Effective: *4/16/2021*
Last Approved: *6/9/2021*
Next Review: *6/9/2022*

COVID-19 Therapeutic Treatment Therapies

Applicable Lines of Business:

✓ Commercial - Health Maintenance Organization (HMO), Preferred Provider Option (PPO)and Point of Service (POS) plans
✓ Medicare Advantage - SecureCare HMO (includes the Dual Eligible Special Needs Plan [DSNP])and SecureChoice PPO
✓ Mountain Health Trust (MHT) including WV Medicaid (Temporary Assistance for Needy Families [TANF], Expansion [WV Health Bridge] and Supplemental Security Income [SSI] populations) and West Virginia Children's Health Insurance Program (WVCHIP)
✓ Self-Funded/Administrative Services Only (ASO)
✓ West Virginia Public Insurance Agency (WV PEIA)

Applicable Claim Type:

Dental
✓ Facility
✓ Pharmacy
✓ Professional

Definitions:

Term	Definition
Bamlanivimab (Olumiant®)	An investigational and experimental monoclonal antibody therapy for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.
Bamlanivimab (Olumiant®) and Etesevimab	Investigational monoclonal antibody therapies that are available under FDA emergency use authorization (EUA) for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.
Baricitinib (Olumiant®)	Janus kinase (JAK) inhibitor
Centers for Medicare and Medicaid Services (CMS)	A federal agency that provides health coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace.
Children's Health Insurance Program (CHIP)	The Children's Health Insurance Program (CHIP) provides low-cost health coverage to children in families that earn too much money to qualify for

	Medicaid.
Claim Adjustment Reason Code (CARC)	A code used in medical billing to communicate a change or an adjustment in payment.
Casirivimab and Imdevimab	Recombinant human IgG1 monoclonal antibodies that target the receptor binding domain of the spike protein of SARS-CoV-2. These are an investigational and experimental drugs.
Coronavirus	A kind of common virus that causes an infection in the nose, sinuses, or upper throat.
COVID-19	Coronavirus disease 2019 (COVID-19) is an infectious respiratory illness caused by a virus called SARS-CoV-2.
COVID-19 Convalescent Plasma	Human plasma from donors who have recovered from COVID-19. A FDA investigational and experimental product approved under an EUA for the treatment of patients hospitalized with COVID-19 to help suppress the virus and modify the inflammatory process.
Emergency Use Authorization (EUA)	An authority that allows the Food and Drug Administration (FDA) to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear (CBRN) threats by facilitating the availability and use of medical counter measures (MCMs) needed during public health emergencies.
Medicare Administrative Contractor (MAC)	A Medicare Administrative Contractor (MAC) is a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B (A/B) medical claims or Durable Medical Equipment (DME) claims for Medicare Fee-For-Service (FFS) beneficiaries. They are the primary operational contact between the Medicare FFS program and the health care providers enrolled in the program.
Monoclonal Antibodies	Monoclonal antibodies are laboratory-produced molecules that act as substitute antibodies that can restore, enhance or mimic the immune system's attack on cells.
Remdesivir (marketed under the brand name Veklury®)	A SARS-CpV-2 nucelotide analog RNA polymerase inhibitor with full *Federal Drug* Administration (FDA) *approval* used in the treatment of adult and pediatric patients hospitalized with COVID-19.

Policy Purpose:

Originating on February 12, 2021 and effective on March 12, 2021, this policy was revised on May 7, 2021.

The purpose of this policy is to address general payment guidelines related to COVID-19 therapeutic treatment therapies as defined by the Centers for Medicare and Medicaid Services (CMS).

Policy Description:

This policy addresses FDA-approved and experimental and investigational COVID-19 therapeutic treatment therapies. This policy applies to in-network and out-of-network providers and facilities for all of The Health Plan's (THP) Commercial, Medicare Advantage, Mountain Health Trust, Self-Funded/ASO and WV PEIA

members.

