

SHO# 21-006

**RE: Mandatory Medicaid and
CHIP Coverage of COVID-19-
Related Treatment under the
American Rescue Plan Act of 2021**

October 22, 2021

Dear State Health Official:

The Centers for Medicare & Medicaid Services (CMS) is issuing this guidance on Medicaid and Children’s Health Insurance Program (CHIP) coverage of COVID-19-related treatment under the American Rescue Plan Act of 2021 (ARP) (Pub. L. No. 117-2, enacted on March 11, 2021). As discussed below, the ARP requires state Medicaid and CHIP programs¹ to cover COVID-19-related treatments, without cost-sharing. CMS will apply the statutory interpretations in this guidance on a prospective basis beginning with the date of issuance of this letter.

ARP Sections 9811 and 9821

Section 9811(a) of the ARP added a new mandatory Medicaid benefit at section 1905(a)(4)(F) of the Social Security Act (Act). Section 9821 of the ARP added the same mandatory benefit for all CHIP enrollees at section 2103(c)(11)(B) of the Act. Under these amendments, beginning March 11, 2021, state Medicaid programs and separate CHIPs² are required to cover treatments for COVID-19, including specialized equipment and therapies (including preventive therapies). Additionally, under these amendments, beginning March 11, 2021, state Medicaid programs and separate CHIPs must cover the treatment of a 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 demonstration) for individuals who are diagnosed with or presumed to have COVID-19 during the period such an individual has (or is presumed to have) COVID-19.³ Section 9811(a)(2) of the ARP amended the statutory language following section 1902(a)(10)(G) of the Act to require coverage of the same COVID-19-related treatment for individuals eligible for the Medicaid optional COVID-19 group (formerly referred to by CMS as the “optional COVID-19 testing group”) described at section 1902(a)(10)(A)(ii)(XXIII) of the Act.⁴

¹ Use of the term “state” in this letter includes the territories, as applicable.

² Section 2103(c)(11)(B) applies to child health assistance and pregnancy-related assistance provided through a separate CHIP. Section 1905(a)(4)(F) of the Act applies to Medicaid expansion CHIP funded by title XXI.

³ Under section 1905(a)(4)(F) of the Act, this coverage of treatment for complicating conditions in Medicaid should be provided without regard to the Medicaid comparability requirements of section 1902(a)(10)(B) of the Act.

⁴ Under section 1905(b) of the Act, state expenditures on medical assistance for this optional COVID-19 group, and state expenditures described in section 1903(a)(7) of the Act that a state demonstrates to the satisfaction of the

ARP sections 9811 and 9821 also amended sections 1916, 1916A, and 2103(e)(2) of the Act to specify that states cannot impose cost sharing with respect to the COVID-19-related treatment coverage that is required under the ARP and described at sections 1905(a)(4)(F) and 2103(c)(11)(B) of the Act. ARP section 9811(a)(5) also amended section 1937(b) of the Act to require states to include the same COVID-19-related treatment coverage in Medicaid alternative benefit plans, without any deduction, cost sharing, or similar charge.

These coverage requirements and cost-sharing prohibitions 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. 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). No federal financial participation is available for any state expenditures on benefits for this group, including coverage of COVID-19-related treatments, after the PHE ends.

Below, we discuss the requirements in ARP sections 9811 and 9821 to cover treatment specifically “for” COVID-19 (including preventive therapies), and then discuss the requirements to cover treatments for a condition that may seriously complicate the treatment of COVID-19. We also discuss the cost-sharing prohibition with respect to these items and services (including drugs), as well as state plan considerations for implementing these provisions of the ARP.

Treatment “for” COVID-19, Including Specialized Equipment and Therapies, and Preventive Therapies

Sections 9811 and 9821 of the ARP require states to cover treatments specifically “for” COVID-19, including specialized equipment and therapies, and preventive therapies. This requirement is very broad and encompasses a wide array of possible treatments and therapies, both pharmacological and non-pharmacological, as further explained below. CMS interprets this coverage to also include coverage for treatments and therapies for post-COVID conditions, sometimes called “long COVID.” Long COVID includes a range of symptoms that can last weeks or months after a person is first infected with the virus that causes COVID-19 or that can appear weeks after infection.⁵

With respect to non-pharmacological items and services, CMS interprets the ARP requirements to cover treatments specifically “for” COVID-19 to establish a requirement that is similar to the Medicaid Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirement at section 1905(r)(5) of the Act. That is, CMS interprets this language to require states to cover any non-pharmacological item or service described in section 1905(a) of the Act in Medicaid, and any non-pharmacological item or service described in section 2110(a) of the Act in CHIP, that is medically necessary for treatment of COVID-19.

