Reimbursement of Olumiant for treatment of COVID-19 in the inpatient setting

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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.

Indication:
Olumiant is a Janus kinase (JAK) inhibitor indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

SELECT IMPORTANT SAFETY INFORMATION: WARNING RELATED TO SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

***SERIOUS INFECTIONS*: Olumiant-treated patients are at increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Olumiant if a serious infection occurs until the infection is controlled. Olumiant should not be given to patients with active tuberculosis. Test for latent TB before and during therapy, except for COVID-19; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.**

***MORTALITY*: Higher rate of all-cause mortality, including sudden cardiovascular death was observed with another Janus kinase (JAK) inhibitor vs. tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients.**

***MALIGNANCIES*: Malignancies have also occurred in patients treated with Olumiant. Higher rate of lymphomas and lung cancers was observed with another JAK inhibitor vs. TNF blockers in RA patients.**

***MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)*: Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) was observed with another JAK inhibitor vs. TNF blockers in RA patients.**

***THROMBOSIS*: Thrombosis has occurred in patients treated with Olumiant. Increased incidence of pulmonary embolism, venous and arterial thrombosis was observed with another JAK inhibitor vs. TNF blockers.**

Please see Important Safety Information, including Boxed Warning for Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis on page 6-9. Please click to access Prescribing Information and Medication Guide.

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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 Olumiant to treat those diagnosed with COVID-19.[1]

SELECT IMPORTANT SAFETY INFORMATION RELATED TO SERIOUS INFECTIONS

The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids. Avoid Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant. Closely monitor patients for development of infections during and after Olumiant treatment. In COVID-19 patients, consider the risks and benefits of treatment with OLUMIANT with other concurrent infections.

The Centers for Medicare & Medicaid Services (CMS) has enhanced payments for eligible inpatient treatment of COVID-19[1]

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New COVID Treatments Add-On Payment (NCTAP) program[1]

- 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

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 cases[2]

- 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 claimed[3]

*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

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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]

DID YOU KNOW?

Olumiant is available as 4mg, 2mg, and 1mg tablets for the treatment of COVID-19 in inpatient facilities.[8]

Click here for more information.

Coding for NCTAP[1]

For hospital discharges for claims beginning January 1, 2021, through the duration of the COVID-19 PHE, the following Olumiant 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

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

SELECT IMPORTANT SAFETY INFORMATION RELATED TO TUBERCULOSIS

Evaluate patients for active infection prior to initiating Olumiant. Olumiant should not be given to patients with active TB. Monitor patients for development of signs and symptoms of TB, including patients who tested negative for latent TB prior to initiating therapy.

In 2017, commercial rates for inpatient services were 89% higher than Medicare's FFS rates on average[9]

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For all 3 respiratory diagnoses related to COVID-19, private insurance paid more than double when compared to Medicare[10]

- 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

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

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WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS

Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis (RA) who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt Olumiant until the infection is controlled. Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Test patients, except those with COVID-19, for latent TB before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of Olumiant prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant in patients: with chronic or recurrent infection; who have been exposed to TB; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection.

The risks and benefits of treatment with Olumiant in COVID-19 patients with other concurrent infections should be considered.

Consider anti-TB therapy prior to initiation of Olumiant in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with Olumiant. If a patient develops herpes zoster, interrupt Olumiant treatment until the episode resolves. The impact of Olumiant on chronic viral hepatitis reactivation is unknown. Screen for viral hepatitis in accordance with clinical guidelines before initiating Olumiant.

IMPORTANT SAFETY INFORMATION (Continued)

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MORTALITY

In a large, randomized, postmarketing safety study in RA patients 50 years of age and older with at least one cardiovascular risk factor comparing another Janus kinase (JAK) inhibitor to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers and an additional increased risk of overall malignancies were observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients with a known malignancy (other than successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

NMSCs have been reported in patients treated with Olumiant. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction [MI], and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur.

THROMBOSIS

Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Discontinue Olumiant and promptly evaluate patients with symptoms of thrombosis.

IMPORTANT SAFETY INFORMATION (Continued)

HYPERSENSITIVITY

Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving Olumiant, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue Olumiant while evaluating the potential causes of the reaction.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal perforations have been reported in Olumiant clinical studies. Monitor Olumiant-treated patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Promptly evaluate patients who present with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES

Neutropenia – Olumiant treatment was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3) compared to placebo. Evaluate at baseline and thereafter according to routine patient management.

In patients with RA or alopecia areata (AA), avoid initiation or interrupt Olumiant treatment in patients with an ANC <1000 cells/mm^3. In patients with COVID-19, avoid initiation or interrupt Olumiant treatment in patients with an ANC <500 cells/mm^3.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm^3 were reported in Olumiant clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with Olumiant, but not placebo. Evaluate at baseline and thereafter according to routine patient management.

In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with an ALC <500 cells/mm^3. In patients with COVID-19, avoid initiation or interrupt Olumiant treatment in patients with an ALC <200 cells/mm^3.

