Banner
University Health Plans

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January 2021 Update

Monoclonal Antibody Treatment available for patients at Infusion Center in Tucson

Monoclonal antibody treatment, given within 10 days of symptom onset in eligible patients, may decrease ED and inpatient admissions.

Follow the eligibility and referral process information below if you have a patient who may be a candidate for monoclonal antibody therapy for COVID.

Eligibility Criteria (Patient must meet all criteria below)

- COVID Positive – direct antigen or PCR is acceptable
- Be within 10 days of symptom onset at the time of treatment (asymptomatic patients will not be accepted)
- Meet at least one high-risk criteria (see guidelines)
    - Age 65 or greater
    - Age 55 or greater, with hypertension, COPD, or chronic respiratory condition
    - BMI > 35
    - Diabetes
    - Chronic kidney disease
    - Immunocompromised (immune deficiency or on immunosuppressive drugs)

Exclusion Criteria

- Hospitalized due to COVID
- Require oxygen therapy due to COVID
- If already on oxygen, require increase in baseline oxygen flow due to COVID
- Other systemic infection, such as UTI

Referral Process

1. Identify symptomatic, COVID+ patients based on telephone, face to face, or telehealth encounter
    a. Note: it may be helpful to evaluate and discuss treatment options with the patient before the COVID test is ordered or in the telephone call informing patients of their COVID positive result
    b. Note: patients must be within 10 days of symptom onset before infusion is given
2. Evaluate patient to determine if have any high-risk factors.
3. Review risks and benefits with patients (see EUA Fact Sheet for detail)
4. Complete note that includes the following:
    a. High-risk criteria that the patient meets (based on medical history, lab information, or clinician assessment)

   b. Statement that you have reviewed risks and benefits
   c. Statement that the patient does not have another systemic infection
5. Complete order set and fax, along with clinical note, to Banner Infusion Center
   a. Order must be signed by a physician (NP or PA orders are not accepted)

If you have any questions, please contact Melissa Duke at melissa.duke@bannerhealth.com.

Please note – the Monclonal Antibody order form and guidelines are included at the end of this newsletter.

Plan Materials now available on website

2021 Plan Materials for Banner-University Care Advantage are now available on our website at the following URL:

https://www.banneruca.com/plan-information/2021-plan-materials

You will find several key resources on the site, including the Annual Notice of Changes, Evidence of Coverage, Summary of Benefits, Drug Formulary, and Provider and Pharmacy Directories.

Additional Benefits are listed in Chapter 4 of the Benefits chart to include Chiropractic, Podiatry, and Hearing Services. Please note Sonora Quest Laboratories is the contracted laboratory for Banner University Health Plans.

It is important to note that QMB members do not have cost sharing responsibility for Medicare Parts A and B covered services, including services covered by the Medicare Program but not covered by AHCCCS.

Change in Credentialing requirements for BUHP

Effective Mar. 1, 2021, Banner University Health Plans (BUHP), will begin credentialing urgent care, radiologists, emergency medicine, hospital-based and other practitioners not previously credentialed. With the addition of our Medicare lines of business, practitioners will be required to be credentialed with BUHP regardless of participation with a BUHP Medicare product.

This will ensure that BUHP meets the AHCCCS AMPM Chapter 950, CMS/Medicare requirement under the Social Security Act, Section 1852, the Code of Federal Regulations – 42 CFR 422.204 and the Medicare Managed Care Manual Chapter 6 that credentialing is required for: All physicians who provide services to the Medicare Advantage Organizations (MAO) members and All other types of Health Care Professionals who provide services to enrollees, and are permitted to practice independently under State law.

We will do a system check of Practitioners that are active, but not credentialed, and will begin to initiate the credentialing process for continued BUHP participation. Any new Practitioners will need to be submitted to BUHP utilizing the AzAHP Practitioner form to initiate the credentialing process.

If the Practitioner has a CAQH account that is updated with a current attestation, no action is needed on your part for us to initiate the process. Once the CVO Aperture begins the primary source verification, if any further information is needed, they will contact you directly.

If you do not have a CAQH Provider ID and need to register, information can be found on the CAQH Registration page https://proview.caqh.org/pr/registration

Thank you for your participation with Banner University Health Plans and the care you provide to our members.

If you have any question regarding this change please contact our Provider Relations Department at BUHPProvidernotifications@bannerhealth.com

Electronic Visit Verification Starts Jan. 1

What is EVV?

EVV is an electronic verification system that home-based service providers will be required to use starting January 1, 2021 by AHCCCS. This will eliminate all paper timesheets across the state and help prevent fraud, waste and abuse.

Providers must use an EVV vendor that meets the requirements for AHCCCS. Sandata is a third party EVV vendor for AHCCCS. Providers can choose to use Sandata or another system that meets requirements. At the very minimum the EVV system used must include:

- Type of services performed
- Individual receiving the service
- Date of the service
- Location of service delivery
- Individual providing the service
- Time the service begins and ends

Provider Description	Provider Type
Attendant Care Agency	40
Behavioral Outpatient Clinic	77
Community Service Agency	A3
Fiscal Intermediary	F1
Habilitation Provider	39
Home Health Agency	23
Integrated Clinic	IC
Non-Medicare Certified Home Health Agency	95
Private Nurse	46

You only need to utilize the EVV system you have in place while billing these codes:

Service	**HCPCS Service Code**	**Service**	**HCPCS Service Code**
Attendant Care	S5125	Respiratory Therapy	S5181
Companion Care	S5135	Speech Therapy	G0153/S9128
Habilitation	T2017	Private Duty Nursing	S9123/S9124
Nursing	G2099/G0300	Homemaker	S5130
Home Health Aid	T1021	Personal Care	T1019
Physical Therapy	G0151/S9131	Respite	S5150/S5151
Occupational Therapy	G0152/S9129	Skills Training and Dev	H2014

What you should do:

- Reach out to AHCCCS with any questions related to EVV (EVV@azahcccs.gov)

- Ensure AHCCCS has your agencies main EVV contact name and e-mail (EVV@azahcccs.gov)
- Ensure you have an EVV vendor who meets the criteria
- Sign up for EVV training through AHCCCS

Upcoming trainings and deadlines:
- Sandata EVV Provider Training: 10/19/20-12/9/20
    - If providers are not using Sandata system, a Sandata aggregator training is still required
- Members receive information about devices and training: 10/19/20-12/9/20
- Banner Health Plan Authorizations are currently in production and have been since 10/1/20
- Claims Validation expected to Go Live 1/1/21
- Go Live Date for EVV is 1/1/21

Helpful links:
AHCCCS EVV Page - https://www.azahcccs.gov/AHCCCS/Initiatives/EVV/
AHCCCS Newsletter Sign-up Page -
https://visitor.r20.constantcontact.com/manage/optin?v=001gF-kjPbNwUkjAeak65PHSgLUZfF69ZO6RXBCAAbHv8heAcaheQ_-WfduMQGsN3O2op25HcUg5yFMkioRyBg0yyW6i9m3UkjG6trezpL0LRs%3D

Facilities: Billing with a GO condition code

When a patient is seen in an outpatient setting multiple times in a single day, billing with a GO condition code is required.

https://www.azahcccs.gov/PlansProviders/Downloads/FFSProviderManual/FFS_Chap06.pdf

18-28 Condition Codes **Required if applicable**

Enter the appropriate condition codes that apply to this bill. See the *UB-04 Manual* for codes.