There is no cost-sharing (copay, coinsurance or deductible) for THP members receiving FDA approved therapeutic treatment therapy.

Commercial, Medicare Advantage, Mountain Health Trust (MHT), Self-Funded/ASO and WV PEIA Reimbursement Guidelines:

Covered and reimbursable COVID-19 therapeutic treatment therapy(ies):

Remdesivir

Remdesivir is FDA-approved as medically necessary and is reimbursable by The Health Plan (THP) for any hospitalized member with a confirmed or presumptive diagnosis of COVID-19. For all other conditions it is experimental and investigational.

Per FDA approval, effective **October 22, 2020**, Remdesivir is covered and reimbursable by THP for the Commercial, Medicare Advantage, MHT, Self-Funded/ASO and WV PEIA lines of business (LOB) for up to 10 days if the patient meets the following criteria (A, B, **and** C):

A. Patient is ≥ 12 years of age and weighing at least 40 kg; **AND**
B. Patient has a confirmed or presumptive diagnosis for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); **AND**
C. Patient is being treated in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

Investigational and experimental non-covered, non-reimbursable COVID-19 therapeutic treatment therapies for Commercial, MHT, Self-Funded/ASO and WV PEIA LOB:

The following COVID-19 therapeutic treatment therapies are investigational and experimental and therefore are **excluded** from coverage and reimbursement for members belonging to the plans described in the subsection heading above.

Claims billed to THP for the therapeutic treatments listed below will deny as "N" (non-covered).

Billing the codes for the therapeutic treatments listed below will result in a line item denial on the provider's claim.

Bamlanivimab (Olumiant) *inpatient* administration (Billing Codes MO239 & QO239)

Bamlanivimab (Olumiant), administered alone, was an experimental and investigational treatment under an EUA (from **November 10, 2020 – April 16, 2021)** for emergency use by healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in **hospitalized** adults and pediatric patients.

Bamlanivimab administered alone between **November 10, 2020 – April 16, 2021**, in an **inpatient setting, is non-covered/non-reimbursable** for all THP Commercial, MHT, Self-Funded/ ASO and WV PEIA members.

Bamlanivimab (Olumiant) *outpatient* administration (Billing Codes MO239 & QO239)

Bamlanivimab (Olumiant),administered alone, was an experimental and investigational treatment under an EUA (from **November 10, 2020 – April 16, 2021)** for use by **outpatient** healthcare providers for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.

Bamlanivimab administered alone between **November 10, 2020 – April 16, 2021**, in an **outpatient setting, is non-covered/non-reimbursable** for all THP Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Bamlanivimab (Olumiant) & Etesevimab (Billing Codes MO245 & QO245)

Bamlanivimab (Olumiant) and Etesevimab administered together are considered experimental and investigational treatment under an EUA for emergency use by healthcare providers for the treatment of mild to moderate COVID-19 in adult and pediatric patients who have tested positive for SARS-CoV-2 and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Bamlanivimab (Olumiant) administered in combination with Etesevimab **is non-covered/non-reimbursable** for all THP Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Baricitinib (Olumiant) in combination with Remdesivir (Billing Codes XW0DXF5, 3E0G7GC, 3E0H7GC, XW0DXM6, XW0G7M6 & XW0H7M6)

While Baricitinib does have FDA approval for the treatment of rheumatoid arthritis and could be a covered therapy for that indication, the use of Baricitinib in combination with Remdesivir for the treatment of COVID-19 is experimental/investigational under an EUA from the FDA at this time.

Baricitinib in combination with Remdesivir **is non-covered/non-reimbursable** for all THP Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Casirivimab and Imdevimab (Billing Codes MO243 & QO243)

Casirivimab and Imdevimab administered together are considered experimental and investigational under an EUA for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients.

Casirivimab and Imdevimab are **non-covered/non-reimbursable** for all Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Convalescent Plasma (Billing Codes XW13325 & XW14325)

COVID-19 convalescent plasma for the treatment of COVID-19 is often given in conjunction with Remdesivir. Convalescent plasma does not have full FDA approval and is considered experimental and investigational for all conditions.