Secretary are attributable to administrative costs related to providing for medical assistance to this group under the state plan, are matched at 100 percent.

⁵ CDC guidance on post-COVID conditions is available at: <https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects.html>.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

States will thus need to establish medical necessity criteria, which may incorporate standards of care developed in consultation with recognized medical organizations involved in COVID-19 treatment and care, or otherwise incorporate the judgment of health care professionals, to determine whether a non-pharmacological item or service must be covered under the ARP amendments, and can opt to establish other utilization management controls, consistent with 42 CFR §§ 440.230 and 457.490. Given the breadth of the new coverage requirements established in the ARP, and the beneficiary-specific medical decisions that must be made in the treatment of COVID-19, states should ensure that the determination of whether a non-pharmacological item or service is medically necessary for treatment of COVID-19 is made on a case-by-case basis, and that it takes into account the particular treatment needs of the individual and the judgment of health care professionals. Additionally, the medical necessity criteria that states establish to determine when a non-pharmacological item or service must be covered, without cost-sharing, under the ARP amendments, and any utilization management controls that states apply to that coverage, should not establish unreasonable or arbitrary barriers to accessing the required coverage.

With respect to pharmacological treatments, CMS interprets these ARP amendments to require coverage of any drug or biological that is approved (or licensed) by the U.S. Food & Drug Administration (FDA)⁶ or authorized by the FDA under an Emergency Use Authorization (EUA) to treat or prevent COVID-19, consistent with the applicable authorizations. Section 9811(a)(4) of the ARP expressly provides for the inclusion of covered outpatient drugs used for COVID-19 treatment in the Medicaid Drug Rebate Program. More specifically, the requirements of section 1927 of the Act apply to drugs and biological products furnished as medical assistance for COVID-19-related treatment that satisfy the definition of a covered outpatient drug. Thus, a state may subject any COVID-19 treatment that is a covered outpatient drug to a utilization management approach, consistent with section 1927(d) of the Act, or drug utilization review consistent with section 1927(g). Again, any utilization management controls states apply to drugs or biologicals covered as treatment of COVID-19 should not establish unreasonable or arbitrary barriers to accessing coverage.

States might apply limitations on the amount, duration, or scope of coverage of items or services (including drugs) when those items or services are covered to treat or prevent conditions other than COVID-19. If a state does so, it should not apply those limits when the item or service is covered under the ARP amendments because it is needed to treat or prevent COVID-19. However, (as discussed above) states may apply utilization management controls specifically when the item or service is covered as treatment for COVID-19.

CMS does not interpret the references to “preventive therapies” in sections 1905(a)(4)(F), 2103(c)(11)(B), or the related amendments that ARP sections 9811 and 9821 made to the Act, to include COVID-19 vaccines or their administration. That is because, in a separate set of amendments to the Act, sections 9811 and 9821 of the ARP require state Medicaid and CHIP

⁶ “Licensed” is the statutory term under section 351 of the Public Health Service Act for what is commonly referred to as approval of a biological product. Hereinafter, this SHO Letter will reference FDA approval and licensure collectively as approvals.

programs to cover COVID-19 vaccines and their administration without cost sharing, for a broader range of beneficiaries than the COVID-19-related treatment coverage requirements in sections 9811 and 9821 of the ARP.⁷ As preventive treatments or therapies for COVID-19 (other than COVID-19 vaccines and their administration) become available, they too would be required to be covered as described above.

Pharmacological Treatments for COVID-19

Several pharmacological therapies to treat COVID-19 have been FDA approved or authorized under an EUA. When the Secretary of Health and Human Services declares that an emergency justifies emergency use of a product, the FDA may authorize the use of unapproved drugs or authorize unapproved uses of approved drugs under certain conditions (such as to be used in specific health care settings), pursuant to FDA's emergency authorities as described in section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition to the therapies currently approved or authorized by the FDA, many more products are being tested in clinical trials and will be reviewed by FDA to evaluate whether they are safe and effective in combating or preventing COVID-19.

Under the ARP requirement to cover treatments (including preventive therapies) specifically “for” COVID-19, states would be expected to cover 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 is authorized under an 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 includes coverage for monoclonal antibodies (mAbs) when specifically approved by the FDA to treat or prevent COVID-19, or authorized by the FDA under an EUA to be used for the specific conditions and specific settings to treat or prevent COVID-19, including when such authorizations would permit infusion in the home setting.⁸ States will find the latest information regarding these mAbs found at the FDA website listed below.