Examples:
- In-state, non-HIS inpatient hospitals may request outlier consideration for a claim by entering “61” in any condition code field.

- To bill for self-dialysis training, free-standing dialysis facilities approved to provide self-dialysis training must enter “73” in any Condition Code field and bill revenue code 841 (Continuous Ambulatory Peritoneal Dialysis, per day) or revenue code 851 (Continuous Cycling Peritoneal Dialysis, per day).

- To bill for multiple distinct/independent outpatient visits on the same day, facilities must enter “GO”.

Behavioral Health Home Providers reminder

As a reminder, per the BUHP Behavioral Health Comprehensive Provider Manual Supplement, Banner University Family Care AHCCCS Complete Care (BUFC/ACC) Behavioral Health Home providers are responsible for all medically necessary covered behavioral health services. This is inclusive of those needs related to crisis follow up services.

Regional Behavioral Health Authorities provide crisis services within the communities in their service area. BUFC/ACC Behavioral Health Homes are required to provide crisis planning, coordinate care with local crisis providers, and engage in diversion planning.

Additionally, each Behavioral Health Home provider must have 24/7 telephonic response to meet members' emergent needs and coordinate with crisis providers. Clinically appropriate follow up with the member, following a behavioral health crisis is required within seven days.

Should a prescriber appointment be necessary in follow up of a crisis event, an urgent need appointment must be made available to the member within 24 hours from the time that the need is identified.

In the event that the crisis results in the member being admitted to an inpatient or other out of home treatment setting, the Behavioral Health Home must coordinate discharge planning activities with the treatment facility upon admission to allow the member to discharge as soon as is clinically appropriate.

Connect to AZHIE. Improve Care. Receive $5K.

Join us on **January 26 at noon** to learn how your organization can utilize the statewide HIE to provide better care and better outcomes. Now more than ever it is important for Arizona's providers to have the patient data they need to make better clinical decisions and keep people healthy.

During this session we will review the available technology and services from Health Current, and how you can join the other 820+ organizations across the state who already participate in Arizona's HIE. AHCCCS strongly encourages all Medicaid providers to sign a participation agreement prior to **March 31, 2021.**

https://www.eventbrite.com/e/health-current-arizonas-hie-informational-session-registration-132441312531

Supplemental benefits for B – UCA members

The following supplemental benefits can be located by accessing the link below to access the Banner - University Care Advantage 2021 Plan Materials. Additional Benefits are listed in Chapter 4 of the Benefits chart to include Chiropractic, Podiatry, and Hearing Services. You may also find the 2021 Annual Notice of Changes, 2021 Evidence of Coverage, 2021 Summary of Benefits, 2021 Drug Formulary, and 2021 Provider and Pharmacy Directories.

Please note Sonora Quest Laboratories is the contracted laboratory for Banner University Health Plans.

https://www.banneruca.com/plan-information/2021-plan-materials

Please review important details below related to QMB members.

201 - MEDICARE COST SHARING FOR MEMBERS COVERED BY MEDICARE AND MEDICAID 05/30/19

ACOM Chapter 200, Policy 201

Section A. QMB Duals

1. Contractor Payment Responsibilities a. The Contractor is responsible for payment of Medicare cost sharing amounts (deductibles, coinsurance, and copayments) for Medicare Parts A and B covered services, including services covered by the Medicare Program but not covered by AHCCCS, such as chiropractic services for adults, as detailed in this Policy. For information on AHCCCS covered services and limitations, refer to AMPM Chapter 300. b. A Contractor is prohibited from using the 09 coverage code to deny payment for medically necessary services provided to a QMB Dual. The 09 coverage code is used by AHCCCS to resolve coding discrepancies between Medicare and Medicaid, and shall not be used by a Contractor to deny payment of claims, including Medicare cost sharing claims.
2. b. The Contractor shall have no Medicare cost sharing obligation if the Medicare payment exceeds the Contractor's contracted reimbursement rate for the covered service. The Contractor's liability for Medicare cost sharing amounts, plus the amount of Medicare's payment, shall not exceed the Contractor's subcontracted reimbursement rate for the service. There is no separate Medicare cost sharing obligation if the Contractor has a subcontract with the provider and the provider's subcontracted reimbursement rate includes Medicare cost sharing amounts.

Workforce Development Plan Deliverable Submissions

Health Plans and provider organizations work together to ensure that members receive services from a workforce that is qualified, competent, and sufficiently staffed. ACC contracted Behavioral Health providers are required to submit a Workforce Development Plan (WFDP) via the Arizona Association of Health Plans' Workforce Development Alliance. The

WFDP shall describe the goals, objectives, tasks, and timelines to develop the workforce. The overall approach and philosophy to Workforce Development is to ensure a comprehensive, systematic and measurable structure that incorporates best practices at all levels of service delivery.

Workshops will be held to provide guidance and information on the completion and submission of your WFDP. You may register for the workshop(s) in Relias by running a module search for "workshop", selecting the **AzAHP—WFD Plan Workshop* module, and following the steps to register. The next scheduled workshops are:

- January 19, 2021 10 a.m. to Noon
- February 17, 2021 1 p.m. to 3 p.m.

WFDPs should be submitted between Feb. 1 – 28, 2021. Early and late submissions will not be accepted.

- **Required Provider Types:** Behavioral Health contracted ACC Providers.
- **Exempt Provider Types:** Individually Contracted Practitioners and Behavioral Health Hospitals.
- **Note:** Federally Qualified Healthcare providers (FQHCs) may request exemption from their contracted Health Plan(s). Exemptions may be granted on a case-by-case basis and will take into account the following:
    - Portion of AHCCCS Members enrolled in the network and served by that provider,
    - Geographic area serviced, and
    - Number of other service providers in the surrounding area.

Workforce Development Training Plan Updates

It is required that Behavioral Health contracted ACC/RBHA Providers must ensure that all staff who work in programs that support, oversee, or are paid by the Health Plan contract have access to the Relias Learning Management System and are enrolled in the AzAHP Training plans listed below. The goal is for your employees to have a 90% (or higher) completion rate with all courses. The next completion report will be run on Jan. 29, 2021. Please encourage your staff to login to their Relias accounts and complete their assigned course(s) on or before the due date(s).