Convalescent plasma is **non-covered/non-reimbursable** for all Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Medicare Advantage Reimbursement Guidelines:

COVID-19 therapeutic treatment therapy(ies) covered and reimbursable by THP for the Medicare Advantage LOB:

Remdesivir

Remdesivir is FDA-approved as medically necessary and is reimbursable by The Health Plan (THP) for any THP Medicare Advantage hospitalized member with a confirmed or presumptive diagnosis of COVID-19. For all other conditions it is experimental and investigational.

Per FDA approval, effective **October 22, 2020**, Remdesivir is covered and reimbursable, when submitted to THP, for up to 10 days if the patient meets the following criteria (A, B, **and** C):

A. Patient is ≥ 12 years of age and weighing at least 40 kg; **AND**

B. Patient has a confirmed or presumptive diagnosis for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); **AND**

C. Patient is being treated in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

COVID-19 therapeutic treatment therapies covered and reimbursable when billed to the Centers for Medicare and Medicaid Services (CMS) Medicare Administrative Contractor (MAC) for THP Medicare Advantage LOB:

During the COVID-19 public health emergency (PHE), the following infusions (when furnished consistent with their respective EUAs) are covered and reimbursable for THP's Medicare Advantage members.

For Calendar Years (CYs) 2020 and 2021, Medicare payment for the COVID-19 monoclonal antibody products and administration for beneficiaries enrolled in Medicare Advantage plans will be made through the original fee-for-service Medicare program.

Providers are advised to submit claims for administering the COVID-19 monoclonal antibody administration to the CMS MAC using product-specific administration codes for each COVID-19 monoclonal antibody product approved.

Health care providers should not include the COVID-19 monoclonal antibody codes on the claim when the product is provided for free.

Medicare Advantage claims erroneously submitted to THP for reimbursement will deny FS (fee-for-service).

Providers may also see the Claim Adjustment Reason Code (CARC) listed below, when applicable, on their payment voucher.

Reason code:

109 - Claim/service not covered by this payer/contractor. You must send the claim/service to the correct payer/

contractor.

Bamlanivimab (Olumiant) & Etesevimab (Billing Codes MO245 & QO245)

Effective April 16, 2021, Bamlanivimab (Olumiant) and Etesevimab administered together are covered for Medicare Advantage members under an EUA from the FDA for the treatment of mild to moderate COVID-19 in adult and pediatric patients who have tested positive for SARS-CoV-2 and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Beginning with **April 16, 2021** date of service, Bamlanivimab (Olumiant) administered in combination with Etesevimab is **covered and reimbursable** for all THP Medicare Advantage members when billed to the **CMS MAC.**

Casirivimab and Imdevimab (Billing Codes MO243 & QO243)

Casirivimab and Imdevimab administered together is covered for Medicare Advantage members under an EUA from the FDA for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients.

Casirivimab and Imdevimab are **covered and reimbursable** for all THP Medicare Advantage members when billed to the **CMS MAC.**

Non-covered, non-reimbursable COVID-19 therapeutic treatment therapies for the Medicare Advantage LOB:

Bamlanivimab (Olumiant) inpatient and outpatient administration (Billing Codes MO239 & QO239)

Effective April 16, 2021, the FDA announced that Bamlanivimab (Olumiant) is non-covered for Medicare Advantage members **when used alone** for the treatment of suspected or laboratory-confirmed COVID-19 in adult and pediatric patients in an outpatient or in an inpatient setting.

Dates of service from **November 10, 2020 – April 16, 2021** are reimbursable when billed to the **CMS MAC** for Bamlanivimab, **when administered alone.**

Investigational and experimental non-covered, non-reimbursable COVID-19 therapeutic treatment therapies for the Medicare Advantage LOB:

The following COVID-19 therapeutic treatment therapies are investigational and experimental and therefore are **excluded** from coverage and reimbursement for members belonging to THP's Medicare Advantage LOB.

