DHCS

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ALL PLAN LETTER 22-009

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: COVID-19 GUIDANCE FOR MEDI-CAL MANAGED CARE HEALTH PLANS

PURPOSE:
The purpose of this All Plan Letter (APL) is to provide information to Medi-Cal managed care health plans (MCPs) on changes to federal and state requirements for COVID-19 testing, treatment, and prevention.

BACKGROUND:
The Centers for Medicare & Medicaid Services (CMS) issued guidance on Medicaid coverable COVID-19-related treatment under the American Rescue Plan Act of 2021 (ARP). [1, 2] The ARP not only covers acute COVID related symptoms but also encompasses post COVID-19 conditions such as "long COVID," which includes a range of symptoms that can last months after a member is first infected with the COVID-19 virus. Post COVID complications, occasionally referenced as "Long COVID," can also occur weeks or months after initial infection. Changes to covered services were made to improve health outcomes and reduce health disparities especially for those disproportionately impacted by the pandemic.

Section 9811(a) of the ARP added a new mandatory Medicaid benefit at section 1905(a)(4)(F) of the Social Security Act (Act). Under these amendments, beginning March 11, 2021, state Medicaid programs are required to cover treatments for COVID-19, including specialized equipment and therapies (including preventive therapies).[3] Additionally, under these amendments, beginning March 11, 2021, state Medicaid programs must cover the treatment of any condition that may seriously complicate the treatment of COVID-19, if otherwise covered under the state plan (or waiver of such plan, including a section 1115 or 1915(b) demonstration) for individuals

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[1] CMS State Health Official (SHO) Letter #21-006 is available at:
https://www.medicaid.gov/federal-policy-guidance/downloads/sho102221.pdf
[2] Pub. L. No. 117-2, enacted on March 11, 2021, is available at:
https://www.congress.gov/117/plaws/publ2/PLAW-117publ2.pdf
[3] The ARP is available at: https://www.congress.gov/bill/117th-congress/house-bill/1319/text

who are diagnosed with or presumed to have COVID-19 during the period if such an individual has (or is presumed to have) COVID-19. Members with conditions that may seriously complicate the treatment of COVID-19 include those with underlying comorbidities that create a higher risk of progressing to severe COVID-19. Examples of conditions that may seriously complicate the treatment of COVID-19 include, but are not limited to, cardiovascular diseases, chronic lung diseases, diabetes, cancer, obesity, Down Syndrome, and being a recipient of a transplant or immunosuppressive therapy.[4] The determination of whether a condition could seriously complicate treatment for COVID-19 should be based on a member-specific assessment performed by a provider.

CMS interprets the ARP coverable services requirements as similar to the Medicaid Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirements in section 1905(r)(5) of the Social Security Act (Act).[5] Under federal EPSDT, states are required to furnish all appropriate and medically necessary services that are coverable under a Medicaid State Plan (as described in section 1905(a) of the Act), regardless of whether those services are covered in the state's Medicaid State Plan.[6] Therefore, any non-pharmacological item or service, to include specialized equipment and therapies and preventive therapies, must be covered under ARP if it is considered medically necessary for the treatment of COVID-19 and post-COVID conditions or "long COVID" and is otherwise coverable under a State plan, regardless of whether it is covered under California's Medicaid State Plan.

These coverage requirements generally end on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act.[7] However, under section 1902(a)(10)(A)(ii)(XXIII) of the Act and the statutory language following section 1902(a)(10)(G) of the Act, states can provide Medicaid coverage to the optional COVID-19 group only through the last day of the COVID-19 public health emergency (PHE).[8]

California Senate Bill (SB) 510 also delineates new requirements for diagnostic and screening testing as well as health care services related to the testing of COVID-19, or