The Public Readiness and Emergency Preparedness (PREP) Act authorizes the Secretary of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from suit and liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from administration or use of covered countermeasures to diseases, health conditions, or other threats to health determined by the Secretary to constitute a present, or credible risk of a future public health emergency. Immunity extends to entities and individuals involved in (among other activities) the administration and use of such countermeasures.

⁷ For more information on Medicaid and CHIP coverage and reimbursement of COVID-19 vaccines and their administration under the ARP, please see CMS guidance at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf>.

⁸ As of the date of this letter, there are no monoclonal antibodies approved by the FDA to treat or prevent COVID-19, rather only certain monoclonal antibodies authorized under an FDA EUA. For more information see: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

On March 10, 2020, the Secretary issued a PREP Act declaration, effective February 4, 2020, to provide liability protections for activities related to medical countermeasures against COVID-19 (HHS COVID-19 PREP Act declaration). HHS published a ninth amendment to the HHS COVID-19 PREP Act declaration on September 14, 2021. Under this ninth amendment, licensed pharmacists can now order and administer COVID-19 therapeutics (such as monoclonal antibodies) subcutaneously, intramuscularly, or orally, as authorized, approved, or licensed by the FDA. Additionally, under this ninth amendment, qualified pharmacy technicians and licensed or registered pharmacy interns can also administer COVID-19 therapeutics as authorized, approved, or licensed by the FDA.⁹ A number of criteria (stated in the declaration) must be met in order for these professionals to be considered to be “qualified persons” authorized under the HHS COVID-19 PREP Act declaration to order and/or administer COVID-19 therapeutics. As discussed in the ninth amendment, any state law that would otherwise prohibit these healthcare professionals who are a “qualified person” from prescribing, dispensing, or administering COVID-19 therapeutics is preempted.¹⁰ CMS expects to provide more information to states soon about the implications of the ninth amendment to the HHS COVID-19 PREP Act declaration for Medicaid and CHIP coverage of COVID-19 therapeutics that are administered subcutaneously, intramuscularly, or orally. We anticipate that the Medicaid and CHIP coverage implications of this amendment will be similar to the implications for Medicaid and CHIP coverage of the HHS COVID-19 PREP Act declaration and authorizations related to ordering and administering COVID-19 vaccines.¹¹

As explained above, section 9811(a)(4) of the ARP provides for the inclusion in the Medicaid Drug Rebate Program of covered outpatient drugs used for COVID-19 treatment. More specifically, section 9811(a)(4) of the ARP provides for the requirements of section 1927 of the Act to apply to any drug or biological to which section 1905(a)(4)(F) of the Act applies, or to which the language adding COVID-19-related treatment to the coverage for the optional COVID-19 group applies, that is a covered outpatient drug and furnished as medical assistance in accordance with sections 1902(a)(10)(A) and 1905(a)(4)(F) of the Act or the language adding COVID-19-related treatment to the coverage for the optional COVID-19 group. In determining whether such a drug or biological product satisfies the definition of a covered outpatient drug at section 1927(k)(2) of the Act, ARP section 9811(a)(4)(A)(ii) provides that such drugs are deemed to be prescribed drugs for the purposes of section 1905(a)(12) and meeting the introductory language for the definition of a covered outpatient drug at section 1927(k)(2)(A). Thus, if a drug or biological furnished as medical assistance in accordance with sections 1902(a)(10)(A) and 1905(a)(4)(F) or the language adding COVID-19-related treatment to the coverage for the optional COVID-19 group meets the definition of a covered outpatient drug, it is included in the Medicaid Drug Rebate Program, section 1927 of the Act applies, and such drugs and biologicals would be subject to applicable rebates.

⁹ Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 51160 (Sept. 14, 2021), at <https://www.federalregister.gov/documents/2021/09/14/2021-19790/ninth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical>.

¹⁰ See *id.* at 51162-63.

¹¹ See discussion in section V of the CMS guidance available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf> for more information on the Medicaid and CHIP coverage implications of the HHS COVID-19 PREP Act declaration and authorizations related to ordering and administering COVID-19 vaccines.

The requirements of section 1927 would not apply to drugs and biologicals used to prevent or treat COVID-19 that do not meet the definition of a covered outpatient drug, although such drugs and biologicals would be subject to the ARP's coverage requirements (and states could receive federal financial participation in their expenditures to cover them). In such cases where the requirements of section 1927 would not apply, any such drugs and biologicals used to prevent or treat COVID-19 would not be subject to applicable rebates. For example, a drug that is only authorized to be used under an EUA described in section 564 of the FFDCA to treat or prevent COVID-19 would not meet the definition of covered outpatient drug under section 1927, and as a result, section 1927 requirements would not apply, and the drug would not be eligible for a manufacturer rebate.