AzAHP—Core Training Plan (90 Days)

1. Welcome to Relias (due within 7 days of hire)
2. *AHCCCS—Health Plan Fraud
3. *AHCCCS—NEO—Rehabilitation Employment
4. *AzAHP—AHCCCS 101
5. *AzAHP—Client Rights, Grievances and Appeals
6. *AzAHP—Cultural Competency in Health Care
7. *AzAHP—Quality of Care Concern
8. Corporate Compliance: The Basics
9. Customer Service
10. Ethical Decision Making: The Basics
11. Integrating Primary Care with Behavioral Healthcare
12. Personalized Learning: Understanding the HIPAA Regulations

AzAHP—Core Training Plan (Annual)

1. Personalized Learning: Understanding the HIPAA Regulations Due: Jan. 31
2. Ethical Decision Making: The Basics Due: Mar. 31
3. Abuse and Neglect: What to Look for and How to Respond Due: Apr. 30
4. Corporate Compliance: The Basics Due: May 31
5. *AzAHP—Cultural Competency in Health Care Due: June 30

6. *AHCCCS—Health Plan Fraud Due: Oct. 31
7. *AzAHP—Quality of Care Concern Due: Dec. 31

AzAHP Workforce Development Alliance Provider Forums
The AzAHP Workforce Development Alliance consists of the AzAHP, Relias and the Workforce Development Administrators from all seven ACC Health Plans. On the second Thursday of each month, the Alliance hosts virtual provider forums to update the Behavioral Health Network on Workforce Development related issues, training and Relias.

For additional information on the WFDP requirement, training plans and the provider forums, or to discuss technical assistance needs, please reach out to our Workforce Development Department at workforce@bannerhealth.com, or the Workforce Development Administrator, Selena McDonald, at selena.mcdonald@bannerhealth.com.

Systems of Care

SMART Goals

In behavioral health, the purpose of a SMART Goal is to provide structure and direction of the treatment and support for members. SMART Goals help to ensure that clinically appropriate treatment is meeting the individual needs of members. SMART Goals should be used throughout the treatment process to provide the member with the clarity and motivation that is needed to successfully achieve an identified goal. Some of the collaborative platforms where SMART Goals are developed include the Child and Family Team (CFT) and Adult Recovery Team (ART). B-UFC provides a 'SMART Goal Cheat-Sheet' on the Banner Behavioral Health page, under the Behavioral Health Materials and Forms section, to support providers in better understanding the purpose, use and development for members enrolled with B-UFC: https://www.banneruhp.com/materials-and-services/behavioral-health.

Crisis Planning

Crisis Planning is an important component of service delivery as it promotes the safety of the member, their family and the community. Crisis Planning provides a written method for crisis prevention, support and intervention that identifies the member's needs and preferences in the event of a crisis. Crisis Planning should be trauma informed and should include:

- Consideration of the member's cultural preferences
- Clinical indicators such as the member's needs, symptoms, current placement, health care needs and psychiatric history
- Provide a detailed description of the potentially dangerous behavioral health condition, episode or behavior and highlight strengths
- Effective and ineffective interventions
- Role of family members and other natural supports
- 24-hour crisis response number, 911, nearby hospital(s) when appropriate
- Methods to determine the level of response to align with the severity of the crisis

Crisis Plans should be completed in collaboration with the Child and Family Team (CFT) or the Adult Recovery Team (ART) and a copy of the plan should be provided to all team members to promote consistency. Crisis Plans should be updated at least annually or as often as the team deems necessary to meet member's needs. Crisis Plans are especially important for members who present with a history of suicidal ideation or attempts as they require immediate support to ensure their safety and well-being.

Provider Engagement for Follow-up after Hospitalization for Mental Illness & HEDIS Measures

BH Providers are key to bridging the gap of services when a member is hospitalized. In accordance with AHCCCS and Federal regulatory requirements, BUHP is required to track HEDIS performance measures for follow up care at 7 days and 30 days after discharge to assess progress to recovery for our Adult and Children population. BUHP baseline measures for follow-up after hospitalization are by 7 days and 30 days for both the child and adult populations.

BUHP is committed to improving quality of life for members through an integrated approach. In order to track HEDIS measures, follow up appointments must be completed by a qualified mental practitioner, such as a BHMP or independently licensed BHP. We encourage BH providers to maintain appointment availability for members with recent hospital discharges.

Follow-Up Visit Codes CPT: 98960–98962, 99078, 99201–99205, 99211–99215, 99241–99245, 99341–99345, 99347–99350, 99381–99387, 99391–99397,99401–99404, 99411, 99412, 99510 HCPCS: G0155, G0176, G0177, G0409, G0463, H0002, H0004, H0031, H0034, H0036–H0037, H0039, H0040, H2000, H2010, H2011, H2013-H2020, M0064, T1015 UBREV: 510, 513, 515-517, 519-523, 526-529, 900, 902-904, 911, 914-917, 919, 982, 983 **TCM CPT:** 99495, 99496 CPTs that require a POS code: 90791, 90792, 90832-90834, 90836-90840, 90845, 90847, 90849, 90853, 90875, 90876, 99221–99223, 99231–99233, 99238, 99239, 99251–99255 with one of the following POS codes: 2,3,5,7,9,11-20, 22,33,49,50,52,53,71,72 **Any of the above, with or without Telehealth Monitor CPT**: 95, **GT Observations CPTs**: 99217-99220 Partial Hospital/IOP HCPCS: G410, G411, H0035, H2001, H2012, S2021, S9480, S9484, S9485 UBREV: 905, 907, 912, 913

For additional information, please see the NCQA website: https://www.ncqa.org/hedis/measures/.

Autism Spectrum Disorder

Autism spectrum disorder (ASD) services, professionals who can diagnose/assess for ASD and other applicable resources can be found at: https://www.banneruhp.com/resources/autism-spectrum-disorder.

Children's System of Care

AHCCCS has increased the High Needs Case Management ratios for full-time employees. The caseload ratio of high needs children is not less than 1:8 and not more than 1:25, with 1:15 being the desired target. The caseload cap is 25 to allow for continuity of care for children who have been receiving high needs case management but are not ready to begin transition from that level of care and for high needs case management of siblings.

The Child and Family Support page includes the following resources for behavioral health providers: https://www.banneruhp.com/resources/child-and-family-support.

- Children's Specialty BH Provider Directory for specialty services in Central and Southern Arizona
- School-Based BH Service lists for Southern Arizona
- Birth to Five resources
- Birth to Five High Needs Determination Tool

- Transition Age Youth (TAY) resources
- TAY Tool for transition planning
- TAY Checklist for transitioning to adulthood
- Anti-Human Trafficking treatment and resources
- LGBTQ+ resources
- Adopted child and family resources
- Suicide prevention resources
- Family and community resources and more

If you are not currently listed in the Children's Specialty BH Provider Directory or the School-Based BH Service lists and would like to be added, please contact Program Coordinator, Jennifer Blau, at Jennifer.blau@bannerhealth.com. For questions regarding resource guides or Transition Age Youth, contact Program Coordinator, Mayra Lopez, at Mayra.lopez@bannerhealth.com. If you have other questions, please contact Associate Director, Cameron Cobb, at Cameron.cobb@bannerhealth.com.