Claims billed to THP for the therapeutic treatments listed below will deny as "N" (non-covered).

Billing the codes for the therapeutic treatments listed below will result in a line item denial on the provider's claim.

Baricitinib (Olumiant) in combination with Remdesivir (Billing Codes XW0DXF5, 3E0G7GC, 3E0H7GC, XW0DXM6, XW0G7M6 & XW0H7M6)

While Baricitinib does have FDA approval for the treatment of rheumatoid arthritis and could be a covered therapy for that indication, the use of Baricitinib in combination with Remdesivir for the treatment of COVID-19 is experimental/investigational under an EUA from the FDA at this time.

Baricitinib in combination with Remdesivir **is non-covered/non-reimbursable** for all THP Medicare Advantage

members.

Convalescent Plasma (Billing Codes XW13325 & XW14325)

COVID-19 convalescent plasma for the treatment of COVID-19 is often given in conjunction with Remdesivir. Convalescent plasma does not have full FDA approval and is considered experimental and investigational.

Convalescent plasma is **non-covered/non-reimbursable** for all THP Medicare Advantage members.

Billing Information and Guidelines:

Claims billed to THP for therapeutic treatments not covered by THP will deny as "N" (non-covered).

Billing THP for non-covered therapeutic treatment codes will result in a line item denial on the provider's claim.

Medicare Advantage claims erroneously submitted to THP for reimbursement will deny FS (fee-for-service).

Providers may also see the Claim Adjustment Reason Code (CARC) listed below, when applicable, on their payment voucher.

Reason code:

109 - Claim/service not covered by this payer/contractor. You must send the claim/service to the correct payer/contractor.

The following billing codes for COVID-19 therapeutic treatment therapy(ies) are covered and reimbursable by THP for Commercial, Medicare Advantage, MHT, Self-Funded/ASO, WVCHIP and WV PEIA LOB:

Billing Code	Description
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

The following billing codes for COVID-19 therapeutic treatment therapy(ies) are non-covered and non-reimbursable by THP for Commercial, Medicare Advantage, MHT, Self-Funded/ASO and WV PEIA LOB)

Billing Code	Description
XW13325	Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW14325	Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5
XW0DXF5	Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5
3E0G7GC	Introduction of other therapeutic substance into upper G.I. via natural or artificial

	opening
3E0H7GC	Introduction of other therapeutic substance into lower G.I. via natural or artificial opening
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
XW0H7M6	Introduction of Baricitinib into lower GI, via natural or artificial opening, new technology group 6

More billing information may be found in The Health Plan's Provider Manual located at healthplan.org "For Providers," "Resources."

Review/Revision History:

	Date	Action
Policy Issue Date	3/12/2021	
Date Revised	05/07/2021	• Added the definition for Bamlanivimab (Olumiant®) and Etesevimab under the **Definitions** heading. • Revised the verbiage in the section subheading **Bamlanivimab (Olumiant) *inpatient* administration** to mirror the FDA's policy revised on April 16, 2021. • Revised the verbiage in the section subheading **Bamlanivimab (Olumiant) *outpatient* administration** to mirror the FDA's policy revised on April 16, 2021. • Added a new section under the subheading **Bamlanivimab (Olumiant) & Etesevimab** to mirror the FDA's policy revised on April 16, 2021. • Added a new section under the heading **Non-covered, non-reimbursable COVID-19 therapeutic treatment therapies for the Medicare Advantage LOB** • Created the subheading **Bamlanivimab (Olumiant) inpatient and outpatient administration** and revised the verbiage in the section to mirror the FDA's policy revised on April 16, 2021.