Anemia – Decreases in hemoglobin levels to <8 g/dL were reported in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management.

In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with hemoglobin <8 g/dL. In patients with COVID-19, there is limited information regarding use of Olumiant in patients with hemoglobin less than 8 g/dL.

Liver Enzyme Elevations – Olumiant treatment was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of alanine transaminase (ALT) ≥5x upper limit of normal (ULN) and increases of aspartate transaminase (AST) ≥10x ULN were observed in patients in Olumiant clinical trials.

Evaluate at baseline and thereafter according to routine patient management. Promptly investigate the cause of liver enzyme elevation to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt Olumiant until this diagnosis is excluded.

Lipid Elevations – Treatment with Olumiant was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. Assess lipid parameters approximately 12 weeks following Olumiant initiation in patients with RA or AA. Manage patients according to clinical guidelines for the management of hyperlipidemia.

IMPORTANT SAFETY INFORMATION (Continued)

VACCINATIONS

Avoid use of live vaccines with Olumiant. Update immunizations in patients with RA or AA prior to initiating Olumiant therapy in agreement with current immunization guidelines.

ADVERSE REACTIONS

In COVID-19 trials, the most common adverse reactions (≥1%) reported with Olumiant were: ALT ≥3x ULN, AST ≥3x ULN, thrombocytosis (platelets >600,000 cells/mm^3), creatine phosphokinase >5x ULN, neutropenia (ANC <1000 cells/mm^3), DVT, PE, and urinary tract infection.

PREGNANCY AND LACTATION

Based on animal studies, Olumiant may cause fetal harm when administered during pregnancy. Advise pregnant women and women of reproductive potential of the potential risk to a fetus. Consider pregnancy planning and prevention for women of reproductive potential. Advise women not to breastfeed during treatment with Olumiant and for 4 days after the last dose.

HEPATIC AND RENAL IMPAIRMENT

Olumiant should only be used in patients with COVID-19 and severe hepatic impairment if the potential benefit outweighs the potential risk. Olumiant is not recommended in patients with COVID-19 who are on dialysis, have end-stage renal disease, or with eGFR <15 mL/min/1.73m^2.

Please click to access full Prescribing Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis, and Medication Guide.

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References

1. Centers for Medicare & Medicaid Services. New COVID-19 Treatments Add-On Payment (NCTAP). https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap. Updated January 27, 2021. Accessed January 31, 2021. **2.** Centers for Medicare & Medicaid Services. COVID-19 frequently asked questions (FAQs) on Medicare fee-for-service (FFS) billing. https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf. Updated July 2, 2021. Accessed July 22, 2021. **3.** Congressional Research Service. Medicaid's federal medical assistance percentage (FMAP). https://fas.org/sgp/crs/misc/R43847.pdf. Updated July 29, 2020. Accessed February 17, 2021. **4.** Centers for Medicare & Medicaid Services. Design and development of the diagnosis related group (DRG). https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/Design_and_development_of_the_Diagnosis_Related_Group_(DRGs).pdf. Published October 1, 2019. Accessed February 17, 2021. **5.** Lewis M. Medicare reimbursement for drugs and devices. In: *Emerging Life Sciences Companies*. 2nd ed. Philadelphia, PA: Morgan, Lewis & Bockius; 2008:138-148. **6.** Cunningham P, Rudowitz R, Young K, Garfield R, Foutz J. Understanding Medicaid hospital payments and the impact of recent policy changes. https://www.kff.org/report-section/understanding-medicaid-hospital-payments-and-the-impact-of-recent-policy-changes-issue-brief/. Published June 9, 2016. Accessed February 17, 2021. **7.** Fletcher T. CMS to require positive COVID-19 test results for 20-percent Medicare add-on payment. https://www.icd10monitor.com/cms-to-require-positive-covid-19-test-results-for-20-percent-medicare-add-on-payment. Updated September 1, 2020. Accessed February 19, 2021. **8.** Eli Lilly and Company. Access. https://www.covid19.lilly.com/baricitinib/hcp/access. Accessed February 23, 2021. **9.** Congressional Budget Office. An analysis of hospital prices for commercial and Medicare Advantage plans. https://www.cbo.gov/publication/52819. Published June 26, 2017. Accessed February 17, 2021. **10.** Lopez E, Claxton G, Schwartz K, Rae M, Ochieng N, Neuman T. Comparing private payer and Medicare payment rates for select inpatient hospital services. https://www.kff.org/report-section/comparing-private-payer-and-medicare-payment-rates-for-select-inpatient-hospital-services-methods/. Published July 7, 2020. Accessed February 17, 2021. **11.** Health Resources & Services Administration. COVID-19 claims reimbursement to health care providers and facilities for testing, treatment, and vaccine administration for the uninsured. https://www.hrsa.gov/coviduninsuredclaim. Updated June 2021. Accessed July 22, 2021.