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[4] See the Centers for Disease Control and Prevention's (CDC) information regarding COVID-19 and medical conditions at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
[5] Section 1905 of the Act is available at: https://www.ssa.gov/OP_Home/ssact/title19/1905.htm
[6] For more information regarding EPSDT requirements see APL 19-010, Requirements for Coverage of Early and Periodic Screening, Diagnostic, and Treatment Services for Medi-Cal Members Under the Age of 21. APLs are available at: https://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx
[7] Section 1135 of the Act is available at: https://www.ssa.gov/OP_Home/ssact/title11/1135.htm
[8] Section 1902 of the Act is available at: https://www.ssa.gov/OP_Home/ssact/title19/1902.htm

any future disease declared to be a PHE by the Governor of the State of California.[9]
The bill addresses retroactive coverage of these services beginning from when the
Governor declared a State of Emergency for the COVID-19 pandemic on
March 4, 2020. The bill also addresses coverage for an item, service, or immunization
intended to prevent or mitigate COVID-19 that is recommended by the United States
Preventive Services Task Force (USPSTF) or the Advisory Committee on Immunization
Practices (ACIP) of the federal CDC. COVID-19 vaccinations and vaccination
administration are carved out for MCPs and covered through Medi-Cal fee for service
(FFS).[10] MCPs are contractually required to ensure the provision of all USPSTF Grade
A and B preventive services for adults and children and all American Academy of
Pediatrics Bright Futures recommendations for members less than 21 years of age, and
MCPs are also contractually required to ensure the provision of vaccines in accordance
with ACIP recommendations.

Additionally, President Biden and Governor Newsom have emphasized the importance
of rapidly connecting people who test positive for COVID-19 with treatment as an
effective way to decrease morbidity and mortality from COVID-19.[11, 12] Several
treatments are available, effective, and recommended for treatment of non-hospitalized
adults and children at high risk of progressing to severe COVID-19. However, to be
effective these treatments must be initiated as soon as possible after diagnosis and
within five to seven days of symptom onset, and current use remains low.[13] Medi-Cal Rx
has issued guidance on appropriate billing practices for carved-out treatments.[14]

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[9] SB 510 is available at: https://legi
nfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB510.
DHCS incorporated in the 2022 MCP Contract Knox-Keene Health Care Services Plan Act
requirements by reference.
[10] See APL 20-022, COVID-19 Vaccine Administration.
[11] President Biden's State of the Union Remarks as prepared for delivery is available at:
https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/03/01/remarks-of-president-
joe-biden-state-of-the-union-address-as-delivered/
[12] Governor Newsom's SMARTER Plan is available at:
https://files.covid19.ca.gov/pdf/smarterplan.pdf
[13] The National Institutes of Health (NIH) guidelines on therapeutic management of non-
hospitalized adults with COVID-19 is available at:
https://www.covid19treatmentguidelines.nih.gov/management/clinical-
management/nonhospitalized-adults--therapeutic-
management/?utm_source=site&utm_medium=home&utm_campaign=highlights
[14] Pharmacy guidance for billing COVID-19 oral antivirals is available at: https://medi-
calrx.dhcs.ca.gov/cms/medicalrx/static-
assets/documents/provider/bulletins/2022.01_A_Billing_Guidance_for_Pharmacy_Providers_on
_COVID-19_Oral_Antivirals.pdf

"Test-to-treat" programs are often referenced in regards to COVID-19 therapeutics. The concept highlights the importance of expediting treatment so that all those who test positive are expeditiously funneled into assessment for therapeutic treatment interventions. The federal government has stood up "test to treat" physical sites that enable this to occur within a single encounter for a member at a physical site; information to assist with finding these Test-to-Treat sites is being added to MyTurn.[15] However "test to treat" as a concept applies to generally ensuring the key elements of assessment and treatment (i.e., (1) testing, (2) prescriber, and (3) therapeutic) occur expeditiously regardless of whether they are occurring in a single encounter or physical visit. With the advent of at-home antigen tests and telehealth, expedited access may not necessarily mean members must have (1) testing, (2) prescribing, and (3) therapeutic occurring at a single encounter or at a physical site and may instead be provided in a more streamlined process expediting COVID-19 care delivery.