Non-Pharmacological Treatments for COVID-19

As explained above, to comply with the coverage requirements in sections 9811 and 9821 of the ARP, states must cover any non-pharmacological item or service described in section 1905(a) and 2110(a) of the Act that is medically necessary for treatment of COVID-19, including specialized equipment and therapies (including preventive therapies). States may already cover a wide array of non-pharmacological treatments for COVID-19 through mandatory and optional Medicaid and CHIP benefits such as inpatient hospital services, outpatient hospital services, federally-qualified health center services, physician services, home health care services, services of other licensed practitioners, and freestanding clinic services. If a state does not already cover non-pharmacological items and services to treat COVID-19, the state must now provide coverage for those items and services to comply with the ARP requirements and must cover these items and services without cost sharing, and may need to amend its state plan to add this coverage.

As discussed above, states will have to implement medical necessity criteria and can opt to implement other utilization management controls consistent with 42 CFR §§ 440.230 and 457.490 as long as they do not establish unreasonable or arbitrary barriers to accessing the required coverage. Additionally, as indicated above, any limit typically placed on the amount, duration, or scope of coverage of an item or service when it is covered for purposes other than treatment for COVID-19 should not be applied if the item or service is covered under the ARP amendments because it is needed to treat COVID-19. However, (as discussed above) states can apply utilization management controls specifically when the item or service is covered as treatment for COVID-19.

Treatments for a Condition that May Seriously Complicate COVID-19 Treatment

The coverage required under ARP sections 9811 and 9821 includes not only treatments and preventions specifically “for” COVID-19 (discussed above), but also, during the period when a beneficiary is diagnosed with or is presumed to have COVID-19, treatment of a condition that may seriously complicate COVID-19 treatment for such a beneficiary. Medicaid and CHIP beneficiaries with certain underlying comorbidities are at a higher risk of progressing to severe COVID-19, or have conditions that could seriously complicate the treatment of COVID-19. Examples of these conditions 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.¹² Whether a beneficiary has a condition that could seriously complicate the treatment of COVID-19 should be determined based on a beneficiary-specific assessment.

This coverage of treatment of a condition that may seriously complicate the treatment of COVID-19 is extremely broad, and encompasses a wide array of possible treatments and therapies, including hundreds of drugs, but this component of the mandatory benefit includes only services that are otherwise covered under the state plan(s) or a waiver of the plan(s) (including a section 1115 demonstration) (which CMS will interpret to mean the services covered by the state as of the date of the enactment of the ARP, March 11, 2021).

Therefore, states are not required to provide new coverage under their Medicaid or CHIP programs in order to comply with this part of the ARP coverage requirements. However, states will need to determine when an item or service should be covered without cost-sharing for a beneficiary, and without limits on amount, duration, or scope that would otherwise apply when the item or service is covered for other purposes. States may apply utilization management controls specifically when the item or service is covered as COVID-19-related treatment, including as treatment for a condition that may seriously complicate the treatment of COVID-19, provided that in doing so, states do not establish unreasonable or unnecessary barriers to accessing coverage.

Even though this component of the new ARP coverage does not require states to add new coverage to their Medicaid or CHIP programs, states may always choose to add new coverage to their programs, including in order to cover treatments of conditions that may complicate the treatment of COVID-19.

Additionally, as noted above, section 1927 of the Act and the Medicaid Drug Rebate Program requirements apply to any such drugs or biologicals furnished as medical assistance in accordance with sections 1902(a)(10)(A) and 1905(a)(4)(F) of the Act or the language adding COVID-19-related treatment to the coverage for the optional COVID-19 group, which satisfy the definition of a covered outpatient drug.

Exemption of COVID-19-Related Treatment Services from Cost Sharing

How states opt to effectuate the cost sharing exemptions in ARP sections 9811 and 9821 will depend on the Medicaid and CHIP cost sharing in effect in the state before those exemptions took effect. If, before March 11, 2021, a state imposed cost sharing for any of the items or services (including drugs) that states are required to cover under the ARP amendments, it must stop doing so effective March 11, 2021. If a state continued imposing such cost sharing after March 11, 2021, the state must take all reasonable steps available to the state to ensure that providers reimburse beneficiaries for the amount of the unauthorized cost sharing imposed after that date and that reimbursement to providers is not reduced by the amount of the unauthorized cost sharing imposed after that date.

