- ✓ For information on the authorized use of baricitinib and mandatory requirements under the EUA, please review the [FDA Letter of Authorization](#), [Fact Sheet for Healthcare Providers](#), [Fact Sheet for Patients, Parents and Caregivers \(English\)](#), and [Fact Sheet for Patients, Parents and Caregivers \(Spanish\)](#).
- ✓ Under the EUA, baricitinib is available as 1 mg and 2 mg tablets.

SELECT IMPORTANT SAFETY INFORMATION RELATED TO SERIOUS INFECTIONS AND THROMBOSIS

Serious Infections: There is limited information regarding use of baricitinib in patients with COVID-19 and concomitant active serious infections.

Serious infections have occurred in patients receiving baricitinib. Avoid the use of baricitinib with known active tuberculosis. Consider if the potential benefits outweigh the potential risks of baricitinib treatment in patients with active serious infections other than COVID-19 or chronic/recurrent infections.

Thrombosis: In hospitalized patients with COVID-19, prophylaxis for venous thromboembolism is recommended unless contraindicated. If clinical features of deep vein thrombosis or pulmonary embolism occur, patients should be evaluated promptly and treated appropriately.

The Centers for Medicare & Medicaid Services (CMS) has enhanced payments for eligible inpatient treatment of COVID-19¹

New COVID Treatments Add-On Payment (NCTAP) program¹

- CMS provides a payment enhancement under the NCTAP program for eligible hospital inpatient cases that involve the use of certain new products or treatments with current FDA approval or an EUA to treat COVID-19, including baricitinib

The NCTAP is equal to the lesser of:

- 65% of the operating outlier threshold for the claim, or
- 65% of the amount by which the costs of the case exceed the standard diagnosis-related group (DRG) payment*

[Click here](#) to learn more about NCTAP.

Medicare DRG enhancement for COVID-19 cases²

- Section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act provides for an increase in the weighting factor for an assigned DRG by 20% for an individual diagnosed with COVID-19 and discharged during the public health emergency (PHE)
- In addition to the NCTAP, CMS applies this enhancement to COVID-19-eligible DRGs (U07.1 for discharges on or after April 1, 2020, continuing through the remainder of the COVID-19 PHE period)

Medicaid is required to cover COVID-19 treatment if states accept additional federal funding for COVID-19

- States must cover, under the state plan (or waiver), testing services and treatments for COVID-19, including vaccines, specialized equipment, and therapies, for any quarter in which the temporary 6.2% increase in the federal medical assistance percentage is claimed³

*Including the adjustment to the relative weight under section 3710 of the CARES Act for eligible cases.¹



DID YOU KNOW?

A DRG is a clinically cohesive group of hospital services that require a similar amount of hospital resources and exhibit similar length-of-stay patterns.⁴

Under DRG payment, there is not typically a specific separate payment for drugs, devices, or supplies.⁵



DID YOU KNOW?

Medicaid uses similar payment methods to Medicare to reimburse hospitals for inpatient care.⁶

- **Base payment:** The base payment rates are reimbursed through fee-for-service (FFS) or managed care arrangements for services provided to Medicaid beneficiaries. States have wide discretion in setting these rates
- **Supplemental payments:** Supplemental payments are payments beyond the base rate that may or may not be tied to specific services

ICD-10 codes and NCTAP coding information

The ICD-10-CM diagnostic code set has a new code to distinguish COVID-19 patient discharges.²

U07.1

For discharges on or after April 1, 2020, continuing through the rest of the COVID-19 PHE period

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification

CMS requires a positive COVID-19 test in order for these Medicare claims to be eligible for the 20% increase in Medicare Severity DRG weighting factor.⁷

Coding for NCTAP¹

For hospital discharges for claims beginning January 1, 2021, through the duration of the COVID-19 PHE, the following baricitinib ICD-10-PCS codes can be used:

XW0DXM6

Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6

XW0G7M6

Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6



DID YOU KNOW?

Baricitinib is available as 1 mg and 2 mg tablets for the treatment of COVID-19 in inpatient facilities.⁸

[Click here](#) for more information.

GI, gastrointestinal; ICD-10-PCS, International Classification of Diseases, Tenth Revision, Procedure Coding System

SELECT IMPORTANT SAFETY INFORMATION RELATED TO ABNORMAL LABORATORY VALUES

There is limited information regarding use of baricitinib in patients with COVID-19 and any of the following clinical findings: absolute neutrophil count (ANC) <1000 cells/mm³, absolute lymphocyte count (ALC) <200 cells/mm³, and hemoglobin <8 g/dL.

Evaluate estimated glomerular filtration rate (eGFR), liver enzymes, and complete blood count at baseline and thereafter according to local patient management practice. Monitor closely when treating patients with abnormal baseline and post-baseline laboratory values. Follow dose adjustments as recommended in the Fact Sheet for Healthcare Providers for patients with abnormal renal, hematological and hepatic laboratory values. Manage patients according to routine clinical guidelines.