Adult System of Care

Adult System of Care would like to remind behavioral health providers of helpful resources, including the General Mental Health/Substance Use Specialty Directory of BH providers, found at: https://banneruhp.com/resources/general-mental-health-substance-use. Providers will find the opportunity to collaborate and access supportive services across agencies for members, families and the community. The directory also provides information on Medication Assisted Treatment: highlighting Opioid Treatment Programs (OTP) and Office Base Opioid Treatment (OBOT) across central and southern Arizona.

We would also like to remind OTP and OBOT providers that we request a quarterly report from each of you to assess community needs and the best quality of services for our members.

If you are new to our ACC network, please contact Adult System of Care ASOC@bannerhealth.com so that we can add you to our list serve and as well update and add you to GMH/SU Specialty Directory.

Credentialed Peer/Recovery Support Specialist Deliverable Submission Requirements

Provider agencies employing, utilizing and billing for self-help Peer Support and/or Family Support Services are required, on a quarterly basis on the 5th day of each month to submit the Peer/Recovery Support Specialist and/or Credentialed Parent/Family Involvement in Service Delivery deliverable in secure email format to B – UHP OIFA through the OIFATeam@bannerhealth.com general mailbox.

Links to the deliverable template can be found on AHCCCS website, Medical Policy Manual (AMPM), Chapter 900, Quality Management and Performance Improvement Program, Section 963 and 964 (https://www.azahcccs.gov/shared/MedicalPolicyManual/) and through the following links:

If there are questions regarding the deliverable submission requirements, please contact B – UHP OIFA through the general mailbox address at OIFATeam@bannerhealth.com.

Links to deliverable templates:
AMPM 963 Attachment A: Peer Recovery Support Specialist Report: Peer Recovery Support Specialist Involvement in Service Delivery: Attachment A:
https://www.azahcccs.gov/shared/Downloads/MedicalPolicyManual/900/963a.xlsx

AMPM 964 Attachment A: Credentialed Parent Family Support Specialist Report: Credentialed Parent/Family Support Specialist Involvement in Service Delivery:
https://www.azahcccs.gov/shared/Downloads/MedicalPolicyManual/900/964A.xlsx

Deliverable Submission Due Dates:		
Quarter	**Months reporting**	**Submission Due Date**
Q1:	Jan. Feb & March	Apr. 5
Q2:	April, May & June	July 5
Q3:	July, Aug. & Sept.	Oct. 5
Q4:	Oct., Nov., & Dec.	Jan. 5, 2022

Maternal & Child Health

OB, Pediatric and CRS Care Coordination

The BUHP Maternal Child Health (MCH) team is available to coordinate with both members and providers, offering a fully integrated and multi-disciplinary care management programs to those who need help navigating the health care system.

- Our **OB Care Management team** works to coordinate care and support those with increased risks or unmet needs in pregnancy. We can help resolve barriers to care and address social determinants of care throughout the member's pregnancy and postpartum periods. Care Managers help link mothers to medical as well as community-based resources. We provide direct member support and promote compliance with prenatal care appointments, prescribed medical care regimens and postpartum follow-up. BUHP places a critical importance on early and regular maternity health care. A provider's early submission of the NOP or "Notification of Pregnancy" form to the Health Plan is the key step to ensuring our most expedient and effective maternal outreach and support. An electronic fillable PDF of the NOP form is available in the Banner University Health Plans Provider Manual at: https://www.banneruhp.com/-/media/files/project/uahp/maternity-care/buhp_notice-of-pregnancy-form_oct2018.ashx?la=en

- The **Pediatric Care Management** team supports any member under 21 years of age. Our team of experienced Pediatric RN Care Managers coordinate with providers and facilitate, support and guide members/guardians to positive health outcomes, working closely with the health plan's Children's Behavioral Health team to effectively co-manage and coordinate the complex combination of both physical and behavioral healthcare needs.
- **Children's Rehabilitative Services** – The health plan's MCH department has a special team of coordinators who focus on supporting our current and former CRS-enrolled members, their families and their providers.

REFERRALS or requests for assistance with any OB, Postpartum, Pediatric or CRS member can be sent to: BUHPMaternalChildHealth@BannerHealth.com or simply call our Customer Care line (800-582-8686) and ask to speak with the Maternal & Child Health team.

Well Child/EPSDT Visits and Vaccinations

Well Child/EPSDT Visits and Vaccinations remain important yet may be more challenging than ever to achieve.

You may capture a Well Child/EPSDT visit during a sick visit. These must be in-person visits. Billing codes will be a separate note for sick visit (CPT codes 99201-99215) with modifier 25 added to the Office/Outpatient code. This will identify that a significant, separately identifiable evaluation and management service was provided by the same provider on the same day as the preventable service. The usual schedule vaccinations should be provided during a well visit. Banner – University Family Care (BUFC) DOES NOT limit the number of medically necessary billed Well Child/EPSDT visits.

Additionally, the ADHS has developed a "Pandemic Vaccine Provider Onboarding" program. Should a provider like to administer future COVID-19 vaccines, you may visit https://redcap.link/onboard for job aids, tools and forms.

Substance Abuse Treatment Program Required Reporting

Arizona Revised Statute §36-109 requires that each quarter, each hospital, health care facility and outpatient substance abuse treatment providers that provide substance abuse treatment submit to the Department the following information. For the quarter ending Dec. 31, 2020, please use the below Survey Monkey link and complete the survey **no later than Jan. 18**:

https://www.surveymonkey.com/r/722DS9W

- Name and address of the hospital or health care facility,
- The type of hospital or health care facility
- The number of available substance abuse treatment beds
- The number of days in the quarter that the hospital or health care facility was at capacity and not able to accept referrals for substance abuse treatment

The information you submit is important to assessing Arizona's progress in meeting the treatment needs of people throughout the state. The information is analyzed and compiled into a quarterly report that is provided to the Governor, the Presidents of the Arizona House and Senate, and the Arizona Secretary of State's Office. The quarterly reports are also posted on the ADHS opioid website at https://azhealth.gov/opioid under the reporting tab.

If you have any questions or comments, please e-mail azopioid@azdhs.gov

Provider Relations

Access to Timely Care

The Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey asks patients to report on and evaluate their experiences with health care and their provider. One important component focuses on getting appointments and care quickly. AHCCCS also has a set of required appointment standards. Ensuring your office meets these standards increases the patients positive experience with your office and healthcare. Ease of getting needed care impacts overall health care quality for our members.

BUHP has made a commitment to meet appointment availability standards as set forth by AHCCCS, Medicare and community standards; see chart of standards below. In accordance with AHCCCS and Medicare standards, appointment standards/wait time audits are conducted regularly to ensure members have timely access to care. Should providers not meet appointment or wait time standards, a Corrective Action Plan will be issued.