POLICY:

CMS SHO #21-006 Mandates
Sections 9811 and 9821 of the ARP require coverage of treatments specifically for COVID-19, including specialized equipment and therapies, and preventive therapies for both pharmacological and non-pharmacological services or items. Additionally, during the period when a member is diagnosed with or is presumed to have COVID-19, MCPs are required to cover treatment for a condition that may seriously complicate COVID-19 treatment for a member.

Pharmacological Treatment Services:
MCPs must cover treatment including preventive therapies specifically for COVID-19 and "long COVID" that are billed under a medical claim and not federally reimbursed. Coverable services include U.S. Food Drug and Drug Administration (FDA) approved drugs and FDA-licensed biologicals to treat or prevent COVID-19, FDA-approved drugs and FDA-licensed biologicals that have an indication to treat or prevent COVID-19 that are authorized under an Emergency Use Authorization (EUA), and unapproved drugs that the FDA has specifically authorized to be used to treat or prevent COVID-19 under an EUA.

Mandatory coverage under the ARP also includes coverage for antivirals, monoclonal antibodies (mAbs), and pre-exposure prophylaxis when specifically approved by the FDA to treat or prevent COVID-19, or authorized by the FDA under an EUA to be used

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[15] My Turn test-to-treat resource is available at: https://myturn.ca.gov/testing.html

for the specific conditions and specific settings to treat or prevent COVID-19, including when such authorizations would permit infusion or administration in the home setting.[16]

Non-pharmacological Treatment Services:
MCPs must cover any non-pharmacological item or service described in section 1905(a) of the Act that is medically necessary for treatment of COVID-19, including specialized equipment and therapies (including preventive therapies), and treatment of "long COVID."[17] MCPs can apply utilization management controls specifically when the item or service is covered as treatment for COVID-19; however, controls should not establish unreasonable or arbitrary barriers for accessing coverage.

Treatment for Conditions that May Seriously Complicate COVID-19 Treatment:
MCPs must cover treatment of a condition that may seriously complicate the treatment of COVID-19. MCPs may apply utilization management controls specifically when the item or service is covered as a COVID-19-related treatment, including as treatment for a condition that may seriously complicate the treatment of COVID-19, provided that in doing so, unreasonable or unnecessary barriers to accessing coverage are not established.

Testing Mandates
MCPs, must cover COVID-19 diagnostic, screening, and post exposure or response testing and health care services approved or granted EUA by the FDA for COVID-19, regardless of whether the services are provided by an in-network or out-of-network provider. MCPs must reimburse out-of-network providers at a reasonable rate for these services, and DHCS encourages MCPs to reimburse providers for COVID-19 testing at the Medicare fee schedule rates. MCPs should refer to the Medi-Cal provider manual for additional information about COVID-19 billing codes.[18] Services related to COVID-19 diagnostic, screening, and post exposure or response testing include, but are not limited to, hospital or health care provider office visits for the purposes of receiving testing, products related to testing, the administration of testing, and items and services furnished to a member as part of testing. MCPs are prohibited from imposing prior authorization or any other utilization management requirements on COVID-19 diagnostic and screening testing.

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[16] More information regarding FDA EUA services is available at:
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

[17] Section 1905(a) of the Act is available at:
https://www.ssa.gov/OP_Home/ssact/title19/1905.htm

[18] Provider Manual billing codes are available at: https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/AB57A510-100F-4CBB-865C-B197B359F1F6/pathmicro.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYylPyP5ULO

At-Home Testing:
MCPs must cover all at-home COVID-19 tests that are billed under a medical claim. At-home COVID-19 antigen tests ordered through the pharmacy are covered through Medi-Cal Rx and in accordance with current CDC recommendations. Coverage is restricted to the specific COVID-19 antigen tests listed in the List of Covered EUA COVID-19 Antigen Tests.[19]

Since at-home COVID-19 tests are a partial Medi-Cal Rx carve-out and can be billed and reimbursed through a pharmacy claim, MCPs must educate members on how they can receive at-home test kits, either through their doctor's office or through Medi-Cal Rx. MCPs must provide information on testing access for their members regardless of whether or not they are financially responsible for the payment of antigen tests on a pharmacy claim, and MCPs must continue to utilize existing data sources to help identify, educate, and provide outreach to members about access options for COVID-19 antigen tests in accordance with CDC guidelines.[20] Additionally, when a school or business is required by a federal, state, or local public health order to conduct COVID-19 screening testing, MCPs must cover the costs of the at-home tests used by the school or business to screen their members if billed under a medical claim.