In 2017, commercial rates for inpatient services were 89% higher than Medicare's FFS rates on average⁹

For all 3 respiratory diagnoses related to COVID-19, private insurance paid more than double when compared to Medicare¹⁰

- For patients on a ventilator for more than 96 hours, the average private insurance payment rate was about \$60,000 more than the average amount paid by Medicare
- Private insurance reimbursement for services related to COVID-19 were between 2.1 and 2.5 times higher than average Medicare reimbursement

Commercial health insurance coverage of EUA therapies, including baricitinib, for inpatient treatment of COVID-19

The methods that private insurers use to pay for hospital inpatient care vary by insurer and market area.

- Payment methods used by private insurers for their commercial plans include¹⁰
 - DRG-based flat rate per stay
 - Specified rate per day
 - Discount off the hospital's listed charges for the services provided
- While the NCTAP rule applies to Medicare beneficiaries, some private health plans may be applying the same rule/reimbursement to commercially insured members with COVID-19 who are being treated with COVID-19 therapies, including emergency authorized use of baricitinib



DID YOU KNOW?

The CARES ACT Provider Relief Fund provides support for COVID-19 care or treatment for uninsured individuals, including claims for reimbursement for care or treatment related to:

- **Positive diagnoses of COVID-19 where COVID-19 is the primary reason for treatment**
- **Administering COVID-19 vaccinations provided to individuals who do not have any healthcare coverage at the time the services are provided**

Healthcare providers will generally be reimbursed at Medicare rates, subject to available funding.¹¹

Important Safety Information

The following provides essential safety information on the unapproved use of baricitinib under the Emergency Use Authorization.

WARNINGS

Serious Infections: There is limited information regarding use of baricitinib in patients with COVID-19 and concomitant active serious infections.

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Thrombosis: In hospitalized patients with COVID-19, prophylaxis for venous thromboembolism is recommended unless contraindicated. If clinical features of deep vein thrombosis or pulmonary embolism occur, patients should be evaluated promptly and treated appropriately.

Abnormal Laboratory Values: There is limited information regarding use of baricitinib in patients with COVID-19 and any of the following clinical findings: absolute neutrophil count (ANC) <1000 cells/mm³, absolute lymphocyte count (ALC) <200 cells/mm³, and hemoglobin <8 g/dL.

Evaluate estimated glomerular filtration rate (eGFR), liver enzymes, and complete blood count at baseline and thereafter according to local patient management practice. Monitor closely when treating patients with abnormal baseline and post-baseline laboratory values. Follow dose adjustments as recommended in the Fact Sheet for Healthcare Providers for patients with abnormal renal, hematological and hepatic laboratory values. Manage patients according to routine clinical guidelines.

Vaccinations: Avoid use of live vaccines with baricitinib.

Hypersensitivity: If a serious hypersensitivity occurs, discontinue baricitinib while evaluating the potential causes of the reaction.

See **Warnings and Precautions** in the FDA-approved full [Prescribing Information](#) and [Medication Guide](#) for additional information on risks associated with longer-term treatment with baricitinib.

SERIOUS SIDE EFFECTS

Serious venous thrombosis, including pulmonary embolism, and serious infections have been observed in COVID-19 patients treated with baricitinib and are known adverse drug reactions of baricitinib.

ADVERSE REACTIONS

In the COVID-19 clinical trials, adverse drug reactions in the safety population occurring in $\geq 1\%$ of patients treated with baricitinib were alanine aminotransferase (ALT) ≥ 3 x upper limit of normal (ULN) (18.0%), aspartate aminotransferase (AST) ≥ 3 x ULN (11.5%), thrombocytosis >600,000 cells/mm³ (8.2%), creatine phosphokinase (CPK) >5 x ULN (3.7%), neutropenia <1000 cells/mm³ (2.2%), deep vein thrombosis (1.5%), pulmonary embolism (1.4%), and urinary tract infection (1.3%).

USE IN SPECIFIC POPULATIONS

Pregnancy: Baricitinib should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

Renal Impairment: There are limited data for baricitinib in patients with severe renal impairment. Baricitinib is not recommended for patients who are on dialysis, have end-stage renal disease, or have acute kidney injury.

Hepatic Impairment: Baricitinib has not been studied in patients with severe hepatic impairment. Baricitinib has not been studied in patients with severe hepatic impairment. Baricitinib should only be used in patients with severe hepatic impairment if the potential benefit outweighs the potential risk.

Please see [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents and Caregivers \(English\)](#) or [Fact Sheet for Patients, Parents and Caregivers \(Spanish\)](#).

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