Note: BUHP utilizes a contracted vendor (Contact One) to conduct appointment availability surveys on a quarterly basis. Please share the appointment standards below with your staff. You may designate a representative in your office to complete the quarterly appointment availability survey with Contact One to alleviate confusion.

If you have any questions on implementing this in your office, please reach out to your Provider Relations Representative.

Appointment Standards		
PROVIDER TYPE	**URGENT**	**ROUTINE**
Primary Care Provider (PCP)	No later than 2 business days of request	Within 7 calendar days for non-urgent but in need of attention (SNP) only. Within 21 calendars of request for routine physicals or health maintenance visits
Specialty Provider Referrals	No later than 2 business days of request	Within 45 calendar days of referral
Dental (AHCCCS Oral Health Care is a covered service for AHCCCS members between birth and age 21)	No later than 3 business days of request	Within 45 calendar days of referral
Maternity	High risk pregnancies – no later than 3 business days of identification of high risk by contractor or immediately if an emergency exists	Initial prenatal care appointments 1st trimester – within 14 calendar days of request 2nd trimester – within 7 calendar days of request 3rd trimester – within 3 business days of request Within 45 calendar days for routine care (SNP) Uncomplicated pregnancy – every 4 weeks for the first 28 weeks and every 2 – 3 weeks until 36 weeks of pregnancy and weekly thereafter One postpartum visit at approximately 6 weeks after

		delivery.
Behavioral Health Providers	No later than 24 hours from identification of need	Initial assessment within 7 calendar days of referral or request for service For members 18 years or older – 1st service following assessment no later than 23 calendar days after initial assessment For members under the age of 18, no later than 21 days after the initial assessment All following services no later than 45 calendar days from identification of need
Psychotropic Medications	Urgency will be assessed immediately	Appointment within a timeframe that ensures member does not run out of needed medication or decline in behavioral health condition, but no later than 30 days from the identification of needs

Provider Manuals: All Banner University Health Plans provider manuals can be accessed on the Health Plans website: https://www.banneruhp.com/.

A printed copy of the manuals will be provided upon request, please contact your Provider Relations Representative.

Notify the plan of Updates: According to provider standards and responsibilities, providers must notify plan with any changes to:

- Providers
- Locations
- key contacts
- telephone numbers
- Tax Identification Numbers
- corporate structure

This notification should occur within 30 days of any of the above noted changes. Please send all updates and changes to BUHPProviderNotifications@bannerhealth.com

Compliance Corner

2021 Evaluation and Management (E/M) Office Codes and Guideline Changes to ease Physicians' Documentation Concerns

The AMA worked with CMS to assemble and streamline the coding and documentation guidelines for Evaluation and Management office visits. These changes will reduce documentation overload and provide physicians more time with patients in 2021 and are effective January 1, 2021. Changes Include the following:

Use of history and physical exam only as medically appropriate and not part of the code selection criteria.

Using medical decision-making criteria as a way to focus on the tasks which affect the management of the member's condition and not just adding up scoring.

Practitioners have the option to determine whether the documentation for the service will be based upon medical decision-making or total time. Total time now can include non-face-to-face services.
The goal is to help practices benefit by:

- Decreasing administrative burden of documentation and coding.
- Decrease unnecessary documentation in the medical record that is not needed or relevant for patient care.
- Ensure that payment for E/M is resource-based and that there is no direct goal for payment redistribution between specialties.

Medical decision-making coding (at least 2 of the 3 MDM elements must be met)is based on the:

- Number and complexity of problems addressed at the encounter/visit.
- Amount and/or complexity of data to be reviewed and analyzed.
- Risk of complications and/or morbidity and mortality of patient management.

The following list also clarifies the minutes spent on the following activities can be included in the calculation of time for E/M Services:

- Reviewing tests in preparation of a patient visit.
- Obtaining and/or reviewing separately obtained history.
- Care coordination (not separately reported).
- Communicating and referring with other health care professionals (when not reported separately).
- Documenting clinical info in the electronic or other health record.
- Performing a medically necessary examination and/or evaluation.
- Counseling and educating the patient, family or caregiver.
- Ordering medications, tests or procedures.

New Patient CPT code 99201 is eliminated as both 99201 and 99202 are both straightforward medical decision-making. 99202 – 99205 and 99211- 99215 valid CPT Codes.

A prolonged service code CPT 99417 was created for use only after the time of 99205 and 99215 was extended for 15- minute increments.

Increase work Relative Value Units (RVUs) and reimbursement rates.

CMS and AMA have different times associated with these CPT codes. AMA is a range and CMS is one time per code and the service must be at or over the next amount of time to switch.

Practitioners must only document that they reviewed and verified information regarding the chief complaint and history that is already recorded by ancillary staff or the patient. These changes will ensure more accurate coding, lower audit risks, and the simplification of documentation will increase confidence in code level selection.

Resources:

AMA CPT Evaluation & Management 2021
http://www.ama-assn.org/system/files/2020-08/e-m-health-plan-webinar.pdf
AMA CPT 2021 Medical Decision-Making Grid
http://www.ama-assn.org/system/files/2019-06/cpt-revised-mdm-grid.pdf

Changes to Anti-Kickback Statute and Stark Law

Anti-Kickback:
The Final Rule implements seven new safe harbors, modifies four existing safe harbors, and codifies on new exception under the Beneficiary Inducements Civil Monetary Penalty (CMP).

Final Safe Harbor Regulations Protect:
Value-Based Arrangements including the following:

- Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency
- Value-Based Arrangements with Substantial Downside Financial Risk; and
- Value-Based Arrangements with Full Financial Risk.

These new safe harbors vary by the type of remuneration protected, level of financial risk assumed by the parties and safeguards:

- Patient Engagement and Support – certain tools and supports furnished to patients
- CMS-Sponsored Models – for certain remuneration provided in connection with a CMS-sponsored model
- Cybersecurity Technology and Services – for donations of cybersecurity technology and services.
- Electronic Health Records Items/Services – adds protections for certain related cybersecurity technology, updates for interoperability, and to remove sunset data.
- Outcomes-Based Payments & Part-Time Arrangements – adds flexibility for certain of these payments and arrangements.
- Warranties – revises the definition to provide protection for bundled warranties for one or more items and related services.
- Local Transportation – expands and modifies mileage limits for rural areas for patients discharged from an inpatient facility or released from a hospital after observation for 24 hours.
- Accountable Care Organization (ACO) Beneficiary Incentive Programs – for MSSP codified the statutory exception to definition of “renumeration”.
- Under Beneficiary Inducements CMP project:
    - Telehealth for In-Home Dialysis – new statutory exception to the prohibition on beneficiary inducements for “telehealth technologies” furnished to certain patients.

Physician Self-Referral – Stark Statute
This law was modified to evolve the regulation to keep pace with the transition of fee-for-service or a volume-based system to a value-based system.

In its previous form, the Stark Law prohibited some arrangements that were designed to enhance care coordination, improve quality and reduce waste.