Antibody Testing:
MCPs must cover antibody testing "intended to identify current or past infection and performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2."[21]

Vaccine Administration:
Costs associated with vaccine administration continue to be "carved out" of the Medi-Cal managed care delivery system and are reimbursed through Medi-Cal FFS. However, MCPs remain contractually responsible for providing case management and care coordination for their members regardless of whether or not they are financially responsible for the payment of services. Care coordination may involve, but is not limited to, assisting members with accessing COVID-19 vaccine administration

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[19] List of Covered EUA COVID-19 Antigen Tests: https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/Covered_EUA_COVID-19_Antigen_Tests.xlsx

[20] Information on Medi-Cal Rx coverage of over-the-counter COVID-19 Antigen test Kits is available at: https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/bulletins/2022.01_A_COVID-19_EUA_FDA-Authorized_Antigen_Tests.pdf

[21] See Health and Safety Code section 1342.2(e)(1)(A). State law is searchable at: https://leginfo.legislature.ca.gov/

locations, including non-emergency medical transportation and non-medical transportation as needed, and helping members receive the required number of doses for the COVID-19 vaccines in a timely fashion. MCPs should continue to utilize their existing data sources to help identify members who qualify to receive the COVID-19 vaccine in accordance with the California Department of Public Health (CDPH) guidelines, and attempt outreach to qualifying members and their providers to encourage receipt of the COVID-19 vaccines. MCPs should also ensure they convey relevant and current information on the COVID-19 vaccines to members and encourage providers to communicate with members about vaccination availability as such information is made available.[22]

Expedited Access to Therapeutics (which includes Test-to-Treat programs)
Consistent with the California SMARTER Plan and considering the risk of hospitalization and death from COVID-19, appointments for members who have symptoms of COVID-19 and/or test positive for COVID-19 and present to their MCP or network provider are considered urgent.[23] The urgent appointment status allows for timely assessment of clinical eligibility for and provision of outpatient COVID therapeutics. For maximal clinical effectiveness, outpatient COVID therapeutics should be offered immediately after a member is determined to be clinically eligible since outpatient COVID therapeutics are only effective if used within five to seven days of symptom onset according to current clinical guidelines.[24] Additionally, all eligible patients should be offered pre-exposure prophylaxis if they qualify under the EUA.[25]

MCPs remain contractually responsible for providing case management and care coordination for their members. Care coordination may involve, but is not limited to: assisting members with accessing COVID-19 pre-exposure prophylaxis, testing, and treatment, including non-emergency medical transportation and non-medical transportation as needed, helping members receive prescribed medication in accordance with clinically based guidelines, and providing member and provider education on expedited delivery by mail or courier through Medi-Cal Rx.

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[22] See APL 20-022, COVID-19 Vaccine Administration.
[23] The California SMARTER Plan February 2022 is available at: https://files.covid19.ca.gov/pdf/smarterplan.pdf
[24] See the NIH guidance on Therapeutic Management of Nonhospitalized Adults with COVID-19, available at: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/?utm_source=site&utm_medium=home&utm_campaign=highlights
[25] Information on Evusheld EUA is available at: 6d1d5fea-2532-46e9-a1d4-1504f6dd41b2_viewable_rendition__v.pdf (den8dhaj6zs0e.cloudfront.net)

MCPs and their contracted providers should ensure workflows, processes, and communications align in order to expedite each step of COVID-19 care delivery. In instances where providers have capability to dispense on-site, efforts should be made to link members immediately to dispensing of therapeutics. MCPs must ensure that sites that do not have mechanisms to dispense should have an established process to expedite testing and directly link those who test positive to assessment for therapeutics eligibility and, if clinically appropriate, treatment.[26]