References and Research Materials:

1. COVID-19 Vaccines and Monoclonal Antibodies. Centers for Medicare and Medicaid Services. Available at: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies
2. FDA NEWS RELEASE: Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab. U S Food and Drug Administration. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab
3. FDA Authorizes Revisions to Fact Sheets to Address SARS-CoV-2 Variants for Monoclonal Antibody Products Under Emergency Use Authorization US Food and Drug Administration. Available

at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-revisions-fact-sheets-address-sars-cov-2-variants-monoclonal-antibody-products-under

4. Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction. Centers for Medicare and Medicaid Services. Available at: https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion

Disclaimer:

This policy is intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry standard claims editing logic, benefit design and other factors are considered in developing payment policies. This policy is intended to serve as a guideline only and does not constitute medical advice, any guarantee of payment, plan pre-authorization, an explanation of benefits, or a contract. This policy does not govern whether a specific procedure is covered under any specific member plan or policy, nor is it intended to address every claim situation. The determination that any service, procedure, item, etc., is covered under a member's benefit plan shall not be construed as a determination that a provider will be reimbursed for services provided. Individual claims may be affected by other factors, including but not necessarily limited to state and federal laws and regulations, legislative mandates, provider contract terms, and THP's professional judgement. Reimbursement for any services shall be subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management guidelines. Unless otherwise noted within the policy, THP's policies apply to both participating and non-participating providers and facilities. THP reserves the right to review and revise these policies periodically as it deems necessary in its discretion, and it is subject to change or termination at any time by THP. THP has full and final discretionary authority for its interpretation and application. Accordingly, THP may use reasonable discretion in interpreting and applying this policy to health care services provided in any particular case.

All revision dates: 6/9/2021, 3/9/2021, 2/18/2021

Effective:	*3/12/2021*
Last Approved:	*3/9/2021*
Last Revised:	*3/9/2021*
Next Review:	*3/9/2022*

COVID-19 Therapeutic Treatment Therapies

Applicable Lines of Business:

✓ Commercial - Health Maintenance Organization (HMO), Preferred Provider Option (PPO)and Point of Service (POS) plans
✓ Medicare Advantage - SecureCare HMO (includes the Dual Eligible Special Needs Plan [DSNP])and SecureChoice PPO
✓ Mountain Health Trust (MHT) including WV Medicaid (Temporary Assistance for Needy Families [TANF], Expansion [WV Health Bridge] and Supplemental Security Income [SSI] populations) and West Virginia Children's Health Insurance Program (WVCHIP)
✓ Self-Funded/Administrative Services Only (ASO)
✓ West Virginia Public Insurance Agency (WV PEIA)

Applicable Claim Type:

Dental
✓ Facility
✓ Pharmacy
✓ Professional

Definitions:

Term	Definition
Bamlanivimab (Olumiant®)	An investigational and experimental monoclonal antibody therapy for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.
Baricitinib (Olumiant®)	Janus kinase (JAK) inhibitor
Centers for Medicare and Medicaid Services (CMS)	A federal agency that provides health coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace.
Children's Health Insurance Program (CHIP)	The Children's Health Insurance Program (CHIP) provides low-cost health coverage to children in families that earn too much money to qualify for Medicaid.
Claim Adjustment Reason Code (CARC)	A code used in medical billing to communicate a change or an adjustment in payment.

Casirivimab and Imdevimab	Recombinant human IgG1 monoclonal antibodies that target the receptor binding domain of the spike protein of SARS-CoV-2. These are an investigational and experimental drugs.
Coronavirus	A kind of common virus that causes an infection in the nose, sinuses, or upper throat.
COVID-19	Coronavirus disease 2019 (COVID-19) is an infectious respiratory illness caused by a virus called SARS-CoV-2.
COVID-19 Convalescent Plasma	Human plasma from donors who have recovered from COVID-19. A FDA investigational and experimental product approved under an EUA for the treatment of patients hospitalized with COVID-19 to help suppress the virus and modify the inflammatory process.
Emergency Use Authorization (EUA)	An authority that allows the Food and Drug Administration (FDA) to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear (CBRN) threats by facilitating the availability and use of medical counter measures (MCMs) needed during public health emergencies.
Medicare Administrative Contractor (MAC)	A Medicare Administrative Contractor (MAC) is a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B (A/B) medical claims or Durable Medical Equipment (DME) claims for Medicare Fee-For-Service (FFS) beneficiaries. They are the primary operational contact between the Medicare FFS program and the health care providers enrolled in the program.
Monoclonal Antibodies	Monoclonal antibodies are laboratory-produced molecules that act as substitute antibodies that can restore, enhance or mimic the immune system's attack on cells.
Remdesivir (marketed under the brand name Veklury®)	A SARS-CpV-2 nucelotide analog RNA polymerase inhibitor with full *Federal Drug* Administration (FDA) *approval* used in the treatment of adult and pediatric patients hospitalized with COVID-19.