The final rule creates new, permanent exceptions to Stark Law for value-based arrangements.

Exceptions apply to both arrangements that relate to care for individuals with Medicare or other patients.

Compensation provided to a physician by another healthcare provider generally must be at fair market value and the rule provides guidance on how to determine if compensation meets this requirement.

The final rule also provides clarity and guidance on a wide range of other technical compliance requirements intended to reduce administrative burden.

There is new flexibility for arrangements such as donations of cybersecurity technology.

Banner University Health Plans Contact Information

BUHP Customer Care
Banner - University Family Care – ACC (800) 582-8686 Banner - University Family Care – LTC (833) 318-4146
Banner - University Care Advantage – SNP (877) 874-3930
BUHP Compliance Officers
(520) 548-7862 (Medicaid) or (520) 403-3780 (Medicare)**BUHP Compliance Department FAX**
(520) 874-7072
BUHP Compliance Department Email
BHPCompliance@BannerHealth.com

BUHP Compliance Department Mail:
BUHP Compliance Dept
2701 E Elvira Rd
Tucson, AZ 85756

Confidential and Anonymous Compliance Hotline (ComplyLine)
(888) 747-7989

AHCCCS Office of the Inspector General
Providers are required to report any suspected FWA directly to AHCCCS OIG

Provider Fraud
(602) 417-4045
(888) 487-6686

Member Fraud
(602) 417-4193
(888) 487-6686

Website
www.azahcccs.gov (select **Fraud Prevention**)
Mail:
Inspector General
701 E Jefferson St.
MD 4500
Phoenix, AZ 85034

Medicare
Providers are required to report all suspected fraud, waste and abuse to the Health Plan or to Medicare

Phone: (800) HHS-TIPS (800-447-8477)
FAX: (800) 223-8164
TYY: (800) 377-4950

Website:
https://forms.oig.hhs.gov/hotlineoperations

Mail:
US Department of Health & Human Services
Office of the Inspector General
ATTN: OIG HOTLINE OPERATIONS
PO Box 23489
Washington, DC 20026

Banner
University Health Plans

Attention Providers

2021 Incentive Program

Banner – University Care Advantage HMO/SNP members will receive a **$25 Gift Card*** for completing their Medicare Annual Wellness Visit/Comprehensive Health Assessment.

*Members can choose from a Subway or JCPenney gift card. For more information on our Health & Wellness Programs, visit www.BannerUCA.com.

Banner
University Care Advantage

Banner – University Care Advantage HMO SNP
2701 E. Elvira Road, Tucson, Arizona 85756
Customer Care Center (877) 874-3930 • TTY 711 • Fax (520) 874-3434
Nurse Now Hotline (888) 747-7990
www.BannerUCA.com

Dear Provider,

Banner – University Care Advantage HMO/SNP (B – UCA) is launching a wellness campaign for our D-SNP Medicare Advantage (MA) members. As part of this campaign, we will contact members by letter and encourage them to see their provider for their Annual Wellness/Comprehensive Health Assessment (CHA), visit.

The Annual Wellness/CHA initiative requires the member to complete their Annual Wellness/CHA visit (initial or subsequent) sometime in 2021 per CMS guidelines found at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AWV_chart_ICN905706.pdf. The reward for this initiative is $25. This initiative is available to all B – UCA members.

To receive a $25 gift card, members will be required to obtain a provider signature attesting to the Annual Wellness Visit/CHA visit. The member should present their form for a signature at the time of service. If the member does not bring their form to the appointment, a replacement form may be downloaded on our website at www.BannerUCA.com. Providers must sign the form and fax or mail in the form to the address that is listed.

If you have any questions about this initiative, please contact Kristina Medina at Kristina.Medina@BannerHealth.com or you can contact your provider representative. Thank you for being a valued partner in our mission to provide our members with excellent patient care.

Thank you,

Quality Management Department
Banner – University Care Advantage HMO/SNP

FAX

SUBJECT: COVID-19 Monoclonal Antibody Infusion Order

TO: Please select ONE infusion center location (avoid sending to multiple infusion centers at once). Please note: hours of operation are subject to change.

☐ **BUMC-Phoenix**
Fax: 602-839-2267
Tel: 602-839-6108
Hours: Daily, 7:00am to 3:00pm

☐ **BBMC**
Fax: 480-321-3939
Tel: 480-321-4032
Hours: Daily, 7:30am to 3:00pm

☐ **BUMC-South (Abrams)**
Fax: 520-874-4824
Tel: 520-874-6082
Hours: Daily, 8:00am to 3:30pm

FROM:

Provider Name:_____ Date:_____

Provider Fax:_____ Provider Tel:_____

No. Pages:_____ Comments:_____

_____

_____

ORDER Process: Please follow the steps outlined below to evaluate patients for bamlanivimab infusion. **Please note: infusion orders must be signed by a physician ONLY. Nurse practitioners and Physician's Assistants may not sign infusion referral orders.**

1. Obtain positive direct SARS-CoV-2 test documentation (PCR or direct antigen accepted, antibody tests are not accepted)
2. Evaluate patient for high-risk criteria (can be evaluated by phone, face-to-face, or telehealth)
3. Complete clinical note that documents high-risk criteria and review of patient fact sheet (can be verbal review)
4. Complete order set and attach the following:
   - ☐ History & Physical note, including
     i. evaluation of risk factors
     ii. statement that the patient does not have concurrent systemic infection (UTI, SSI, etc.)
   - ☐ Patient demographics including insurance information
   - ☐ Diagnostics labs (direct positive SARS CoV-2-test)
   - ☐ Documentation that patient has received fact sheet OR that the fact sheet has been verbally reviewed with the patient

The infusion center may contact you for any clarifications needed. To facilitate smooth and rapid scheduling for your patient, please be sure to include all documents listed below and accurate contact information.

Banner Health

OUTPATIENT PROVIDER ORDERS – SARS-COV-2 SPECIFIC MONOCLONAL ANTIBODY

FORM MUST BE COMPLETE (no blanks) AND SIGNED BY THE PHYSICIAN FOR PATIENT TO BE CONSIDERED FOR bamlanivimab or casirivimab/imdevimab

FACILITY: _____ **INFUSION CENTER CONTACT INFORMATION:** _____

PLEASE PRINT

ORDER MUST BE FAXED FROM PROVIDER'S OFFICE

Date: _____

PATIENT NAME: _____ **DOB:** _____

Phone: _____ Height (cm): _____ Weight (kg): _____

Allergies: _____

Diagnosis Code: _____ Diagnosis Name (REQUIRED): _____

Authorization # (date received, name of person giving authorization, date range if applicable): _____