To demonstrate access to clinically appropriate COVID therapeutics in a timely manner, MCPs must submit a COVID Therapeutics Plan highlighting how the three key elements of COVID-19 assessment and treatment will be expedited (testing, prescriber, and therapeutic). The COVID Therapeutics Plan must, at a minimum meet the following:

- Demonstrate how members eligible for outpatient COVID therapeutics will receive pre-exposure prophylaxis or treatment in accordance with evidence based guidelines.[27]
- Demonstrate how the MCP will identify moderately to severely immunocompromised members who may qualify for pre-exposure prophylaxis and provide outreach and education to these members by utilizing claims data and/or by reaching out to appropriate network providers.[28]
- Demonstrate how the MCP will facilitate expedited access to oral therapeutics, including member education for mail-order pharmacy through Medi-Cal Rx.
- Maintain a list of infusion sites providing COVID therapies within the MCP's network, provide the list to DHCS as requested, and maintain an updated list on the provider section of the MCP's website.
- Maintain utilization data and report to DHCS as requested.
- Review and update all member and contracted provider facing content and educational materials, such as clinical advice phone lines, online content, mailed content, internal policies, encouraging testing of those with COVID-19 symptoms, methods to access COVID testing kits, and outlining treatment eligibility with appropriate connection to applicable resources.
- Facilitate provider education on indications and availability of testing and outpatient pre-exposure prophylaxis and treatment for COVID and how to access

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[26] The Test-To-Treat Playbook is available at: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/Test-to-Treat-Playbook.pdf
[27] See the NIH guidance on Therapeutic Management of Nonhospitalized Adults with COVID-19, available at: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/?utm_source=site&utm_medium=home&utm_campaign=highlights
[28] NIH information on prevention of SARS-CoV-2 Infection is available at: https://www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/

it, including information on the NIH COVID Treatment Guidelines[29], the federal Health & Human Services' COVID Therapeutics Locator[30], how to find an appropriate and accessible Test to Treat location, CDPH COVID-19 treatment resources[31], the MCP's network of infusion sites offering COVID treatment, and how to register as a Test-to-Treat provider and receive information about incentives, communications, awareness campaigns, and COVID therapeutics directly from their local health jurisdiction.[32]

MCPs must submit to DHCS their COVID Therapeutics Plan no later than 60 days after the date of this APL. DHCS will share additional resources with MCPs as they become available.

In addition, MCPs are contractually required to ensure urgent appointments are available to members with clinical symptoms of, or who test positive for COVID-19, to enable timely assessment for COVID therapeutics eligibility. MCPs may facilitate this through multiple pathways, including through contracted telehealth providers, mobile clinics, clinics, and/or primary care providers. In addition, MCPs may consider contracting with California Test to Treatment facilities if access through the MCP's existing provider network is not timely and/or if Test-to-Treat facilities are preferred by some members.[33]

MCPs are responsible for ensuring that their subcontractors and network providers comply with all applicable state and federal laws and regulations, contract requirements, and other DHCS guidance, including APLs and Policy Letters.[34] These requirements must be communicated by each MCP to all subcontractors and network providers.

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[29] NIH COVID-19 treatment guidelines are available at:
https://www.covid19treatmentguidelines.nih.gov/
[30] The COVID-19 Therapeutics Locator is available at: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
[31] CDPH COVID-19 treatment resources are available at:
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Treatments.aspx
[32] CDPH information on Distribution and Ordering of Anti-SARS-CoV-2 Therapeutics is available at: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID-19-Treatments-Distribution-and-Ordering.aspx
[33] COVID-19 Test to Treat Locations are listed at:
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Test-to-treat-locations.aspx
COVID-19 Test to Treat Locations
[34] For more information on subcontractors and network providers, including the definition and applicable requirements, see APL 19-001, and any subsequent APLs on this topic.

If you have any questions regarding this APL, please contact your Managed Care Operations Division Contract Manager.

Sincerely,

Original Signed by Dana Durham

Dana Durham, Chief
Managed Care Quality and Monitoring Division