Policy Purpose:

The purpose of this policy is to address general payment guidelines related to COVID-19 therapeutic treatment therapies as defined by the Centers for Medicare and Medicaid Services (CMS).

Policy Description:

This policy originated February 12, 2021 and became effective March 12, 2021. It addresses FDA-approved and experimental and investigational COVID-19 therapeutic treatment therapies. This policy applies to in-network and out-of-network providers and facilities for all of The Health Plan's (THP) Commercial, Medicare Advantage, Mountain Health Trust, Self-Funded/ASO and WV PEIA members.

There is no cost-sharing (copay, coinsurance or deductible) for THP members receiving FDA approved therapeutic treatment therapy.

Commercial, Medicare Advantage, Mountain

Health Trust, Self-Funded/ASO and WV PEIA Reimbursement Guidelines:

Covered and reimbursable COVID-19 therapeutic treatment therapy(ies):

Remdesivir

Remdesivir is FDA-approved as medically necessary and is reimbursable by The Health Plan (THP) for any hospitalized member with a confirmed or presumptive diagnosis of COVID-19. For all other conditions it is experimental and investigational.

Per FDA approval, effective **October 22, 2020**, Remdesivir is covered and reimbursable by THP for the above lines of business (LOB) for up to 10 days if the patient meets the following criteria (A, B, **and** C):

A. Patient is ≥ 12 years of age and weighing at least 40 kg; **AND**

B. Patient has a confirmed or presumptive diagnosis for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); **AND**

C. Patient is being treated in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

Investigational and experimental non-covered, non-reimbursable COVID-19 therapeutic treatment therapies for Commercial, Mountain Health Trust, Self-Funded/ASO and WV PEIA LOB:

The following COVID-19 therapeutic treatment therapies are investigational and experimental and therefore are **excluded** from coverage and reimbursement for members belonging to the plans described in the subsection heading above.

Claims billed to THP for the therapeutic treatments listed below will deny as "N" (non-covered).

Billing the codes for the therapeutic treatments listed below will result in a line item denial on the provider's claim.

Bamlanivimab (Olumiant) *inpatient* administration (Billing Codes MO239 & QO239)

Bamlanivimab (Olumiant) is an experimental and investigational treatment under an EUA for emergency use by healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in **hospitalized** adults and pediatric patients.

Bamlanivimab administered in an **inpatient setting is non-covered/non-reimbursable** for all THP Commercial, MHT, Self-Funded/ ASO and WV PEIA members.

Bamlanivimab (Olumiant) *outpatient* administration (Billing Codes MO239 & QO239)

Bamlanivimab (Olumiant) is an experimental and investigational treatment under an EUA for use by **outpatient** healthcare providers for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.

Bamlanivimab administered in an **outpatient setting is non-covered/non-reimbursable** for all THP Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Baricitinib (Olumiant) in combination with Remdesivir (Billing Codes XW0DXF5, 3E0G7GC, 3E0H7GC, XW0DXM6, XW0G7M6 & XW0H7M6)

While Baricitinib does have FDA approval for the treatment of rheumatoid arthritis and could be a covered therapy for that indication, the use of Baricitinib in combination with Remdesivir for the treatment of COVID-19 is experimental/investigational under an EUA from the FDA at this time.