_____

Physician Name (PRINT FIRST & LAST): _____

Physician office phone #: _____ Physician Fax #: _____

Contact person and Ext # at physician office: _____

SARS-CoV-2 Specific Monoclonal Antibody Guidelines

- Banner Monoclonal Antibody Guidelines for the use of bamlanivimab or casirivimab/imdevimab available in Banner COVID Toolkit.
- **Bamlanivimab and casirivimab/imdevimab are investigational drugs and are not currently FDA approved for any indication.**
- The FDA issued two separate Emergency Use Authorization (EUA) to authorize the emergency use of bamlanivimab or casirivimab/imdevimab respectively for the treatment of mild to moderate COVID-19 with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19 and/or hospitalization.
    - Bamlanivimab EUA provider fact sheet available at https://www.fda.gov/media/143603/download
      Casirivimab and imdevimab EUA provider fact sheet available at https://www.fda.gov/media/143892/download
    - Data supporting bamlanivimab EUA was based on interim analysis from Part A of the BLAZE-1 Clinical Trial that demonstrate possible clinical benefit. Data supporting casirivimab and imdevimab EUA was based on an interim analysis from Phase 1/2 from Study 1 that demonstrated possible clinical benefit. Limited clinical data available for either bamlanivimab or casirivimab/imdevimab. The FDA's explanation for issuing EUA states that "it is reasonable to believe that bamlanivimab or casirivimab/imdevimab may be effective."

SARS-CoV-2 Specific Monoclonal Antibody CRITERIA FOR USE

Patient must meet **ALL** criteria to be eligible for bamlanivimab or casirivimab/imdevimab consideration.

- ❑ 18 years of age or older weighing at least 40 kg
- ❑ COVID-19 postive by PCR or Antigen testing
- ❑ Less than 10 days from symptom onset (Date of Symptom Onset: _____)
- ❑ Meets the following oxygen therapy requirements:
    - Not requiring oxygen therapy due to COVID-19 **OR**
    - If on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity, not requiring an increase in baseline oxygen flow rate due to COVID-19
- ❑ Does not have suspected or proven serious, active bacterial, fungal, viral, or other infection (excluding COVID-19)
- ❑ High risk - defined as meeting one or more of the following criteria (select **all** that apply):
    - ❑ Body Mass Index (BMI ≥ 35)
    - ❑ Chronic Kidney Disease
    - ❑ Diabetes
    - ❑ Immunosuppressive Disease
    - ❑ Receiving immunosuppressive treatment
    - ❑ Age ≥ 65 years
    - ❑ Cardiovascular disease AND age ≥ 55 years
    - ❑ Hypertension AND age ≥ 55 years
    - ❑ COPD/other chronic respiratory disease AND age ≥ 55 years
- ❑ Patient or caregiver has received bamlanivimab factsheet at https://www.fda.gov/media/143604/download and casirivimab/indevimab factsheet at https://www.fda.gov/media/143893/download (Available in Krames in English and Spanish), was informed of alternatives and that the drug is an unapproved drug authorized for use under the Emergency Use Authorization and agreed to accept treatment with either drug based on availability.

Banner Health

OUTPATIENT PROVIDER ORDERS – SARS-COV-2 SPECIFIC MONOCLONAL ANTIBODY

SARS-CoV-2 Specific Monoclonal Antibody Allocation

Banner Locations excluding Colorado

- Banner guidelines follow a utilitarian approach: the most good for the most people, consistent with scientific guidelines, known literature, and expert consensus
- Not all patients will be able to receive drug. Allocation priority is determined by a pre-defined protocol. Patients eligible to receive drug will be contacted by infusion scheduling within 48 to-72 hours of order being received.
- Pharmacy to dispense bamlanivimab or casirivimab/imdevimab based on availability

Banner Locations in Colorado

- Allocation through Online Lottery Process managed by the Colorado State Health Department, Provider License Number: _____

Labs

❑ HCG Qualitative, Urine prior to administration of bamlanivimab or casirivimab/imdevimab, if positive contact physician
❑ HCG Qualitative, Serum prior to administration of bamlanivimab or casirivimab/imdevimab, if positive contact physician
❑ Other: _____

SARS-CoV-2 Specific Monoclonal Antibody DOSING

Pharmacy can interchange between bamlanivimab or casirivimab/imdevimab per P & T Protocol based on availability

bamlanivimab 700 mg IV Piggyback Once, Infuse over at least 60 minutes, use 0.2/0.22 micron in-line filter

or

casirivimab 1200 mg and imdevimab 1200 mg IV Piggyback Once, Infuse over at least 60 minutes, use 0.2/ micron in-line filter

MONITORING

1. Obtain vital signs prior to bamlanivimab or casirivimab/imdevimab administration
2. Monitor vital signs every 15 minutes during infusion and every 30 minutes thereafter
3. Clinically monitor patients during infusion and for at least 1 hour after infusion completes
4. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy (see ADVERSE REACTIONS below)

ADVERSE REACTIONS

MINOR REACTIONS (e.g. nausea, itching, joint pain, rash)	**SEVERE REACTIONS** (e.g. bronchospasm, loss of airway, fainting, severe flushing)
STOP infusion	**CALL A CODE OR RAPID RESPONSE**
diphenhydrAMINE 50 mg IV Push Once	**STOP** infusion
Famotidine 20 mg IV Push Once	EPINEPHrine 0.3 mg/0.3 mL SubCutaneous Once
dexaMETHasone 10 mg IV Push Once	Oxygen PRN
Notify Physician	Notify Physician

Physician signature Date / Time

2026-0175
(12/2020)

PRINT SAVE AS EMAIL RESET

Pharmacy and Therapeutics Clinical Consensus Group
COVID-19 Monoclonal Antibody Guidelines
December 17, 2020

SARS-CoV-2 Specific Monoclonal Antibody Treatment

- Several monoclonal antibodies are being investigated
- Lily and Regeneron both granted Emergency Use Authorization (EUA)
- Information on safety and efficacy for COVID-19 is evolving with new literature released regularly
- Banner recommendations based on current literature, drug availability and disease severity

Bamlanivimab Monoclonal Antibody Treatment Guidelines

- Bamlanivimab is an investigational drug and is not currently FDA approved for any indication.
- The FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab EUA issued November 9, 2020. Review Bamlanivimab EUA fact sheet for providers.
- Limited clinical data. Data supporting EUA was based on an interim analysis from Part A of the BLAZE-1 Clinical Trial that demonstrated possible clinical benefit. FDA's explanation for issuing EUA states: "it is reasonable to believe that bamlanivimab may be effective".
- Benefit of bamlanivimab has not been observed in patients hospitalized due to COVID-19.
- Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.
- Bamlanivimab must be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS).
- If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy.

Casirivimab and Imdevimab Monoclonal Antibody Treatment Guidelines

- Casirivimab and imdevimab are investigational drugs and not currently FDA approved for any indication.
- The FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of casirivimab and imdevimab, to be administered together, for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Casirivimab and Imdevimab EUA issued November 21, 2020. Review Casirivimab and imdevimab EUA fact sheet for providers.
- Although packaged separately, casirivimab (REGN10933) and imdevimab (REGN10987) must be administered together after dilution by single intravenous (IV) infusion only.
- Limited clinical data. Data supporting EUA was based on an interim analysis from Phase ½ from Study 1 that demonstrated possible clinical benefit. FDA's explanation for issuing EUA states: "it is reasonable to believe that casirivimab and imdevimab may be effective".
- Benefit of casirivimab and imdevimab has not been observed in patients hospitalized due to COVID-19.
- Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.
- Casirivimab and imdevimab must be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS).
- If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy.