¹² See <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

Because the statutory language describing the mandatory coverage is the same as the statutory language describing the cost-sharing exemptions, states must generally align their implementation of the cost-sharing exemptions with their implementation of the corresponding coverage requirements. As discussed above, states should ensure that the determination of whether a non-pharmacological item or service is considered to be treatment or prevention specifically “for” COVID-19 is made on a case-by-case basis and that it takes into account the particular treatment needs of the individual and the judgment of health care professionals. Additionally, states must cover, under these ARP amendments, any drug or biological that has an FDA-approved or FDA-authorized use for treatment or prevention of COVID-19, consistent with the applicable authorizations. And, whether an item or service (including drugs) is a treatment for a condition that may seriously complicate COVID-19 treatment during the period when a beneficiary is diagnosed with or is presumed to have COVID-19 should be determined on a case-by-case basis.

Providers may not impose any otherwise applicable cost sharing for any items or services (including drugs) that states must cover without cost-sharing under these ARP provisions. Additionally, states must reimburse providers using the full payment rate for the items or services provided (i.e., not reduce the provider’s payment by the amount of any cost sharing). That said, any state can opt to suspend cost-sharing for all Medicaid and CHIP services, and if a state does so, it would necessarily also comply with the ARP cost-sharing exemptions.

Submission of State Plan Amendments to Implement ARP Requirements

As noted above, many of the COVID-19-related treatments that states are required to cover without cost sharing under ARP sections 9811 and 9821 will already be included under other benefits in the state plan or a waiver of the plan (including a section 1115 demonstration). Indeed, this will always be the case with respect to the required coverage for treatment of a condition that may seriously complicate the treatment of COVID-19. However, states might cover some such benefits under amount, duration, and scope parameters, or with cost-sharing obligations, that are not permissible with respect to the COVID-19-related treatment coverage requirements in the ARP.

Accordingly, to ensure that all states’ state plans reflect the statutory requirements, states must submit a Medicaid state plan amendment (SPA) attesting to coverage and reimbursement of COVID-19-related treatments without cost-sharing, in accordance with sections 1905(a)(4)(F), 1937(b)(8)(B), 1916(a)(2)(I), 1916(b)(2)(I), and 1916A(b)(3)(B)(xiii) of the Act, and without amount, duration, or scope limitations that would otherwise apply when items and services are covered for purposes other than COVID-19-related treatment. If states are covering the optional COVID-19 group described at section 1902(a)(10)(A)(ii)(XXIII) of the Act, they may also need to amend the state plan to reflect the ARP’s amendments to the coverage that states provide to members of that group. States may also need to amend the Medicaid state plan to include payment methodologies for items and services covered under the amendments made by ARP section 9811.

States must also submit a CHIP SPA pursuant to CMS requirements at 42 CFR § 457.60(a). States will need to indicate that they are providing coverage of COVID-19-related treatments without cost sharing or amount, duration, or scope limitations that would otherwise apply when

items and services are covered for purposes other than COVID-19-related treatment, in accordance with the requirements of section 2103(c)(11)(B) and 2103(e)(2) of the Act.

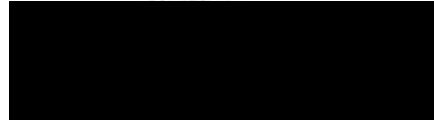
States may also need to amend their Medicaid or CHIP state plans to add coverage of treatments specifically “for” COVID-19 that are not already covered in the state plan.

CMS will provide additional information on submission of Medicaid and CHIP SPAs to reflect ARP changes and is available to provide technical assistance on SPA development.

Conclusion

This guidance describes provisions of the ARP that require state Medicaid and CHIP programs to cover COVID-19-related treatment without cost sharing. As previously stated, CMS will apply the statutory interpretations in this guidance on a prospective basis beginning with the date of issuance of this letter. Please contact John M. Coster, Director of the Division of Pharmacy, at John.Coster@cms.hhs.gov for additional information on prescribed drug issues, Kirsten Jensen, Director of the Division of Benefits and Coverage, at Kirsten.Jensen@cms.hhs.gov for non-pharmacological issues, and Meg Barry, Director of the Division of State Coverage Programs at Meg.Barry@cms.hhs.gov, for CHIP issues.

Sincerely,

A large black rectangular redaction box covering the signature of Daniel Tsai.

Daniel Tsai

Deputy Administrator and Director