Baricitinib in combination with Remdesivir **is non-covered/non-reimbursable** for all THP Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Casirivimab and Imdevimab (Billing Codes MO243 & QO243)

Casirivimab and Imdevimab administered together are considered experimental and investigational under an EUA for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients.

Casirivimab and Imdevimab are **non-covered/non-reimbursable** for all Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Convalescent Plasma (Billing Codes XW13325 & XW14325)

COVID-19 convalescent plasma for the treatment of COVID-19 is often given in conjunction with Remdesivir. Convalescent plasma does not have full FDA approval and is considered experimental and investigational for all conditions.

Convalescent plasma is **non-covered/non-reimbursable** for all Commercial, MHT, Self-Funded/ASO and WV PEIA members.

Medicare Advantage Reimbursement Guidelines:

COVID-19 therapeutic treatment therapy(ies) covered and reimbursable by THP for the Medicare Advantage LOB:

Remdesivir

Remdesivir is FDA-approved as medically necessary and is reimbursable by The Health Plan (THP) for any THP Medicare Advantage hospitalized member with a confirmed or presumptive diagnosis of COVID-19. For all other conditions it is experimental and investigational.

Per FDA approval, effective **October 22, 2020**, Remdesivir is covered and reimbursable, when submitted to THP, for up to 10 days if the patient meets the following criteria (A, B, **and** C):

A. Patient is ≥ 12 years of age and weighing at least 40 kg; **AND**

B. Patient has a confirmed or presumptive diagnosis for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); **AND**

C. Patient is being treated in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

COVID-19 therapeutic treatment therapies covered and reimbursable when billed to the Centers for Medicare and Medicaid Services (CMS) Medicare Administrative Contractor (MAC) for THP Medicare Advantage LOB:

During the COVID-19 public health emergency (PHE), the following infusions (when furnished consistent with their respective EUAs) are covered and reimbursable for THP's Medicare Advantage members.

For Calendar Years (CYs) 2020 and 2021, Medicare payment for the COVID-19 monoclonal antibody products and administration for beneficiaries enrolled in Medicare Advantage plans will be made through the original fee-for-service Medicare program.

Health care providers should not include the COVID-19 monoclonal antibody codes on the claim when the product is provided for free.

Providers are advised to submit claims for administering the COVID-19 monoclonal antibody administration to the CMS MAC using product-specific administration codes for each COVID-19 monoclonal antibody product approved.

Medicare Advantage claims erroneously submitted to THP for reimbursement will deny FS (fee-for-service).

Providers may also see the Claim Adjustment Reason Code (CARC) listed below, when applicable, on their payment voucher.

Reason code:

109 - Claim/service not covered by this payer/contractor. You must send the claim/service to the correct payer/contractor.

Bamlanivimab (Olumiant) inpatient administration (Billing Codes MO239 & QO239)

Bamlanivimab (Olumiant) is covered for Medicare Advantage members under an EUA from the FDA for emergency use by healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in **hospitalized** adults and pediatric patients.

Bamlanivimab administered in an inpatient setting is **covered and reimbursable** for THP Medicare Advantage members when billed to the **CMS MAC**.

Bamlanivimab (Olumiant) outpatient administration (Billing Codes MO239 & QO239)

Bamlanivimab (Olumiant) is covered for Medicare Advantage members under an EUA from the FDA for use by **outpatient** healthcare providers for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.

Bamlanivimab administered in an outpatient setting is **covered and reimbursable** for all THP Medicare Advantage members when billed to the **CMS MAC**.

Casirivimab and Imdevimab (Billing Codes MO243 & QO243)

Casirivimab and Imdevimab administered together is covered for Medicare Advantage members under an EUA from the FDA for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and

pediatric patients.