SARS-CoV-2 Specific Monoclonal Antibody for the Treatment of Mild to Moderate COVID-19 in Adult and Pediatric	
Banner Emergency Authorization Criteria for Use for bamlanivimab and casirivimab/imdevimab	
Inclusion Criteria	**Exclusion Criteria**
COVID positive by PCR or Antigen Testing **+** **Less than 10 days from symptom onset** **+** **18 years of age or older weighing at least 40 kg** **+** **High Risk for progressing to severe COVID-19 and/or hospitalization** ***High risk is defined as patients who meet at least one of the following criteria:*** • Body mass index (BMI) ≥ 35 • Chronic kidney disease • Diabetes • Immunosuppressive disease • Receiving immunosuppressive treatment • Age ≥ 65 years • Cardiovascular disease if age ≥ 55 years • Hypertension if age ≥ 55 years • COPD/other chronic respiratory disease if age ≥ 55 years	• Hospitalized due to COVID-19 • Require oxygen therapy due to COVID-19 • Require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity • Suspected or proven serious, active bacterial, fungal, viral or other infection
	Dosing and Administration
	• **Pharmacy can interchange between bamlanivimab or casirivimab/imdevimab per P & T Protocol based on availability** Bamlanivimab 700 mg IV Infusion Once **Or** Casirivimab 1200 mg and imdevimab 1200 mg IV Infusion Once • Infuse over at least 60 minutes, • Use 0.2/0.22 micron in-line filter • No dosage adjustments are recommended • **Administered <u>as soon as possible</u> after positive COVID PCR or Antigen test and within 10 days of symptom onset**
Requirements for Use	**Monitoring**
• Provider should discuss COVID Monoclonal antibody therapy with patient and provide bamlanivimab patient fact sheet or casirivimab/imdevimab patient fact sheet based on drug to be administered prior to administering med. (Available in Krames) • Report all serious adverse events to FDA Medwatch	Clinically monitor patients (vital signs, infusion reactions) during infusion and observe patients for at least 1 hour after infusion complete

Prioritization for all locations outside Colorado	
Patients must meet Banner Emergency Authorization Criteria for Use in addition to prioritization criteria below	
Highest Priority	Health Care Workers in Direct Patient Care First Responders (Fire, Ambulance, Law Enforcement)
Second Highest Priority	2 or more High Risk Factors
Third Highest Priority	1 High Risk Factor

Prioritization in Colorado
Patients must meet Banner Emergency Authorization Criteria for Use in addition to prioritization criteria below
Allocation through an Online Lottery Process managed by the State Health Department

SARS-CoV-2 Specific Monoclonal Antibody Allocation Process (excluding Colorado)

- Banner guidelines follow a utilitarian approach: the most good for the most people, consistent with scientific guidelines, known literature, and expert consensus
- Weekly shipments of bamlanivimab and/or casirivimab/imdevimab based on state allocations. Amounts of drug unknown (state allocation will be based on utilization and number of COVID-19 patients).
- On-Site supply of bamlanivimab and casirivimab/imdevimab will be allocated based on weekly allocation or daily infusion chair availability.
- The EUA criteria for use for bamlanivimab or casirivimab/imdevimab are equivalent with comparable clinical efficacy and safety data. Pharmacy to dispense bamlanivimab or casirivimab/imdevimab based on availability. Pharmacy can interchange between bamlanivimab or casirivimab/imdevimab per P & T Protocol based on availability
- All orders received by 12 PM will be evaluated based on prioritization criteria for administration the following day. If there is a "tie" at time of ordering, preference will be given to patients in the highest priority followed by those who are second highest and then third highest priority. If there is still a "tie", random allocation will be employed.
- If patient is not chosen on a given day, they will roll into the following day until prioritized or reach ≥ 8 days from symptom onset whichever occurs first.
- Appeals will be accepted by pharmacy based solely on whether criteria in use at the time the drug was ordered were accurately applied and not on objections to the criteria themselves. Drug will be dispensed to eligible patients as available and as described above.
- If a patient does not receive the drug as ordered, a notation will be placed on the order and communicated to the provider to reflect why patient will not receive medication a) because the patient did not meet criteria or b) there was currently no available drug due to limited supply in the pandemic.
- Medically irrelevant criteria such as sex, gender, race, ethnicity, color, national origin, religion, disability, veteran status, sexual orientation, gender identity, insurance or quality of life will not be considered in allocations.
- Allocation guidelines will be reviewed and updated as new clinical information becomes available. P & T CCG leadership are committed to expeditiously reviewing available literature to provide the most up-to-date guidance. Final guidelines to be made by the AdHoc COVID P & T CCG and approved by CMOs. Each set of guidelines will remain in effect until new guidelines are formally adopted/approved.

SARS-CoV-2 Specific Monoclonal Antibody: Additional Comments

- There are insufficient data on the use of bamlanivimab or casirivimab/imdevimab during pregnancy. Bamlanivimab or casirivimab/imdevimab should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.
- Although the EUA included criteria for patients ages 12-17, Banner AdHoc COVID P&T CCG is not including them in our recommendations because the one trial available for review included no one in that age group. Additionally, morbidity and mortality form COVID is lowest in that age group.
- The Banner AdHoc COVID P&T CCG is excluding patients with "suspected or proven serious, active bacterial, fungal, viral or other infection". We have no data on bamlanivimab or casirivimab/imdevimab use in such patients and existing monoclonal antibodies are generally withheld in patients with such infections.

COVID-19 Related Medication Treatment Summary

Adapted from Assessment of Evidence for COVID-19-Related Treatments. Bethesda, MD: American Society of Health-System Pharmacists, Inc.

Medication	Class	Comments	Banner Recommendation
SARS-CoV-2 Specific Monoclonal Antibodies			
bamlanivimab	Neutralizing Monoclonal Antibodies	The BLAZE -1 study showed that viral load was significantly decreased by day #11 in the 2800 mg dose. Hospitalizations/ER visits were less in the bamlanivimab group (1.6%) compared to placebo (6.3%). This is the only published study that presents data on bamlanivimab.	See P&T Guidelines for bamlanivimab criteria for use
casirivimab & imdevimab		The Study 1 study showed that viral load was significantly decreased by day #7 in the treatment arms compared to placebo. Medically attended visits (Hospitalizations/ER/Urgent Care/Clinic visits) were less in the casirivimab and imdevimab group (2.8%) compared to placebo (6.5%). This is the only clinical data available for casirivimab and imdevimab.	See P&T Guidelines for casirivimab and imdevimab criteria for use