Casirivimab and Imdevimab are **covered and reimbursable** for all THP Medicare Advantage members when billed to the **CMS MAC.**

Investigational and experimental non-covered, non-reimbursable COVID-19 therapeutic treatment therapies for the Medicare Advantage LOB:

The following COVID-19 therapeutic treatment therapies are investigational and experimental and therefore are **excluded** from coverage and reimbursement for members belonging to THP's Medicare Advantage LOB.

Claims billed to THP for the therapeutic treatments listed below will deny as "N" (non-covered).

Billing the codes for the therapeutic treatments listed below will result in a line item denial on the provider's claim.

Baricitinib (Olumiant) in combination with Remdesivir (Billing Codes XW0DXF5, 3E0G7GC, 3E0H7GC, XW0DXM6, XW0G7M6 & XW0H7M6)

While Baricitinib does have FDA approval for the treatment of rheumatoid arthritis and could be a covered therapy for that indication, the use of Baricitinib in combination with Remdesivir for the treatment of COVID-19 is experimental/investigational under an EUA from the FDA at this time.

Baricitinib in combination with Remdesivir **is non-covered/non-reimbursable** for all THP Medicare Advantage members.

Convalescent Plasma (Billing Codes XW13325 & XW14325)

COVID-19 convalescent plasma for the treatment of COVID-19 is often given in conjunction with Remdesivir. Convalescent plasma does not have full FDA approval and is considered experimental and investigational.

Convalescent plasma is **non-covered/non-reimbursable** for all THP Medicare Advantage members.

Billing Information and Guidelines:

The following billing codes for COVID-19 therapeutic treatment therapy(ies) are covered and reimbursable by THP for Commercial, Medicare Advantage, MHT, Self-Funded/ASO, WVCHIP and WV PEIA LOB:

Billing Code	Description
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

The following billing codes for COVID-19 therapeutic treatment therapy(ies) are non-covered and non-reimbursable by THP for Commercial, Medicare Advantage, MHT, Self-Funded/ASO and WV PEIA

LOB)

Billing Code	Description
XW13325	Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW14325	Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5
XW0DXF5	Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5
3E0G7GC	Introduction of other therapeutic substance into upper G.I. via natural or artificial opening
3E0H7GC	Introduction of other therapeutic substance into lower G.I. via natural or artificial opening
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
XW0H7M6	Introduction of Baricitinib into lower GI, via natural or artificial opening, new technology group 6

More billing information may be found in The Health Plan's Provider Manual located at healthplan.org "For Providers," "Resources."

References and Research Materials:

1. FDA Combating COVID-19 with Therapeutics. Emergency Use Authorization. U S Food and Drug Administration. Available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
2. COVID-19 Treatments Add-On Payment (NCTAP). Centers for Medicare and Medicaid Services. Available at: https://www.cms.gov/medicare/covid-19/covid-19-treatments-add-payment-nctap
3. Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction. Centers for Medicare and Medicaid Services. Available at: https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

Disclaimer:

This policy is intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry standard claims editing logic, benefit design and other factors are considered in developing payment policies. This policy is intended to serve as a guideline only and does not constitute medical advice, any guarantee of payment, plan pre-authorization, an explanation of benefits, or a contract. This policy does not govern whether a specific procedure is covered under any specific member plan or policy, nor is it intended to address every claim situation. The determination that any service, procedure, item, etc., is covered under a member's benefit plan shall not be construed as a determination that a provider will be reimbursed for services provided. Individual claims may be affected by other factors,

including but not necessarily limited to state and federal laws and regulations, legislative mandates, provider contract terms, and THP's professional judgement. Reimbursement for any services shall be subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management guidelines. Unless otherwise noted within the policy, THP's policies apply to both participating and non-participating providers and facilities. THP reserves the right to review and revise these policies periodically as it deems necessary in its discretion, and it is subject to change or termination at any time by THP. THP has full and final discretionary authority for its interpretation and application. Accordingly, THP may use reasonable discretion in interpreting and applying this policy to health care services provided in any particular case.

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